In Search of Regulatory Compatibilities:

The Constraints on the European Commission's Strategies in Transatlantic Regulatory Cooperation

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Acknowledgements

My interest in regulatory cooperation is the result of a longer engagement with the question if processes of globalisation, trade liberalisation and the protection of consumer safety, health and environment standards need to be in competition with each other. Since I have discovered Dani Rodrik's argument of the 'globalisation trilemma' on a reading list of a seminar in political economy that I took as a Master's student at the London School of Economics, I have wondered if the nation state, democratic politics and deep economic integration inevitably need to lead to irresolvable conflicts. My interest in transatlantic regulatory cooperation arose when I was an intern in the Directorate General Trade of the European Commission between October 2012 and February 2013. At the time, my colleagues were involved the preparation of trade negotiations with the United States that would later become known as the negotiations over a Transatlantic Trade and Investment Partnership. Their endeavour to engage in a large exercise that would seek to establish mechanisms in order to cooperate on regulatory policy-making appeared as a fascinating case study for a process that could resolve the trilemma about which I had been thinking. Soon, I found myself immersed in academic literature on ways to determine equivalence, processes of standardisation in different jurisdictions and approaches to good and better regulation. The fascination for these processes encouraged me to pursue this topic more intensively through a doctoral dissertation.

The idea for the present book came when the TTIP negotiations became increasingly politicised, especially in Germany where I had begun my PhD studies in Cologne, and critics accused the Commission of reducing the level of protection for citizens and the environment in the EU. I began to question if I had underestimated the negative effects transatlantic regulatory cooperation could have on the level of protection for people and the environment in both the EU and the US. At the same time, I observed how the politicisation of the topic in which my research interest lay let boundaries between my research and my private life blur. On a few occasions, I was confronted with situations in my private life in which I had to explain why I was interested in a process that would put downward pressure on the consumer protection and environmental standards. This reinforced my motivation to understand under which circumstances the Commission would pursue the harmonisation and mutual recognition strategies of which many people, especially in Germany, were afraid. Staying politically unengaged and neutral in policy debates which have been as politicised as the object of the present book has not always been easy. Even if full objectivity is arguably impossible to achieve on any issue of scientific inquiry, I hope that I have given equal consideration to arguments of both supporters and critics of regulatory cooperation, where I have restated them in this book.

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Abstract

The emergence of bilateral regulatory cooperation between large states and jurisdictions is one of the most notable trends in global governance. Advocates underline its contribution to the protection of consumer safety, public health and the environment. It would further liberalise trade flows in a world of economic interdependence and support administrative efficiency in adopting and implementing regulations. Critics argue that regulatory cooperation would exert downward pressure on the stringency of regulations, provide asymmetric benefits for firms and business associations relative to civil society organisations and undermine the democratic accountability of law-makers. The relevance of these arguments depends on the extent to which states and jurisdictions engage in bilateral regulatory cooperation. The extent of regulatory cooperation usually corresponds to their choice of a bilateral regulatory cooperation strategy.

This book aims to explain which factors constrain the choice of a bilateral regulatory cooperation strategy by large states and jurisdictions. It addresses an important puzzle. The existing literature uses factors, such as a large internal market, high regulatory capacity and high regulatory stringency, to explain the ability of states to externalise regulations and market-related measures. These factors, however, only partly, if at all, account for variation in their choice among different bilateral regulatory cooperation strategies. This puzzle also applies to the European Union, arguably the most prominent actor in bilateral regulatory cooperation at the time of writing. The research question that this book addresses is thus the following: What constrains the formation and choice of a bilateral regulatory cooperation strategy of a state or jurisdiction with high regulatory capacity?

The answer that this book develops results from the deduction of a new integrative theoretical framework, the Inter-relational Institutionalism. It combines the two most prominent approaches in governance and interdependence research, the actor-centred institutionalism and the New Interdependence Approach. Moreover, this book integrates the different conceptualisations of bilateral regulatory cooperation strategies in the existing literature into a new typology. This typology differentiates strategies according to their ‘dimension’, i.e. their reference to regulatory policies or implementation procedures, and ‘depth’. It thus distinguishes between ‘regulatory alignment’, ‘equivalence’, ‘alignment of implementation procedures’ and ‘information exchange’.

The Inter-relational Institutionalism developed in this book argues that the formation and choice of a bilateral regulatory cooperation strategy is constrained by three factors: the presence of bureaucratic pressure, the compatibility of regulatory institutions and the mobilisation of societal actors in support of regulatory cooperation. These factors become relevant at different steps in the process. First, bureaucratic pressure within regulatory bodies by the politically appointed or administrative leadership reduces uncertainty and the reluctance of technical regulatory officials to pursue regulatory cooperation. It initiates the formation of a regulatory cooperation strategy.

Second, the subsequent choice among the regulatory cooperation strategies is constrained by the compatibility of regulatory institutions between the domestic and the foreign jurisdiction. Regulatory institutions comprise regulatory competence allocations, called 'regulatory authority structures', and regulatory approaches, called 'regulatory principles'. They are compatible if they do not allocate regulatory responsibilities to different authority levels and do not establish conflicting objectives and ideas. Regulators can choose 'regulatory alignment' if both regulatory authority structures and regulatory principles are compatible. They are, however, constrained to choose 'equivalence' if regulatory principles differ even if regulatory authority structures are compatible. Regulators can only opt for an 'alignment of implementation procedures' if regulatory principles are compatible but regulatory authority structures are not. Moreover, they can choose 'information exchange' even if both regulatory authority structures and regulatory principles between the domestic and foreign jurisdiction are incompatible. Finally, the mobilisation of societal actors in support of regulatory cooperation pushes technical officials and bureaucratic leaders to adopt a regulatory cooperation strategy in accordance with the distribution of regulatory compatibilities.

The ability of the Inter-relational Institutionalism to explain the choice of a regulator with high regulatory capacity is tested in four industry-sectoral regime case studies: chemicals, engineering, food safety as well as information and communication technology (ICT). This study investigates regulatory cooperation activities of the European Commission. The European Union is arguably the most active jurisdiction in bilateral regulatory cooperation. The analysis focuses on cooperation with the United States of America, a 'least likely' case for European Union regulators to require bureaucratic pressure for the initiation of regulatory cooperation. The case selection combines a 'least-likely' logic for the explanatory capacity of the Inter-relational Institutionalism with a 'method of difference' logic for variation on the independent variable 'regulatory compatibilities'. The study selects the New Transatlantic Agenda (NTA), the Transatlantic Economic Council (TEC) and the negotiations over a Transatlantic Trade and Investment Partnership (TTIP) from the history of transatlantic regulatory cooperation initiatives. It uses process-tracing to establish the causal mechanism and the role of societal actor mobilisation therein. The empirical analysis builds on an analysis of public and non-public documents as well as 26 expert interviews conducted between 2015 and 2017.

The theoretical contribution of this book is twofold: It refines the conceptualization of domestic constraints in international cooperation by linking previously separated literatures. The integration of actor-centred institutionalism and the New Interdependence Approach re-specifies the 'domestic constraints' argument by focussing on structural constraints on state and sub-state actors. Second, it specifies an alternative, complementary theoretical micro-foundation for the engagement of state and sub-state actors in international cooperation. It assumes a certain degree of autonomy for state

and sub-state actors in international cooperation and considers their own preference for using interdependence as an opportunity structure.

Empirically, the findings of this book imply that the points of criticism towards regulatory cooperation can be soothed. The constraints imposed by regulatory compatibilities on regulators' choice of a strategy makes it highly unlikely that bilateral regulatory cooperation lowers the level of protection for consumer safety, public health and the environment. At the same time, the results offer arguments why bilateral regulatory cooperation is likely to enhance administrative efficiency without undermining the democratic accountability of legislators and regulators. The concluding section of this book derives suggestions how bilateral regulatory cooperation may be designed effectively.

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Abbreviations

ANSI	American National Standards Institute
APHIS	Animal and Plant Health Inspection Service
CAB	Conformity Assessment Body
CEN	Comité Européen de Normalisation; European Committee for Standardization
CENELEC	Comité Européen de Normalisation Électrotechnique; European Committee for Electrotechnical Standardization
CETA	Comprehensive Economic and Trade Agreement
CPSC	Consumer Product Safety Commission
DG	Directorate General
DIN	Deutsches Institut für Normung
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EP	European Parliament
EPA	Environmental Protection Agency
ESO	European Standardisation Organisations
ETSI	European Telecommunications Standards Institute
EU	European Union
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FSIS	Food Safety Inspection Service
FSMA	Food Safety Modernisation Act
FTA	Free Trade Agreement
FTC	Federal Trade Commission
GDPR	General Data Protection Regulation
GHS	Globally Harmonised System
HLRCF	High-Level Regulatory Cooperation Forum
HLWG	High-Level Working Group
IEC	International Electrotechnical Commission
ICT	Information and Communication Technology
ISO	International Standardisation Organisation
ITU	International Telecommunications Union

MRA	Mutual Recognition Agreement
NRTL	Nationally Recognised Testing Laboratory
NTA	New Transatlantic Agenda
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PEA	Positive Economic Agenda
REACH	Regulation on Registration, Evaluation and Authorisation of Chemicals
SDO	Standards Development Organisation
SDoC	Supplier's Declaration of Conformity
SHEC	Safety, Health, Environment, and Consumer Protection
SPS	Sanitary and Phytosanitary Measures
SVHC	Substance of Very High Concern
UN	United Nations
US	United States
USDA	United States Department of Agriculture
USTR	United States Department of Trade
TABC	Transatlantic Business Council
TABD	Transatlantic Business Dialogue
TACD	Transatlantic Consumer Dialogue
TAED	Transatlantic Environment Dialogue
TALD	Transatlantic Legislator Dialogue
TEC	Transatlantic Economic Council
TEP	Transatlantic Economic Partnership
TFEU	Treaty on the Functioning of the European Union
TPC	Trade Policy Committee
TSCA	Toxic Substances Control Act
TTIP	Transatlantic Trade and Investment Partnership
VEA	Veterinary Equivalence Agreement
WTO	World Trade Organisation

1. Introduction

Regulatory cooperation is arguably the most important trend in global governance. It often takes place in international organisations such as committees of the United Nations (UN) and the Organisation for Economic Cooperation and Development (OECD). Since the late 1990s and in particular since the late 2000s, regulatory cooperation also takes place between states and jurisdictions bilaterally. Institutional reforms in many jurisdictions have led to the creation of regulatory agencies and networks of regulators.

Regulatory cooperation as a form of international cooperation follows the rise and continuation of globalisation and economic internationalisation. The advent and expansion of regulatory cooperation is especially accompanied by hopes to solve three important challenges in a globalised and interdependent world: First, regulatory cooperation is an instrument for regulators to shape and control international markets and ensure a high level of consumer safety and environmental protection even as markets grow and the boundaries of jurisdictions become blurred. Regulatory cooperation follows the establishment of 'regulatory states' (Majone, 1996) and the creation of regulatory capacity in many jurisdictions. Issues of consumer protection, health and environmental protection have been delegated to regulators and regulatory agencies from the United States (subsequently: US) to the European Union (subsequently: EU) to Japan. The coordination of regulations and their implementation among regulators from different jurisdictions shapes possibilities for regulators to ensure a high level of consumer safety and environmental protection in their own jurisdiction. Besides, it creates possibilities for regulators to extend their influence beyond the boundaries of their jurisdiction and raise the level of protection of consumers and the environment in states and jurisdictions outside their control. As markets internationalise, regulatory cooperation arguably helps to rein in frequently feared downward pressure on safety and environmental protection. The underlying argument runs as follows: As regulatory cooperation establishes a 'level playing field' for domestic and foreign firms, it protects firms from being undercut by competitors from other jurisdictions which are subject to less stringent regulation. It therefore reduces the pressure on regulators to lower the stringency of regulations to maintain the competitiveness of domestic firms. Standards can be safeguarded, if not raised as a result of regulatory cooperation.

Second, regulatory cooperation promotes new ways of international trade liberalisation. As multilateral trade liberalisation and additional bilateral trade liberalisation have reduced or abolished most tariffs between countries, the main impediment to international trade flows are divergent rules and standards. Although they individually pursue legitimate objectives with regard to the protection of consumer safety, health and the environment, divergent regulations and administrative procedures between states constitute impediments to further international market integration. Regulatory cooperation that entails a coordination of regulations and administrative procedures between regulators thus helps create 'a level playing field' for domestic and foreign firms and reduces adjustment costs for firms that seek to enter a

new market. Regulatory cooperation is thus an important instrument of trade liberalisation especially for smaller firms that do not have the resources to adapt products and production processes to divergent regulatory requirements of different markets. The export or uploading of domestic standards and procedures particularly benefits domestic firms because it creates 'first-mover advantages' for firms which already comply with these standards and procedures (Zeitlin, 2015: 10). The economic benefits attributed to regulatory cooperation reflect arguments among economists that trade liberalisation enhances economic growth by increasing productivity through specialisation, enabling the use of economies of scale, fostering technology transfer, facilitating access to high-quality and low-cost imports, and increasing competition.

Third, regulatory cooperation is an instrument for regulators to maintain their ability to regulate products and ensure consumer, health and environmental protection even as their budgets and administrative resources are being cut. With the entry into office of the Trump Administration, the US Administration has announced budget cuts for regulatory agencies to counteract what it perceives as a growing over-regulation of products and processes in the US. Similarly, in the EU, the prospect of Brexit will most probably reduce financial resources available to Commission regulators to elaborate new proposals for laws on consumer, health and environmental protection, adopt technical regulations and monitor their implementation. Cooperation and coordination among regulators from these and other jurisdictions therefore create possibilities for regulators to ensure their ability to act effectively despite the prospect of budget cuts. Cooperation and coordination can be envisioned in different forms: It may entail a division of tasks between regulators for the identification of regulatory challenges, the collection of data and the development of potential solutions as well as an exchange of ideas and best practices how effective regulation can be organised most efficiently. Regulatory cooperation thus protects regulatory effectiveness even if executives and legislatures implement budget cuts on regulators.

Regulatory cooperation is, however, not only a technical exercise (Pollack, 2005: 912). It encompasses a redistributive dimension not only between firms of different jurisdictions, but according to critics of regulatory cooperation also between different actors within a jurisdiction. The criticism of regulatory cooperation addresses primarily three concerns: First, regulatory cooperation seeks to liberalise trade at the expense of the protection of consumers, public health and the environment. Regulatory cooperation often takes place within trade negotiations and is consequently promoted by trade negotiators. Critics argue that trade negotiators pay closer attention to liberalising trade flows through strategies such as mutual recognition and equivalence rather than ensuring that regulations and standards for which equivalence is recognised indeed achieve equivalent levels of protection (Siles-Brügge & de Ville, 2015). This may trigger downward pressure on the level of consumer, health and environmental protection in the jurisdiction with the higher level of protection. Second, regulatory cooperation transfers issues relating to the safety and health of consumers into the technical competences of regulators and therefore contributes to disempower parliaments. Even if regulators are not able to change overarching

framework legislation through regulatory cooperation, information exchange between regulators and the recognition of regulations as equivalent in effect may constrain the scope for parliamentary decisions in the future. Critics call this effect the 'regulatory chill' (Bode, 2015). For this reason, Corporate Europe Observatory, together with other NGOs, has called regulatory cooperation a "threat to democracy" (Corporate Europe Observatory, 2016). Third, opponents of regulatory cooperation argue that it enhances the influence of firms and business associations in a jurisdiction at the expense of citizens and civil society organisations (Beuc, 2016; Greenpeace, 2016; Siles-Brügge & de Ville, 2015). Corporate Europe Observatory (2017) puts forward that regulatory cooperation gives disproportionate access to standard-setting and regulatory policy-making to firms. Firms and business associations often have more organisational and financial resources to monitor and participate in regulatory cooperation dialogues than non-governmental organisations and thus asymmetrically benefit from these processes.

The objective of this book is not to analyse the validity of the arguments regarding the benefits and costs of regulatory cooperation or to take sides in this debate. It acknowledges that advocates of regulatory cooperation offer powerful arguments why cooperation between regulators from different jurisdictions in an interdependent environment is an advantageous instrument that warrants a closer examination. Yet, this book neither considers arguments proposed by critics and opponents of regulatory cooperation as less relevant nor argues that they lack a strong empirical basis. Its motivation to study regulatory cooperation lies in the increasing level of attention that regulatory cooperation attracts among both academic and practitioners.

This chapter begins with a specification of the research interest that underlies this book (chapter 1.1.). Subsequently, it formulates the puzzle that has motivated the research for this book and presents the research questions (chapter 1.2). A next section summarises the main argument of this book (chapter 1.3). A concluding section presents its outline (chapter 1.4).

1.1. Relevance of bilateral regulatory cooperation strategies

The observation that regulatory cooperation is a highly important trend in global governance constitutes the point of departure that helps explain the research interest of this book. This section begins with a brief overview of the regulatory cooperation activities by the EU, arguably the jurisdiction which has globally engaged the most in regulatory cooperation. It shows how regulatory cooperation that initially mostly took place within international organisations and at the multilateral level has additionally entered bilateral relations. It then addresses the response of academic literature to the emergence of regulatory cooperation as a prominent trade in global governance and identifies an important gap in this literature. Lastly, it outlines the relevance of the research interest that was the motivation for this book.

Regulatory cooperation shall be defined as coordination activities between regulators from different jurisdictions with a view to the promote the exchange of information and joint policy-making of regulatory policies and market-related measures. Regulatory cooperation reflects and reinforces the development of the 'regulatory state' (Majone, 1996) as well as the incidence of economic internationalisation. The development of the regulatory state describes the delegation of discretionary authority to independent regulators, regulatory agencies and commissions (Majone, 1996). Within the logic of the regulatory state, regulators and regulatory agencies set up transnational regulatory networks both within a jurisdiction (Groenleer, 2011) and with regulators and regulatory agencies from third countries (Zeitlin, 2015). Through these networks, regulators and regulatory agencies within their discretionary authority exchange information and promote joint regulatory policy-making.

Two different levels of regulatory cooperation should be differentiated. On the one hand, governments and regulators engage in regulatory cooperation within international organisations and through multilateral agreements. International organisations in which governments and regulators seek regulatory cooperation include the Codex Alimentarius Commission (CAC) for the development of food safety standards, the International Standardisation Organisation (ISO) for the development of technical product standards, the United Nations Economic Commission for Europe (UNECE) for the vehicle standards and the OECD for standards and procedures across numerous industry sectors and policy areas. Multilateral agreements in which regulatory cooperation has been anchored include the Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Standards (SPS) Agreements concluded within the WTO. Therein, mostly large states and jurisdictions attempt to vertically upload their standards and procedures and shape the decisions taken within international organisations and through multilateral agreements. For the purpose of this book, regulatory cooperation which takes place within international organisations and as a result of multilateral agreements shall be called 'international regulatory cooperation'.

On the other hand, governments and regulators also promote regulatory cooperation in bilateral relations. In the latter case, regulatory cooperation takes place through regulatory dialogues, interactions within transnational regulatory networks, and increasingly through the conclusion of bilateral free trade and economic partnership agreements. In doing so, regulators seek to horizontally expand the influence of domestic rules and procedures to third countries. This shift in the level of regulatory cooperation reflects a multitude of reasons, including the difficulty to reach common decisions in a growingly multipolar international environment and the perceived usefulness of individual bilateral coordination in advance of multilateral discussions (Peterson & Young, 2014; Young, 2010). Regulatory cooperation that occurs through regulatory dialogues and bilateral free trade and economic partnership agreements shall be referred to as 'bilateral regulatory cooperation'.

The spread of regulatory cooperation is a result and at the same time a driver of economic internationalisation and globalisation. Economic internationalisation shall be understood as "the

expansion of markets from the domestic level to the international level" (Damro, 2006: 175). It follows processes of trade liberalisation, the deregulation of domestic economies and technological development. Economic internationalisation and globalisation imply that decisions taken in one jurisdiction do not only affect the domestic jurisdiction, but also interact with decisions taken in other jurisdictions.

The development of the regulatory state with numerous independent regulatory agencies has initially been a characteristic of the US (for a brief history of the development of regulatory agencies in the US see e.g. Pérez & Dudley, 2016). Yet, with the establishment of the Single European Market since the 1990s, this development has become more pronounced in the EU and has subsequently put the EU ahead of all other jurisdictions in this regard (e.g. Levi-Faur, 2011; Thatcher, 2011; Majone, 1996). With the emergence of the EU as a 'regulatory state', the European Commission (subsequently 'Commission') has become particularly open to the engagement in regulatory cooperation. Correspondingly, the perception of US hegemony in international regulation (Simmons, 2001; Braithwaite & Drahos, 2000) has since the mid-2000s given way to the view that the EU has gained a decisive impact on international regulation, across a range of issues and sectors, often also in opposition to the US (Peterson & Young, 2014; Bradford, 2012; Vogel, 2012; Lütz, 2011; Jacoby & Meunier, 2010; Newman & Posner, 2010; Sapir, 2007; Drezner, 2007; Bach & Newman, 2007).

Regulatory cooperation received a first mention as a policy objective of the EU in its Market Access strategy from 1996:

> "The Community's trade objectives can be summarised simply. First, to reduce technical barriers in overseas markets and prevent the emergence of new ones. Secondly, to encourage our trading partners to adopt standards and regulatory approaches based on, or compatible with international and European practice. […] The regulatory solutions developed by Europe, particularly under the Single Market programme, offer, by virtue of their flexibility, trade-friendliness and consistency with international practice, an appropriate reference point for other countries or regions as they establish or reform their own regulatory systems" (European Commission, 1996: 4-5)

Since then, the external projection of EU policies has been described as one of the core objectives and characteristics of the EU (Bretherton & Vogler, 2006; Orbie, 2009). The Commission reiterated the importance it attaches to exporting its regulatory approaches in the context of the Global Europe strategy 2006. The Global Europe strategy states that the EU "must play a leading role in sharing best practice and developing global rules and standards" (European Commission, 2006: 7). The Commission revealed that it aimed at "making European norms the reference for global standards". In its 2007 Single Market Review, the Commission concluded that "the EU must also be able to learn: examining global standards when devising Europe's own policy solutions and taking inspiration from best practices of foreign regulators should serve to improve EU regulations and facilitate their acceptance abroad" (European

Commission, 2007: 8).[1] Likewise, in the Staff Working Document accompanying the Global Europe strategy, the Commission underlined that an externalisation of EU rules and standards would not only offer benefits to European firms and citizens, but also their foreign counterparts, because of the high quality, innovative character, and broad applicability of EU regulation (Zeitlin, 2015: 7).

The Commission has mostly sought to extend the impact of EU rules and standards through trans-governmental regulatory dialogues and networks (Zeitlin, 2015; Bradford, 2012; Lavenex & Schimmelfennig, 2010). It has established regulatory dialogues with other large economies in the global political economy, including the US, Japan and Canada. Regulatory cooperation has been pursued through numerous forums, including the G20 and the G7/8. Besides, regulatory cooperation has been a key component of networks established in the context of the European Neighbourhood Policy, including Ukraine, Belarus, Georgia, Armenia, Azerbaijan, Morocco, Algeria, Tunisia, Libya, Egypt, Israel, the Palestinian Territories, Jordan, Lebanon and Syria (Lavenex, 2014; Lavenex & Schimmelfennig, 2010). Since the late 2000s, the Commission has also sought to promote regulatory cooperation through the negotiation of 'deep and comprehensive free trade agreements (FTAs)', notably with South Korea, Canada, Japan and the US (Zeitlin, 2015; Peterson & Young, 2014; Siles-Brügge, 2014; Siles-Brügge, 2011).

Reflecting the expansion of international regulatory cooperation as "one of the most notable trends" in global governance (Abbott, 2014: 1; Keohane & Victor, 2011: 5), regulatory cooperation has also attracted the attention of researchers in economics, law and political science (Shaffer, 2016; Abbott, 2014; OECD, 2013b; Keohane & Victor, 2011; Evenett, 2011; Pollack & Shaffer, 2005)[2]. Researchers have particularly focused on regulatory cooperation in international organisations, i.e. the form of regulatory cooperation which this book refers to as 'international regulatory cooperation'. Moreover, they have concentrated on outcomes of regulatory cooperation and sought to examine to what extent regulatory cooperation achieves or leads to regulatory convergence across jurisdictions (Heichel et al., 2005; Knill, 2005). Authors examine sources of power in regulatory cooperation (Newman & Posner, 2015), look at facilitators and obstacles to regulatory cooperation (Shaffer, 2016; OECD, 2013b) and identify 'success factors' (OECD, 2013b; Evenett, 2011). With regard to regulatory convergence, in turn, scholars have hypothesised that regulatory convergence between the EU and other large countries, notably the US, is limited if regulatory approaches differ (e.g. Pollack & Shaffer, 2006; Vogel, 2003). However, at the time of writing, a large body of academic work on this issue remains descriptive (e.g. Josling & Tangermann, 2015; Maier, 2008; Poli, 2004).

[1] In the same document, the Commission argues that such openness of EU regulation to external influences could be expected to become progressively more important. On the one hand, the international environment was changing rapidly. On the other hand, challenges growingly needed coordinated global action, e.g. climate change or counterfeiting and piracy (Commission, 2007: 7).

[2] Global governance shall be defined as the "institutional arrangements to monitor, enforce and amend transnational rules and regulations" (Drezner, 2007: 11).

Nonetheless, with the "slow killing of the WTO" (Elsig & Pollack, 2017) and other international organisations, bilateral interactions between third countries will rise in importance. At the time of writing, the EU's bilateral regulatory cooperation efforts already cover the US, Japan, Canada and South Korea. They may expand to Russia, China and India in the future as these economies develop regulatory capacity and interdependence between the EU and these countries increases. Yet, despite its growing empirical relevance, bilateral regulatory cooperation remains heavily understudied. Bilateral regulatory cooperation is especially a research desideratum as insights gained from the study of international regulatory cooperation are only partly transferable.

Insights from international regulatory cooperation are only partly transferable because the strategies pursued by governments and regulators in bilateral cooperation differ from those in international cooperation. At this point it should additionally be noted that both international and bilateral regulatory cooperation assume increasingly differentiated forms. The identification and delineation of these forms has driven work both by practitioners and scholars. In a comprehensive study on international regulatory cooperation, the OECD (2013b) identifies and delineates eleven different mechanisms. Academics in EU studies (Newman & Posner, 2015; Peterson & Young, 2014; Falkner & Müller, 2013; Lavenex, 2014) also distinguish different forms of interaction between the EU, third countries and international organisations. Moreover, these authors agree that governments or regulators, including the Commission, do not necessarily always export domestic standards and rules, but often limit regulatory cooperation to less deep or comprehensive strategies.

This differentiation of the forms and strategies through which governments and regulators seek to promote regulatory cooperation gives rise to a new set of questions. Recent empirical investigations of the EU's international policy strategies (Young, 2015b; Falkner & Müller, 2013) observe that the EU, represented by the Commission, does not only not succeed in achieving regulatory convergence, in many cases it does not even try to do so. On the contrary, they find that the EU is reluctant to attempt exporting domestic standards and norms and instead chooses to pursue regulatory cooperation to a 'less ambitious' extent. This implies that there must be factors in addition to power resources that restrict the ability or the willingness of regulators to engage in regulatory cooperation and export domestic standards and rules. To reveal these factors, research needs to concentrate on exploring and understanding the choices of governments and regulators. Little benefit can in this regard be gained from looking at outcomes alone.

Identifying factors that constrain regulators in the pursuit of bilateral regulatory cooperation is crucial to move the understanding of political science of regulatory cooperation beyond the status quo. Understanding the constraints that a regulator faces in its choice of a bilateral regulatory cooperation strategy has relevance from both a theoretical and an empirical perspective. Theoretically, two-level games (Putnam, 1988) and theories of domestic politics (Lake, 2009; Drezner, 2007; Raustiala, 2002; Milner, 1997) certainly offer a useful point of departure to understand constraints on international

cooperation that does not rely on treaty ratification. Yet, as especially bilateral regulatory cooperation often takes place through non-treaty cooperation within the discretion of regulators (Pollack & Shaffer, 2006; Damro, 2006; Pollack, 2005), existing domestic politics theories risk falling short of providing a comprehensive answer to explaining the constraints and determinants of international cooperation. Going beyond existing studies is therefore necessary to understand the factors which shape and constrain the behaviour of state and regulatory actors from large jurisdictions in an environment shaped by political and economic interdependence.

Empirically, the extent to which governments and regulators pursue regulatory cooperation has immediate implications for the presence of costs and benefits of regulatory cooperation described in the introduction to this chapter. The size of economic benefits from regulatory cooperation accruing to firms with transnational activities arguably grows with the extent of regulatory cooperation. Likewise, the contributions of bilateral regulatory cooperation to administrative efficiency and effectiveness vary between different 'forms' of bilateral regulatory cooperation. At the same time, potential risks to environmental, labour or health standards are higher under certain 'forms' of bilateral regulatory cooperation. To assess the potential costs and benefits to bilateral regulatory cooperation thus presupposes that researchers and practitioners can anticipate the extent of regulatory cooperation that is likely to occur.

Yet, until the time of writing, the choices of governments and regulators among different bilateral regulatory cooperation strategies remain a research desideratum. An important reason why this research desideratum persists reflects the lack of studies which engage in a systematic comparative analysis on regulatory cooperation (Newman & Posner, 2015 and Falkner & Müller, 2013 are an exception). Previous research has been constrained by the focus on one or at best two industry sectoral regulatory regimes or policy areas, which makes it difficult to generalise findings beyond the specific case analysed. To move towards an understanding of the constraints on regulatory cooperation, especially on bilateral regulatory cooperation that is growing in importance, it is indispensable to go beyond the specific case and seek to analytically uncover potential structural factors which constrain the choices of governments and regulators across cases.

This book is the first to conduct a systematic analysis of bilateral regulatory cooperation strategies across several (sectoral) case studies. The comparative perspective adopted in this book thus allows a deduction and identification of the (structural) constraints that shape the behaviour of the Commission not only in one policy field in one specific contexts, but across a wider range of policy issues and interaction contexts. The EU and the Commission in particular are a relevant actor to study in this context as the EU holds the relevant power resources identified by existing regulatory cooperation literature (e.g. Newman & Posner, 2015; Damro, 2012) and has since the establishment of the Single Market expressed a keen interest in regulatory market integration with third countries beyond its borders. For this reason, this book concentrates on the engagement of the Commission in bilateral regulatory cooperation.

The research interest of this book can thus be summarised as follows: Rather than concentrating on regulatory cooperation among states and jurisdictions in international organisations, it emphasises regulatory cooperation between states and jurisdictions in bilateral interactions. Besides, and even more importantly, it does not aim at identifying success or facilitating factors to regulatory cooperation, but seeks to examine the behaviour of states and jurisdictions in regulatory cooperation that take a particularly active role in this process. This book seeks to understand how, under which conditions and to which extent regulators use bilateral regulatory cooperation in practice. What are the constraints that regulators see on the use and engagement in bilateral regulatory cooperation? Under which conditions do regulators use regulatory cooperation? The research interest of this book thus lies in understanding the strategies that regulators choose in bilateral regulatory cooperation and in shedding light on the factors that drive and explain the choice of regulators for a particular strategy.

1.2. Puzzle and research question

The previous section has indicated that governments and regulators rely on increasingly differentiated forms and strategies as they engage in regulatory cooperation. While strategies differ for international and bilateral regulatory cooperation, both levels of regulatory cooperation have in common that they occur through various, differentiated strategies. This differentiation of the strategies that regulators choose as they pursue regulatory cooperation is puzzling. This section elaborates on the nature of this puzzle and subsequently presents the research question that this book seeks to address.

A growing body of literature presents arguments why the export of domestic rules and standards is beneficial to governments and regulators (e.g. Zeitlin, 2015; Farrell & Newman, 2014, Lavenex, 2014; Damro, 2012; Schimmelfennig & Lavenex, 2009). Governments and regulators from jurisdictions with a large internal market, high regulatory capacity and a set of regulations are in a privileged position to export their rules and standards. Nonetheless, externalisation, i.e. an export of domestic rules and standards, is not always chosen by regulators. Indeed, it seems to be chosen far less frequently than suggested by the corresponding literature (see Newman & Posner, 2015: 862 for this argument). This puzzle especially applies to bilateral regulatory cooperation (Josling & Tangermann, 2015: 185).

The puzzle that regulators rarely choose externalisation as a strategy in bilateral regulatory cooperation has both a theoretical and an empirical dimension. From a theoretical perspective, the reluctance to engage in regulatory cooperation through rule export poses a puzzle to institutionalist literature which dominates political science research on the emergence of international cooperation (Keohane, 2017; Zürn, 2016; Damro, 2012; Drezner, 2007). This institutionalist literature has often studied the emergence of international cooperation, including regulatory cooperation, through the lens of the 'two-level game' concept (Milner, 1997; Putnam, 1988). The latter describes international negotiations as a strategic interaction between two different levels of decision-making and focuses on these two levels of analysis – the international level (level I) and the domestic level (level II) - to explain international outcomes. According to this concept, negotiators act as the domestic-international interface. They are constrained by the need for an agreement with foreign negotiators at the international level and the need to ensure ratification of the agreement by domestic legislatures at the domestic level (Peterson & Young, 2014; Moravcsik, 1993; Putnam, 1988).

Authors examining regulatory cooperation have noted, however, that rather than through international treaty agreements, regulatory cooperation often takes place through non-treaty agreements (Damro, 2006). These are not subject to domestic ratification by legislatures. Even in cases where regulatory cooperation is promoted in the context of free trade agreements which are subject to domestic ratification, regulatory cooperation provisions are often kept out of the final agreement and instead are

included in a separate text[3]. The pursuit of regulatory cooperation through non-treaty agreements thus softens the domestic constraint that regulators face.

If they are not constrained by the need to secure domestic ratification, it should be expected that actors use their discretionary authority to realise their preferences. The observation that in practice, regulators pursue regulatory cooperation through numerous, diverse strategies contradicts theoretical expectations. These predict that regulators should use their discretion to pursue their preferences if domestic veto players have limited institutional possibility to oppose strategy choices of regulator. Indeed, the decision that a regulatory actor with discretionary authority does not necessarily seek to externalise own regulatory policies and processes thus challenges existing accounts from the rational-choice and historical institutionalist literatures.

Empirically, the observation that also the Commission, arguably the 'most likely' promoter of regulatory cooperation and externalisation of its domestic regulatory measures, does not necessarily choose to do so is equally puzzling. Reasons why the Commission is a 'most likely' candidate for the engagement in regulatory cooperation will be examined in greater depth in chapter 5.1. At this point it shall suffice to refer to the large size of the Single Market, the high regulatory capacity of the Commission and the high stringency of its regulatory measures that according to international regulatory cooperation literature constitute crucial power resources for the ability to externalise domestic regulatory measures (see chapter 2.4 for an in-depth discussion). Yet, despite its alleged power resources empirical studies show that the Commission only partially seeks to externalises its domestic regulatory measures (Falkner & Müller, 2013). Moreover, stark differences exist for its externalisation attempts across different policy issues (Young, 2015b). The observation that even the Commission is reluctant to externalise its regulatory measures through regulatory cooperation although it supposedly has the power resources to do so is puzzling. Authors acknowledge that some of these power resources lose influence as factors such as geographical proximity and trade interdependence change. Damro (2015b) e.g. states that the power and attractiveness of the EU internal market decrease with lower geographical proximity between the EU and a third country. Yet, this argument raises the question why the Commission for certain policy issues does pursue regulatory export even if the geographical distance with a third country is high (Young, 2015b). Indeed, while regulatory export appears to be much more seldom than discussed by the external governance literature (Lavenex, 2014), it appears to be only weakly correlated with the proximity between a third country and the EU (Young, 2015b).

Existing political science research lacks a theoretical framework that explains which factors constrain a regulator in its choice among different potential regulatory cooperation strategies. To clarify the puzzle

[3] The separation of regulatory cooperation provisions negotiated in the context of free trade agreements (FTAs) from market access provisions ensures that regulatory cooperation commitments are not subject to dispute settlement in the implementation and enforcement phase of the FTA. One interview partner noted that the subjection of regulatory cooperation to dispute settlement would reduce the willingness of regulators to make cooperation commitments (Interview 18).

that this book seeks to address, it shall be assumed that bilateral regulatory cooperation strategies can be 'ranked' on a scale according to their effect on existing regulations, trade flows or other factors (chapter 3.3.1 will propose criteria how bilateral regulatory cooperation strategies can be grouped). Given also the observed reluctance of the Commission to pursue regulatory export, this book proposes that, for certain policy issues, structural constraints exist which deter a regulator from pursuing a strategy which has a deeper effect on domestic regulations or trade flows. These constraints do not imply that the regulator will pursue this strategy on the issue in question across all contexts. Factors including those proposed by existing literature (Evenett, 2011; Quick, 2011, Young, 2010; Damro, 2006; Vogel, 2003) may support or undermine the pursuit of regulatory cooperation. However, this book suggests that structural constraints exist which prevent a regulator from even attempting a strategy such as rule export and policy externalisation across all contexts.

In abstract terms, the puzzle that this book seeks to address can thus be re-phrased as follows: Why does a regulator with high regulatory capacity only seek to export and externalise on certain policy issues? And why does it not choose to do so on other policy issues? It therefore aims at resolving the puzzle that a regulator with high regulatory capacity exports its rules to a specific third country only on some issues although prominent explanations propose similar strategies for all issues towards a given third country. To develop an answer, it is necessary to understand the formation and choice of a regulatory cooperation strategy other than externalisation or rule export. The development of an explanation should exclude cases in which a regulator does not seek externalisation or rule export because it is not 'powerful' enough to do so. This restriction can be controlled by assuming that the regulator is in principle powerful enough to export its rules. This can be assumed if it has high 'regulatory capacity' (Bach & Newman; 2007; see chapter 2.4 for a closer discussion). The research question that this book seeks to address is thus the following:

What constrains the formation and choice of a bilateral regulatory cooperation strategy of a state or jurisdiction with high regulatory capacity?

This puzzle can in particular be applied to the Commission. The Commission is often argued to have high regulatory capacity (e.g. Bach & Newman, 2010). Yet, despite its claimed high regulatory capacity and although existing explanations would expect similar strategies (for empirical data showing this differentiation see Young, 2015b), the Commission in practice pursues highly differentiated strategies of bilateral regulatory cooperation although. Applied to the Commission, the research question reads as follows:

What constrains the formation and choice of a bilateral regulatory cooperation strategy of the Commission?

This research question entails a number of sub-questions:

Who decides on the pursuit of bilateral regulatory cooperation within the Commission?
Among which bilateral regulatory cooperation strategies does the Commission choose?
How does the context in which regulatory cooperation takes place influence the behaviour of the Commission?
How do societal actors influence and alter the Commission's choice of a regulatory cooperation strategy?

To sum up, this section has presented the puzzle that motivates this book. This puzzle consists in the reluctance of the Commission, as observed by previous studies, to export its rules to third countries on certain issues although rule export should create benefits for both the Commission and societal actors and, according to previous literature, should be an expected choice of the Commission. This section has sketched out both the theoretical and empirical dimension of this puzzle. From this puzzle it has derived the main research question that this book seeks to address: What constrains the formation and choice of a bilateral regulatory cooperation strategy of a regulator with high regulatory capacity?

1.3. Summary of the main argument

After the research question has been developed, this section presents the main argument that will be subsequently elaborated in this book.

Regulators' choice of a regulatory cooperation strategy depends on bureaucratic pressure to engage in regulatory cooperation, the distribution of regulatory compatibilities between the domestic and the foreign jurisdiction as well as on the presence of societal mobilisation in support of regulatory cooperation.

Bureaucratic pressure within regulatory bodies by the politically appointed or administrative leadership initiates the formation of a regulatory cooperation strategy. Due to their limited resources, burden overload and uncertainty towards the success of regulatory cooperation, regulatory officials, i.e.. technical officials from the Commission Directorates General (DGs), usually concentrate their efforts on ensuring an adequate level of consumer health, safety and environmental protection at the domestic level. In the absence of bureaucratic pressure, regulatory divergences and differences across jurisdictions thus remain frequently unaddressed. Yet, the relative prioritisation between domestic regulation and international engagement of politically appointed top-level officials and non-technical DGs differs from the prioritisation of technical officials. Politically appointed officials and administrative leaders have discretion to pursue non-technical objectives; non-technical bureaucrats have different mandates than technical regulatory officials. Both therefore see regulatory cooperation as an opportunity structure under interdependence to prevent political intervention and enhance the autonomy and legitimacy of the Commission. As politically appointed officials, administrative leaders and non-technical bureaucrats become involved in the formation of regulatory cooperation strategy Commission strategy, they reduce uncertainty for technical regulatory officials. Hence, the priorities of technical regulatory officials change. Under bureaucratic pressure, they seek to protect their discretion vis-à-vis politically appointed officials, top-level bureaucrats and non-technical DGs and demonstrate that their regulatory efforts ensure a high level of consumer and environmental protection while enabling a competitive business environment. As a result, they shift organisational resources from domestic regulation to international cooperation and explore if regulatory cooperation is an opportunity structure to achieve regulatory objectives and enhance their discretion.

The compatibility of regulatory institutions between the domestic and the foreign jurisdiction constrains the subsequent choice of regulatory officials among different bilateral regulatory cooperation strategies. Regulatory institutions comprise regulatory competence allocations which this book calls 'regulatory authority structures', and regulatory approaches, called 'regulatory principles'. They are compatible if they do not allocate regulatory responsibilities to different authority levels and do not establish conflicting objectives and approaches. In bilateral regulatory cooperation, a regulator is unlikely to

achieve cooperation with a third country if it demands significant changes to foreign institutions. It can thus only cooperate with third-country regulators by accepting or recognising their regulatory institutions. At the same time, domestic regulatory officials seek to prevent losing domestic autonomy and legitimacy. Regulatory officials thus seek to prevent a loss of their authority to regulate their domestic market and avoid additional power claims from sub-central regulators. Moreover, they seek to prevent a loss of their legitimacy towards legislators and societal actors by recognising regulations and procedures which conflict with the principles institutionalised in domestic legislation.

The ability of officials to use bilateral regulatory cooperation with regulators from a third-country as an opportunity structure is thus constrained by the presence of non-centralised regulatory authority and conflicting regulatory principles in the foreign jurisdiction. Regulatory officials can choose 'regulatory alignment' if both regulatory authority structures and regulatory principles are compatible. They are, however, constrained to choose 'equivalence' if regulatory principles differ even if regulatory authority structures are compatible. Regulators can only opt for an 'alignment of implementation procedures' if regulatory principles are compatible but regulatory authority structures are not. Moreover, they can choose 'information exchange' even if both regulatory authority structures and regulatory principles between the domestic and foreign jurisdiction are incompatible.

The mobilisation of societal actors in support of regulatory cooperation pushes technical officials and bureaucratic leaders, i.e. politically appointed officials and administrative leaders, to adopt a regulatory cooperation strategy in accordance with the distribution of regulatory compatibilities. Societal mobilisation offers technical expertise and guidance to regulatory officials on which issues within a regulatory regime they can cooperate with a third country or jurisdiction. It assures them that societal actors consider their pursuit of regulatory cooperation as legitimate. If societal mobilisation takes place across jurisdictional boundaries, it raises expectations among regulatory officials that their counterparts from the third country may respond to their chosen regulatory cooperation strategies. Societal mobilisation can, however, not push regulatory officials to pursue bilateral regulatory cooperation beyond the constraints imposed by regulatory compatibilities.

1.4. Approach and outline of the book

This section summarises the approach and offers an outline of this book. It thus sheds light on the structure that this study uses to theoretically deduce and empirically test the proposed argument.

This book begins with a discussion of the existing literature that offers theoretical approaches to the study of strategy formation in external governance (chapter 2). It distinguishes approaches that identify explanatory factors at the domestic and international level and that follow a rational-choice and constructivist logic. This study places itself in the field of research which sees explanatory factors at the domestic level and follows a rational-choice logic. The discussion defines a theoretical gap in the shortcoming of domestic-level rational-choice approaches to account for the variation and differentiation of bilateral regulatory cooperation strategies. At the same time, it points out a theoretical incoherence regarding the influence of 'state' actors in external governance. While theoretical studies emphasise the relevance of state actors, they lack a micro-theory that focuses on 'state' actors and can account for the decision-making process underlying the choice for a strategy.

To develop a theory on the constraints under which bilateral regulatory cooperation strategies are formed and chosen, this book first develops a typology of the various, differentiated bilateral regulatory cooperation strategies. This allows the operationalisation of the dependent variable for the following analysis (chapter 3). Bilateral regulatory cooperation strategies are placed within prior categories of governance mechanisms. Subsequently, a stock-taking of all bilateral regulatory cooperation strategies as understood by different approaches is conducted. Identified strategies are then synthesised and organised into a 2x2 typology. This typology aims at reducing analytical complexity while maximising the difference between types. It clusters bilateral regulatory cooperation strategies based on the 'dimension' and 'depth' of cooperation.

The next chapter (chapter 4) deduces the independent variables of this book. To address the theoretical gap identified in chapter 2, it integrates the emerging interdependence research paradigm, the New Interdependence Approach, into the most widely used approach in governance studies, actor-centred institutionalism. From this incorporation, it derives a new integrative framework, the Inter-relational Institutionalism. The first independent variable of Inter-relational Institutionalism, 'bureaucratic pressure', is derived from the 'actor characteristics' building block of actor-centred institutionalism. It reflects the key conclusion of the New Interdependence Approach that interdependence creates endogenous incentives for actors to seek transnational engagement. The second independent variable are the 'regulatory compatibilities' constraining the choice of regulators of a regulatory cooperation strategy. It is derived from the conclusion of the New Interdependence Approach that institutional conditions determine the access and ability of actors to engage transnationally under interdependence. From the actor-centred institutionalism, two elements of this independent variable are deduced: the

compatibility of regulatory authority structures and the compatibility of regulatory principles. Constraints on the choice of a bilateral regulatory cooperation strategy are linked to the pursuit of a strategy through the introduction of a third independent variable, the 'mobilisation of societal actors' by bureaucratic actors. This mobilisation completes the causal mechanism which links variation in regulatory compatibilities to the choice of different bilateral regulatory cooperation strategies.

The subsequent chapter (chapter 5) introduces the methodology that is used by this book to empirically test the refined theoretical framework deduced in chapter 4. It presents the reasons for the choice to adopt a qualitative approach and pursue a comparative case study of the Commission's pursuit of regulatory cooperation in transatlantic regulatory cooperation across three different phases in four different sectors. Different regulatory cooperation initiatives are delineated to ensure variation on the independent variable 'bureaucratic pressure'. Moreover, different industry sectoral regimes are chosen as least likely case studies for the explanatory strength of the Inter-relational Institutionalism. While the chosen sectoral regimes agree on almost all rival explanatory factors, they disagree on their outcomes on the second independent variable, the 'constellation of regulatory compatibilities' between the EU and the US. Within-case process-tracing is used to identify the causal mechanism that accounts for the Commission's formation of a regulatory cooperation strategy on a particular issue within a sector.

Chapter 6 then presents the four sectoral empirical case studies which link variation in internal Commission constellations to variation in the distribution of regulatory compatibilities between the EU and the US. The chemicals case study (chapter 6.1.) shows that demands of Commissioners and DG Trade for regulatory cooperation on chemicals led to the pursuit of 'information exchange' due to the constraints of incompatible regulatory authority structures and incompatible regulatory principles. The engineering case study (chapter 6.2.) shows that demands of Commissioners and top-level bureaucrats led officials pursue an 'alignment of implementation procedures' due to the compatibility of principles, but incompatibility of authority structures. In the food safety case study (chapter 6.3.), it is laid down that demands of Commissioners and the DG Trade for cooperation led to the choice of 'equivalence' due to the compatibility of regulatory authority structures, but incompatibility of regulatory principles. Finally, in the ICT case study (chapter 6.4) it is demonstrated that demands of Commissioners and top-level bureaucrats for cooperation allowed the pursuit of 'regulatory alignment' because of the compatibility of both regulatory authority structures and principles.

Chapter 7 discusses the findings of the empirical case studies in light of their reliability, validity and objectivity and draws out limitations of the generalisability of these findings beyond the case studies examined. Moreover, it lays down the theoretical and empirical contribution of the findings of this book and sketches out avenues for future research.

2. Literature review: Strategy formation in external governance

While research on strategy formation on regulatory cooperation and policy coordination is an underdeveloped field of research, theoretical approaches can be identified if related streams of literature are taken into consideration. Indeed, a comprehensive body of literature can be found if regulatory cooperation is considered more broadly as a form of global governance. This is particularly the case if regulatory cooperation is approached as a form of external governance which includes institutional arrangements and processes to monitor and enforce rules and regulations in external relations. Much of the literature on external governance concentrates on the behaviour of the EU in external governance[4]. This chapter discusses the external governance literature with a view to the puzzle and research question on strategy formation underlying this book. It structures the discussion around the objective to delineate the theoretical gap that this book seeks to address.

Existing theories and approaches can be largely distinguished along three dimensions: their level of analysis, their identification of actors, and their conception of actor behaviour. With regard to the level of analysis, approaches identify causal factors both at the domestic and international level. Moreover, while some approaches conceive of a relatively great autonomy of state actors from societal actors, others see the behaviour of state actors as largely determined and shaped by societal pressures. Besides, approaches can be distinguished based on whether they model the behaviour of actors in either rationalist or idealist terms. With a view to the theoretical ambition of this book to the literature, this review organises existing studies along two dimensions. The first dimension distinguishes if approaches identify explanatory factors at the domestic or international level. The second one divides contributions into those that employ rational-choice frameworks and those that see ideational factors as drivers of the behaviour of actors. The typology in figure 1 illustrates the division of the literature on external governance with a focus on the EU into four categories.

Behaviour of actors	**Level of analysis**	
	Domestic	**International**
Rational-Choice	Domestic politics	International political economy
Constructivist	Domestic regulatory culture	Global regulatory capitalism

Figure 1: Typology of external governance literature

[4] 'Governance' has become associated with a form of governing which puts emphasis on effective and efficient problem-solving and an orientation of state and non-state actors towards problem-solving for the 'public good' (Kohler-Koch & Rittberger, 2006: 28).

This chapter first discusses constructivist approaches that identify explanatory factors for the behaviour of actors at the international level (chapter 2.1.). Contributions to this literature emphasise the emergence of a global regulatory capitalism. It then discusses rational-choice literatures that see explanatory factors at the international level (chapter 2.2.). This literature has mostly dominated research in "the first wave of scholarship" (Drezner, 2007: 12) in the 1980s and early 1990s and has more recently enjoyed a renewed interest on the role of international organisations in mediating and orchestrating the behaviour of states and sub-state actors. Contributions to this field often identify themselves as part of the 'international political economy' literature. Subsequently, it discusses domestic-level constructivist approaches that propose the existence of distinct domestic regulatory cultures which reflect underlying ideas and normative orientations (chapter 2.3). In a fourth step, it examines domestic-level rational-choice explanations to which also this book seeks to contribute (chapter 2.4). These contributions underlining the influence of 'domestic politics' have arguably become mainstream with the emergence of the 'Open Economy Politics' paradigm in international political economy. More recently, the New Interdependence Approach has sought to build a bridge between domestic- and international-level approaches. Lastly, the shortcomings of each approach are summarised and the theoretical gap is specified that this book seeks to address.

2.1. Global regulatory capitalism

This section begins with a discussion of approaches that identify explanatory factors for the behaviour of actors at the international level. Many studies within the "first wave of scholarship" (Drezner, 2007: 12) have adopted a constructivist stance. Constructivist approaches put forward that the behaviour of actors is shaped by the beliefs and values that they hold (Siles-Brügge, 2014). Actors are driven by internalised norms and rules of appropriate behaviour (Checkel, 2005). From this perspective, the ideas, values and priorities that actors hold regarding the meaning and objective of a policy are thus responsible for the strategies that they pursue (Beland, 2009).

This review groups contributions that see factors determining the behaviour of actors at the international level and which follow a constructivist logic under the heading of a 'global regulatory capitalism' literature. Two different streams within this literature can be delineated. A first stream borrows from sociological institutionalism and underlines the influence of a 'World Society' of NGOs, epistemic communities and scientific networks. It underlines the role of trans-governmental networks as place for socialisation among regulators. This literature is summarised in the sub-section 'transnational regulatory networks'. The second stream is more strongly grounded in conventional constructivist thinking and emphasises the emergence of a global ideational framework that encapsulates a 'regulatory capitalism'. This ideational framework underlines the role of experts and epistemic communities. Both streams of the 'global regulatory capitalism' literature imply that regulators should seek to engage in deep regulatory cooperation.

Transnational regulatory networks

Sociological institutionalists propose that the socialisation of governments and regulators from different jurisdictions in transnational regulatory networks leads to the development of common norms and identities (Barnett & Finnemore, 2004; Ruggie, 1993). They thus imply that socialisation promotes the engagement of regulators in regulatory cooperation.

Sociological institutionalists put forward that through their socialisation in international organisations and trans-governmental networks, governments and regulators establish common norms. International organisations and trans-governmental networks define meanings and norms of good behaviour and in particular establish which choices can be considered as appropriate or legitimate behaviour (Barnett & Finnemore, 2004; Ruggie, 1993). As international organisations networks encourage and support socialisation and learning among government actors, they promote the spread of ideas, norms and understandings of appropriate behaviour and good governance (Djelic & Sahlin-Anderson, 2006;

Finnemore, 1996). Authors argue that as a consequence of these learning processes, actors internalise shared norms and develop common identities. Regulators exchange best practices, learn from each other and develop an interest in maintaining their reputation vis-à-vis other officials from other entities (Eberlein & Grande, 2005; Sabel & Zeitlin, 2008; Slaughter, 2004: 59; Trondal, 2010: 22). As a result, the socialisation and embeddedness of government officials in international organisations and trans-governmental networks are argued to drive governments to mutually harmonise their policies (Finnemore & Sikkink, 1998; Checkel, 1999). Likewise, socialisation in trans-governmental networks acts as an 'external reflexive discipline', causing officials to take greater account of the impact of internal decisions on other states (Zeitlin, 2015b: 346). The OECD (2013b) has claimed that trans-governmental networks not only contribute to the development of a common language and identities, but socialisation also promotes trust in the ability of foreign government to implement shared commitments. Moreover, trust-building among governments helps overcome reluctance among governments to pursue regulatory cooperation.

Scholars in EU studies have underlined the influence of internationally shared norms and socialisation on the engagement of the Commission in regulatory cooperation and externalisation. Schwellnus (2013) argues that convergence on common ideas of human rights in the ILO support the EU's promotion of labour standards. At the same time, Niemann and Bretherton (2013) explain the difficulty of the EU to incorporate international competition policy commitments into WTO Agreements with absence of shared norm establishment in international institutions. Bretherton and Vogler (2006) add that shared common understandings between the Commission and foreign government officials developed in trans-governmental networks has supported EU efforts for cooperation through global governance. Schimmelfennig and Sedelmeier (2005) put forward that socialisation in trans-governmental networks promotes perceptions among foreign government officials that policy solutions of the EU are legitimate and that EU policy actors have technical expertise. They claim this reinforces intentional strategies of the Commission to export its 'normative capabilities'. Niemann (2004) notes that a high degree of institutionalisation and dense socialisation of Commission officials with representatives of other states in transnational networks support the reliance of the Commission on communicative action and normative discourses. Slaughter (2004) adds that this engagement in deliberative and problem-solving discourses paves the way for regulatory harmonisation through exchanges of best practices.

Regulatory capitalism

The second constructivist approach that locates explanatory factors for the formation of regulatory cooperation strategies at the international level are agency-centred explanations. These draw attention to the influence of global epistemic communities of scientists and experts on the behaviour of regulators. They note that the spread of 'global regulatory capitalism' (Braithwaite, 2008; Levi-Faur, 2005) has strengthened the role of scientific knowledge in policy-making. According to the 'regulatory capitalism' argument, the rise of epistemic communities connected by shared scientific knowledge facilitates cooperation efforts among regulators and promotes regulatory convergence.

Contributions adopting the argument of 'regulatory capitalism' propose that the spread of regulatory capitalism has strengthened transnational epistemic communities made up of transnational NGOs and global communities of researchers and scientists (Haas, 1992). They can act as 'norm entrepreneurs' across borders. Epistemic communities and scientific experts guide the choices of policy-makers and government officials across jurisdictions, define policy problems and shape government officials' perceptions which solutions to policy problems are legitimate. As transnational NGOs and researchers organise in advocacy or issue networks, connected by shared beliefs and values, they provide scientific knowledge about cause-and-effect relationships to governments and regulators (Keck & Sikkink, 1998). Consequently, the global spread of scientific discourses by epistemic communities is thus argued to promote a convergence in meaning structures among government officials. Authors argue that this encourages efforts of government officials and regulators to achieve institutional isomorphism (Finnemore & Sikkink, 1998; Checkel, 1999; DiMaggio & Powell, 1983).

Scholars in EU studies offer confirming evidence for this argument. Holzinger and Sommerer (2013) argue that the rationalisation and globalisation of scientific discourse on climate change has driven the EU's promotion of adopting international environmental regulation. Schwellnus (2013) underlines the influence of global NGOs and human rights movements on pushing and encouraging Commission officials to promote human rights internationally. The OECD (2013b: 111) outlines that epistemic communities support e.g. the alignment of testing methods and laboratory practices and thus support the development of a common language and definitions among government officials, which it sees as a driver of efforts for regulatory approximation.

Yet, both sociological institutionalist approaches and contributions to the 'regulatory capitalism' literature cannot offer a strong explanation for the observation that in practice, governments or regulators choose regulatory cooperation strategies which differ from harmonisation or policy imitation. This is not to call into question that socialisation in international institutions, learning through trans-governmental networks and norm entrepreneurship by global epistemic communities and advocacy networks does not influence strategy formation of government officials or policy-makers at all.

However, these approaches first overemphasise the influence of ideas and scientific discourse on the behaviour of actors. Even if actors share common understandings and norms, they may fail to act upon them (Falkner & Müller, 2013: 219). Moreover, where scientific evidence is ambiguous, regulators and governments may instrumentally employ scientific studies that conform to their preferences derived otherwise[5] to justify their behaviour. At the same time, they cannot account for strategies other than regulatory approximation or the persistence of regulatory competition. Second, their empirical applicability remains limited. Sociological institutionalism and approaches emphasising the role of epistemic communities approaches often employ biased case selection as they concentrate on empirical cases supportive of their theory. Checkel (2005) thus argues that epistemic communities and trans-governmental networks are most likely to influence the strategy formation of policy-makers in depoliticised settings if the latter face complex or uncertain issues (Checkel, 2005). Moreover, Garrett and Weingast (1993: 168) state that epistemic communities can influence the behaviour of state actors if distributional differences between different solutions are small and power asymmetries between involved actors are small. However, they neglect 'hard cases' in which regulators and governments refuse to pursue approximation despite the availability of global scientific discourse and the existence of transnational advocacy groups. Third, they do not specify or examine a causal mechanism that links the behaviour of regulators and governments to trans-governmental networks and expert communities. They thus infer the development of shared values and internalised norms from the observation of similar policy responses across jurisdictions rather than tracing specific actors or decisions (Tarrow, 2001).

In sum, this section has presented two main constructivist approaches that can be joined into a 'global regulatory capitalism' literature. They see explanatory factors for (regulatory) cooperation at the international level. Sociological institutionalists argue that international organisations and trans-governmental networks lead to the development of common norms and identities, promote trust and mutual learning and thus drive regulators and governments to promote regulatory approximation. 'Global regulatory capitalism' approaches argue that the rising importance of scientific experts promotes an alignment of discourses across jurisdictions and thus implies that epistemic communities influence regulators to pursue regulatory cooperation. Empirical evidence confirming these approaches remains selective, however. Consequently, these approaches overestimate the extent to which governments and regulators pursue harmonisation. Indeed, they are unable to explain the pursuit of differentiated regulatory cooperation strategies other than approximation. Besides, authors insufficiently demonstrate a causal mechanism that leads regulators to internalise norms and scientific discourse and struggle to explain regulatory cooperation outside depoliticised settings with little distributive implications.

[5] The employment by various governments from EU member states of different scientific studies with divergent findings on the public health impact of glyphosate in the debate on the re-authorisation of the pesticide in the EU in autumn 2017 is arguably a good example for this.

2.2. International political economy

This section looks at rational-choice approaches which see explanatory factors at the international level. Rational-choice approaches assume that actors build their choices on instrumental maximisations of utility, expressed and measured in terms of welfare and power (March & Olsen, 2008; Shepsle, 2005; March & Olsen, 1989). This section distinguishes between two streams of rational-choice approaches within the 'international political economy' literature that see explanatory factors for the cooperation behaviour of state actors, i.e. governments and regulators, at the international level. A first stream underlines the creation of international institutions, notably the role of international organisations and trans-governmental networks, on altering the behaviour of actors at the international level. A second one emphasises the effect of economic internationalisation and the influence it has exerted on the influence of transnational firms on decisions of state actors at the domestic level. This section first reviews contributions to the international institutions literature and then looks at contributions to literature emphasising economic internationalisation.

International institutionalisation

Authors that propose a causal role of international organisations on the behaviour of actors at the domestic level distinguish two functions and influences of international organisations. They view international organisations as a) coordination mechanisms to resolve coordination problems and b) independent orchestrators.

The role of international organisations in influencing the behaviour of governments is treated both as an intervening and independent variable. Liberal institutionalists (e.g. Keohane & Nye, 1977; Moravcsik, 1993) mainly treat international institutions, comprising international organisations and dense transnational regulatory networks, as an intervening variable. They argue that international organisations or dense transnational regulatory networks influence the behaviour strategies of governments because they help solve coordination problems at the international level and encourage governments to seek cooperative outcomes rather than relative gains (Keohane & Nye, 1977). International institutions can thus push governments to act upon something that they would not have responded to in the absence of international organisations (Dai, 2007; Checkel, 1997; Risse-Kappen, 1995). Moreover, international institutions create focal points and thus push government officials to concentrate regulatory cooperation strategies on selected, focused initiatives (Zeitlin, 2015). They therefore help resolve transnational externalities of regulations or regulatory differences across jurisdictions. Authors note, however, that the ability of international organisations to push states to cooperate is linked to their monitoring and

enforcement capacities (Slaughter, 2004; Mattli & Büthe, 2003; Koremenos, Lipson & Snidal, 2001; Keohane, 1984).

More recently, liberal institutionalists borrowing from historical institutionalism have come to view international organisations not only as a coordination facilitator, but as institutions with an independent causal influence (Abbott, Snidal, Genschel, & Zangl, 2015; Farrell & Newman, 2014; Fioretos, 2011; Börzel, 2005; Dai, 2005). According to this argument, international institutions can constrain the discretion and autonomy of domestic government officials through hierarchical intervention and thus condition the scope of possible strategies (Börzel, 2005; Dai, 2005). As 'endogenous actors', international institutions are argued to create feedback effects, trigger distributional implications for political and societal actors and thereby bias policy in a particular direction. International institutions thus initiate processes of 'institutional drift' and push states to pursue cooperation with each other (Farrell & Newman, 2014; Fioretos, 2011). Besides, liberal institutionalists have suggested that international institutions may act as 'orchestrators' rather than through hierarchical intervention and enlist and support intermediary actors in pursuit of their goals (Abbott, Snidal, Genschel, & Zangl, 2015). International organisations empower societal actors and 'policy entrepreneurs' by allowing them to build alliances with other transnational or supranational actors or increase the political leverage and improve the informational status of domestic actors (Farrell & Newman, 2014). This empowerment of societal actors by international organisations is argued to push governments to cooperate internationally (Abbott et al., 2015; Zeitlin, 2015).

Numerous studies discuss the effect of international institutions on the strategies pursued by the EU. Falkner and Müller (2013) argue that international institutions with monitoring and enforcement capacities induce the EU to engage in policy export and policy promotion. De Bièvre, Poletti and Thomann (2014) have proposed that the enforcement capacities of the WTO and judicialisation through the Dispute Settlement Mechanism has allowed hierarchical intervention and pushed the EU to adapt its regulatory policies. Zeitlin (2015) argues that the SPS Agreement under the WTO has pushed the EU and US to initiate cooperation in managing the risks of unauthorised contamination with genetically modified organisms (GMO). Newman and Posner (2015) add that the density of international institutions determine the policy strategies used by the EU at the international level. More specifically, dense international institutions are argued to encourage the EU to use 'deeper' forms of cooperation. Costa and Jorgensen (2012: 4), however, put this finding into perspective, arguing that international organisations have influence on decisions in the EU if they are legalised and have strong organisational backing.

Authors also examine why international organisations shape the behaviour of the EU. Dai (2007: 138) puts forward that international organisations have a particularly high influence on the EU because of its multiple access points and potential 'policy entrepreneurs'. Abbott et al. (2015) underline that international organisations as orchestrators are likely to influence the behaviour of the EU through the

provision of technical expertise. As the Commission frequently seeks scientific and technical expertise for its decision-making, including to assess the impact of proposed legislation, international organisations can influence decision-making in the EU through the provision of this expertise (Costa & Jorgensen, 2012: 6). Other studies note that international organisations encourage the EU to conduct regulatory cooperation. Conceicao-Heldt and Meunier (2014) argue that the structure of the international trade regime pushes the EU to negotiate cooperation multilaterally. Similarly, de Bièvre et al. (2014) suggest that the high degree of judicialisation and the scope for issue linkage make the WTO a preferred venue for the EU to address and negotiate regulatory issues at the international level.

However, the ability of these approaches to explain strategy formation on regulatory cooperation is limited. First, regulatory cooperation is not only a coordination problem as suggested by liberal institutionalists relying on game theory. Even if international organisations may facilitate coordination among governments, they may not push governments to pursue regulatory cooperation. Regulatory cooperation may entail such high adjustment costs for one side that cooperation may not be in the mutual interest of both sides (Büthe & Mattli, 2011). Second, despite individual counter-examples the influence of international organisations on the formation of regulatory cooperation strategies of governments or regulators remains limited. On the one hand, multiple or overlapping regimes among international organisations offer both the EU and other parties opportunities to shift among alternative international solutions and engage in forum-shopping (Alter & Meunier, 2009). Moreover, they can use alternative venues to create conflicting solutions to existing rules and thus widen their discretion against the influence of international institutions and organisations (Alter & Meunier, 2009: 17). On the other hand, international organisations have limited capacities to force states and governments to cooperate. They usually have restrictive treaty mandates, are subject to close oversight by member states and have limited financial and administrative resources (Abbott et al., 2015: 3). Even if international organisations have succeeded to promote the adoption of an international standard or decision, states retain considerable discretion in the adoption and implementation of international rules. Policy evidence proves that the EU too builds selectively on international standards and multilateral objectives in its internal regulations (Zeitlin, 2015b: 344). Third, international organisations have limited possibilities to resolve major conflicts of interest especially among large states (Drezner, 2007). Orchestration is mainly supported by states if they share common governance goals with international organisations, but lack the capabilities to achieve them (Abbott et al., 2015: 30). Possibilities of international organisations for entrepreneurship thus remain restricted to issues on which states have capability gaps. These are commonly limited to issues of low salience. This is not to argue that international organisations do not influence strategy formation of governments at all. Yet, their influence is likely to prevail in the case of issues on which governments are willing to maintain capability gaps because issues are not salient to them. Influence may also be indirect as international organisations rely on the support and engagement of actors at the domestic level.

Economic internationalisation

The second rational-choice approach that proposes explanatory factors for the formation of regulatory cooperation strategies at the international level underline the influence of economic internationalisation and the trans-nationalisation of firms on the behaviour of governments and regulators. Many of these contributions build on the assumption that economic internationalisation and globalisation have led to an 'erosion' of the state (e.g. Strange, 1996). They put forward that economic internationalisation leads to regulatory convergence, including through regulatory cooperation. Moreover, they argue that transnational firms, whose emergence has been facilitated by trade liberalisation and growing economic interdependence, influence strategy formation of government officials at the domestic level, including by undermining governments' scope for action. They disagree, however, on the direction of this regulatory convergence, i.e. its implication for the protection of health, consumer and environmental standards.

According to the 'race-to-the-bottom' hypothesis (e.g. Siles-Brügge & de Ville, 2015; Frieden, 2006; Prakash & Potoski, 2004; Long & Quek, 2002; Klein, 2000; for a discussion see Drezner, 2007; Vogel & Kagan, 2004), transnational firms put pressure on governments to lower regulatory standards that otherwise raise production costs (for a discussion see: 14; Vogel & Kagan, 2004: 2). Moreover, they threaten governments to shift production or investments to jurisdictions with lower regulatory standards. In order to maintain employment and tax revenues and to attract additional investment, governments will bow to firm pressure and lower regulatory standards, thus raising profit rates for multinational firms. As governments compete for highly mobile investments of multinational firms, they set in motion a downward spiral of lower regulatory standards towards a lowest common denominator and trigger a 'Delaware effect' (see also Kahler & Lake, 2003).

According to the 'race-to-the-top' or 'trading up' hypothesis (Vogel, 2012; 1995), the liberalisation of trade and capital flows facilitates a raise in regulatory standards across jurisdictions. This argument puts forward that firms advocate a restriction of competition through stringent domestic regulatory standards that are similar to their current production methods to raise their profitability. In doing so, they find support from NGOs. Within 'Baptist-bootlegger' coalitions (Vogel, 1995: 260), firms advocate more stringent regulatory standards that make market access conditional upon compliance with these stringent standards. The latter benefit domestic producers and reflect the interest of domestic NGOs, but disadvantage foreign producers. Yet, transnational firms which operate in several markets have an interest in uniform regulations across jurisdictions to reduce their production costs and lower regulatory certainty. If the jurisdiction that imposes more stringent regulatory standards has a large domestic market, the argument runs that foreign producers will lobby their own governments to raise regulatory standards and align them with those of the more stringent jurisdiction. In response to pressure from export-oriented producers, foreign governments will adjust their national regulations to the more

stringent regulatory standard to retain market access for their producers (Princen, 2004; Vogel, 1997). In this view, liberalisation of trade and the growing importance of export-oriented producers increases support for the export and spread of stringent regulatory standards, thus triggering a 'California effect'. The 'experimentalist governance' literature (Zeitlin, 2015: 17) adds that transnational firms not only lobby their domestic government to align its regulatory standards with the more stringent ones required by large foreign markets, but also lobby the foreign government to consider practices elsewhere in revising their own regulation. They thus suggest that 'trading up' sets off mutual influences and promote cross-national learning.

While both the 'race-to-the-bottom' and the 'race-to-the-top' hypotheses have received significant attention in the academic literature, their applicability to explain regulatory cooperation strategies is limited. On the one hand, empirical evidence for both remains limited. With regard to the 'race-to-the-bottom' hypothesis, Newland (1999) puts forward that trade liberalisation has exerted downward pressure on labour standards. Vogel (1995: 250) acknowledges that the construction of the Single Market has weakened national regulations of some member states on food additives and packaging directives. Nonetheless, cross-sectoral analyses fail to find empirical support for a systematic downward pressure exerted by multinational firms on domestic regulatory standards (for a discussion and review see Drezner, 2007: 16; Garrett & Lange, 1995). The establishment of private regimes by transnational firms has not undermined domestic regulatory frameworks, but mostly been a response to government inaction (Zeitlin, 2015) or have been restricted to emerging policy issues. As policy debates have developed, private regimes have been complemented or replaced with government regulation.

Likewise, empirical evidence remains limited for the broad applicability of the influence of transnational firms in promoting a 'race-to-the-top' or engaging in 'trading up'. Even if Vogel (1995) identifies examples of trading up in environmental and consumer safety regulation, the mutual strengthening of regulatory standards across jurisdictions as a result of transnational firm influence is limited. The mobilisation of foreign firms in favour of more stringent regulatory standards rather depends on the size and attractiveness of the market that imposes stricter regulatory standards in the first place (Vogel, 1995: 261). Only if the market is sufficiently attractive for foreign exporters, may they support a strengthening of standards to maintain market access. If, in turn, the market is too small, exporters may rather forego export opportunities than support a strengthening of regulatory standards in their own market. Besides, foreign producers may not mobilise in favour of more stringent regulatory standards if they perceive these more stringent regulatory standards as only motivated by protectionist interests (Princen, 2004). Likewise, if the strengthening of regulatory standards is perceived to reflect protectionist interests, the existence of Baptist-bootlegger coalitions may prevent a California effect in the country affected by trade restrictions (Princen, 2004: 141). In this case, foreign producers will seek to challenge them in front of international dispute settlement mechanisms or will seek to set rival regulatory standards rather than mobilise in favour of an adoption of the more stringent regulatory standards.

At the same time, international political economy approaches provide limited insight into the particular process of regulatory cooperation. They merely assume a regulatory dynamic without coordination among governments and regulators (see chapter 3.1). As a result, they do not specify which preferences a 'state' pursues that is transformed (even if it not eroded) by globalisation (Kahler & Lake, 2003). Functional pressures, i.e. regulatory divergences against a context of increasing interdependence, may well be considered a necessary condition for the pursuit of regulatory cooperation by the 'government' of a large economy. Certain authors, however, even call into question that it is necessary at all (Falkner & Müller, 2013: 280). In any case, these approaches leave unclear why high functional adaptation pressure should encourage governments to align or approximate their regulatory policies with those of other countries. High adaptational pressure may also reinforce government strategies to protect domestic policies under the status quo, e.g. making them more stringent, to maintain and protect their own regulatory scope.

In sum, this section has presented two main rational-choice approaches that see explanatory factors for regulatory cooperation at the international level. Liberal institutionalists argue that international organisations are coordination facilitators, act as focal points and orchestrators and thereby encourage states to engage in cooperation. International political economy scholars propose that transnational firms push governments to cooperate, either in a downward direction of regulatory stringency according to the 'race-to-the-bottom' hypothesis or an upward direction based on the 'race-to-the-top' argument. Empirical evidence for both arguments remains limited, though. Besides, they propose explanations that mostly reject an active role of the state in regulatory dynamics and thus fail to offer a mechanism that could explain the engagement of regulators in cooperation.

2.3. Domestic regulatory culture

Constructivist contributions that identify explanatory factors for the strategy formation of actors at the domestic level commonly share references to a 'domestic regulatory culture'. Within the literature that is relevant to understand constraints on strategy formation and choice in bilateral regulatory cooperation, this field of research is arguably the smallest. Constructivist approaches that see explanatory factors for the behaviour of regulators at the domestic level again share the assumption that the behaviour of an actor is shaped by its beliefs, values and identities. The embedding of actors within institutions shapes their identity and thereby constitutes meaning for them. According to approaches in this field, ideas and institutions thus influence what actors consider as legitimate behaviour.

Domestic-level constructivist approaches on international governance and regulatory cooperation identify two main explanations for the behaviour choice: the identity of a government and the presence of distinct regulatory approaches that constitute for a government what can be regarded as legitimate behaviour. These two explanations have been particularly influential in research that examines the influence of the EU's and the Commission's identity on its behaviour choices.

Approaches that follow identity-based explanations are rooted in both actor-centred and structural constructivism as well as sociological institutionalism. Actor-centred constructivism assumes that actors use ideas they hold strategically to advance what they consider as legitimate and appropriate behaviour (Saurugger, 2013). Sociological institutionalism, in turn, assumes that institutions shape the identities of actors and therefore constitute actors' behaviour (Eising & Jabko, 2001). Institutions thus define which claims and demands can be considered legitimate (Goldstein, 1988; Goldstein & Keohane, 1993). If ideas, values, and norms are embedded in an institutional setting, they can affect the strategic choices of policy-makers. Societal actors can exert influence on policy-makers as 'norm entrepreneurs' because they carry new ideas, values, or principles (Risse, 2000). To advance their norms at the international level, state actors thus seek to persuade other states about the legitimacy of their proposals (March & Olsen, 1989).

Within EU studies, approaches that may be placed into actor-centred constructivism have noted the Commission's pursuit of governance strategies that correspond to ideas that it holds. The latter support hypotheses for an engagement in deep regulatory cooperation and rule externalisation. To protect and extend the 'European model', authors note that the Commission seeks to combine deep economic integration with high social, environmental, health, and safety standards (Laïdi 2008; Zielonka 2008). Siles-Brügge (2011) puts forward that the internalisation and strategic use of neoliberal economic ideas explain the Commission's strategy to reduce non-tariff barriers to trade. Van den Hoven (2006) suggests that the Commission's decision to pursue rules-based multilateralism aiming at a fair redistribution of economic gains reflects its belief in justice and its belief in the inability of markets to deliver fair distributions of economic gains.

At the same time, authors have emphasised the influence of the EU's own multilateral identity and its experience of integration within the Single Market as an explanation for the pursuit of external governance (Jorgensen, 2006; Lucarelli & Manners, 2006). These studies have, however, not explicitly addressed the EU's or the Commission's pursuit of regulatory cooperation. Still, they have analysed related questions such as the role of the EU in promoting regionalism (Grugel, 2007), the relationship between the EU and state-centric international organisations (Laatikainen & Smith, 2006) and the potential of the EU to shape norms and rules of the international system (Smith, 2010; Chaban, Elgström & Holland, 2006). Falke (2005) argues that the Commission's pursuit of a rules-based trade policy and global governance architecture reflects its own post-modern identity.

An important contribution in this field are characterisations of the EU as a "civilian power" (Hill, 1990; Orbie & Tortell, 2009) and a "normative power" (Manners, 2002). The 'civilian power' perspective argues that the strength of the EU as a foreign policy actor relies primarily on the application of its own model of regional integration. Manners (2002) emphasises that the external behaviour of the EU is rooted in its particular and unique identity based on universal values such as freedom, human rights and democracy. He has coined the term 'Normative Power Europe' for the EU's distinctive identity (Manners, 2008). Empirical discussions focus on the EU's approach to promote human rights, democracy, and the rule of law through economic means (Orbie & Tortell, 2009; for a discussion see Schimmelfennig, 2010).

Authors further draw attention to the distinct regulatory cultures in jurisdictions that are rooted in regulatory ideas and public values. Regulatory cultures link ideas to institutions of regulatory convergence. In EU studies, Pollack and Shaffer (2005) and Vogel (2003) have drawn attention to the EU's distinct regulatory culture in assessing and managing risks and meeting consumer expectations for safety. Vogel (2003) argues that the prevalence of the EU's distinct regulatory culture and public value explain the persistence of regulatory divergence over time despite high levels of economic and political interdependence. The existence of distinct regulatory cultures reflecting specific public values hinders the engagement in regulatory cooperation if the regulatory cultures differ across jurisdictions.

The influence of distinct regulatory cultures especially on regulatory cooperation between large jurisdictions is admittedly difficult to disregard. Existing studies on transatlantic regulatory cooperation convincingly argue that distinct regulatory approaches in the EU and the US on many issues explain the persistence of divergences in regulations and standards (Vogel, 2012; Pollack & Shaffer, 2005; Steffenson, 2005). The distinction according to domestic regulatory cultures can, however, only support a dichotomous explanation between cooperation and non-cooperation. It cannot explain the multiple variation and the differentiated outcomes related to regulatory cooperation strategies that are observed empirically. Moreover, contributions to this field lack the specification of a causal mechanism that connects distinct regulatory cultures to the choice for different strategies of regulatory cooperation. This point will be resumed in greater depth in chapter 2.5.

2.4. Domestic politics

This section discusses rational-choice approaches that see explanatory factors for the governance behaviour of regulators at the domestic level. Drawing from an earlier characterisation by Drezner (2007), contributions to this field are summarised under the title 'domestic politics'. Rational-choice explanations that identify explanatory factors at the domestic level have become mainstream in both wider studies of international political economy and specific studies on the EU during what may be called a "second wave of scholarship". They maintain that 'great power' states with large internal markets remain the key actors and determine the extent of regulatory cooperation and convergence (Drezner, 2007). This literature argues that despite globalisation and economic internationalisation, the state has not disappeared, but rather changed its shape (Raustiala, 2002; Abbott & Snidal, 2009). Majone (1996) specifies this, observing the emergence of the 'regulatory state'. Slaughter (1997: 183) argues that "the state is not disappearing, but disaggregating into its separate, functionally distinct parts with these parts networking with their counterparts abroad". Abbott and Snidal (2009) put forward that multi-actor models of regulation can be better described as 'governance triangle' consisting of states, firms and NGOs, where decentralised regulatory powers are shared by state agencies and private actors. Within this governance triangle, the state retains a central role in transnational regulation and regulatory cooperation due to its competencies, its legitimacy and its credibility to act in the public interest (Abbott & Snidal, 2009). Many studies examining strategies, but also patterns of international governance fall into this field of research. It is also the field in which the theoretical contribution of this book shall be placed.

The 'domestic politics' literature can be broadly divided into four different streams: A first stream derives explanations for the behaviour of state actors from neo-realist theory. A second stream, the 'Open Economy Politics' literature builds on Liberal Institutionalism and explains the behaviour of actors with domestic societal preferences and domestic institutions which shape their aggregation. A third stream, the 'experimentalist governance' literature relaxes the strict assumptions of rational-choice theory for the behaviour of actors and proposes a behavioural framework which incorporates uncertainty and learning. Lastly, the 'New Interdependence Approach', relies on historical institutionalism and puts forward arguments for patterns of cross-jurisdictional institutional change in a context of high interdependence. This section will review each of these streams, examining whether and how they can be applied to the puzzle that this book seeks to address.

Neo-realism

Neo-realists (e.g. Gilpin, 1987; Krasner, 1976) emphasise that the states and jurisdictions with large internal markets are able to shape international regulatory outcomes. Relatively more powerful countries are assumed to have leverage over other countries and can therefore shape outcomes in line with their interests. States and jurisdictions with large internal markets will use their power strategically to shape global policy regimes in view of their own domestic policies and thus achieve relative gains over other powers. At the same time, they seek to protect their domestic policy choices by coercing others into compliance when necessary. Regulatory cooperation is thus also driven by geopolitical considerations. According to this argument, states will pursue regulatory coordination if adjustment costs that actors face in altering their pre-existing rules and regulations are not too high (Drezner, 2007).

States and jurisdictions will thus pursue regulatory cooperation where they have hegemonic or at least relative power. Simmons (2001) thus explains harmonisation in international capital regulation in the 1990s with the reliance of the US on its hegemonic power. Drezner (2007) also stresses the market power of the EU as a determinant of its willingness and ability to shape global regulatory outcomes alongside the US.

Many authors emphasise that the size of the Single Market is an essential power resource of the EU (Bach & Newman, 2007; Damro, 2012; Bretherton & Vogler, 2006; Meunier & Nicolaidis, 2006). Yet, a large market is increasingly considered a necessary, but not sufficient power resource. At the same time, few studies have found evidence for geopolitical considerations as a determinant of the motivation for the EU's interactions at the international level (Zimmermann, 2007; Aggarwal & Fogarty, 2004). Conceicao-Heldt and Meunier (2014) on the contrary argue that the EU mostly uses its material power where it negotiates with symmetrical power whereas it is more likely to act as a normative power when it negotiates with smaller or less powerful actors.

Correspondingly, the scope for power-based bargaining especially in bilateral regulatory cooperation is small. Bilateral regulatory cooperation usually involves the contestation among rival solutions with one tending to prevail in the end (Peterson & Young, 2014: 160). Under an equivalence decision, each side maintains its rules. Compromise is only possible if one side accepts the other side as equivalent in effect. Even where the EU found itself in an unfavourable bargaining situation in the past, it did not change its regulations due to external pressure (Alons, 2014). Moreover, regulatory externalisation has been stronger with states similar in market size to the EU than with smaller states (Young, 2016). Power-based bargaining has been particularly constrained where the positions of the EU have been "isolated" (Falkner & Müller, 2013: 219) or the preference differential between the EU and third countries has been very high (Young, 2014).

Open Economy Politics

The arguably most widely applied rational-choice institutionalist model to understand strategy formation in international political economy is the so-called 'Open Economy Politics' framework (Lake, 2009). It conceptualises strategy formation of governments in a two-step process: preferences of economic actors, i.e. firms, trade unions and NGOs, are aggregated into a strategy whereby the aggregation of these preferences is conditioned by the domestic institutions of a country, i.e. its decision rules. The subsequent application of the framework to understand a state or jurisdiction's behaviour in international negotiations employs the metaphor of the 'two-level game'. One 'game' is the domestic game in which the range of outcomes is determined for which the government can ensure ratification, i.e. the 'win-set'. The other 'game' represents the bargaining of the government negotiators as the interface between the domestic and the international level at the international level with other governments[6].

Within the domestic 'game', the constraints on strategy formation by government negotiators are influenced by the constellation of societal preferences and the pattern of political institutions (Lake, 2009). The constellation of societal preferences constrains the negotiating room for government negotiators at the international level. The preference of a societal actor with regard to a specific outcome reflects the anticipated gains or losses from that potential outcome (Dür & De Bièvre, 2005; Bouwen, 2002; Grossman & Helpman, 1994; Frieden, 1991; Rogowski, 1989; Milner, 1988). Subsequently, the aggregation of the preferences of societal actors into state preferences is determined by the domestic institutional framework. The domestic institutional framework thus determines how many actors can influence the formulation of a strategy and their relative power on its adoption or eventual ratification.

With regard to regulatory cooperation, the preferences of societal actors are argued to reflect the pattern of 'regulatory politics' or 'new trade politics', i.e. societal contestation among economic and non-economic interest groups (Kelemen 2010; Kelemen & Vogel 2010; Peterson & Young, 2014; Young & Peterson, 2007). Import-competing firms are expected to prefer protection through non-cooperation while export-oriented firms are expected to prefer liberalisation. Authors argue that a shift in the balance of power among economic interests as a result of trade integration, trade diversion effects, the emergence of global value chains and the growing importance of import-dependent firms has recently led to an increasing pursuit of trade liberalisation and regulatory cooperation (Kim, 2017; Eckhardt & Poletti, 2016; Siles-Brügge, 2011; Dür, 2010;; Manger, 2009; Woll, 2008; McGuire, 2006).

[6] There has been a debate if regulatory cooperation can be modelled with the help of the two-level game. Studies (Peterson & Young, 2014: 162; Damro, 2006) have put forward that regulatory cooperation does not entail the participation or involvement by government leaders, but government officials or regulators. However, these are argued to represent domestically agreed positions and behave in ways grasped by the two-level game metaphor. (Peterson & Young, 2014: 162).

At the same time, authors put forward that the growing importance of NGOs and the emerging politicisation of regulatory cooperation constrains the ability of state actors to engage in trade politics or regulatory cooperation (Dür & De Bièvre, 2007; Young & Peterson, 2006). The literature suggests that NGOs and trade unions prefer a strengthening of regulations which protect their constituency (Young & Peterson, 2006). NGOs thus tend to support an export or uploading of domestic consumer, labour, environmental and public health regulations (Peterson & Young, 2014). Yet, most environmental and consumer organisations are assumed to oppose regulatory cooperation because they fear downward pressure on domestic regulations (Vogel, 2003, 2012; Evans, 2003: 155). In these constellations, high issue salience and the mobilisation of societal actors are argued to constrain the space for government negotiators to act upon their own preferences (Peterson & Young, 2014; Klüver, 2012; Mahoney, 2007).

From these considerations, Open Economy Politics deduces the preferences of societal actors in 'regulatory politics'. Regulatory approximation through changes to national regulations is argued to be opposed by NGOs that support the substantive objective of a policy as well as firms that would face increasing competition (Peterson & Young, 2014: 161; Nicolaidis, 2000: 159). Actors that may favour a foreign regulation to the domestic one are argued to be in the minority as they likely lost the corresponding political debate previously. Negotiated mutual recognition is argued to reflect the patterns of traditional trade politics, i.e. the confrontation between export-oriented and import-competing firms. NGOs may question if a foreign regulation is equivalent in effect to the domestic one. Import-competing firms are argued to question 'equivalence' to avoid higher competition. Societal actors should favour negotiated mutual recognition where export-oriented interests prevail (Peterson & Young, 2014: 162; Eckhardt & Poletti, 2016).

In EU studies, Eberle and Lauter (2011) argue that the increase in powers for the European Parliament with the Lisbon Treaty increased the importance of veto points for the Commission. Newman (2011) puts forward that the multi-level structure of the EU allowed national data privacy authorities and NGOs in the dispute on the sharing of airline passenger records to leverage their access to opportunity structures at the EU level. This prevented an agreement on the exchange of airline passenger records against the support for data sharing among the interior ministries of the EU member states. Authors further point out that NGOs in the EU oppose regulatory cooperation as the stringency of EU regulations often tends to exceed that of other countries (Young, 2016; Eliasson, 2014; Peterson & Young, 2014: 27). Ziegler (2011) argues that the politicised regulatory process of risk management in the EU with its openness to the participation of NGOs give rise to a prevention-focused approach. The mobilisation of NGOs has been connected to a 'politicisation' of trade and regulatory politics (Eliasson, 2014; Zürn, 2015). Pollack argues that this domestic politicisation "has constrained the ability of regulators to engage in substantive compromises with their counterparts" (Pollack, 2005: 911; see also Pollack, 2003). Besides, Vogel (2012: 32) draws attention to the public, arguing that the public in the EU displays a pronounced concern for the protection from risks that could be challenged through regulatory cooperation (Vogel, 2012: 32).

Yet, 'regulatory politics' struggles to explain the Commission's choice of regulatory cooperation strategies in practice. First, in many cases, societal mobilisation is muted or reactive. The Commission's struggle to raise civil society participants for all regulatory cooperation dialogues except those with the US shows this. Societal mobilisation is at best reactive as it mainly occurs when regulators have provided incentives to mobilise. Second, authors also call into question if regulatory cooperation can be explained with the deduction of preferences according to the 'Open Economy Politics' framework. On the one hand, anticipated costs and benefits are harder to predict for regulatory cooperation (Peterson & Young, 2014: 27; Jacoby & Meunier, 2010: 311; Woll, 2008: 18). On the other hand, negotiations on regulatory cooperation do not (only) revolve around the question whether to liberalise, but rather how to liberalise economic relations. Existing studies have mostly proposed that the preferences of firms reflect the expected adjustment costs of regulatory adjustments or approximations (Büthe & Mattli, 2011). Firms are thus expected to prefer regulatory outcomes with which they are familiar to avoid adjustment costs. If expected adjustment costs outweigh the anticipated benefits of a reduction in regulatory barriers, even export-oriented firms prefer a maintenance of the regulatory status quo.

Third, in the presence of the NGOs and after the adoption of rules and standards on risk regulation firms advocate an externalisation of domestic rules and standards and demand that they are also applied to imported products. As domestic firms adapt their products to domestic regulatory requirements, they have a competitive advantage in applying these rules and standards relative to their foreign competitors. Yet, frequently EU regulatory cooperation does not entail changes to domestic rules. Fourth, the public salience of regulatory cooperation has been low for the most part of the discussions, leaving aside perhaps the dispute over the authorisation of chlorine washes for chicken in 2008. Until the launch of the TTIP negotiations transatlantic regulatory cooperation has taken place in a technical environment[7] without much scrutiny by the wider public (Pollack & Shaffer, 2005). Fifth, public opinion lacked a transmission mechanism to influence the choice of regulatory cooperation strategies. Newman (2011) suggests that public opinion can play an important role on decision-making when the European Parliament has participation rights and acts as an opportunity structure for the wider public. Regulatory cooperation discussions outside the TTIP negotiations, however, took place in face-to-face interactions among officials and politically appointed officials without continuous consultation requirements of the European Parliament (Pollack & Shaffer, 2005; Green Cowles, 2001). Sixth, public opinion is often politically constructed at a specific point in time and thus subject to change (Vogel, 2012). This makes it difficult to argue that public opinion defends socially or historically rooted risk cultures and forces the Commission not to pursue regulatory externalisation where this could be reciprocated with demands to introduce changes to EU risk regulation. On the contrary, the Commission is itself argued to construct public opinion in order to pursue its own interests and preferences (e.g. Siles-Brügge & de Ville, 2015).

[7] Majone (1996) argues that regulatory politics is per se a technical exercise and does not attract the attention of the public.

Experimentalist governance

The 'experimentalist governance' literature (Zeitlin, 2015; de Burca, Keohane & Sabel, 2014; Sabel & Zeitlin, 2010) relaxes the rational-choice assumption of full information to understand the emergence of less hierarchical forms of governance. Rather than assuming full information of government officials and their ability to engage in informed cost-benefit analyses, authors have put forward that actors have limited foresight and act in an environment of strategic uncertainty and a polyarchic distribution of power. Strategic uncertainty implies that actors need to learn what their goals should be and to learn how they can achieve these goals, for both of which they rely on cooperation with other actors (Sabel & Zeitlin, 2010: 9). Government officials are supported by civil society actors who can act either or both as agenda-setters and problem-solvers (de Burca, Keohane & Sabel, 2014: 13). Zeitlin (2015) as well as Sabel and Zeitlin (2010) find that 'experimentalist governance' can explain the Commission's regulatory approach both within domestic regulatory networks and transnational regulatory networks. They argue that within these networks, the Commission relies on policy experimentation and cooperation with both state and non-state actors. Moreover, rather than hierarchical forms of governance, it employs 'information exchange' and leaves scope to sub-state or private actors for the implementation of initial commitments.

Experimentalist governance has proven valuable to understand the Commission's pursuit of information exchange and its wide involvement of both member state authorities and societal actors in the implementation of policy commitments. Yet, despite an arguable rise in importance of these forms of governance, 'hierarchical forms of governance' through negotiated mutual recognition or regulatory approximation remain important in the Commission's approach to third countries. Experimentalist governance thus at best partly explain the Commission's choice of regulatory cooperation strategies.

New Interdependence Approach

The New Interdependence Approach implies that regulatory cooperation strategies of government officials reflect the institutional power resources of a jurisdiction. Rooted in historical institutionalism, it puts forward that the preferences of actor are not exogenously given, but constituted by institutions in which they are embedded. Institutions created in the past thus structure decision-making in path-dependent ways with often unintended constraints and consequences (Ikenberry, 2001). The New Interdependence Approach will be reviewed in greater depth in chapter 4.1.2.

Studies within this approach agree that institutional power resources in international regulatory cooperation, enabling a jurisdiction to externalise policies and regulations, derive not only from its market size, but also from its regulatory capacity and the stringency of its regulations (Damro, 2012;

Bach & Newman, 2010, 2007). 'Regulatory capacity' describes the ability of a state to enforce its rules based on its personnel, knowledge and expertise (Bach & Newman, 2007). It determines the ability to generate and present information and maintain engagement in highly technical discussions (Büthe & Mattli, 2011). Moreover, it is considered an important source of power in bilateral regulatory cooperation, "in both negotiated mutual recognition and regulatory approximation" (Peterson & Young, 2014: 162). Stringent regulations and the existence of 'regulatory peaks' push policy-makers to engage in policy export or promote the adoption of international standards which resemble the stringency of domestic rules to avoid a race-to-the-bottom (Young & Peterson, 2006). According to this approach, both regulatory stringency and regulatory capacity structure the behaviour of government actors. At the same time, interdependence triggers a functionalist dynamic and pushes domestic regulators, i.e. government officials, to coordinate with government officials from other jurisdictions with whom they would not have coordinated in the absence of interdependence.

Mixed approaches

Insights from Open Economy Politics and the New Interdependence Approach have been combined in the 'Market Power Europe' conceptual framework (Damro, 2015b, 2012). Damro proposes that market size, regulatory capacity and societal contestation should be taken as analytical dimensions to understand the ability of a large economy such as the EU to externalise its domestic policies and regulatory measures. Damro (2012: 683) argues that "the single market provides the material existence of the EU as a market power Europe that externalizes its economic and social market-related policies and regulatory measures". Damro delineates market power as "intentional behaviour" which can be displayed through both persuasive and coercive means (Damro, 2012: 690). Persuasive means reflect the channels of Normative Power while coercion implies strategic leverage through conditionality (Damro, 2012: 690).

EU studies note that the EU has developed considerable regulatory capacity across many policy areas, notably because of institutional and legislative reforms linked to the creation of the Single Market (Peterson & Young, 2014: 155; Bach & Newman, 2010; Bach & Newman, 2007). Moreover, they note that some EU regulations, e.g. on risk regulation, data privacy, and some financial service, are among the most stringent in the world (Vogel, 1995). At the same time, Lavenex (2014) implies that EU's the reliance on functionalist extensions increases with geographical proximity where interdependence between the EU and third countries is high. Functionalist extensions are argued to exist in the interactions of the EU with its neighbourhood and the frameworks of accession, partnership, and association agreements. Newman and Posner (2015) add the density of international institutions as an explanatory variable for the policy strategies of the Commission in international regulatory cooperation.

Yet, institutional power resources and an environment of interdependence are not sufficient to push the Commission to engage in regulatory cooperation across all policy areas. Empirical studies have found that the Commission's choice of policy strategies (including regulatory cooperation strategies in the terminology of this book) differs substantially across different sectors and issues. Falkner and Müller (2013) conclude that the Commission is both a policy exporter, policy shaper, policy importer and policy defender. Young finds that in bilateral FTAs, the Commission only pursues limited regulatory export in specific sectors, e.g. food safety and car safety, while it does not pursue regulatory export in many others (2015b). Zeitlin (2015) also argues that the Commission does not necessarily promote an externalisation of EU rules even where it has regulatory capacity, but has adopted a 'dual strategy' to promote an externalisation of EU rules, standards and norms and to develop mechanisms for establishing 'equivalence' of EU and foreign rules and standards. The Commission, however, has considerable autonomy towards member states where their preferences are heterogeneous or where member states' preferences do not substantially differ from the Commission's preferences on regulatory cooperation (Peterson & Young, 2014: 161). A focus on member states alone can therefore not explain the Commission's behaviour in cases in which the Commission has discretionary authority or would externalise common EU regulations to which member states would not raise opposition. Explanations resorting to international-level variables (Newman & Posner, 2015) to solve the empirical puzzle of strategy differentiation lack the specification of a causal mechanism that would explain why international regulatory cooperation explanations may be transferred to bilateral interactions between states and jurisdictions.

In sum, domestic level rational-choice institutionalist arguments propose that the patterns of societal contestation and domestic decision-making rules shape the possibility of 'government officials', i.e. Commission officials, to engage in regulatory cooperation and an externalisation of regulatory measures and policies. The increasing integration of firms into global value chains and the opportunity to use economies of scale create support among businesses for regulatory cooperation according to 'open economy politics'. Yet, anticipated effects of such regulatory cooperation on domestic regulations give rise to opposition among NGOs, leading to a politicisation of regulatory cooperation and reducing the size of domestic 'win-sets' for government officials.

Agenda-setting possibilities, delegated authority and the unwillingness or inability of member states to organise opposition are argued to increase the autonomy and discretion of the Commission. At the same time, a large internal market, regulatory stringency and regulatory capacity are considered as institutional power resources allowing the EU to engage in policy externalisation. An additional explanation is thus necessary to show how the Commission sets its behaviour in cases in which it has discretionary authority.

2.5. Summary

The previous sections have demonstrated that existing empirical studies identify numerous strategies that large jurisdictions pursue in international governance. In contrast, the theoretical literature proposes variables which mostly derive a dichotomous understanding of international governance strategies. Based on this contrast, this section thus specifies the theoretical gaps that this book seeks to address. It will first reiterate why neither domestic-level and international-level theoretical approaches can offer a full explanation with regard to the constraints that governments face in choosing a strategy for regulatory cooperation. The first step thus makes clear why existing studies are unable to fully resolve the puzzle with a focus on the dependent variable of this book. Second, it will show why bilateral-level theoretical approaches, to which this dissertation will contribute, require a further refinement of independent variables that studies have considered in the past. Third, it will demonstrate that existing approaches do not specify a causal mechanism that connects outcomes on the independent variables with those on the dependent variable.

The literature discussed in the previous sections suggests various explanatory variables for the constraints on the choice of governments and regulators on international governance strategies. Yet, taken individually, each of these approaches displays important shortcomings in relation to the puzzle raised by this book. International-level rational-choice approaches overestimate the influence of international institutions and the constraints that interdependence and globalisation exert on the autonomy of domestic state actors. Correspondingly, they also overestimate the extent of regulatory cooperation that a large jurisdiction will seek to promote. International-level constructivist approaches overestimate the influence that ideas and norm entrepreneurs have on transnational policy convergence. They imply that socialisation should lead to 'institutional isomorphism'. However, they cannot explain why domestic state actors do not necessarily promote transnational regulatory approximation even where socialisation and shared values are present. Besides, neither approach can explain why governments may choose not to pursue regulatory cooperation.

Likewise, domestic-level constructivist literature taken alone lack a causal mechanism that connects the influence of ideas to the behaviour of actors. This limitation mostly also holds for studies that seek to integrate constructivist and rational-choice approaches, especially for contexts in which the level of uncertainty is low. Respective studies insufficiently clarify how ideas shape behaviour patterns when the level of uncertainty is low. Instead, explanations proposed for the behaviour patterns of actors in contexts of relatively high certainty reflect conventional rational-choice accounts.

Lastly, domestic-level rational-choice approaches suggest explanatory factors which are arguably necessary for a jurisdiction to pursue regulatory cooperation, i.e. market size, regulatory capacity and internal unity. At the same time, they propose factors that may account for the reluctance of state actors to pursue regulatory cooperation, e.g. societal contestation and contestation. However, they struggle to

explain the empirically observed variation in governance and interaction strategies. Moreover, they lack a causal mechanism when societal contestation is muted or societal mobilisation is contested. In these cases, state actors should have discretion to strategically mobilise societal actors with preferences close to their own ones, making it necessary to identify a causal mechanism that relates strategy choice to the decision-making problem of state actors.

In this regard, existing domestic-level rational-choice approaches display a certain theoretical incoherence. Although recent contributions increasingly stress the influence that state and sub-state actors exert on the behaviour of a state or jurisdiction in international governance, the majority of explanations continue to rely on the aggregation of societal preferences as the principal determinant of state or jurisdictional preferences. The acknowledgement of an autonomy of state actors on the one hand appears to contradict with the search for a theoretical micro-foundation of state behaviour in the constellation of societal preferences. Indeed, this apparent contradiction raises the question if a theoretical micro-foundation of state or jurisdictional behaviour cannot be deduced from the preferences of state or sub-state actors themselves.

From this discussion of the shortcomings of existing literature it can be concluded that the political science literature lacks a theoretical foundation for the variation in international governance strategies observed in empirical studies. To clarify, this is not to argue that existing literature does not put forward relevant explanatory factors. The domestic rational-choice literature to which also this book seeks to contribute identifies several independent variables that describe the ability of a jurisdiction to engage in regulatory cooperation and policy externalisation. The book does not call the relevance of these factors into question. Rather, it seeks to specify additional variables that explain the actual behaviour of a state or jurisdiction in international governance, especially in bilateral interactions.

To specify these variables, this book thus seeks to address the gap if and how domestic-level constructivist approaches can be incorporated into the domestic rational-choice literature to derive a more refined and concise framework. Rather than integrating domestic-level constructivist approaches into the ‘Open Economy Politics’ framework, this book aims at combining domestic-level constructivist approaches into the rational-choice approaches that themselves have incorporated international-level literature elements. Through an integrative combination of existing theoretical approaches, this book should obtain a more nuanced theoretical framework. The latter should help to provide a theoretical explanation for the variation in governance strategies, including regulatory cooperation strategies, that previous empirical studies have observed.

Moreover, in specifying variables for the constraints and the choice of regulatory cooperation strategies, this book also seeks to address the theoretical gap resulting from the lack of a theoretical micro-foundation that foresees a decisive role for state and sub-state actors. In deducing variables, this study thus seeks to specify them with a view to formulate the decision problem and explain constraints on the choice of a strategy from the perspective of state and sub-state actors. To clarify this point further, the

theoretical gap to be addressed does not consist in the lack of an explanation that assumes full autonomy of state actors. Rather, it consists in the lack of a micro-founded explanation that gives state and sub-state actors autonomy in moderating opposing positions expressed by societal actors. This includes the possibility that state and sub-state actors take autonomous decisions because societal contestation is muted.

This entails that this book needs to develop a causal mechanism that links the decision problem of state actors, the independent variables deduced from a combination of constructivist and rational-choice approaches and the variation in international governance, i.e. bilateral regulatory cooperation, strategies. This causal mechanism should specify a) how outcomes on independent variables constrain the decision of state actors and b) how state actors form a strategy based on different outcomes of the independent variables.

To conclude, this book identifies three main theoretical gaps that it aims to address. First, it seeks to overcome the fragmentation of prior theoretical approaches and thereby address the under-theorising of the variation of governance strategies. Contributing to domestic-level rational-choice approaches, it seeks to deduce how constructivist approaches can be integrated into and combined with domestic-level rational-choice approaches that themselves have incorporated international-level explanatory elements. This gap thus addresses the contradiction between the manifold variation in forms and strategies of regulatory cooperation observed empirically and the mostly dichotomous distinction of governance forms derived theoretically. Second, in doing so, it seeks to derive the constraints on the choice and formation of a regulatory cooperation strategy with state and sub-state actors as the main object of analysis. This gap thus addresses the theoretical incoherence between a broad acknowledgement of the centrality of state and sub-state actors in international governance and the derivation of behaviour from the constellation and societal actor preferences. Third, and related to the former, it derives and specifies a causal mechanism that links the variation in state actor-centred explanatory factors to constraints on the choice and the formation of international governance, i.e. bilateral regulatory cooperation, strategies.

3. Developing a typology of bilateral regulatory cooperation strategies

This book seeks to explain the constraints under which the regulator of a large jurisdiction forms and chooses different strategies for regulatory cooperation. In a comprehensive stock-taking exercise, the OECD (2013b) differentiates eleven different 'mechanisms' of regulatory cooperation. Yet, delineations and operationalisations of regulatory cooperation strategies in other literature differ starkly. Regulatory cooperation strategies differ along dimensions including their scope, depth, enforceability and policy dimension. Frequently discussed strategies in bilateral regulatory cooperation include harmonisation, mutual recognition, equivalence and mutual recognition of conformity assessment (Peterson & Young, 2014, Veggeland, 2011).

This chapter elaborates a new analytical specification for the dependent variable of this book, i.e. bilateral regulatory cooperation strategies. Its objective is to aggregate the considerable number of alternative operationalisations into one analytical model that captures the breadth of empirically relevant bilateral regulatory cooperation strategies, but is applicable to empirical investigation. The ensuing typology of bilateral regulatory cooperation strategies deduces the possible outcomes on the dependent variable of this book.

First, for analytical clarity, the chapter introduces and defines bilateral regulatory cooperation strategies (chapter 3.1). Second, it maps regulatory cooperation strategies as identified by existing alternative studies and analyses the overlap of existing delineations (chapter 3.2.). Third, it synthesises bilateral regulatory cooperation strategies and develops a typology (chapter 3.3.). This typology will be used in chapter 4 to deduce how variation in the independent variables leads to differences in outcomes on the dependent variable.

3.1. Strategies of bilateral regulatory cooperation

Within this section, this book defines the term 'strategies' and delineates it from the related concepts 'preferences' and 'interests' that are frequently used in studies of international political economy (chapter 3.1.1). Besides, it places bilateral regulatory cooperation within the related concepts of active and passive external governance and horizontal and vertical governance (chapter 3.1.2.). This clarifies the scope of the argument presented in this book in relation to these concepts that characterise a large body of the literature on external governance. Furthermore, it provides an overview of different regulatory instruments to delineate the 'dimensions' to which regulatory cooperation can apply (chapter 3.1.3.).

3.1.1. Strategies as a concept

Strategies are a frequently used concept in international political economy (e.g. Newman & Posner, 2015; Woll, 2008; Frieden, 1999). They must be delineated from outcomes, preferences and interests.

'Strategies' are defined by Frieden (1999) as the pursuit of an actor of its most preferred outcome. A strategy is thus the attempt of an actor "to come as close as possible to the outcome it prefers the most." (Frieden, 1999: 41). Strategies are thus different from outcomes, which are frequently the dependent variable in political science research. Frieden (1999: 45) argues that strategies reflect "the anticipated actions of others, differential capabilities, knowledge and information". They therefore take into consideration important contextual factors and information. Actors may, however, miscalculate the actions of others or have insufficient information or knowledge of contextual factors that determine the 'success' of a strategy and their ability to realise an 'outcome' that is as close as possible to the outcome it prefers the most. This book concentrates on strategies rather than outcomes for two distinct reasons: First, bilateral regulatory cooperation is a recently emerging phenomenon and has featured on the agenda even of the EU only for some years. The population of regulatory cooperation outcomes is thus still relatively small. Second, bilateral regulatory cooperation is subject to numerous 'technical' challenges, e.g. methods how to assess the 'equivalence' of two regulations and regulatory approaches (Peterson & Young, 2014: 163). These challenges are still not entirely understood and continue to raise the interest of legal science scholars (e.g. Chase & Pelkmans, 2015). An analysis of outcomes is thus likely obstructed by what quantitative researchers call 'omitted variable bias'. At the same time, strategies as the outcome that an actor aims to achieve has relevance in itself for both political science scholars and practitioners, including societal actors, that expect benefits or losses from regulatory cooperation (chapter 1.3).

On the other hand, strategies must be delineated from preferences. Preferences are prior to strategies and reflect the costs and benefits resulting from an outcome. Scholars of international political economy understand preferences to derive from stable, underlying interests of actors (Frieden, 1999). Preferences translate this interest into a policy- or outcome-specific evaluation of costs and benefits. Strategies, in turn, denote behaviour that an actor chooses to realise its preference. They consider how the preferences of an actor relate to the structural constraints of an interaction context and the preferences of other actors. The formation of a strategy is thus dependent on the "possibilities presented by the environment" and the "constraints of circumstance" (Frieden, 1999: 45). Figure 2 shows the relationship between interest, preferences, strategies and outcomes (adapted from Woll, 2008: 44).

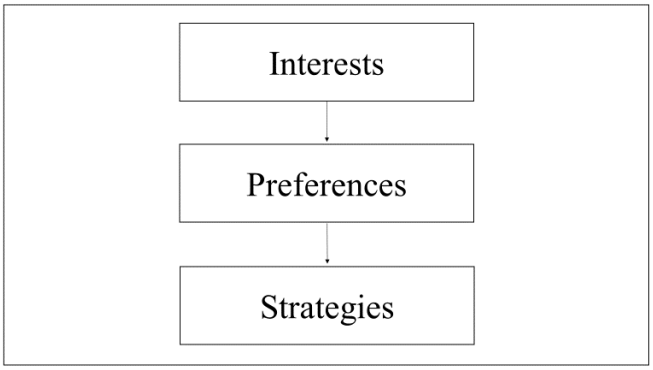


Figure 2: Strategies as a concept

3.1.2. Bilateral regulatory cooperation in external governance

This section places bilateral regulatory cooperation within the concepts used in studies of external and international governance. This will help to clarify the scope of the argument subsequently proposed in this book. This section first delineates bilateral regulatory cooperation as an 'active' mechanism of external governance from 'passive' ones such as diffusion and trading up. Second, it delineates bilateral regulatory cooperation as a 'horizontal' mechanism from vertical ones that apply to international regulatory cooperation.

Active versus passive mechanisms of external governance

This first sub-section delineates regulatory cooperation from 'trading up' and 'emulation' as passive mechanisms of external governance and places it within 'coordination' as an active mechanism.

Regulatory cooperation is an active mechanism of external governance. Active mechanisms, also referred to as political-administrative extensions or intentional mechanisms, must be delineated from passive mechanisms, also called indirect socio-economic or unintentional mechanisms (Falkner & Müller, 2013; Lavenex, 2014: 891). Active mechanisms describe that the 'government' of a country intentionally engages in the projection of policies or the coordination of policies with the government of another country. Passive mechanisms of external governance, in contrast, entail that policy export occurs without the deliberate action of a country's governance, but only relies on its presence (Falkner & Müller 2013: 8; Bradford, 2012).

As an active mechanism, regulatory cooperation must be delineated from the two most common mechanisms of passive policy transfer, 'trading up' and 'emulation'. Both can be subsumed under processes of 'diffusion' that may lead to regulatory policy convergence (Elkins and Simmons, 2005).

'Trading up' (Vogel, 1995) is a passive mechanism of policy export and transfer discussed by the rational-choice literature. It refers to the strengthening of regulations of a foreign country reflecting domestic regulations as a response to pressure on the foreign government by transnational firms. According to the 'trading up' logic, foreign exporters lobby their government to approximate the rules of the domestic market which has more stringent regulations than the foreign jurisdiction in order not to forego market access. They thus advocate the adoption of similar rules in fields such as environment, health, and product safety as the jurisdiction with more stringent regulations. The transfer of stringent regulations to other jurisdictions thus follows the advocacy of transnational firms and foreign exporters that have an interest in uniform or similar regulations across jurisdictions to maintain market access, use economies of scale and establish regulatory certainty (Vogel 2012; Bradford 2012). 'Trading up' thus describes behaviour of societal actors and governments from mostly smaller jurisdictions that change their behaviour in order to correct the negative externalities of the policies of larger jurisdictions (Zielonka, 2008; Dobbin et al., 2007; Raustiala, 2002). Due to the size of its internal market that is attractive to exporters from other countries and the stringency of EU regulations, 'trading up' has been described as an important mechanism through which EU regulations are transferred across jurisdictions. The prior strengthening of domestic EU regulations may be an intentional choice of the 'domestic government', i.e. the Commission, to protect domestic producers from competitive pressures and respond to demands of NGOs. Yet, 'trading up' does not arise as a result of deliberate strategies of the Commission to externalise EU policies or procedures but is initiated by advocacy activities of transnational or non-EU firms. It therefore falls outside the scope of regulatory cooperation strategies.

'Emulation' describes passive rule transfer and indirect rule approximation from a constructivist perspective (Gilardi, 2012; Braun & Gilardi, 2006). Under emulation or learning, regulators and government officials approximate or align their regulations with those of another country because they perceive them as legitimate or normatively superior. They learn about the regulations of other countries as they socialise with government officials and regulators from other countries within transnational networks or international institutions. Regulations are thus argued to diffuse across jurisdictions and to be emulated by other jurisdictions if underlying domestic norms resonate with norms held or shared by foreign governments. The logic of emulation lies at the core of Manners' argument about the role of the EU in norm diffusion (Manners, 2002: 251). Yet, similar to the mechanism underlying 'trading up', 'emulation' does not require the proactive promotion of regulations by the government of the jurisdiction whose regulations are emulated.

Within active mechanisms of external governance, regulatory cooperation must be placed within the realm of 'coordination' rather than 'coercion'.

Under 'coercion', the government of a state enjoying an asymmetric power advantage urges another government to adopt or adapt to its norms and standards. The domestic government offers rewards to the foreign government for the adoption of its norms and standards or threatens the use of sanctions if a foreign government refuses to adopt them. Coercion builds on power-based bargaining and the use of conditionality. It also implies that the domestic government enjoying an asymmetric power advantage will seek to 'export'[8] or 'transfer'[9] its existing policies rather than adjusting its behaviour, i.e. strategy, to the preferences of the foreign government. Yet, the use of coercion presupposes a power asymmetry, resulting e.g. from differences in market size. Yet, bilateral regulatory cooperation often takes place between 'states' of comparable market size[10].

Under 'coordination', governments "adjust their behaviour to the actual or anticipated preferences of others" (Keohane, 1984: 51). This implies that government actors exchange ideas, coordinate efforts and negotiate common standards with officials from governments of other countries (Kudrna & Müller, 2016; Lavenex, 2014; Gilardi, 2012; Holzinger et al., 2007; Lütz, 2007; Braun & Gilardi, 2006).[11] Under

[8] 'Policy export' is understood as "process through an actor actively and passively projects beyond its borders formal and informal norms or policy paradigms" (Müller & Falkner, 2014: 6).

[9] 'Policy transfer' is defined as "processes by which knowledge about policies, administrative arrangements, institutions and ideas in one political system (past or present) is used in the development of policies, administrative arrangements, institutions and ideas in another political system" (Dolowitz & Marsh, 2000: 5).

[10] Lavenex and Schimmelfennig (2009) note that coercion has e.g. been important in interactions between the EU and its neighbourhood.

[11] Coordination may not only involve top-level government representatives and government officials, but often also administrators and private sector regulators. These organise in trans-governmental networks (Slaughter, 2000; Raustiala, 2002).

coordination, governments and regulators thus work towards a harmonisation or alignment of standards, regulations and procedures. Regulatory cooperation can thus placed within the realm of 'coordination'[12].

Horizontal versus vertical governance

In a next step, bilateral regulatory cooperation shall be placed within horizontal mechanisms of governance in contrast to vertical ones.

Vertical mechanisms take place within international organisations and global trans-governmental networks. They are thus mostly multilateral. Outcomes of vertical pathways are multilaterally negotiated policies and rules (Jorgensen et al, 2011; Jorgensen 2009, Laatikainen & Smith, 2006; see also Wunderlich & Bailey, 2011; Tèlo, 2009; Bretherton & Vogler, 2006). Horizontal pathways, in turn, take place between individual or a group of 'states' as well as between regions. They can be both unilateral, bilateral and plurilateral. Examples for horizontal pathways of transfer and coordination are bilateral and regional free trade agreements as well as bi- and plurilateral regulatory and trans-governmental networks[13].

A government may pursue horizontal and vertical mechanisms in parallel, engaging in venue-shopping to pursue decisions in several settings and environments simultaneously (Damro, 2005). Nonetheless, it is likely to select a venue strategically in which it can most effectively advance its preference (Alter & Meunier, 2009; Drezner, 2009). Vertical and horizontal pathways should therefore be distinguished for analytical purposes. The pursuit of regulatory cooperation in a horizontal or vertical setting imposes different constraints on the discretion of a government to pursue its most preferred outcome. Horizontal mechanisms are argued to give governments more discretion in pursuing their most preferred outcome than vertical mechanisms (Young, 2016). Vertical settings impose high constraints on governments due to potential independent effects of agenda-setting by international organisations as well as voting and decision rules (Young, 2015a; Jorgensen, 2011; Jorgensen 2009, Laatikainen & Smith, 2006). Moreover, the large number of other actors, i.e. states, involved and the heterogeneity of their preferences reduce the likelihood of a successful pursuit of vertical strategies in contrast to horizontal strategies (Newman & Posner, 2015). The lower likelihood of 'success' in vertical relative to horizontal cooperation should not influence the choice of a specific strategy, but may impact the decision to engage in regulatory cooperation at all.

[12] Lavenex (2014: 891) argues that active and passive mechanisms often mutually support each other. Harmonisation of regulations may thus e.g. result from the simultaneous occurrence of 'trading up' demands of transnational firms and coercion efforts of the Commission in an international organisation. Yet, for analytical purposes, they shall be delineated to allow statements about the causal mechanism producing an observed outcome.
[13] Zeitlin (2015b: 335) argues that although trans-governmental networks are not coercive in nature, the EU often uses them for 'disguised policy transfer' rather than mutual learning (see also Lavenex, 2015).

At the same time, horizontal mechanisms entail a lower geographical scope of possible transfer and coordination. Societal actors may therefore be reluctant to mobilise resources in favour of horizontal mechanisms (Peterson & Young, 2014). At the same time, government officials may be reluctant to mobilise administrative resources in support of 'complex' strategies such as harmonisation for vertical coordination (Egan & Pelkmans, 2015). Only some international regulatory cooperation strategies may thus be applicable to bilateral regulatory cooperation, which is the object of this book.

To clarify the analytical scope of the argument developed in this book, this section has placed bilateral regulatory cooperation into wider distinctions of the external governance literature. It has delineated bilateral regulatory cooperation as an active mechanism from 'trading up' and 'emulation' as passive mechanisms and contrasted its reliance on 'coordination' with 'coercion'. Besides, this section has determined bilateral regulatory cooperation as a vertical rather than horizontal mechanism. The discretion of the government and the impact of a potentially low willingness of societal actors and regulators and governments to mobilise resources in bilateral regulatory cooperation will be re-considered in the delineation of strategies in chapter 3.2.

3.1.3. Regulatory instruments

This section sketches an overview of regulatory instruments used in domestic regulatory policy-making with a view to delineate the dimensions of bilateral regulatory cooperation. This will help to clarify to which regulatory instruments bilateral regulatory cooperation can apply. This section will distinguish legislation, regulatory policies and implementation procedures.

Legislation covers all legislative acts that transpose constitutional objectives and put policies into practice. Legislative acts are adopted by the legislative bodies within a political system. They can regulate, authorise or restrict. In the EU, legislative acts come from the principles and objectives laid down in the EU Treaties. Their adoption follows the legislative procedures set out in the EU Treaties, i.e. the Ordinary Legislative Procedure or special legislative procedures. In the Ordinary Legislative Procedure, legislative acts are adopted by the Council or the European Parliament. The most relevant types of legislative acts in the EU are Regulations and Directives. While Regulations apply directly and automatically to all EU member states, Directives need to be transposed by member states into national law. Directives specify a result that member states need to achieve, but allow them to choose how to achieve that result (for an overview of EU legislative acts see Wessels, 2008: 342-347). In the US, Federal Laws are introduced as bills into Congress and debated and adopted by both chambers of Congress, i.e. the House of Representatives and the Senate. The President signs and approves the bill and thus enacts it as law (Burnham, 2011).

Regulatory policies include technical regulations and standards. Technical regulations specify elements of legislation and include technical specifications and requirements (European Parliament & Council, 2015). In goods regulation, technical regulations specify terminology, symbols, packaging or labelling requirements (World Trade Organisation, 1995a; art. 2 WTO TBT Agreement). Technical regulations are adopted by executives as non-legislative acts. Compliance with technical regulations is mandatory to enter a product onto the market in a jurisdiction. In the EU, technical regulations are mostly adopted as delegated acts and implementing acts by the Commission (Parker & Alemanno, 2014: 21). In the US, regulations are issued mostly by federal regulatory agencies, boards or commissions and specify the implementation of objectives laid down in Congress legislation (Parker & Alemanno, 2014: 25).

Standards are technical specifications which define requirements for products, production processes and services in support of legislation or regulation (World Trade Organisation, 1995a; art. 4 WTO TBT Agreement). They differ from technical regulations as compliance with standards is usually voluntary. Standards are mostly developed by private and market actors following basic principles of standardisation such as consensus, openness, transparency and non-discrimination (European Parliament & Council, 2012; Büthe & Mattli, 2011: 28). In the EU, standards are developed by the European Standardisation Organisations CEN, CENELEC and ETSI (European Commission, 2003). In the US, standards are also developed by market and private actors under the coordination of the American National Standards Institute (ANSI; Büthe & Mattli, 2011: 35-38).

In addition to technical regulations and standards, the 'regulatory state' relies on a number of conformity assessment procedures and administrative procedures to effectively implement regulatory policies (Parker & Alemanno, 2014: 30; Mattli & Woods, 2009). For the remainder of this book, these procedures shall be referred to as 'implementation procedures'. Implementation procedures summarise the processes executing and implementing the rules and specifications of legislation and technical regulations. They include conformity assessments and 'administrative procedures' that ensure that regulatory requirements laid down in legislation and technical regulations[14] are met. Conformity assessments include testing and inspection and certification (European Commission, 2016; World Trade Organisation, 1995a; art. 5 WTO TBT Agreement). Conformity assessment procedures are defined and described in the corresponding legislation and regulation (European Commission, 2016j: 64-86). Administrative procedures verify the application of regulatory requirements and enforce the implementation of requirements. They include market surveillance procedures and redress procedures (European Commission, 2016j: 97-101). In goods regulation, market surveillance procedures include product controls, including import controls, product withdrawals, recalls and sanctions against non-compliant products (European Commission, 2016j: 107-109). In the EU, Regulation 765/2008 lays down the requirements for market surveillance for the marketing of products (European Parliament &

[14] As standards are voluntary for procedures, compliance with standards is usually not subject to specific implementation procedures.

Council, 2008). Under market surveillance, competent authorities can require documentation from producers on the conformity of products with regulatory requirements, enter the premises of producers and take samples for testing (European Commission, 2016j: 105-109). For the pharmaceutical and food sectors, often additional procedures apply, i.e. import authorisations for specific establishments, countries or products (European Commission, 2016j: 114-117).

In sum, this chapter has introduced the distinction between different regulatory instruments, differentiating between legislation, technical regulations, standards and implementation procedures. While legislation, technical regulations and standards define rules and regulatory requirements, implementation procedures include the applicable processes to carry out and verify the adherence to the rules and regulatory requirements defined in legislation, technical regulations (and standards). Legislation defines objectives and results with regard to a product or process. It is mandatory and adopted by the legislative bodies of a political system, i.e. the Parliament. Technical regulation specifies elements of legislation and includes technical specification and requirements. Compliance of market participants with technical regulation is mandatory, but unlike legislation, technical regulations are adopted by executive bodies. Standards also specify technical requirements in support of legislation and technical regulation, but are voluntary and adopted by private and market actors.

3.2. Mapping bilateral regulatory cooperation strategies

This section aggregates the numerous existing delineations of regulatory cooperation strategies and demonstrates their respective overlap. The contrast of existing operationalisations of regulatory cooperation strategies with alternative approaches helps to verify the comprehensiveness of the range of strategies covered by an operationalisation to be developed in this chapter and its compatibility with alternative theoretical approaches. It thus prepares the incorporation of these delineations into one analytical model to be presented in chapter 3.3. This section first presents the strategies most frequently discussed in the literature looking at the engagement of the EU in bilateral regulatory cooperation. Second, it will contrast this delineation with a growing recent literature on regulatory cooperation strategies by both political science scholars, the OECD as well as the delineation of policy strategies of the EU's interactions with international 'policy regimes'. Third, it will aggregate these delineations into one comparison and demonstrate their respective overlap.

Political science literature on bilateral regulatory cooperation

The existing literature on bilateral regulatory cooperation often concentrates on the following strategies of regulatory cooperation: harmonisation or approximation, negotiated mutual recognition or 'equivalence', Mutual Recognition Agreements, guidelines of good regulatory practices and commitments to 'information exchange' (e.g. Peterson & Young, 2014; Pollack & Shaffer, 2009; Nicolaidis, 2000).

'Approximation' or 'harmonisation' entails the alignment of national rules. Peterson and Young (2014: 159) understand 'approximation' as standard-setting in international standard-setting organisations, e.g. the International Standardisation Organisation (ISO), the United Nations Economic Commission for Europe (UNECE) or the Codex Alimentarius Commission (CAC)[15]. They note that approximation is the "most intense and demanding form of regulatory cooperation" (Peterson & Young, 2014: 159). It requires that jurisdictions agree on what the approximated rule should be. The requirement to agree on a specific rule also limits the scope for compromise (Büthe & Mattli, 2011: 11; Drezner, 2007: 34; Pollack & Shaffer, 2009: 126; Krasner, 1991: 336)[16].

'Negotiated mutual recognition' or 'equivalence' implies that two jurisdictions "agree that specific regulations are equivalent in effect" (Peterson & Young, 2014: 160; Nicolaidis, 2000: 595). It only takes

[15] International standards exist mostly with regard to the regulation of goods, less with regard to services.
[16] Nonetheless, international standards remain mostly voluntary. International standards only become binding if they are cited as a mandatory requirement in domestic regulations (i.e. they are 'referenced') or if they are cited in international agreements whose provisions can be enforced through forms of dispute settlement.

place in bilateral interactions. In order to establish 'equivalence', regulators from different jurisdictions agree that regulatory objectives are equivalent and that different domestic means are conducive to realising these objectives (see e.g. Council, 2005). While under 'negotiated mutual recognition' or 'equivalence' a policy change may be necessary, it is usually not the main objective (Peterson & Young, 2014: 161; Nicolaidis, 2000: 595). Besides, 'negotiated mutual recognition' leaves scope to choose among several alternatives.

'Mutual Recognition Agreements' establish "that specified bodies in each jurisdiction can certify that products produced on its territory conform to the standards of the other territory" (Peterson & Young, 2014: 159). They thus neither aim at nor lead to a change of domestic policies. On the contrary, they accept the divergence of domestic standards and rules and only align procedures that have been established to implement domestic policies.

Contributions to the regulatory cooperation literature also note that cooperation occurs through the establishment of 'guidelines on good regulatory practice' and 'commitments to information exchange'. The latter entail provisions to notify other countries of new regulatory measures (Peterson & Young, 2014: 159). Table 1 summarises the delineation of regulatory cooperation strategies based on Peterson and Young (2014) and Pollack and Shaffer (2009):

Harmonisation / Approximation
Negotiated mutual recognition / 'equivalence'
Mutual Recognition Agreements
Guidelines of good regulatory practices
Commitments to 'information exchange'

Table 1: Delineation of regulatory cooperation based on political science literature

<u>New Interdependence Approach literature on international regulatory cooperation</u>

Within a contribution of the New Interdependence Approach literature on international regulatory cooperation, Newman and Posner (2015) distinguish four strategies: regulatory export, first-mover agenda-setting, mutual recognition and coalition-building. 'Regulatory export' implies the externalisation of domestic policy solutions (Lavenex & Schimmelfennig, 2009; Newman, 2008; Falkner & Müller, 2013; Hartlapp & Treib, 2007; Kelemen & Vogel, 2010). 'First-mover agenda-setting' describes the early setting of policy and negotiation agendas in international organisations and trans-governmental networks to shape the design of future international standards and rules (Mattli & Büthe, 2003). 'Mutual recognition' is understood as the concession of market access to exporting firms from other countries, given that the domestic government accepts that the "other's regime meets a

negotiated minimum of standards, said by each to be equivalent of their own" (Newman & Posner, 2015: 1328; Nicolaidis & Shaffer, 2005; Farrell, 2003). 'Coalition-building' refers to the formation of alliances in support of preferred rules and against rules promoted by other coalitions in order to influence global standards (Alter, 2014; Kissack, 2015; Risse-Kappen, 1995; Sabel & Zeitlin, 2010; Tarrow, 2001). Table 2 illustrates these strategies:

Regulatory export
First-mover agenda-setting
Mutual recognition
Coalition-building

Table 2: Delineation of regulatory cooperation strategies based on the NIA

OECD survey of international regulatory cooperation

The OECD (2013b) has derived a comprehensive list of regulatory cooperation mechanisms in a comprehensive stock-taking exercise. Authors have called the OECD list "the most comprehensive survey of regulatory cooperation forms and mechanisms up-to-date" (e.g. Egan & Pelkmans, 2015: 5). Apart from policy strategies this list, however, also covers mechanisms which do not involve policy or procedure interactions, but forms of institutional creation. Table 3 presents the forms and mechanisms compiled by the OECD (2013b):

Economic integration and harmonisation through supra-national law-making and institutions
Mutual recognition
Specific conventions and treaties
Joint regulatory partnerships
Mutual recognition of conformity assessment
International regulatory cooperation through international organisations
Trans-governmental networks
Formal requirements to consider all relevant frameworks for cooperation in other jurisdictions
Recognition of international standards
Soft law
Regulatory dialogues

Table 3: Delineation of regulatory cooperation strategies based on the OECD survey

'Economic integration and harmonisation through supra-national law-making and institutions' refers to the creation of supranational institutions and the establishment of supranational law-making. The empirical frequency of this form is low and the OECD notes that "harmonisation as a broader principle of economic regionalism is difficult to conceive at least for the time being" (OECD, 2013b: 44). 'Mutual recognition' establishes the functional 'equivalence' in effect of the rules of two countries or jurisdictions regarding safety, health, environment, and consumer protection (SHEC) objectives and their enforcement. Mutual recognition refers to policy objectives governing an entire sector or a set of sectors and not a case-by-case examination of specific regulations. Empirical examples are equally rare, including mostly the mutual recognition negotiated under the Single European Act and the Australia-New Zealand 'Trans-Tasman' Mutual Recognition Agreement.

'Specific conventions and treaties' establish binding international policies in a specific area or sector, but leave regulatory authority with domestic governments. Examples are cooperation treaties on tax matters or the Montreal convention on protecting the ozone layer as well as the United Nations Framework Convention on Climate Change. 'Joint regulatory partnerships' establish commitments and cooperation agreements for a greater coordination of regulatory practices, processes, and activities between countries (OECD, 2013b: 48). Resulting agreements are not treaty-based and therefore not enforceable under international law. 'Joint regulatory partnerships', however, cover a broad range of strategies that can be pursued within them. The OECD (2013b: 48) acknowledges that their content depends "on the regulatory principles, disciplines and obligations for cooperation that are set in such a partnership". They may thus cover harmonisation of rules just as 'equivalence' agreements demanding a case-by-case examination of product regulations. Examples cited for joint regulatory partnerships are the Transatlantic Economic Partnership or the US-Canada Regulatory Cooperation Council.

'Mutual recognition of conformity assessment', established through Mutual Recognition Agreements, allows conformity assessment bodies from the cooperation partner to certify that products from a specifically covered sector meet the regulatory requirements of the other partner. Examples are the Mutual Recognition Agreements concluded between the EU and the US in 1998. 'International regulatory cooperation through international organisations'' covers a wide range of interactions among regulators and technical experts. Policy outcomes envisaged through these interactions range from common standards to common procedures for the implementation of domestic rules. Cited examples are interactions in the ILO, WTO and the OECD.

'Trans-governmental networks' bring together experts and regulators in informal networks and rely on peer-to-peer collaboration, memoranda of understanding and other informal agreements. They develop rules that members of the network are expected to implement into national law. The OECD notes that trans-governmental networks exist in the field of competition policy (the International Competition Network), financial regulation (the Basel Committee on Banking Supervision) and pharmaceuticals regulation (ILAC), but also in environmental policy. 'Formal requirements to consider all relevant

frameworks for cooperation in other jurisdictions' implies that domestic regulators take into account the relevant international regulatory environment when formulating regulatory proposals. 'Recognition of international standards' promote the harmonisation of the technical specifications of products, but remain non-binding for domestic regulators. 'Soft law' refers to cooperation based on legally non-binding instruments such as codes of conduct, roadmaps or peer reviews. 'Regulatory dialogues' establish informal dialogues among regulators.

Political science literature on policy strategies in international regime interaction

Strategies for regulatory cooperation can also be approached from the perspective of international regime interaction. Falkner and Müller (2013) distinguish four strategies for the EU's interactions with 'international policy regimes': policy export, policy promotion, policy import, and policy protection. Crucially and in contrast to many previous contributions, they argue that the EU does not only export its domestic policy-making, but also promotes policy-making internationally. 'Policy export' is understood as the projection or externalisation of domestic policies to the international environment (Young, 2016; Damro, 2012; Börzel & Risse, 2012; Lavenex et al., 2009; Young & Peterson, 2006; Bretherton & Vogler, 2006; Schimmelfennig & Sedelmeier, 2005; Manners, 2002). 'Policy promotion' describes the shaping and promotion of global policy outcomes, often universal international rules which reflect domestic solutions (Falkner & Müller, 2013: 214).'Policy import' refers to the adoption and translation of international rules into domestic policy solutions. The EU seeks to adopt domestic policy solutions according to international rules to make these rules more binding or to achieve greater internal convergence, policy integration and/or to reform domestic policies. International negotiations or rules serve as an opportunity structure to change the domestic status quo. 'Policy protection' implies that the EU shields domestic policies from external pressure. It delays or blocks the adoption of decisions which are not in line with its own policies and/or seeks to exclude decisions which oppose its preferences from the agenda of negotiations. Moreover, the EU may promote international policy solutions which protect its domestic policies. Table 4 summarises these strategies:

Policy export
Policy promotion
Policy import
Policy protection

Table 4: Policy strategies in international regime interaction

The survey above demonstrates that delineations of strategies and mechanisms differ based on the scope of their analysis, their unit of analysis and the explanatory objectives of their study. The contrast of existing definitions of the regulatory cooperation strategies with alternative approaches nonetheless helps to verify the comprehensiveness of the range of strategies covered by an operationalisation and its compatibility with alternative theoretical approaches.

Not all regulatory cooperation strategies and mechanisms identified by the literatures above are, however, relevant to bilateral regulatory cooperation strategies. Some strategies can only be pursued in international organisations as they presuppose participation of multiple actors. Others are only pursued in multilateral regulatory cooperation because they entail the mobilisation of large resources that neither the EU nor another large political actor is willing to mobilise in the interaction with only a single other entity. Still others require the presence of institutional architectures for their effective enforcement and implementation which have, at least until present, not been established for bilateral relations.

Theoretically, the EU may adjust its own policies to those of other actors. While adjustment of domestic policies to global standards has occurred in multilateral settings (e.g. Kudrna & Falkner, 2016), there is no single empirical case up-to-date in which the EU has either adjusted its domestic policies or policy-making processes to those of another country. This option shall therefore not be taken into account for the further analysis in this book.

Table 5 contrasts the strategies discussed by the existing literature on regulatory cooperation, policy interactions, international regulation and the international regulatory cooperation mechanisms by the OECD, illustrates their degree of overlap and indicates their relevance regarding bilateral regulatory cooperation strategies. The relevance of the strategies and mechanisms identified by the different literatures and authors with regard to bilateral regulatory cooperation is assessed on the basis of the following criteria:

- Do decisions made within a mechanism or strategy require / presuppose an institutional architecture which only exists within a specific region or at the global level?
- Does a mechanism or strategy require the participation of more than two countries/actors?
- Does a mechanism or strategy require the creation of new institutions?[17]

[17] This criterion builds on an insight from previous literature that the EU does not create new formal institutions with only one country (Lavenex, 2014).

IRC mechanisms OECD	**Bilateral regulatory cooperation literature**	**Policy strategies in international regime interaction**	**New Interdependence Approach**	**Relevance for bilateral regulatory cooperation**
Economic integration and harmonisation through supra-national law-making and institutions	-	-	-	-
Mutual recognition	-	-	-	-
Specific conventions and treaties	(Approximation)	Policy export/ policy promotion	Regulatory export/ First-mover agenda-setting/ Coalition-building /	-
Joint regulatory partnerships	Approximation/ 'equivalence'	Policy export	Regulatory export/ Mutual recognition	✓
Mutual recognition of conformity assessment	Mutual recognition of conformity assessment	(policy protection)	-	✓
International regulatory cooperation through international organisations	Approximation / 'equivalence'	Policy export / policy import/ policy promotion	Coalition-building/ First-mover agenda-setting	-
Trans-governmental networks		Policy export / policy promotion	Regulatory export	-
Formal requirements to consider all relevant frameworks for cooperation in other jurisdictions		-	-	✓
Recognition of international standards	-	- (Policy protection)	-	✓
Soft law	Guidelines	-	-	✓
Regulatory dialogues	Information exchange	-	-	✓

Table 5: Contrast of different operationalisations of regulatory cooperation strategies

A number of lessons can be drawn from the table 5: First, not all forms or mechanisms of international regulatory cooperation are relevant for bilateral regulatory cooperation. At least until present, neither economic integration nor comprehensive mutual recognition are conceivable for bilateral regulatory cooperation. The signature of new specific conventions or treaties is equally unlikely given that bilateral cooperation only foresees two signatories and thus has limited capacity to solve the global problems usually addressed by these conventions. International organisations as a forum for the promotion of

cooperation are equally irrelevant although some New Interdependence Approach authors argue that international organisations as a coordination mechanism influence regulatory cooperation between two jurisdictions (Newman & Posner, 2015). The emergence of trans-governmental networks may in principle also occur bilaterally, but actors commonly see the limited reach of bilateral networks as an impediment or as insufficient to address wider international problems (for an in-depth discussion of this question see Parker & Alemanno, 2014). For this reason, the reliance on trans-governmental networks is likely to be limited to regional, if not global regulatory cooperation. Likewise, at least until the time of writing, entities have not yet established a bilateral transnational agency.

Second, with regard to the explanatory objective of this dissertation, existing political science literature on regulatory cooperation continues to offer the arguably most relevant classification of strategies. Yet, the incorporation of certain mechanisms from the OECD compilation complements this classification and enhances its comprehensiveness. Third, for the strategies among which the Commission can choose, based on the derivation from political science literature and the OECD list, it follows mostly policy export or policy protection. While policy import shall not be excluded as a motivation for bilateral regulatory cooperation, according to the literature its empirical relevance until present is low (Young, 2015a; Falkner & Müller, 2013). Policy promotion does not apply as there are empirically no bilateral institutions or organisations in which decisions are taken jointly. Yet, single strategies identified by the regulatory cooperation literature often involve combinations of policy export and policy protection. Fourth, and similarly, while regulatory cooperation strategies used in bilateral relations include mutual recognition or regulatory export, the strategies differentiated by the New Interdependence Approach literature do not offer significant variation with regard to the strategies relevant to bilateral relations. Importantly, due to the interactions between only two entities, first-mover agenda-setting and coalition-building do not play a role.

In view of these lessons, the different approaches contrasted above can be synthesised to deduce that the universe of possible outcomes consists of the following strategies: harmonisation, approximation, negotiated mutual recognition/equivalence, mutual recognition of conformity assessment, guidelines for good regulatory practices, recognition of international standards, requirements to consider relevant frameworks, soft law, regulatory dialogues and information exchange. Table 6 summarises these strategies:

harmonisation
approximation
negotiated mutual recognition/equivalence
mutual recognition of conformity assessment
guidelines for good regulatory practices
recognition of international standards
requirements to consider relevant frameworks
soft law
regulatory dialogues
information exchange

Table 6: Synthesis of different regulatory cooperation strategies

This universe of outcomes goes beyond the strategies defined by previous regulatory cooperation literature. The delineation of regulatory cooperation strategies needs to be refined accordingly. The criteria for this refinement are developed in the next section.

3.3. Synthesis of bilateral regulatory cooperation strategies

This section synthesises the findings from the previous section and deduces two analytical criteria for the differentiation of bilateral regulatory cooperation strategies in this book, i.e. 'dimension' and 'depth' (chapter 3.3.1). It then integrates the regulatory cooperation strategies presented in chapter 3.2 into a typology (chapter 3.3.2.).

3.3.1. Criteria for a typology

This section defines the categories according to which regulatory cooperation strategies shall be delineated in this book. The objective of this definition of categories is to reduce analytical complexity to the greatest extent possible. Categories shall thus be defined which help to clearly differentiate between strategies while at the same time allowing grouping similar strategies. The objective of the definition of categories is to facilitate the construction of a dependent variable whose outcomes can be explained with a theoretical framework that can itself be reductionist and avoid excessive analytical complexity. It is put forward that the greatest reduction of analytical complexity can be achieved with a delineation of bilateral regulatory cooperation strategies based on their 'dimension' of reference and their 'depth'. This section first discusses existing categories of delineation drawn from both previous policy literature and related literatures such as convergence and governance literatures. A first step reviews the policy literature and shows why among previous approaches only 'depth' is conducive to delineate bilateral regulatory cooperation strategies. A second step then shows why a distinction according to the 'dimension' of cooperation helps capture observed strategies that are not captured by a distinction based on 'depth' alone.

Existing regulatory cooperation research mostly borrows from policy research to deduce criteria for the delineation and categorisation of strategies (Niemann & Bretherton, 2013; van Schaik, 2013; Elsig, 2013; Lavenex & Schimmelfennig, 2009; Schimmelfennig & Sedelmeier, 2005; Schimmelfennig & Wagner, 2004; Lavenex, 2004). Within policy research, measuring the 'intensity' of policies and rules has been a long-standing issue (Alesina et al., 2005; Hooghe & Marks, 2001; Schmitter, 1996). Authors distinguish the 'intensity' of international policy cooperation and domestic adoption based on the functional scope of rules, the depth of rules, their binding effect and the direction of policy change (Falkner & Müller, 2013: 5; Breitmeier et al., 2006).

The 'functional scope' measures the degree to which a sector or a set of sectors is governed by international rules and international 'regimes'. The 'depth' measures the specificity and density of the rules that are applied or adopted domestically. The 'binding effect' has been operationalised to specify if the application or adoption of internationally or bilaterally agreed rules can be enforced through

mechanisms such as dispute settlement (see Breitmeier et al., 2006). The following paragraphs discuss if and to what extent these criteria are relevant for bilateral regulatory cooperation.

Delineating strategies based on their 'functional scope' is the basis for the ranking of international regulatory cooperation mechanisms by the OECD. The differentiation on the functional scope helps delineate mechanisms which trigger comprehensive supranational polity-making from cooperation in specific sectors and on specific issues. Yet, delineations based on functional scope deliver little analytical benefit with regard to regulatory cooperation strategies, in particular bilateral ones. Previous contributions have emphasised that cooperation rarely covers all policies that govern a particular policy area (Zeitlin, 2015). On the contrary, strategies such as regulatory export, mutual recognition or harmonisation are applied to specific policies that cover only a marginal functional scope (Young, 2015b; Egan & Pelkmans, 2015). A delineation based on functional scope thus does not help to differentiate the use of approximation or mutual recognition.

The 'binding effect' of regulatory cooperation is the second criterion according to which the OECD has ranked regulatory cooperation mechanisms. It is also used by Young (2015b) to measure the 'intensity' of regulatory export through EU free trade agreements. A delineation based on the 'binding effect' of the regulatory cooperation mechanism is conducive to delineating a) cooperation through conventions, treaties and regulatory partnerships from b) cooperation in international organisations, trans-governmental networks and the establishment of soft law. Previous studies including Damro (2006), however, note that bilateral regulatory cooperation often occurs outside formal treaty agreements. The non-treaty agreements through which regulatory cooperation is initiated or concluded often do not include provisions that subject the enforcement of the informal agreement to any form of dispute settlement. The 'binding effect' of cooperation rather depends on the negotiation or coordination context, but does not help to delineate strategies such as regulatory export, harmonisation or mutual recognition which are pursued through both treaty and non-treaty agreements. While the 'binding effect' of regulatory cooperation is a relevant a criterion especially for multilateral regulatory cooperation, its application to bilateral regulatory cooperation is not useful to significantly reduce analytical complexity either.

The 'direction of policy change' is used by Falkner & Müller (2013) to delineate strategies of the EU's interaction with international policy regimes. This criterion is useful to identify if the EU (or possibly any other large political actor) engages in 'regulatory export' as stipulated by a large body of previous contributions, protects its domestic status quo policies or contributes to international policy-making. Still, its conduciveness to delineating bilateral regulatory cooperation strategies is limited because policy change is rarely the objective or outcome of bilateral regulatory cooperation. A distinction based on the 'direction of policy change' arguably helps to differentiate approximation and mutual recognition. It is, however, not able to delineate approximation from any of the other strategies pursued in bilateral regulatory cooperation.

The 'depth' of cooperation, measured as the specificity and density of cooperation (Alesina et al., 2005), in turn, suggests a possible way to delineate both approximation and mutual recognition and mutual recognition of conformity assessment and other forms of exchange. Approximation entails the development of provisions which specify what and how regulations are approximated whereas mutual recognition only stipulates the functional equivalence of standards and rules. It thus entails a higher specificity and density of provisions than equivalence. Moreover, mutual recognition of conformity assessments entails more specific and dense rules than 'information exchange' which often only specifies the modalities of the interaction.

A consideration of the 'depth' of cooperation can also explain the differences in ranking notably between previous regulatory cooperation literature and the ranking of mechanisms of the OECD. Insights from research on the design of free trade agreements on the 'depth-flexibility nexus' (Dür & Mateo, 2014) imply that deeper forms of cooperation are often complemented with more flexible forms as decision-makers want to maintain a certain degree of discretion in particular if they choose to agree on 'deeper' forms of cooperation.

Yet, 'depth' alone cannot delineate approximation or equivalence from mutual recognition of conformity assessment or other forms of interaction which do not change or affect the substance of policies. Existing contributions note the importance of distinguishing notably 'equivalence', or 'negotiated mutual recognition', from 'mutual recognition of conformity assessment' (Josling & Tangermann, 2015b; Nicolaidis, 2000), but do not offer a criterion by which these strategies could be delineated.

Further criteria to delineate strategies can be deduced from literatures related to policy research, notably the literatures on convergence (Heichel et al., 2005; Knill, 2005), Europeanisation (Radaelli, 2003; Börzel & Risse, 2003) and, increasingly, experimentalist governance (Zeitlin, 2015; Sabel & Zeitlin, 2010). These literatures distinguish between different 'dimensions' of convergence or Europeanisation respectively. The convergence and Europeanisation literatures share an analytical differentiation between substance and process (Heichel et al., 2005; Radaelli, 2003). Damro (2006: 870) defines procedural convergence as the "development of common procedures among authorities from different jurisdictions", including measures for collecting, evaluating and sharing information. He understands substantive convergence, in turn, as "the adoption of common rules and understandings" (Damro, 2006: 870).

The distinction between substance and process is taken up by experimentalist governance authors who differentiate the adoption and transfer of policies specifying 'framework goals' from administrative decisions and procedures (Sabel & Zeitlin, 2010; Zeitlin, 2015). Moreover, the definition of framework goals is analytically separated from their implementation, which is often guided by administrative procedures. Administrative procedures are thus understood as the processes which execute and implement the rules and understandings conceived in policies. Yet, while drawing attention to this

distinction, the experimentalist governance literature does not offer a clear definition of administrative decisions and procedures. An instrumental definition of administrative procedures can, however, be approximated. The Commission (2017) describes administrative procedures as those procedures "to ensure that applicable regulatory requirements are met". Administrative procedures verify the application of regulatory requirements, correct inadequate application and enforce the implementation of requirements. They involve procedures of conformity assessment, market surveillance, infringement complaints and redress as well as communication between authorities (Commission, 2017). Delineating strategies based on the 'dimension' of regulation thus offers an additional factor along which approximation, 'equivalence' and mutual recognition of conformity assessment can be differentiated.

To conclude, this section argues that the complexity of bilateral regulatory cooperation strategies can be reduced to two key aspects: the dimension of regulation to which they refer, i.e. procedure or substance, and the depth of cooperation. This is not to argue that the range of criteria discussed in related literatures, e.g. the functional scope, binding nature and direction of cooperation, is not useful to delineate regulatory cooperation strategies. However, the benefits of delineating bilateral regulatory cooperation strategies based on the dimension and depth of cooperation are higher analytical clarity and the reduction of analytical complexity. This makes an operationalisation of the dependent variable based on the dimension and depth of cooperation easier to apply in the empirical analysis that follows in the second half of this book.

3.3.2. Typology of bilateral regulatory cooperation strategies

This section draws together the conclusions of the previous sections and develops a typology of regulatory cooperation strategies that will be used as the operationalisation of the dependent variable of this book.

The discussion in section 3.3.1 has indicated that depth and dimension are complementary criteria. For the purpose of this dissertation, the depth of a cooperation strategy shall be operationalised on a dichotomous scale, distinguishing 'low depth' and 'high depth', or 'deep' and 'low' respectively. In line with the definition of 'depth' by previous studies, 'high depth' is assigned to strategies that entail specific and dense prescriptions or changes to existing policies or procedures (Falkner & Müller, 2013: 20). 'Low depth', in turn, is assigned to strategies that have vague prescriptions to existing policies and procedures or leave these unchanged.

'Dimension' is also understood dichotomously, with strategies either addressing substance, i.e. policies, or procedures. Strategies are categorised as addressing policies if they concern the substance of

regulations, i.e. the goals, content, structure and concepts of policies[18]. They shall be considered as addressing procedures if they entail prescriptions on the formulation, execution and implementation of rules, including administrative structures and techniques[19]. To reduce analytical complexity to the greatest extent possible and enable an empirical application of the theoretical , the strategies mapped in section 3.2. are grouped into four categories. These categories are defined along the two complementary criteria of dimension and depth.

Only the strategies of harmonisation, approximation, negotiated mutual recognition and equivalence refer to policy substance, i.e. goals, content, structure and concepts. They are therefore placed under the dimension 'policy'. Among them, only harmonisation and approximation are deep strategies of policy cooperation. Harmonisation entails highly specific prescriptions with regard to both the goals, content and structure of a policy, eliminating regulatory diversity between entities (Radaelli, 2003). Approximation equally entails specific prescriptions with regard to the alignment of goals, content and structure of a policy, but does not require identity of policies as a result. Empirically, however, the pursuit of harmonisation is rare. While approximation also entails a shared specific understanding of goals, concepts, and structures of policies, it is suggested to be more common than harmonisation as it leaves both the domestic and the foreign side room for own deviating content. Deep and policy cooperation shall thus be subsumed under the label 'regulatory alignment'. As laid down, it contains the pursuit of harmonisation as well as the pursuit of an approximation of regulations. 'Equivalence' is understood as a 'low' cooperation strategy as it only establishes functional 'equivalence' of the goals and content of a policy without, however, changing its structure or underlying concepts. The specificity of the agreed policies is thus relatively low. Low and policy cooperation shall be labelled 'equivalence'.

All other strategies refer to the formulation, execution and implementation of rules and are therefore placed under the dimension 'procedures': mutual recognition of conformity assessment, guidelines for good regulatory practices, recognition of international standards, requirements to consider relevant frameworks. 'Mutual recognition of conformity assessment' entails detailed rules according to which conformity assessment bodies in other jurisdictions need to assess the conformity of a product. Due to the specificity of these rules 'mutual recognition of conformity assessment' shall therefore be considered as a deep strategy of cooperation. 'Guidelines for good regulatory practices' shall also be classified as a deep strategy if the guidelines specify clear rules. A strategy promoting the 'recognition of international standards' shall be considered a deep strategy as it entails a clear specification as to how regulators and government officials should align decisions and procedures. The same applies to requirements to consider relevant frameworks if these requirements specify individual frameworks. Deep and procedure cooperation shall be called 'alignment of implementation procedures'. It shall include mutual

[18] This borrows from Dolowitz and Marsh (1996: 350) who define elements of policy transfer as "policy goals, content, instruments, structure and policy concepts, attitudes, ideas".
[19] The latter specification is also adopted from Dolowitz and Marsh (1996: 350).

recognition of conformity assessment as well as commitments to consider mutual standards and rules how to adopt and implement administrative decisions.

Unspecific 'requirements to consider relevant frameworks', 'soft law', 'regulatory dialogues' and 'information exchange', in turn, shall all be classified as low strategies because they do not contain any (specific) prescriptions as to how regulators and governments should formulate, execute or implement rules, but only set up exchanges and interactions among officials. Low and procedure cooperation shall be called 'information exchange' and include the establishment of regulatory dialogues, exchanges of data and other information as well as the conduct of benchmarking, peer reviews and the exchange of best practices. Although dialogues and exchanges risk being perceived and used as 'talk-shops', they encourage exchanges among regulators and therefore contribute to mutual trust in each other, promote confidence in the rules of cooperation partners and their ability to enforce rules. They can facilitate cooperation notably if otherwise there "is little common ground between jurisdictions" (Chase & Pelkmans, 2015: 3).

It should hereby be underlined that 'depth' is treated as a relative concept. Across the two dimensions 'policy' and 'procedures', 'depth' cannot be operationalised analogously as policies usually have a much higher specificity and density than 'procedures'. As a relative concept, the two operationalisations of 'depth' shall rather be understood as an indicator to which degree a strategy affects and constrains the behaviour of government officials relative to the absence of cooperation.

Figure 3 shows the classification of strategies of this book in the form of a typology:

Depth	**Dimension**	
	Implementation procedure	**Regulatory policy**
Low	Information exchange	Equivalence
High	Alignment of implementation procedures	Regulatory alignment

Figure 3: Typology of regulatory cooperation strategies

Beside the engagement in one of these strategies, regulators and government officials may also choose to maintain regulatory competition. Again, this does not preclude that third countries adjust their own regulatory policies or implementation procedures according to the regulatory policies or implementation procedures of the jurisdiction with larger market size or higher regulatory stringency. If some form of regulatory adjustment occurs, however, it is the result of diffusion or emulation processes across jurisdictions. It is not the result of 'deliberate' or 'active' regulatory cooperation. Furthermore,

regulators and government officials of a jurisdiction with large market size or high regulatory stringency may choose not to engage in regulatory cooperation in order to create pressure on other jurisdictions to modify their own regulatory policies and thus respond to potential demands of firms or citizens. If such 'trading up' occurs, however, it is again not the result of deliberate coordination and regulatory cooperation between jurisdictions. As the decision to maintain regulatory competition implies the absence of cooperation, the corresponding strategy shall be called 'no cooperation'.

Aggregating the potential regulatory cooperation strategies delineated in the typology and the possibility of 'non-cooperation', the outcomes on the dependent variable of this study, 'bilateral regulatory cooperation strategies', can be operationalised with five possible outcomes as follows in figure 4:

Non-cooperation	*Information exchange*	*Alignment of implementation procedures*	*Equivalence*	*Regulatory alignment*

Figure 4: Outcomes on the dependent variable

The operationalisation of the dependent variable that has been made in this section inevitably represents a simplification. Here, it should be re-iterated that the motivation for the operationalisation of the dependent variable has been a reduction of analytical complexity. Nuances among strategies that have been grouped into a single outcome for the purpose of the subsequent empirical analysis persist either with regard to criteria that have been omitted or with regard to the precise level of depth that they foresee. Two examples shall illustrate this point. Indeed, 'requirements to consider relevant frameworks' have a different functional scope from 'regulatory dialogues' or the enactment of 'soft law'. As argued above, summarising them under a single category is nonetheless justified if the specificity of the envisioned cooperation is taken into account. Likewise, as already noted, the outcome 'regulatory alignment' aggregates strategies which differ with regard to the extent of policy change. Here again, the reason to group them has been a practical one: Adding a separate category would have made the analytical framework much less reductionist without offering a major empirical benefit. The examples that would be covered with a more extensive framework are few, given that harmonisation is regulatory cooperation is empirically rare. Nonetheless, limits to the typology developed in this section certainly merit greater scrutiny in light of their empirical validity. This point will be addressed in greater depth in the discussion following the empirical analysis of this book (chapter 6).

3.4. Summary

This chapter has elaborated a new analytical specification for the dependent variable of this book, bilateral regulatory cooperation strategies. It was guided by the objective to aggregate the growing number of definitions and delineations of regulatory cooperation in the academic and practitioners' literature into one analytical model that captures the breadth of empirically relevant bilateral regulatory cooperation strategies, but is applicable to empirical investigation. It has placed bilateral regulatory cooperation within the broader literature on external governance and identified it as an active, horizontal governance mechanism that relies on coordination rather than coercion. Regulatory cooperation can cover both regulations, standards as well as administrative procedures such as conformity assessments, import authorisation procedures and market surveillance measures while cooperation applying to legislation is highly unlikely.

The chapter has laid down the definitions of regulatory cooperation strategies by the different streams of academic and practitioners' literature, contrasted them and derived a comprehensive universe of potential regulatory cooperation strategies. It has argued that a categorisation of these strategies based on the complementary criteria of depth and dimension (substance or procedure) achieves the highest reduction of analytical complexity and makes an operationalisation of the dependent variable based on these values applicable to empirical examination. Subsequently, it has attributed the possible bilateral regulatory cooperation strategies to one of the four categories that result from the combination of the complementary depth and dimension. The ensuing typology of bilateral regulatory cooperation strategies has led to the operationalisation of the dependent variable of this book. Incorporating the possibility of non-cooperation, the dependent variable, bilateral regulatory cooperation strategies, is operationalised with five possible outcomes: regulatory competition, information exchange, 'alignment of implementation procedures', 'equivalence', 'regulatory alignment'.

The next chapter (chapter 4) links these outcomes on the dependent variable to variation in the independent variables. It thus deduces the explanatory factors of the Inter-relational Institutionalism.

4. Explaining bilateral regulatory cooperation strategies

The theoretical objective of this book is to refine existing theoretical frameworks and thus contribute to the research lacunae in explaining under which conditions the EU chooses which strategy of regulatory cooperation in bilateral regulatory cooperation. Put differently, it seeks to understand why the EU does not necessarily pursue harmonisation and regulatory approximation in its interactions with countries outside its neighbourhood although its jurisdiction overlaps with these countries and creates regulatory conflicts.

The motivation for refining existing theoretical frameworks builds on gaps in existing research and the shortcomings of previous literature identified in the literature review in chapter 2. This refined theoretical framework to explain the puzzle of this book needs to draw on three main theoretical literatures: First, it requires an actor-centred framework to be able to explain the creation of rules and institutional structures with the decisions of (bureaucratic) actors rather than with structural or functionalist accounts. Second, it needs to combine and integrate rational-choice and constructivist approaches in line with recent literature to overcome the shortcomings of both accounts individually with regard to the deduction of actor preferences. Third, it needs to adopt a domestic-level approach to identify the constraints that restrict the behaviour of actors in an interdependent environment.

The refined theoretical framework is based on six main assumptions: (1) Rules, structures and rule regimes are intentionally created by actors. The creation of rules, structures and rule regimes cannot be understood without attention to the preferences and interests of actors who are able to shape them. (2) Institutions in which actors are embedded shape and constitute the preferences of actors. The preferences of actors cannot be deduced from material interests alone. (3) Institutions shape and constrain the behaviour of actors, determining which behavioural choices are feasible within an institutional context. (4) Trade liberalisation and the emergence of interdependence among jurisdictions is endogenous to the behaviour of actors. Interdependence constitutes and constrains the behaviour of actors and the choices they can pursue. (5) A large internal market and a high degree of regulatory capacity are important for the ability of a jurisdiction to influence rules and norms at the international level. (6) Through regulatory cooperation, regulators and governments do not seek to significantly change the institutions of another jurisdiction, but accept them as constraints on their behaviour.

This chapter proceeds as follows: A first section (chapter 4.1.) presents the ‘building blocks’ of the refined theoretical framework which respond to the theoretical gaps identified in chapter 2, i.e. actor-centred institutionalism and the New Interdependence Approach, and reiterates the shortcomings of each approach taken individually. A second section (chapter 4.2.) shows how the New Interdependence Approach can be integrated into actor-centred institutionalism to derive a new theoretical framework, the Inter-relational Institutionalism. The third section (chapter 4.3.) specifies and applies the Inter-relational Institutionalism to decision-making of regulators in bilateral regulatory cooperation along two

analytical elements: actor characteristics and actor constellations. It thus deduces the three independent variables of the Inter-relational Institutionalism: bureaucratic pressure, regulatory compatibilities and societal mobilisation.

Chapter 4.3.1. first specifies the formation of preferences of regulators on regulatory cooperation for an individual technical regulatory body without bureaucratic pressure and subsequently aggregate regulatory preferences under bureaucratic pressure. Chapter 4.3.2. deduces that 'regulatory institutions' which shape and constrain the preferences of regulators can be distinguished into 'regulatory authority structures and 'regulatory principles'. It then specifies the other independent variables which constrain the formation of strategies that actors form based on their preferences, i.e. 'regulatory compatibilities' between the domestic and the foreign jurisdiction. Following the deduction of preference-constituting 'regulatory institutions' as 'regulatory authority structures' and 'regulatory principles', it distinguishes the independent variable 'regulatory compatibilities' into 'compatible regulatory authority structures' and 'compatible regulatory principles'. Based on the presence of bureaucratic pressure and the constellations of 'regulatory compatibilities' between the domestic and the foreign jurisdiction on an issue, it deduces the hypotheses that link variation in the independent variables to the outcomes on the dependent variable delineated in chapter 3.3. Chapter 4.3.3. lays down the causal mechanism that leads to the formation of a regulatory cooperation strategy and clarifies the relationship between the independent variables and the dependent variable.

Chapter 4.4. operationalises the independent variables 'bureaucratic pressure' and 'compatible regulatory authority structures for the formation of regulatory cooperation strategies of the Commission. The independent variable 'compatible regulatory principle' will be operationalised at the beginning of each of the empirical case studies in chapter 6. Chapter 4.5. summarises the hypotheses specified and deduced in this chapter.

4.1. Building blocks for an integrated theory

This section introduces the building blocks of the theoretical framework that is developed in the next sub-section. The choice for these buildings blocks reflects their respective dominance in political science research on policy choice and strategy formation as well as institutional developments under interdependence. This section first presents the contours of actor-centred institutionalism and then sketches out the main components of the New Interdependence Approach. The shortcomings of each approach taken individually are raised at the end of each discussion.

4.1.1. Actor-centred institutionalism

A first step introduces the actor-centred institutionalism. Actor-centred institutionalism corresponds to two out of three demands for a refined theoretical framework derived in the literature review: First, it is an actor-centred framework and explains the design of rules, policies and institutional structures with the intentional behaviour of actors. Second, it is theoretically neutral to rational-choice and constructivist assumptions and instead seeks to incorporate elements of both. Actor-centred institutionalism explains the adoption and choice of a policy within a three-step analytical process: actor characteristics, actor constellations and modes of interaction. The following paragraphs will present each of these three steps.

Actor-centred institutionalism has become a crucial framework in public policy analysis to explain the development of public policies. Its main achievement has been to overcome the debate between agency- and structure-based explanations in policy development. Rather, it seeks to analytically distinguish the interaction dynamics between actors and institutional factors. Actor-centred research has moved beyond the rational-choice, game-theoretic framework within which it was originally developed by Scharpf (1997) and opened itself up to historical and sociological institutionalist approaches.

Actor-centred institutionalism shares the assumption of all streams of institutionalist literature, i.e. rational-choice, historical and sociological institutionalism, that institutions shape and constrain the behaviour of actors and influence processes of institutional change (Hall & Taylor, 1996). It defines institutions as "a collection of formal rules which structure the cooperation between actors" (Scharpf, 1997: 21). Actor-centred institutionalism establishes the notion of intentional, actor-centred steering (Mayntz, 1987; Mayntz & Scharpf, 1995). Analytically, it relies on three core building blocks: First, it puts forward a crucial role of 'actors' as determinants of policy outputs, acknowledging that policy developments are above all the "outcome of interactions among purposeful actors" (Scharpf, 1997: 1). It emphasises the causal role of actors and agency in policy development. Analytical attention is shifted to the preferences of actors as explanatory variables for policy development and policy output. Orientations and capabilities thus shape what Scharpf calls 'actor characteristics'. Actors are argued to

have distinct preferences which are shaped by both (subjectively defined) material interests and normative and cognitive dimensions (Scharpf, 1997: 19-22). Material interests include the considerations by actors of costs and benefits resulting from different policy alternatives. Norm-induced preferences relate to the role and identify and interaction orientations of an actor (Scharpf, 1997: 21). This proposes that human action is culturally shaped and reflects socially constructed beliefs about the world (Scharpf, 1997: 21). Whether actors can realise their preferences is argued to depend on their capabilities, i.e. their resources, access and political power. The adoption and reflection of a methodological individualism thus pushes back institutions as the sole explanatory factors of policy development and instead concentrates on actors as immediate causal factors. The focus on actors and the strategic use of opportunity structures has been underlined by contributions to implementation and Europeanisation research (Graziano et al., 2011; Jacquot & Woll, 2003; Treib, 2003).

Second, actor-centred institutionalism distinguishes not only material from cognitive and ideational dimensions of agency, but also preferences from processes of strategy formation. Most actors studied by actor-centred institutionalism are not individuals, but organisations. They coordinate their behaviour through the adoption of aggregate and collectively binding decisions. Actor-centred institutionalism draws attention to interaction dynamics and processes of strategy formation with complex collective actors and looks at the interactions among different collective actor members in the development of a collective actor strategy.

Third, actor-centred institutionalism incorporates that actors are embedded within a set of institutions that influence their perception of reality, structure the interactions of actors at the domestic level and thus shape processes of policy development. Mayntz and Scharpf (1995: 43) formulate that institutions stimulate, facilitate and restrict the action context. Scharpf (2000: 775) puts forward that institutions affect the preferences and behaviour as (a) formal rules restrict the choice of feasible policy alternatives, (b) formal rules create ‘constellations of actors’ and (c) social norms shape normative and cognitive orientations. The embedding of actors in an institutional structure creates what Scharpf calls ‘actor constellations’. Institutions therefore shape and determine the constellations of actors that a specific actor faces in the pursuit of her preferences. They determine which veto players can vote on a policy and fix the threshold of agreement which is necessary to adopt a policy change. Authors examining the impact of institutions on the aggregation of interests derive hypotheses in particular from the literature on comparative political institutions (Tsebelis, 2002). Institutions are found to vary according e.g. to the size of constituencies, the number of veto points, and the domestic electoral system, as well as between democracies and non-democracies. Formal rules discourage actors from pursuing goals which conflict with the content of rules. Moreover, they are argued to create incentive structures and to shape expected payoffs resulting from certain strategies, thus influencing the likelihood that certain strategies are adopted by rational actors. Formal rules also equally determine veto positions or constitute certain

actors. The interdependence of jurisdictions is, however, treated as an independent phenomenon exogenous to the formation of actor strategies.

As social norms, institutions define and shape value orientations and preferences of actors (Lewis, 2005). Institutions thus also determine the "mode of interaction" (Scharpf, 1997: 44), i.e. the choice of an actor how to resolve a conflict and interact with other actors. Figure 5 shows the decision-making problem of actors according to actor-centred institutionalism (based on Scharpf, 1997: 44).

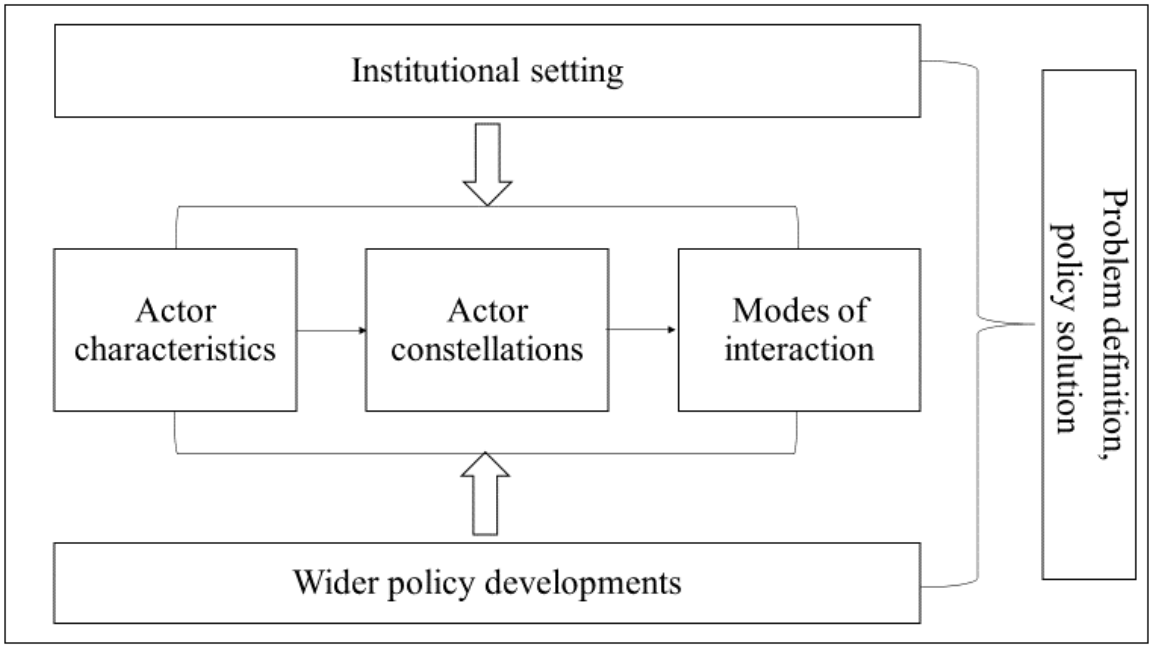


Figure 5: Decision-making problem of actors according to actor-centred institutionalism

Actor-centred institutionalism, however, mostly assumes processes of strategy formation within independent individual units. Although it acknowledges influences of "wider policy developments" on the preferences and behaviour of actors, it offers little theoretical clarification as to how wider policy developments exert influence on actor characteristics, actor constellations and modes of interaction. Domestic strategy formation is analytically separated from the behaviour of actor in 'international' interactions. Actors develop 'domestically' individually optimal strategies, but do not consider if their strategies allow cooperation with actors from other jurisdictions. Instead, actor-centred institutionalism assumes that cooperation is enabled and facilitated through communication mechanisms, side payments and commitment mechanisms for repeated interactions. Interdependence is thus treated as a factor exogenous to the strategy formation. As discussed in chapter 2.1, the assumption of domestic jurisdictions as independent units of analysis leads to empirically false conclusions (cf. Oatley, 2011).

4.1.2. New Interdependence Approach

This section introduces the New Interdependence Approach as an emerging theoretical literature that addresses the main shortcoming of the 'independent unit of analysis' assumption of actor-centred institutionalism (Newman & Farrell, 2016; Farrell & Newman, 2014; Büthe & Mattli, 2011; Krasner, 2011; Posner, 2009).

The New Interdependence Approach is a structural argument, examining the sequential cross-national diffusion of institutional patterns in a context created by trade liberalisation and economic and political interdependence. It makes the following assumptions and statements: First, interdependence is not only an intervening variable, but a causal factor of domestic institutional change. Interdependence creates rule overlap and conflicting rules across jurisdictions as well as an opportunity structure for actors to change domestic institutions. The New Interdependence Approach thus acknowledges that jurisdictional boundaries are often no longer bound to the nation state (Putnam, 2009). "Interdependence" is understood as the "interpenetration of national polities and markets, so that decisions made in one jurisdiction have consequences in another" (Farrell & Newman, 2014:2). Consequently, states are not assumed to be independent units of domestic preference aggregation.

Second, institutions are viewed as constitutive and thus endogenous to the preferences and power of domestic actors in interdependent relations. Domestic institutions influence the ability of domestic actors to shape transnational and international rules. Third, processes of institutional change across borders are not only initiated by government negotiators through intergovernmental agreements, but by multiple sub-state actors that seek to respond to rule overlap. These sub-state actors are notably regulators, trans-national interest groups or the secretariats of international organisations. They are assumed to engage in contestation across boundaries and use both foreign jurisdictions and the global level as opportunity structure to advance their preferences. Fourth, outcomes of cross-national interactions are not stable policy equilibria such as intergovernmental agreements, but reiterated sequences of institutional changes across borders and new institutions 'layered' above existing institutions.

The argument proposed by the New Interdependence Approach runs as follows: Interdependence gives rise to rule overlap across jurisdictions and clashes between the rules of different markets. As actors are subjected to conflicting rules, they seek to resolve these disputes and establish certainty. At the same time, however, interdependence and overlapping jurisdictions create new opportunities and opportunity structures for actors subjected to diverging rules as they can shift their activities across jurisdictions to take advantage of overlapping and conflicting rules. Actors, notably regulators, trans-national interest groups or the secretariats of international organisations, seek to resolve regulatory disputes, establish certainty and facilitate cross-national coordination. For this purpose, they use interdependent relations as an opportunity structure to advocate domestic institutional change across jurisdictions.

According to the New Interdependence Approach, domestic policy choices of interdependent jurisdictions are therefore not only determined by previous domestic institutional choices, but also by institutional asymmetries with other states and their institutional choices (Farrell & Newman, 2014: 12; Farrell & Newman, 2010: 623; Krasner, 2011; Simmons & Elkins, 2004). More specifically, institutional asymmetries across states at the international level trigger processes of domestic institutional change. Importantly, rule overlap changes domestic reversion points. A domestic institutional change subsequently reshapes institutional asymmetries at the international level and triggers endogenous change in another jurisdiction. This leads to a dynamic of "an iterated sequence of domestic institutional moves across national borders" (Farrell & Newman, 2014: 13). Interdependence destabilises the domestic and global regulatory status quo, making globalisation an endogenous process.

Theoretically, the New Interdependence Approach mostly adopts a historical institutionalist framework. In doing so, it concentrates on examining processes of institutional change across jurisdictions. Dependent variables of its research are processes of diffusion across jurisdictions and trans-governmental coordination rather than policy outcome equilibria. To describe this dynamic, the New Interdependence Approach borrows the historical institutionalist terminology of 'layering' and 'sequencing', emphasising the importance of temporality. Layering describes the creation of a new and additional layering of cross-national institutions which overlay domestic institutions and over time subsumes or replaces them (Farrell & Newman, 2014: 26; Thelen, 2004). Sequencing within the New Interdependence Approach denotes a dynamic "in which particular institutional change in one country can produce endogenous effects in another, spurring reactions that lead to further institutional change." (Farrell & Newman, 2014: 17)

The New Interdependence Approach also identifies power resources to shape the direction of institutional change across borders, the causal mechanism underlying institutional change across borders and the role of international institutions. Authors note that power is constituted through institutions that determine the access of actors to opportunity structures created by interdependence. Institutions offering access are a high relative domestic regulatory capacity (Raustiala & Sprigma, 2009; Putnam, 2009; Bach & Newman, 2007), first-mover advantages (Newman & Posner, 2015), a hierarchical domestic institutional structure and a high degree of institutional fit between domestic and international institutions (Büthe & Mattli, 2011) as well as a large internal market (Simmons, 2001; Drezner, 2007). Market size essentially shapes the ability to benefit from asymmetric interdependence (Keohane & Nye, 2001) and to exert adaptational pressure on exporters and other jurisdictions through the exclusion of foreign products from the domestic market. Regulatory capacity denotes "the expertise, resources, organisation, and authority to develop, implement, and enforce rules" (Bach & Newman, 2007: 831). The ability to define, monitor and enforce market rules is argued to put actors in a better position to control their markets and demand access to transnational structures. Yet, the New Interdependence Approach emphasises relational considerations more than absolute power conditions. Relational

considerations put the power of actors in contrast with the power of other actors involved[20]. Moreover, they compare the timing of policies and the development of regulatory capacity in one state to the development of policies in other states. New Interdependence Approach authors thus consider high relative regulatory capacity and first-mover advantages as more important power resources rather than a large internal market and regulatory capacity. They argue that if a market develops regulatory capacity before other states, foreign firms and other actors which are exposed to international markets are likely to converge on the preferences of the market with early regulatory capacity. Besides, they stress that actors who were present at the time when the first-mover state established institutions are more likely to influence the trajectory of subsequent institutional development than those whose influence came in later. At the same time, actors are likely to be in a situation of disadvantage if regulatory conflict arises on an issue in which they have not established regulatory capacity before economic interdependence set in (Farrell & Newman, 2010: 622). Yet, authors also stress that first-mover advantages do not deliver permanent relative power resources as they are embedded in continuously evolving processes of institutional change (Farrell & Newman, 2014: 18). Access to opportunity structures is argued to also depend on the degree of fit between domestic institutions and international structures. Büthe and Mattli (2011) have described a fit between domestic institutions and international opportunity structures as 'regulatory complementarities'.

Researchers investigating the causal mechanism leading to sequences of institutional change across jurisdictions acknowledge that institutional change is triggered by actors that seek to resolve regulatory conflicts under rule overlap and to establish certainty. These actors are often sub-state actors, including regulators and societal actors. The overlap of jurisdictions creates shifting boundaries of political contestation and opportunity structures outside the domestic set of institutions. domestic actors also influence foreign institutions and the positions of foreign governments (Krasner, 2011). They use interdependence as an opportunity structure to advance their preferences. As they take advantage of international opportunity structures and interact with actors in other states, they can change even 'sticky' domestic institutions (Farrell & Newman, 2014: 19; Cerny, 2010; Slaughter, 2004). The New Interdependence Approach argues that the likelihood and ability of actors to use interdependence as an opportunity structure is shaped by their preferences and their access to transnational fora and opportunity structures. Authors differentiate between actors who seek to maintain the institutional status quo and thus who seek to change or overturn it. Actors who prefer to overturn existing domestic institutions and who enjoy a high degree of transnational access are assumed to pursue 'cross-national layering', i.e. the creation of a "new layer of cross-national institutions, whether formal or informal, which overlay domestic institutions" which may, but need not over time subsume or replace domestic institutions

[20] Relational considerations are, however, neither specific nor original to the New Interdependence Approach. They are also a common feature of traditional rational-choice approaches and realist approaches. Yet, the New Interdependence Approach applies relational considerations more broadly and uses them to derive explanations for outcomes on the dependent variable.

(Farrell & Newman, 2014: 24). As a causal mechanism of institutional change, authors propose that actors with a preference to change institutions and access to international opportunity structures build trans-national coalitions with actors from other jurisdictions and use these coalition to create argumentative pressure (Posner, 2009). International institutions and organisations are seen as mediating actors, reflecting the characterisation of liberal institutionalism (Keohane & Nye, 2001). They influence institutional change as they provide information and monitoring capacities to actors with access to international opportunity structures (Farrell & Newman, 2014).

Although the New Interdependence Approach is designed as a structural approach, it cannot explain institutional changes across borders without agency and the deliberate behaviour of actors. The main limitation of the New Interdependence Approach is its neglect of actor strategies. Authors agree that the power resources identified by the New Interdependence Approach are rather necessary conditions to shape cross-national layering rather than sufficient condition to explain the exercise of this power in an interdependent context (Farrell & Newman, 2010: 614). Yet, as discussed above, observed actor strategies often deviate from their assumed or deduced preferences. This deviation of actor strategies from their preferences is not addressed by the New Interdependence Approach. Instead, it implies that actors with access to transnational fora and preferences to change the domestic status quo are able and willing to pursue their preferences and advance a change of domestic institutions.

Yet, it offers an important insight that helps to refine and adapt the actor-centred institutionalist framework. The New Interdependence Approach addresses the 'insulated unit of analysis' problem of actor-centred institutionalism. It suggests that interdependence is not only a 'wider policy development', but constitutive to the ability of actors to pursue their preferences. In this regard, it defines the 'actor constellations' determining the ability of actors to realise their most preferred outcome. The adapted conceptualisation of 'actor constellations' based on the assumptions of the New Interdependence Approach will be specified in the next section which combines actor-centred institutionalism and the New Interdependence Approach into an integrative theoretical framework (chapter 4.2).

To conclude, this section has reviewed both actor-centred institutionalism and the New Interdependence Approach. It has identified the treatment of jurisdiction as an independent unit of analysis as an important theoretical shortcoming of actor-centred institutionalism. Moreover, it has shown that the emerging New Interdependence Approach framework offers a response to this shortcoming because it suggests that institutional asymmetries across jurisdictions are both an opportunity structure and a constraint to the behaviour of actors at the international level. It lacks, however, a theoretical micro-foundation that specifies the translation of theoretically deduced preferences of actors into observable strategies. The next section (chapter 4.2.) specifies how both theoretical approaches can be combined.

4.2. Inter-relational Institutionalism

This section incorporates the New Interdependence Approach into actor-centred institutionalism and derives a new theoretical framework, the Inter-relational Institutionalism. This framework addresses the shortcomings of both theoretical frameworks taken individually. Thus, it aims at deriving a theoretical model that can better account for the constraints and behaviour of actors in an environment of interdependence. This framework will guide the deduction of hypotheses in chapter 4.3. and direct the empirical analysis of this book in chapter 6.

The Inter-relational Institutionalism shares the definition of an institution as "a relatively enduring collection of rules and organized practices, embedded in structures of meaning and resources that are relatively invariant in the face of turnover of individuals and relatively resilient to the idiosyncratic preferences and expectations of individuals and changing external circumstances" (March & Olsen, 2008: 2). For analytical clarity, the derivation of the Inter-relational Institutionalism follows the structure and building blocks of actor-centred institutionalism. In line with the analytical focus of this book, this framework, however, only incorporates two out of three building blocks of actor-centred institutionalism, i.e. 'actor characteristics' and 'actor constellations', while leaving aside the 'mode of interaction'. As outlined in the previous section, the 'mode of interaction' defines the logic of action which existing governance literature differentiates into interaction through bargaining and persuasion (Lavenex, 2014; Falkner & Müller, 2013; Börzel & Risse, 2012). While bargaining relies on the use of coercion and conditionality, persuasion builds on socialisation, deliberation and learning.

The decision to leave out the mode of interaction reflects findings from previous studies. On the one hand, existing literature has already extensively analysed scope conditions for the prevalence of either mode of interaction, e.g. the institutional context (Falkner & Müller, 2013), the complexity of issues discussed (Keohane & Goldstein, 1993), politicisation of the setting (Peterson & Young, 2014; Lavenex, 2014; Checkel, 2001) or the clarity or ambiguity of distributive implications (Poletti, 2011). There is little reason to presume that these scope conditions should not hold for regulatory cooperation. On the other hand, and more importantly, the literature implies that the mode of interaction and the prevalence of bargaining or persuasion is without effect on the research object of this book, i.e. the constraints on strategy formation. Falkner & Müller (2013) suggest that frequently bargaining interactions complement, but do not replace persuasion mechanisms. Moreover, the complexity of regulatory cooperation (Shaffer, 2016; Egan & Pelkmans, 2015) is highly unlikely to replace persuasion mechanisms and create room for coercion and conditionality even when regulatory cooperation is embedded in a bargaining context. While the 'mode of interaction' as a variable may be addressed in future research, it is not further theorised in the Inter-relational Institutionalism.

This section thus proceeds as follows: A first sub-section (chapter 4.2.1.) specifies the 'actor characteristics', defining the preferences of actors in the context of interdependence. This sub-section

addresses the combination of both rational-choice and sociological-constructivist assumptions into one coherent theory. The second sub-section (chapter 4.2.2.) derives the 'actor constellations' under institutional asymmetries in interdependence.

4.2.1. Actor characteristics

This first sub-section deals with the first building block of actor-centred institutionalism and derives the preferences of actors. It first shows how the assumption of actor behaviour as intentionally rational offers a model to incorporate sociological-constructivist understandings of behaviour into rational-choice models. Second, it derives differences in preferences of 'sub-actors' that are a part of collective actors. Third, it specifies the preference of actors under interdependence.

Due to its foundation in rational-choice theory, Scharpf's actor-centred institutionalism defines the characteristics of actors as their have distinct preferences, orientations and capabilities. The emphasis on preferences as an analytical instrument to understand the decision-making problem of an actor is also shared by the New Interdependence Approach (Farrell & Newman, 2014: 32). In line with actor-centred institutionalism, preferences shall be defined as the most preferred outcome of an actor regarding a specific issue, given its fixed underlying interest (Frieden, 1999; see also chapter 3.1.).

In its original, purely rational-choice form, actor-centred institutionalism derives the preference of an actor from its underlying material interest. This material interest is assumed to be fixed and clearly discernible. It results from cost-benefit calculations of the consequences of policy alternatives to their fixed, underlying interests (Frieden, 1999). From the sociological-constructivist perspective, in turn, the constitution of actors' self-interest and their preferences depend on their identity and the beliefs that they hold. Identities shape interests because they offer information about the normative expectations which are addressed to an actor. They thus shape the perception of actors of what constitutes an opportunity or threat and the pursuit of which goals they can consider as appropriate for their behaviour (Ziegler, Campbell, Hall & Pedersen, 2011). Beliefs and ideas influence the ends which actors pursue because they offer guidance for action and specify the causal and normative relationships that pertain to a particular action.

More recent contributions to neo-institutionalist (including actor-centred institutionalist) theory offer a way to combine this understanding of preferences derived from the material interest of actors with sociological-constructivist conceptions of behaviour as driven by normative and cognitive orientations They assume that actors are intentionally rational, i.e. that actors seek to behave rationally (e.g. Woll, 2008). Intentional rationality means that actors are not able to deduce rational behaviour from a clear ranking of preferences. Instead, rationality is socially constructed within the structural embeddedness of actors in a given social system. Actors do not have full knowledge of the relationship between means

and ends in an environment of uncertainty. The institutional context in which actors are embedded shapes their beliefs about how means are connected to ends and which ends are politically feasible. Uncertainty is a reflection of lack of knowledge about the relationship between means and ends. Actors make sense of the connection between means and ends through interacting with their social environment, establishing how means and ends are connected and establishing the most appropriate means to pursue in a context of constraint. Within this context, institutions reduce uncertainty and establish ideas about the mechanisms between means and ends.

The model of intentional rationality thus incorporates both material interest and normative orientations and identities as motifs for intentionally rational behaviour. When conflicts occur within cognitive frameworks or perceived means-ends relationships fail, actors perceive that existing beliefs no longer serve legitimate behaviour. Following cost-benefit considerations, they look for other ideas that can establish relationships between means and ends. A strive for rationality and an efficient use of resources in actors, however, induces them to engage with ideas that are proposed by authoritative actors. In evaluating the costs and benefits and normative implications of different policy alternatives, actors are assumed to prefer a solution which is close to the status quo (Woll, 2008).

Actors that the New Interdependence Approach and actor-centred institutionalism study are mostly organisations, not individuals. Organisations are composite actors of different individual sub-actors. Neither actor-centred institutionalism nor the New Interdependence Approach specifically address the question how aggregate actors form aggregate preferences. However, proxy rational-choice institutionalist theories, especially the principal-agent approach, have been proposed to fill this gap. Following the distinction between different sub-actors, their respective preferences and orientations can be derived from the assumption of intentionally rational behaviour. The preferences of different sub-actors differ in line with their structural embeddedness in a specific context and their particular identity. Sub-actors thus have different beliefs how means are connected to ends. Based on their degree of uncertainty and their evaluation of the relationship between ends and means under the status quo, they attribute different roles to new ideas and deviate in their conception of rational behaviour.

The preferences of sub-actors are translated into the aggregate preference of an actor, i.e. organisation. Actor-centred institutionalism puts forward that the formation of a collective preference results from the interaction dynamics among different members of a collective actor. These interaction dynamics shape the capabilities of sub-actors to shape the aggregate preference of an actor. Actor-centred institutionalism suggests that resources, power and access strengthen the capability of a sub-actor to shape the aggregate preference of an actor.

For analytical clarity, the relative capabilities of sub-actors to shape the aggregate preference can be modelled using the principal-agent approach, thus following a large body of rational-choice institutionalist theoretical literature (Elsig & Dupont, 2012; Dür & Elsig, 2011; Damro, 2007). Although typically applied to study the relationship between executives and legislatures, the concept can also

grasp the behaviour of sub-actors within an organisation (Elsig & Dupont, 2012). The principal-agent approach notes that in delegated relationships, actors, called 'agents', have a certain degree of autonomy that they obtain e.g. from agenda-setting, information asymmetries and the active use of strategies (Pollack, 2003; Kiewiet & McCubbins, 1991). The intervention of other actors, however, decreases their autonomy. Variation in the participation of different 'agents' or sub-actors in agenda-setting thus shapes and constrains the capabilities of sub-actors in the formation of an aggregate preference in a collective organisation. This point will be specified in chapter 4.3.2.

Incorporating the New Interdependence Approach now allows specifying the preference of actors (including sub-actors) in an environment of interdependence. The New Interdependence Approach proposes that interdependence possibly increases uncertainty to actors because rule overlap increases the likelihood that other actors may intervene (Farrell & Newman, 2014; Damro, 2006). The intervention by other actors, however, unfavourably affects the material interest to maximise its utility. Rule overlap also gives rise to cognitive conflicts. As a consequence, it can be derived that actors in seeking to reduce uncertainty prefer avoiding divergent decisions across jurisdictions. The individual cost-benefit analyses of sub-actors, the uncertainty that they perceive due to the emergence of cognitive conflict as well as their beliefs in the possibility to use interdependence as an opportunity structure to reduce uncertainty, however, differ.

To summarise, this sub-section has addressed the first building block of Inter-relational Institutionalism and derived the preferences of actors. It has shown that the conception of actor behaviour as intentionally rational allows incorporating sociological-constructivist understandings of behaviour into rational-choice preference models. Moreover, it has specified variations of intentionally rational behaviour among sub-actors within actors as organisations, drawing from the principal-agent concept in rational-choice institutionalist frameworks. Third, it has incorporated the New Interdependence Approach into actor-centred institutionalism and specifies the preference of an actor in the face of interdependence.

4.2.2. Actor constellations

After the first sub-section has derived the preferences of actors under interdependence and specified parameters for the capacity of individual sub-sector to influence the collective preference of a collective actor, the goal of this second sub-section is to deduce the potential actor constellations that allow an actor to use interdependence as an opportunity structure. It is here that the focus of this book and its development of the Inter-relational Institutionalism lies. This sub-section shows how the incorporation of the New Interdependence Approach specifies potential domestic actor constellations and thus the constraints on actors that arise from the overlap of jurisdictions and institutional asymmetries.

As explained in chapter 4.1.1., actor-centred institutionalism understands actor-constellations as determined by the set of domestic institutions in which an actor is embedded. These institutions influence actors' perception of reality and structure their interactions[21]. Institutions also determine the autonomy of actors vis-à-vis potential veto players. They lay down the rules for decision-making and the delegation of authority. Chapter 4.1.2., however, discussed the assumption of the New Interdependence Approach that institutions shaping the interactions and constellations of actors are not distinct sets or independent units of analysis, but overlapping structures. The incorporation of the New Interdependence Approach therefore crucially adds to the actor-centred institutionalism that the use of interdependence as an opportunity structure is subject to potential actor constellations at the domestic level. Potential domestic actor constellations that an actor expects, in turn, reflect the conflict between domestic and foreign incentive structures. They therefore constrain the decision of an actor to use interdependence as an opportunity structure.

For argumentative clarity, some of the assumptions of the Inter-relational Institutionalism that have been stated in the introduction to this chapter shall be briefly recalled before the actor constellations resulting from institutional asymmetries across jurisdictions are further elaborated. First, power resources in regulatory cooperation are shaped by domestic institutions, notably regulatory capacity, regulatory stringency as well as a large internal market. These assumptions reflect the deduction of power resources according to the New Interdependence Approach. Although this view is not uncontested (Elsig, 2013; Falkner & Müller, 2013; Gehring et al., 2013; Jorgensen et al, 2011; Niemann & Bretherton, 2013; Oberthür & Rabitz, 2013), the Inter-relational Institutionalism adopts the finding of the New Interdependence Approach that centralised regulatory authority is a source of asymmetric power. It thus assumes that actors pursue regulatory cooperation in areas that fall under their regulatory authority. At the same time, the Inter-relational Institutionalism does not concentrate on the role of domestic institutions as rules determining ratification rules. Regulatory cooperation by means of non-treaty and formal cooperative agreements often entails that regulators can enter cooperation without requiring formal domestic ratification.

Second, in regulatory cooperation, radical institutional change is rare. The resilience of institutions reflects the increasing returns they offer to previously enacted actors and thus makes changes to institutions often path-dependent. Even actors seeking to resolve regulatory clashes do not necessarily support overturning foreign institutions (Farrell & Newman, 2014: 26). Rather, actors promote policy coordination within existing rules and structures and seek adaptations within status quo institutions[22,23].

[21] This resonates with Frieden's (1999) argument that the formation of an actor's strategy is dependent on the "possibilities presented by the environment" and the "constraints of circumstance" (Frieden, 1999: 45).
[22] This reflects the conclusion of Thelen (2004) that most forms of policy adaptation take place outside 'critical junctures' and take an incremental form.
[23] This assumption differs from the focus of the New Interdependence Approach literature on institutional change across borders through cross-layering or the use of interdependence as an opportunity structure to change international-level institutions (Büthe & Mattli, 2011; Bach & Newman, 2010).

The strategy choice of actors is therefore constrained by the need for agreement with foreign actors given foreign institutions (Damro, 2006).

Chapter 4.2.1. has deduced that interdependence creates incentives for actors to use rule overlap as an opportunity structure to reduce the uncertainty of intervention against their preferences. Beside the availability of the power resources regulatory capacity, regulatory stringency and market size, the ability of an actor to use overlap as an opportunity structure depends on the actor constellations that result from the institutional conditions. The New Interdependence Approach offers an argument for the ability of domestic actors to use international institutions as an opportunity structure (Büthe & Mattli, 2011): the complementarity argument. While the argument of the New Interdependence Approach refers to a 'vertical mechanism' (chapter 3.1.2.), the essence of this theoretical argument can be transferred to a horizontal mechanism too.

The complementarity argument states that the ability of an actor to use international institutions as an opportunity structure depends on the complementarity between domestic and international incentive structures, where complementarity describes the level of fit between institutions (Büthe & Mattli, 2011). It posits that domestic institutions yield higher benefits if they are combined with a 'fitting' international institution (Büthe & Mattli, 2011: 29). Complementarity between domestic and international institution is a power resource as it determines the constellations between domestic and foreign actors and among different domestic actors. Put differently, the complementarity of domestic and international institutions implies that the incentive structures of the different sets of institutions are not in conflict with each other.

The complementarity argument can easily be adapted to incentive structures and actor constellations between a domestic and a foreign jurisdiction horizontally. The argument then takes the assumption of actor-centred institutionalism, i.e. that an actor's ability to pursue a preference depends on the constellation of actors, as the point of departure. Under interdependence, however, actor constellations are not defined purely 'domestically', but transnationally. The incorporation of New Interdependence Approach into actor-centred institutionalism hence proposes that not only domestic institutions, but the relation between domestic and overlapping foreign institutions determines actor constellations. The overlap of jurisdictions potentially creates conflict among the rules and structures of the domestic and the foreign jurisdiction. More specifically, if overlapping jurisdictions give rise to conflicting incentive structures, the foreign institutions set incentives which conflict with the preferences of the 'main' domestic actor that are derived from domestic incentive structures[24]. Thus, if incentive structures

Zdenek and Müller (2016), examining the case of accounting standards, also propose that if domestic institutions are 'weak' relative to foreign institutions, actors with the necessary capabilities can seek to strengthen domestic institutions by changing domestic institutions in line with foreign institutions. The international level may constitute a 'global exit mechanism' from a 'joint-decision trap' at the domestic level reflecting divergent and incompatible preferences of member states. The Commission thus leverages 'international' institutions by creating policy options that were not available at the domestic level and creating previously unavailable side-payments.

[24] This argument reflects the assumption of actor-centred institutionalism that institutions constitute and shape preferences.

conflict, also the preferences of actors constituted by these incentive structures must conflict. Neglecting or ignoring the conflict in incentive structures by assuming the equality of incentive structures must violate the preferences of the 'main' domestic actor.

At the same time, if an overlap of jurisdictions and institutions leads to conflicting incentive structures, the main domestic actor would either need to change domestic or foreign institutions to resolve the conflict. This institutional change may, however, be assumed as unlikely (see assumption (6) in the introduction to chapter 4). If the domestic main actor nonetheless sought to use rule overlap as an opportunity structure to reduce uncertainty, other domestic actors would mobilise and seek to intervene. If domestic and foreign incentive structures then conflict, the potential actor constellation is conflictual. The intervention of other domestic actors would increase uncertainty and violate the material interest of the actor. Conflicting incentive structures created by conflicting domestic and foreign institutions thus give rise to a conflictual actor constellation. The latter then constrains the ability of the main actor to use interdependence as an opportunity structure.

From this reasoning, it follows that interdependence is only an opportunity structure for actors to pursue their preferences beyond their domestic institutional embeddedness if overlapping jurisdictions do not create conflicting incentive structures. The latter would give rise to a conflictual actor constellation against the main actor at the domestic level. Put differently, actors are only able to pursue their preferences under overlapping jurisdictions if these overlapping jurisdictions do not create conflicting incentive structures. Note that this condition strongly differs from the condition formulated by Scharpf (1997) that (only) institutions in which actors are 'embedded' shape the actor constellations under which a (capable) actor pursues its preferences.

If, in turn, incentive structures of domestic and foreign institutions do not conflict, the actor constellation is non-conflictual. The ability of the main actor to use interdependence as an opportunity structure at the domestic level is thus constrained by the conflict or non-conflict between domestic and foreign incentive structures. This constraint also relates to the risk perceived by an actor that other domestic actors may intervene and impede its autonomy as they seek to avert a negative influence of conflicting foreign institutions. Büthe and Mattli (2011) argue that the vertical absence of conflict in incentive structures gives rise to institutional complementarities. This argument can be adapted to the use of interdependence horizontally. The absence of a conflict in horizontal incentive structures shall be called 'compatibility', adopting terminology used earlier by Nicolaidis (2000) and Pollack (2003). Two sets of institutions are 'compatible' with each other if they do not have underlying conflicting incentive structures. From the latter it follows that compatibilities determine the access and ability of actors to use opportunity structures resulting from overlapping jurisdictions. More specifically, if two sets of overlapping institutions are compatible, actors can use them as an opportunity structure to pursue their preferences beyond the set of institutions in which they are embedded domestically.

Compatible institutions present an opportunity structure because they allow actors who prefer to cooperate with other actors building alliances in support of cooperation across borders. Theoretically, actors with a preference to cooperate will want to choose a strategy that they can pursue without conflictual actor constellations. Combining the actor-centred institutionalism with the New Interdependence Approach now derives the conclusion that the ability of actors to pursue their preferences depends on the constellations of actors in the domestic and the overlapping foreign jurisdiction. If incentive structures conflict that shape the behaviour of two actors in interaction, an actor seeking cooperation with an actor from the foreign jurisdiction will face the threat of intervention and will be unable to build an alliance. If incentive structures do not conflict, though, the actor interested in cooperation will not face opposition and will be able to form an alliance that reflects the preferences of actors in both the domestic and foreign jurisdiction.

Lastly, this reasoning now also allows formulating a causal mechanism to describe the use of interdependence as an opportunity structure by the domestic 'main' actor. To address domestic opposition by actors against institutional change or cooperation, actors who seek to use interdependence as an opportunity structure form argumentative coalitions. These coalitions consist of actors with similar preferences and access to opportunity structures across jurisdictions. They are initiated by the actor with power resources, high access to interdependence opportunity structures and low collective action problems. The actor who initiates coalition-building uses these coalitions to enhance the legitimacy of its demands and build up domestic argumentative pressure.

To conclude, this section has deduced the analytical dimensions of the Inter-relational Institutionalism based on two building blocks of actor-centred institutionalism: actor characteristics and actor constellations. Related to actor characteristics, it has shown that the conception of actor behaviour as intentionally rational allows incorporating sociological-constructivist understandings of behaviour into rational-choice preference models. It has specified that under interdependence, actors develop a preference to use rule overlap as an opportunity structure to reduce uncertainty and avoid negative intervention by other actors. Moreover, it has argued that intentionally rational behaviour may vary among different sub-actors within collective actors, based on their structural embeddedness in different contexts and their different identities.

With regard to actor constellations, this section has deduced that institutional compatibilities between the domestic and foreign jurisdictions constrain the ability of actors to use interdependence as an opportunity structure. The conflict between the incentive structures created by domestic and foreign institutions constrain the ability of the main domestic actor to use interdependence as an opportunity structure at the domestic level as it risks an intervention by other domestic actors to avert the influence of conflicting foreign institutions. This section has therefore deduced that an actor only uses interdependence as an opportunity structure if incentive structures between the domestic and foreign jurisdiction are non-conflicting.

Moreover, it has deduced the causal mechanism that describes the use of interdependence as an opportunity structure by the domestic 'main' actor. An actor who comes to prefer using interdependence as an opportunity structure mobilises other actors with similar preferences to form argumentative coalitions to enhance the legitimacy of its demands and build up domestic argumentative pressure. The next section will apply the abstract theoretical framework to bilateral regulatory cooperation.

4.3. Inter-relational Institutionalism and bilateral regulatory cooperation

This section now applies the Inter-relational Institutionalism deduced in section 4.2. to bilateral regulatory cooperation and specifies the hypotheses that shall be tested in the empirical part of this book. In doing so, it specifies regulators as the main actors in bilateral regulatory cooperation. This specification reflects the conclusion of the New Interdependence Approach that "sub-state actors" including regulators as well as transnationally organised societal actors are the main players shaping global governance as well as cross-national patterns of institutional change (Farrell & Newman, 2014: 24). Likewise, it reflects the insight of more recent liberal institutionalist literature that with the transformation of the state and the emergence of the regulatory state, regulators obtain a major role in international governance (Raustiala, 2002; Majone, 1996).

This section first begins with a specification of regulator preferences as the analytical basis for the deduction of regulator strategies. It connects the preferences of regulators to regulatory authority structures and regulatory principles which are shaped by different sets of institutions (chapter 4.3.1.). It then deduces the independent variables of the analytical framework of this book, in line with the building blocks 'actor characteristics' and 'actor constellations' of the Inter-relational Institutionalism. Second, it deduces bureaucratic pressure from the 'actor characteristics' building block as the first independent variable constraining regulators' choice of a regulatory cooperation strategy (chapter 4.3.2.). Third, it deduces the compatibility of domestic and foreign regulatory authority structures and the compatibility of domestic and foreign regulatory principles as the second and third independent variables from the 'actor constellations' building block. Fourth, it lays down the causal mechanism that links regulator preferences to the pursuit of a specific regulatory cooperation strategy.

4.3.1. Bureaucratic pressure

This sub-section introduces the first independent variable of this book, based on the 'actor characteristics' building block of the Inter-relational Institutionalism. Chapter 4.2.1. has noted that most actors studied by the New Interdependence Approach and actor-centred institutionalism study are

organisations composed of different sub-actors, not individuals. This statement also applies to regulators, which are the subject of analysis in this book. Although neither the 'New Interdependence Approach nor actor-centred institutionalism specifically address decision-making within organisations, chapter 4.2.1. has explained why the principal-agent approach may be used to study decision-making within composite actors. In line with the argument proposed in chapter 4.2.1., this sub-section therefore uses a variant of the principal-agent approach to deduce 'bureaucratic pressure' as the first independent variable that determines the choice of a bilateral regulatory cooperation strategy.

In order to deduce the intra-organisational patterns that shape the strategy formation of regulators, this sub-section in a first step specifies the actor-specific preferences of regulators based on insights from previous literature. In line with the approach of this book to follow the integrated rational-choice-constructivist approach initiated by previous authors, it takes into consideration both the material interest of regulators and a deduction of their preferences from the institutional context in which they are embedded. Reflecting institutionalist literature, it identifies the institutions which shape and constrain the preferences of regulators. For this purpose, it distinguishes the influence of 'regulatory authority structures' and 'regulatory principles' on the preferences of regulators. It shows how the introduction of sociological-constructivist elements in accordance with the actor-centred institutionalism and the New Interdependence Approach helps refine regulator preferences according to a rational-choice, materialist understanding.

In a second step, it deduces the 'policy preferences' of domestic central-level regulators on bilateral regulatory cooperation. Policy preferences with regard to regulatory cooperation are differentiated into a support for cooperation, called 'regulatory cooperation', and a rejection of cooperation, called 'regulatory competition'.

In a third step, it introduces and distinguishes the policy preferences of different sub-actors within a regulatory organisation and entity. To this purpose, this sub-section follows previous literature in distinguishing different sub-actors within a regulator, i.e. technical regulatory officials, politically appointed regulatory leaders and non-technical bureaucratic actors. Based on their different sub-actor-specific preferences on uncertainty, it deduces different policy preferences of these sub-actors on bilateral regulatory cooperation. From the differentiation of the policy preferences of the different sub-actors within a regulatory entity it deduces the relevance of bureaucratic pressure and its influence on the formation of a bilateral regulatory cooperation strategy.

Actor-specific preferences

From a rational-choice perspective, authors argue that the fixed, underlying material interest of regulators is power (Wilson, 1989; Peters, 1995). To protect and possibly enhance their power, regulators seek to protect their autonomy (Wilson, 1989; Peters, 1995; see also Thatcher, 2011; Groenleer, 2014; Bach, de Francesco, Maggetti & Ruffing, 2016). Autonomy ensures that no other actors can erode the power of the regulator. Intervention of other actors, e.g. political 'principals' such as legislators or societal actors, curtails the autonomy of actors. The space in which regulators can act autonomously, i.e. the "relatively undisputed jurisdiction over specific tasks and ways of doing them", is called their 'turf' (Wilson, 1989: 183). To protect or enhance their autonomy, it can be deduced that regulators therefore prefer avoiding intervention by other actors. 'Turf' and autonomy protection can thus be deduced as the preference of a regulator (Heims, 2016: 3; Dunleavy, 1991).

From a sociological perspective, the normative and cognitive orientations of a regulator are derived from its identity and the beliefs they hold. The identity of a regulator is shaped by its mission, also called its 'mandate'. Ideas, shared economic and non-economic beliefs and cognitive frameworks guide the choice among alternative policy choices (Blyth, 2002: 11). A regulator prefers to behave in a way which does not conflict with the cognitive orientations adopted through ideas as well as its mission. Prevailing ideas and the identity of a regulator thus influence what it constitutes 'legitimate' behaviour. Obtaining legitimacy is thus also a preference of a regulator.

As has been argued in chapter 4.2.1., these sociological elements do not represent an alternative specification of individual preferences, but can be incorporated into the rational-choice institutionalist specification[25]. Institutionalist accounts incorporating sociological elements into a rational-choice framework emphasise that the actor-specific preference of an actor, i.e. its most preferred outcome among alternative choices, is shaped by evaluations which choice reflects rational behaviour. These evaluations are shaped by the institutions in which an actor is embedded. domestic institutions are thus constitutive to the actor-specific preferences of regulators (Keohane, 2009; Katzenstein, 2009; Farrell & Finnemore, 2009). Incorporating these sociological elements into a rational-choice logic, it follows that regulators use institutionalised cognitive frameworks to derive and approximate rational behaviour. Accordingly, the pursuit of legitimacy and action in accordance with their mandate constitute rational behaviour for an actor. If other actors have concerns about the legitimacy of the choices pursued by the actor in question, they may choose to intervene and restrict the autonomy of that actor. Autonomy restrictions cannot only be one-time measures, but can also be made permanent. Regulators often have an understanding they know best how a specific task should be carried out (Heims, 2016). As they defend their mandate in their jurisdiction, they ensure political support (Bach et al., 2016: 15). Different

[25] For a detailed discussion why and how sociological-constructivist elements can be incorporated into a rational-choice framework see chapter 4.2.1.

regulators, however, have different mandates that shape their identity, implying that e.g. an environmental regulator considers different policy choices as 'legitimate' than a trade regulator. This point will be reconsidered in the discussion of the formation of collective preferences below. Here it can be maintained that regulators prefer to pursue 'legitimate' policies to protect their autonomy and turf.

This raises the question which institutions shape and constitute the preferences of regulators. To deduce an answer, recall the definition of 'institutions' by Hall and Taylor (1996) as "the formal and informal rules, norms, precedents, and organizational factors that structure political behaviour" (Hall & Taylor, 1996: 5). This definition has two elements: organisational factors on the one and norms and precedents on the other hand. Existing institutionalist accounts have used this definition to derive the content of policy preferences from policy legacies and formal political institutions (Lieberman, 2002).

To deduce the institutions that shape and constitute the preferences of a regulator, it is necessary to adapt the distinction between policy legacies and formal institutions to regulatory policy-making. Essentially, this distinction can be translated into a differentiation between 'regulatory principles' and 'regulatory authority structures'. 'Regulatory principles' reflect what previous accounts have referred to as 'policy legacies' (Lieberman, 2002) or 'regulatory approaches' (Vogel, 2003). These comprise the encoded norms which actors are required to follow when they adopt decisions. Regulatory principles reflect prior social and economic ideas, but are institutions as they are formally encoded by legislators in a jurisdiction's rules and regulations or informally encoded in regulatory practices across an extended period of time. Besides, encoded norms create actors which ensure their implementation and further their application. Regulatory principles shape the preferences of regulators because they guide their understanding which decisions constitute legitimate behaviour. Regulators therefore seek to maintain and protect regulatory principles to pursue legitimate policies and avoid intervention and opposition to their decision-making by other actors including legislators or societal actors. Examples of regulatory principles in the EU are the precautionary principle or the polluter-pays principle.

Regulatory principles and policy legacies are shaped by policy paradigms, but should not be confused with them. 'Policy paradigms' are "a framework of ideas and standards that specifies not only the goals of policy and kind of instruments that can be used to attain them, but also the very nature of the problems they are meant to be addressing" (Hall, 1993: 279). They legitimise existing institutions or policies or challenge them and guide the evaluation of policy legacies. Policy legacies, in turn, are formal rules guiding the interaction of actors in response to a policy problem. They reflect policy paradigms, i.e. the ideational frameworks, which have shaped the adoption of policies in the past, but in addition enact specific actors to support them. Changes to policy paradigms follow an ideational logic, result from learning processes or the emergence of cognitive conflicts particularly in periods of uncertainty. Changes to policy legacies require a change in rules and norms in accordance with formal decision-making rules.

'Regulatory authority structures' reflect formal political institutions. The latter describe the rules and structures determining the role and participation of actors in adopting and implementing a decision (Scharpf, 1997). They establish voting and veto rights to certain actors and determine which actors can participate to which extent in decision-making. Regulatory authority structures thus describe the allocation of competences to and the structures determining the aggregation of interests in a jurisdiction. The allocation of competences thereby reflects the delegation of regulatory functions studied by principal-agent literature (Zimmermann & Dür, 2007; Damro, 2007; Pollack, 2005).

Two dimensions of the allocation of competences can be differentiated: the vertical and horizontal allocation of competences. The vertical dimension refers to allocation of competences between the federal and the sub-federal level[26]. Not all competences are allocated at the federal level because the central level may lack the power, resources and the capacity to adopt or implement decisions. The horizontal dimension, in turn, refers to the allocation of competences between different state and private actors[27].

Regulatory principles and regulatory authority structures apply to both regulatory policies and implementation procedures (for the distinction between regulatory policies and implementation procedures see chapter 3.1.3). For analytical purposes, the regulatory principles and regulatory authority structures shaping regulatory policies are arguably more important, though. First, implementation procedures are designed in accordance with regulatory policies. Therefore, implementation procedures commonly follow similar regulatory principles as regulatory policies (at least they do not follow regulatory principles that substantially conflict with overarching regulatory policies). Second, control over implementation procedures is less important for the material interest of regulators to protect their turf and autonomy than control over regulatory policies. This reflects the argument made above that implementation procedures are designed in accordance with regulatory policies. Moreover, regulators frequently delegate the conduct of implementation procedures to lower-level authorities which helps reinforce the argument that implementation procedures matter less for the definition of the material interest of a regulator than regulatory policies (see the empirical chapters of this book for examples of this delegation). Third, implementation procedures are likely less intensively monitored by citizens and societal actors and thus less relevant for the preference of regulators to safeguard their legitimacy than regulatory policies.

This is not to argue that regulatory authority structures and regulatory principles shaping implementation procedures are irrelevant. Due to the lower salience of implementation procedures relative to regulatory policies, implementation procedure principles are usually established and institutionalised under the

[26] This is tantamount to the distinction of EU governance mechanisms made by Lavenex (2014), distinguishing if decisions are made by the EU as a unitary actor or whether EU-level and national administrative representatives act cooperatively in network forms of governance.
[27] The division of competences between state and private actors and reasons for the emergence of private regulation are discussed by Büthe and Mattli (2011).

influence of other societal actors than regulatory policies[28]. Regulatory principles underlying implementation procedures can therefore differ from the regulatory principles underlying regulatory policies. Moreover, implementation procedures are relevant to the power and autonomy of regulators if changes in the responsibility for implementation threaten the effective conduct of implementation procedures. To reduce analytical complexity, however, implementation procedures shall be considered less relevant for the autonomy and legitimacy preferences of regulators than regulatory policies.

To briefly conclude, the actor-specific preference of regulators is specified by this book as the protection and enhancement of their turf or autonomy and the protection and enhancement of their legitimacy. The 'content' of regulators' turf and legitimacy is shaped and constituted by regulatory institutions, which can be divided into regulatory authority structures, i.e. formal institutions, and regulatory principles, i.e. institutionalised norms and policy legacies. Regulatory authority structures and regulatory principles shape regulator preferences with regard to both regulatory policies and implementation procedures although for analytical simplicity their influence is assumed to be greater regarding regulatory policies.

Policy preferences

The next paragraphs specify the policy preferences of a domestic central-level regulator with regard to (bilateral) regulatory cooperation. Policy preferences with regard to regulatory cooperation can be conceptualised as the support for cooperation, which shall be called 'regulatory cooperation'[29], and the rejection of cooperation, which shall be referred to as 'regulatory competition'[30]. Based on the specification above, the policy preference of a regulator on regulatory cooperation can be deduced from the anticipated effects of cooperation on its turf and legitimacy and thus on its autonomy. Insights from previous literature imply that regulators should see cooperation with other regulators as a potential impediment to their turf (Bach et al., 2016: 10; Heims, 2014; Wilson, 1989). Regulatory cooperation might lead to "turf battles" (Wilson, 1989: 188). As a domestic regulator cooperates with a foreign regulator, the latter may seek to expand its power at the expense of the power of the domestic regulator. Moreover, if the domestic regulator allows cooperation through coordination with a foreign regulator, rival domestic regulators from sub-central levels might also seek to enhance their power at the expense

[28] This reasoning builds on the conclusion of e.g. Klüver (2012) that NGOs are likely to exert a stronger influence on decision-making than business actors if issue salience is high.
[29] The policy preference in support of 'regulatory cooperation' entails the choice of a strategy among the potential strategies delineated in chapter 3.3.2.
[30] For an explanation why the preference for a rejection of cooperation is called 'regulatory competition' see the delineation of strategies in chapter 3.2.

of the domestic regulator. As a result, regulators should not prefer regulatory cooperation as it infringes upon their autonomy and reduces their turf[31].

Likewise, if a regulator needs to coordinate and cooperate with a foreign regulator, its ability to pursue 'legitimate' policies may be impeded. Cooperation with a foreign regulator entails 'coordination costs' and distracts resources from the pursuit of its original mandate. Based on his empirical work, Pollack (2005: 911-912) introduces the argument that regulators see cooperation with foreign regulators as a distraction from their core regulatory mandate. Regulators have limited resources and often already suffer from overload in the absence of regulatory cooperation. As cooperation entails coordination costs, they prefer to not engage in cooperation to prevent an increase in their burden. Taking up this argument, it follows that a regulator should not prefer regulatory cooperation because it leads to an increase in its burden and possibly negatively affects its legitimacy. Therefore, it can be deduced that the domestic central-level regulator prefers 'regulatory competition'.

At the same time, authors have also proposed and discussed the flip-side of the argument above. This states that regulatory cooperation enhances the autonomy of regulators (Peters, 1998; Heims, 2016: 4). Regulatory cooperation strengthens the role of domestic regulators in domestic policy-making and implementation procedures (Bach et al., 2016). As they face new 'actor constellations', regulators such as Commission officials enhance their autonomy from actors with potentially conflicting interests and preferences (Ruffing, 2015). These can be both societal actors (Maggetti, 2012) and domestic political actors (Maggetti, 2014; Bach & Ruffing, 2013; Egeberg & Trondal, 2009). From this perspective, regulatory cooperation supports and reinforces the power of the domestic central-level regulator. Moreover, as officials of the domestic regulator share resources with foreign regulator officials, they can draw on their experiences and enhance the 'quality' of their decision, thus enhancing the legitimacy of their decisions. Following this argument, the domestic regulator interested in power prefers 'regulatory cooperation' because it enhances its autonomy and legitimacy.

In sum, actors' policy preferences reflect their resource constraints. In assessing potential benefits and costs of a policy choice, regulators weigh the benefits of this choice against its costs. Costs arise as regulators, like all actors, have limited resources, i.e. time, organisational and administrative resources. Devoting resources to regulatory cooperation may require regulators to reduce resource input to domestic regulatory activities. Benefits to autonomy and legitimacy arising from regulatory cooperation thus contrast possible costs in terms of autonomy and legitimacy resulting from the lower availability of resources for domestic regulatory activities. The interview evidence cited by Pollack (2005: 912) and Shaffer (2003: 325) shows that material constraints, the perceived burden for regulators arising from

[31] A largely shared view within the existing literature holds that regulators and government officials are reluctant to work with others because they seek to protect their autonomy and bureaucratic practices (Bardach, 1996, 1998; Wilson, 1989). The 'turf protection' argument has been employed as a crucial factor explaining the preferences of government and government agency officials on coordination with other bureaucratic actors (Peters, 1998; for a literature review see McGuire & Agranoff, 2011).

regulatory cooperation and regulatory overload make regulators reluctant to engage in regulatory cooperation substantiates this point.

Bureaucratic pressure: Policy preferences of different sub-actors

As a next step, the policy preferences of different 'sub-actors' within a collective actor should be examined more closely. A variant of the principal-agent approach (importantly Elsig & Dupont, 2012) explains variation in decision-making of 'agents' within organisations with the relative influence and access of different 'agents' to decision-making[32]. It divides 'agents' into technical regulatory officials, politically appointed regulatory leaders and non-technical bureaucratic actors. The capability of an 'agent' or 'sub-actor' to pursue and realise a preference is argued to depend on the degree of access to decision-making (Elsig & Dupont, 2012). Pollack (2005) states that technical regulatory officials usually have discretion in shaping the strategy of a regulator on regulatory cooperation[33]. This discretion changes, however, if regulatory leaders and non-technical bureaucratic actors seek access to decision-making and thus constrain the discretion of technical regulatory officials. In chapter 4.2.1., this book has argued that the preferences of different sub-actors are shaped by their structural embeddedness in specific contexts and their identities. Their degree of uncertainty and their evaluation of the relationship between ends and means under the status quo shapes the influence of (new) ideas on their behaviour and their conception of rational behaviour. From this reasoning it follows that the assessment of costs and benefits of regulatory cooperation regarding the legitimacy and autonomy of the regulator should vary based on the structural embeddedness of a regulatory sub-actor and its identities.

Likewise, based on these criteria, the policy preferences of different 'agents' or sub-actors on regulatory cooperation can be deduced. Regulatory leaders are likely to have a weaker preference in favour of maintaining the status quo because of their relatively lower structural embeddedness in a regulatory organisation relative to technical regulatory officials. Moreover, due to their identity as political actors, they are likely to be consider new ideas more frequently than technical regulatory officials. As a result, regulatory leaders should be more likely to consider rule overlap as an opportunity structure to enhance the autonomy and legitimacy of a regulator than technical regulatory officials.

Similarly, other non-technical bureaucratic actors are likely to assess the benefits of regulatory cooperation as higher than the costs. On the one hand, they are structurally less embedded in a specific technical regulatory policy-making process than technical regulatory officials. To some extent, this lowers the influence of regulatory principles and regulatory authority structures on their preferences[34]. On the other hand, non-technical bureaucratic actors have a different identity than technical regulatory

[32] This explanation is notwithstanding and thus complementary to most principal-agent explanations (e.g. Conceicao-Heldt, 2014; Dür & Elsig, 2011) that account for variation in decision-making with differences in the discretion of agents relative to oversight and intervention by principals.

[33] Damro (2006) suggests support for this statement in his examination of the Commission's choice of venues for regulatory cooperation on competition policy.

[34] However, even if the influence is marginally smaller, this does not mean that the influence of regulatory institutions of a jurisdiction on their preference is zero.

officials because they have a different mandate. Regulatory cooperation may facilitate the attainment of the objective formulated by the mandate. As a result, non-technical bureaucratic actors are likely to assess the benefits of regulatory cooperation as higher than the costs.

Technical regulatory officials, in turn, are structurally deeply embedded in a regulatory institution. The assessment of the legitimacy of their behaviour strongly depends on meeting the regulatory objectives defined in their mandate. Given their limited administrative resources to reach these regulatory objectives, technical regulatory officials are likely to assess the costs of regulatory cooperation as higher than regulatory leaders and non-technical bureaucratic actors. Consequently, they should be more likely to prefer a maintenance of the status quo, i.e. regulatory competition, than regulatory leaders and non-technical bureaucratic actors.

This reasoning now allows the specification of the first independent variable, 'bureaucratic pressure'. Since technical regulatory officials usually have discretion, bureaucratic pressure is present if regulatory leaders and non-technical bureaucratic actors are involved in decision-making. Likewise, if regulatory leaders and non-technical bureaucratic actors do not seek access to decision-making, bureaucratic pressure is absent. Given the likely different assessment of these sub-actors or 'agents' of the costs and benefits of regulatory cooperation regarding the autonomy and legitimacy of a regulator, bureaucratic pressure should have an influence on the choice of a regulatory cooperation strategy. As regulatory leaders and non-technical actors are likely to have a stronger policy preference in favour of regulatory cooperation, the presence of bureaucratic pressure should constrain technical regulatory officials to choose a cooperation strategy. The absence of bureaucratic pressure, in turn, should allow officials to pursue regulatory competition. Hypothesis 1 can therefore be formulated as follows:

H1a: The presence of bureaucratic pressure leads regulators to choose 'regulatory alignment', 'equivalence', 'alignment of implementation procedures' or 'information exchange'.

H1b: The absence of bureaucratic pressure leads regulators to pursue regulatory competition.

4.3.2. Regulatory compatibilities

This sub-section introduces the second independent variable of this book, based on the 'actor constellations' building block of the Inter-relational Institutionalism, i.e. the 'regulatory compatibilities' between the domestic and the foreign jurisdiction. Following the deduction of preference-constituting 'regulatory institutions' as 'regulatory authority structures' and 'regulatory principles', it divides the independent variable 'regulatory compatibilities' into 'compatible regulatory authority structures' and 'compatible regulatory principles'. Based on the constellations of 'regulatory compatibilities' between the domestic and the foreign jurisdiction on an issue, it deduces four hypotheses that combine variation in regulatory compatibilities to the outcomes on the dependent variable delineated in chapter 3.3.

It is in this sub-section that the Inter-relational Institutionalism differs substantially from the conventional actor-centred institutionalism due to the incorporation of the interdependence assumptions from the New Interdependence Approach. To emphasise this distinction, this sub-section first reiterates the understanding of actor constellations of the Inter-relational Institutionalism. It then presents possible combinations of regulatory authority structures and regulatory principles between the domestic and the foreign jurisdiction. Based on these combinations, it then deduces four hypotheses that connect combinations of regulatory compatibilities to the constraints on the choice of a regulatory cooperation strategy.

Chapter 4.2.2. has argued that the compatibility of domestic and foreign incentive structures shapes the conflictiveness of domestic actor constellations and thus determines the ability of actors to cooperate within their discretionary authority. 'Compatibility' has been defined as the absence of conflicting incentive structures in regulatory institutions. It has argued that cooperation under conflicting incentive structures constituted by domestic and foreign institutions would set incentives which conflict with the preferences of the 'main' domestic actor that are derived from domestic incentive structures. If the domestic main actor sought to engage in cooperation, other domestic actors would mobilise and seek to intervene, increasing uncertainty. Chapter 4.2.2. has concluded that conflictual potential domestic actor constellations due to conflicting incentive structures between the domestic and foreign jurisdiction lead the main domestic actor not to pursue cooperation. Compatibility can be conceived with regard to both regulatory authority structures and regulatory principles. The following paragraphs will discuss possible combinations of regulatory compatibilities.

To keep analytical complexity manageable, regulatory authority structures shall be conceived as compatible and incompatible. As defined above, compatibility denotes the absence of conflicting incentive structures. To derive expectations for the influence of the compatibility of regulatory authority structures on regulators' formation of strategies, actor constellations under different constellations of domestic and foreign authority structures shall be examined. Chapter 4.3.1. has deduced that the preferences of regulators constituted by domestic regulatory authority structures are shaped by the horizontal and vertical distribution of regulatory authority, i.e. the division of regulatory authority between different levels of government and the division between state and private actors. Moreover, the Inter-relational Institutionalism shares the assumption of the New Interdependence Approach (see also Young, 2015a) that regulators at the central level are mostly likely to seek regulatory cooperation with regulators from other jurisdictions on issue areas in which they have regulatory authority themselves[35].

[35] This assumption does not exclude that regulators at the central level may intentionally engage in regulatory cooperation on issue areas on which they do not have regulatory authority yet in order to change domestic institutions. This case is studied by Zdenek and Müller (2016). The authors acknowledge, however, that their argument on the ability to use the 'international' level as an 'exit from the domestic institutions' relies on the shared perception of a crisis of domestic institutions among some societal actors and the legitimacy of a solution to the crisis of domestic institutions provided by an international organisation. While societal actors can be mobilised to advocate the domestic adoption of an international policy solution that subsequently offers them global market access, it is difficult to mobilise societal actors for domestic institutional change entailing the

It also shares the assumption of both 'Open Economy Politics' and the New Interdependence Approach that regulators (as well as societal actors) from the domestic central level mostly engage with regulators (and societal actors) from the foreign central level.

If regulatory authority in the domestic jurisdiction is centralised – it shall be assumed to be so by definition for the purpose of this analytical framework, this leaves two options for the allocation of regulatory authority in the foreign jurisdiction. First, regulatory authority can be allocated to regulators (or government actors) at the central level. Second, regulatory authority may be non-centralised. In the latter case, it may be shared between government actors at central- and sub-central levels. Besides, it may be shared with or entirely allocated to private actors. This is the case if the foreign regulator does not consider an issue sufficiently salient to have it regulated by state actors.

If regulatory authority in the foreign jurisdiction is non-centralised, a foreign regulator with which the domestic regulator interacts is likely to be reluctant to adopt or recognise policies because it faces opposition from regulators at sub-central levels who act as veto players. If the domestic and foreign regulator agreed to cooperate, the foreign regulator would be unable to commit to an implementation of the cooperation by both the central and the sub-central regulators. At the same time, the foreign regulator would be unwilling to mobilise resource unless 'its' institutions are perceived to be in crisis (for this argument see Thelen, 2004). Regulatory cooperation with the foreign regulator in this constellation would thus asymmetrically expand the geographical scope of domestic and foreign regulations. The acceptance of this asymmetry and the acknowledgement of regulatory authority to sub-central foreign regulators by the central domestic regulator would then provide sub-central regulators with an incentive to demand greater authority over the setting of rules themselves. This would give rise to a conflictual domestic actor constellation.

Likewise, if in the foreign jurisdiction regulatory authority is delegated to private actors, the agreement of the domestic regulator to adopt or accept the regulations of the foreign jurisdiction developed by private actors would provide an incentive for domestic private actors, which are societal actors, to demand a regulation by private actors in the domestic jurisdiction as well. The foreign regulator would unlikely change the distribution of authority in its jurisdiction as the concession of authority to private actors indicates that it does not consider the issue as sufficiently salient to merit an allocation of limited regulatory resources. The mobilisation of domestic societal actors would again give rise to a conflictual domestic actor constellation.

The emergence of a conflictual domestic actor constellation would, however, reduce and undermine the 'turf' of the domestic regulator. In this constellation, the domestic regulator cannot enhance its autonomy

adoption of a foreign solution due to the competitive disadvantage this would create for them with regard to foreign competitors (cf. Newman & Farrell, 2014: 27; Büthe & Mattli, 2011). To advocate institutional change, central-level regulators then rely on the perception of institutional change. Both conditions restrict the applicability of the argument of Zdenek and Müller (2016) to bilateral regulatory cooperation.

through regulatory cooperation. From the preference function of the domestic regulator outlined in chapter 4.3.1. it thus follows that in this constellation it cannot use the overlap of jurisdictions as an opportunity structure. A reduction of autonomy opposes the preferences of the domestic regulator, making the status quo preferable to an outcome under regulatory cooperation.

If regulatory authority is allocated at the central level in both the domestic and foreign jurisdiction, in turn, both domestic and foreign regulators share a perception of salience and similar veto players on an issue. This makes their incentive structures comparable. From the definition above it follows that regulatory authority structures are also compatible. Regulatory cooperation does thus not undermine the autonomy of the domestic regulator. Instead, as the domestic regulator cooperates with a foreign regulator with whom it shares an overlapping jurisdiction, the resolution of regulatory conflict reduces the scope for intervention by other actors. If the domestic and the foreign regulator resolve regulatory conflict, they reduce the possibility for other domestic regulators to introduce alternative policies. At the same time, they reduce the possibility for societal actors to engage in arbitrage between domestic and foreign regulations. Moreover, they reduce the possibility for societal actors to lobby regulators in either jurisdiction for a lowering of the regulatory burden in order to increase the competitiveness of domestic firms. It follows from the theoretical argument laid down above that if regulatory authority is allocated at the central level in both the domestic and the foreign jurisdiction, regulators can use regulatory cooperation to enhance their autonomy in line with their preferences.

The distribution of regulatory authority structures can now be combined with the adherence to regulatory principles, reflecting the integration of structure and substance outlined in chapter 4.1.1. To reduce analytical complexity, regulatory principles shall also be operationalised dichotomously as ‘compatible’ and ‘incompatible’. From the definition of compatibility above it follows that regulatory principles are compatible if they do not entail conflicting incentive structures. From the definition of regulatory principles, in turn, it follows that incentive structures are not conflicting if they do not produce cognitive conflict that leads regulators to approximate rational behaviour differently. Incentive structures are conflicting if regulatory principles encoded in past policies establish a guideline for legitimate behaviour which rules out the full compliance with an alternative guideline[36].

This now allows making statements about the choices of regulators that seek to behave rationally. If regulatory principles are incompatible, regulators in the domestic and foreign jurisdictions approximate rational behaviour differently. As a consequence, they have different understandings of legitimate regulatory behaviour. If the domestic regulator adopts or accepts a regulation of the foreign regulator, it creates a cognitive conflict. The alternative acceptance or the deviation from the domestically institutionalised regulatory principles would establish the possibility to regulate an issue or to launch a

[36] To illustrate this point through an example, the principle to follow the precautionary principle in the EU and to take precautionary measures in case available scientific evidence is inconclusive (e.g. Vogel, 2003) conflicts with a principle to only adopt measures if these can be positively supported by scientific evidence.

product for firms which is not allowed under domestic regulatory principle. This would undermine the subjectively defined legitimacy of the behaviour of the domestic regulator. In line with the preferences deduced in 4.3.1., the domestic regulator therefore expects that other actors, government officials or societal actors will intervene as a response to the regulator's choice and thus curtail its autonomy. To avoid this political intervention, the domestic regulator should thus not cooperate with the foreign regulator if regulatory principles on an issue are incompatible.

If regulatory principles are compatible, the domestic and foreign regulator share understandings of legitimacy and approximate rational behaviour in a similar way. If they adopt or recognise mutual decisions, they can therefore confirm to each other that their regulations are legitimate responses to an issue. The confirmation of the legitimacy by a regulator with whom the domestic regulator shares understandings of legitimacy thus enhances the subjectively defined legitimacy of its choices. As the foreign jurisdiction adopts or accepts the regulatory choices of the domestic regulator, it can interpret the geographical expansion of its choices as evidence that their choices represent a legitimate response. At the same time, this contributes to insulate the domestic regulator against demands from other regulators or societal actors and enhances its autonomy. Cooperation under compatible regulatory principles thus enhances the legitimacy as well as the autonomy of the domestic regulator and is in line with her preferences deduced in chapter 4.3.1.

In a next step, the actor constellations for different compatibility constellations of regulatory authority structures and regulatory principles need to be applied to and connected with the regulatory cooperation strategies defined in the typology in chapter 3.3. Four possible constellations are theoretically conceivable.

First, if both regulatory authority structures and regulatory principles between the domestic and the foreign jurisdiction are compatible, regulatory cooperation can enhance the autonomy and the legitimacy of the domestic regulator. The domestic regulator should therefore seek to make regulatory cooperation as deep and comprehensive as possible. This implies that it should seek to cooperate with the foreign regulator on policies at high depth. Due to domestic institutional restrictions, notably the binding adoption of legislation by the legislator, the domestic regulator cannot adopt legislation without the consent of the legislator. However, it can propose to the legislator to harmonise legislations. To avoid political intervention, the domestic regulator will concentrate on regulatory approximation through the formulation and adoption of technical regulations and standards under its discretionary authority. Besides, the domestic regulator can seek to elaborate draft structures for the adoption of future regulation together with the foreign regulator with a view to shape the space for political intervention by the legislator. For this reason, if both regulatory authority structures and regulatory principles are compatible, the domestic regulator should pursue a strategy of 'regulatory alignment':

H2a: If both regulatory authority structures and regulatory principles are compatible between the foreign and domestic jurisdiction, the domestic regulator chooses a strategy of 'regulatory alignment'.

Second, if regulatory authority structures are compatible, but regulatory principles are incompatible, the compatibility of regulatory authority structures suggests that regulatory cooperation can enhance the autonomy of the domestic regulator. As regulatory authority lies with the central-level regulator in both the domestic and the foreign jurisdiction, the domestic regulator can strive to cooperate over policies to enhance its autonomy. However, as the regulatory principles shaping the behaviour of the domestic and the foreign regulator are incompatible, the domestic regulator simultaneously seeks to avoid adopting policies of the foreign regulator to protect its legitimacy at the status quo level. This suggests that the domestic regulator seeks to avoid changes to domestic regulations.

Nonetheless, the domestic regulator can enhance its legitimacy by establishing regulatory certainty and creating new market access opportunities to certain societal actors, notably firms with transnational activities. As regulations shall not be changed through regulatory cooperation, cooperation can only consist in recognising the 'equivalence' of specific regulations. To ensure that this increase in subjectively defined legitimacy towards transnational firms does not come at the expense of other societal actors, the domestic regulator will conduct tests and assessments to show that existing domestic regulatory principles are not undermined as a consequence of regulatory cooperation. This is likely to be possible for only very specific regulations, restricting the depth of regulatory cooperation the domestic regulator seeks to pursue. If regulatory authority structures are compatible, but regulatory principles are incompatible, the domestic regulator should thus pursue a strategy of 'equivalence'.

H2b: If regulatory authority structures are compatible, but regulatory principles are incompatible between the foreign and domestic jurisdiction, the domestic regulator chooses a strategy of 'equivalence'.

Third, if regulatory authority structures are compatible, but regulatory principles are incompatible, the domestic regulator can seek regulatory cooperation to enhance its legitimacy. The incompatibility of regulatory authority structures suggests that the domestic regulator should not seek to cooperate on regulations to protect its autonomy. According to the theoretical considerations above, the domestic regulator is thus restricted to cooperate on implementation procedures to enhance its legitimacy (for a clarification of cooperation on regulations and implementation procedures see chapter 3.1.3). The subjectively defined legitimacy of the domestic regulator increases as the implementation procedures institutionalised domestically are also recognised in the foreign jurisdiction and considered as an adequate method to ascertain the achievement of a regulatory objective. Moreover, the legitimacy of the domestic regulator increases as cooperation on implementation procedures resolves conflicts and divergences on implementation procedures. Cooperation then facilitates trade flows, with benefits accruing in particular to firms with transnational operations. Since regulatory principles underlying regulatory principles are compatible, the domestic regulator can expect that the foreign regulator pursues similar objectives with regard to implementation procedures to define its own legitimacy. This results from the argument made in chapter 4.3.1. that implementation procedures are usually designed in

accordance with the principles underlying regulatory policies. In line with the argument laid down in chapter 4.3.1., the domestic regulator verifies, however, if foreign implementation procedure principles are compatible implementation procedure principles. If implementation procedure principles were to conflict, regulatory cooperation would lead to legitimacy losses and regulatory cooperation would be against the preference of the regulator.

Yet, regulatory cooperation in this constellation still requires that the domestic regulator overcomes incompatible regulatory authority structures. This is more likely for implementation procedures than for regulatory policies. As noted in chapter 3.1.3., implementation procedures are in most jurisdictions subject to networks of administrative authorities due to resource constraints of regulators. Besides, because of their lower salience they are subject to political intervention only in times of a crisis of existing implementation procedures. Even in the case that implementation procedures are allocated to sub-central administrative authorities, cooperation on implementation procedures is thus unlikely to lead to domestic political intervention and a loss of autonomy. The domestic regulator might, however, demand reassurances from the foreign regulator and likewise offer reassurances to the foreign regulator that cooperation on implementation procedures does not lead to a loss of autonomy. As a result, if regulatory authority structures are incompatible, but regulatory principles are compatible, the domestic regulator should pursue a strategy of 'alignment of implementation procedures'.

H2c: If regulatory authority structures are compatible, but regulatory principles are incompatible between the foreign and domestic jurisdiction, the domestic regulator chooses a strategy of 'alignment of implementation procedures'.

Fourth, if both regulatory authority structures and regulatory principles are incompatible, the domestic regulator can neither expect to enhance its autonomy or legitimacy through regulatory cooperation. Regulatory cooperation can only be an opportunity structure for the regulator to save administrative resources while protecting its autonomy and legitimacy. The domestic regulator can only seek to protect its autonomy and legitimacy through regulatory cooperation by avoiding future regulatory uncertainty, conflict or arbitrage. To save administrative resources, it can seek to shift administrative tasks to the foreign regulator and thereby concentrate its resources on making legitimate regulations. It follows from the categorisation proposed in chapter 3.3. that a strategy to save administrative resources is to exchange information and data with the foreign regulator, given that the foreign regulator supplies this information and data in the quality demanded by the domestic regulator. At the same time, 'information exchange' and data exchange also correspond to the policy preference of the domestic regulator to avoid future regulatory uncertainty. As a consequence, if both regulatory authority structures and regulatory principles are incompatible, the domestic regulator should pursue a strategy of 'information exchange'.

H2d: If both regulatory authority structures and regulatory principles are incompatible between the foreign and domestic jurisdiction, the domestic regulator chooses a strategy of 'information exchange'.

To summarise, this sub-section has laid down the possible combinations of variation in the distribution of regulatory authority structures and the incorporation of regulatory principles in the domestic and foreign jurisdictions. Based on the presentation of possible combinations, it has identified the compatibilities between domestic and foreign regulatory authority structures and regulatory principles. In a last step, it has connected the combination of variation in the compatibility of regulatory authority structures and regulatory principles between the domestic and foreign jurisdiction to the bilateral regulatory cooperation strategies delineated in chapter 3.3. This has led to the formulation of four hypotheses that link variation in the independent variables 'regulatory compatibilities' to constraints in the choice among outcomes on the dependent variable 'regulatory cooperation strategy'. Figure 6 summarises these constraints of the domestic regulator on the choice of a bilateral regulatory cooperation strategy:

Regulatory authority structures	**Regulatory principles**	
	Incompatible	**Compatible**
Incompatible	Information exchange	Equivalence
Compatible	Alignment of implementation procedures	Regulatory alignment

Figure 6: Summary of hypotheses 2a-2d

4.3.3. Societal mobilisation

Lastly, this sub-section lays down the causal mechanism that connects variation in the independent variables to outcomes on the dependent variable. In a first step, it proposes how bureaucratic pressure initiates the process of strategy formation. In a second step, it lays down how the regulator mobilises societal actors to ensure that the pursuit of regulatory cooperation is considered as legitimate. In a third step, it borrows from principal-agent literature to illustrate how the regulator gives preferential access to those actors that mobilise in line with maximum constraints on regulatory cooperation given by regulatory compatibilities.

In line with hypothesis 1, strategy formation is initiated by bureaucratic pressure. Bureaucratic pressure arises if either a regulatory leader or a non-technical bureaucratic actor proposes to consider the engagement in regulatory cooperation. Bureaucratic pressure is thus likely to arise after the politically

appointed leadership in a regulatory body or a non-technical bureaucratic organisation changes[37]. Regulatory leaders or non-technical bureaucratic actors task regulatory officials to evaluate opportunities for regulatory cooperation with another jurisdiction.

Recall that to deduce rational behaviour, regulators rely on intersubjective understandings translate their actor preferences into policy preferences (e.g. Woll, 2008). Therefore, they interact with other actors and gather information about their understandings of empirical phenomena. Upon the task by regulatory leaders or leaders of other non-bureaucratic actors, regulatory officials collect information about regulatory institutions in the foreign jurisdiction. In doing so, they coordinate their activities within their regulatory institution and other bureaucratic institutions. Moreover, they launch consultations with societal actors to obtain information about regulatory institutions in the foreign jurisdiction. Besides, they seek to obtain information about regulatory conflicts between the domestic and foreign jurisdiction that societal actors perceive as particularly disadvantageous.

Actors then structure the information and intersubjective understandings of phenomena that they have gathered. Regulatory officials thus compare information gathered through the public consultations with their own information of the regulatory institutions of the foreign jurisdiction. This information is evaluated with regard to their objective to avoid a reduction of their turf and a reduction of their legitimacy. Regulatory officials then discard cooperation that they expect would trigger a negative actor constellation. Instead, they propose a strategy in line with their assessment of the implications of regulatory cooperation for their turf and their legitimacy.

Regulatory officials then coordinate and consult with other domestic bureaucratic actors that can legally participate in the adoption of a regulatory cooperation strategy. Moreover, they mobilise societal actors that have participated in the public consultation in support of their strategy under the internal coordination. The principal-agent literature proposes that actors, i.e. regulatory officials, with a certain degree of autonomy can thereby rely on two main mechanisms: 'managing permeability' and 'buffering' (Hawkins & Jacoby, 2006). Regulatory officials have larger autonomy if the public consultation reveals that societal actors mobilise both in favour and against regulatory cooperation or only in favour of regulatory cooperation. If societal actors mobilise only against regulatory cooperation, the actor constellation becomes negative. This implies regulatory officials expect that the pursuit of regulatory cooperation reduces their legitimacy. Under contested mobilisation or a muted actor constellation, however, regulatory officials in coordination with regulatory leaders and other non-bureaucratic actors can be assumed to follow 'managing permeability' and 'buffering':

[37] The decision of the regulatory leader or a non-technical bureaucratic actor to propose the engagement in regulatory cooperation reflects personal convictions as well as an openness to consider new ideas for the achievement of regulatory objectives. The latter also reflects a lower structural embeddedness of regulatory leaders and non-technical bureaucratic actors in a regulatory organisation (for this argument see chapter 4.2.1.).

Under 'managing permeability', an actor gives preference to some societal actors by "structuring public input and information-gathering in such a way as to favour outsiders with similar preferences" (Hawkins & Jacoby, 2006: 209). Under 'buffering', an actor interacts with societal actors which have similar preferences as itself. This allows them to buffer against criticism in the future and create focal points for other actors. If opposition to the actor's preference arises, it can build on the support of ad-hoc coalitions of societal actors (Elsig & Dupont, 2012: 891)[38].

The mobilisation of societal resources helps regulatory officials and regulatory leaders to raise the domestic salience of regulatory cooperation and create domestic support, notably. among legislators, for regulatory cooperation (for the underlying theoretical argument see Elsig & Dupont, 2012; Posner, 2010). Moreover, if societal actors mobilise in favour of regulatory cooperation that corresponds to the strategy already proposed by regulatory officials during the internal coordination, regulatory officials can feel ensured that the pursuit of regulatory cooperation enhances their legitimacy towards societal actors. For this reason, it can be assumed that under 'managing permeability' and 'buffering', regulatory officials and regulatory leaders give preferential access to societal actors, in particular if these are 'embedded' in the corresponding jurisdiction (see Beyers & Kerremans, 2005).[39]

If societal actors fail or refuse to mobilise in support of the strategy in line with regulatory compatibilities, regulatory officials become reluctant to insist on adopting this strategy for the pursuit of regulatory cooperation. Regulatory officials re-consult internally, with other bureaucratic actors and with societal actors to pursue a strategy that they expect will safeguard their legitimacy. Consequently, they propose a lower dimension or less deep regulatory cooperation strategy for which they can mobilise support by some domestic societal actors.

In a last step, regulatory officials send the proposed strategy to the regulatory leaders. The latter formally adopt the proposed regulatory cooperation strategy. A third hypothesis can thus be formulated:

H3: If regulatory leaders and regulatory officials succeed to mobilise societal actors in support of the strategy that is in line with regulatory compatibilities, regulators will pursue a strategy in line with regulatory compatibilities.

[38] Note that this 'bureaucratic' explanation of changes in regulator behaviour differs from the argument of functionalist literature that an external 'penalty default mechanism' is necessary to change the status quo and push officials towards cooperation (Zeitlin, 2015).

[39] Besides, regulatory officials mobilise societal actors to lobby the foreign regulator in favour of agreeing to engage in regulatory cooperation. Regulatory officials should thus mobilise societal actors to form alliances, coalitions and networks with societal actors in the foreign jurisdiction. The deliberate mobilisation of societal actors thus helps to build up argumentative pressure to shape the strategy of the foreign regulator.

The specification of the causal mechanism under hypothesis 3 also allows clarifying the relationship between the independent variables and the dependent variable 'choice of a regulatory cooperation strategy'. The presence of bureaucratic pressure (IV1) initiates the process of strategy formation. In the absence of bureaucratic pressure, regulatory officials prefer to maintain regulatory competition. Once bureaucratic pressure has initiated the process of strategy formation, regulatory compatibilities (IV2) constrain the extent, i.e. the dimension and depth, to which regulatory officials consider engaging in regulatory cooperation. They thus also determine if regulatory officials take into consideration suggestions and demands by other actors. The distribution of regulatory compatibilities determines if regulatory officials pursue 'information exchange', an 'alignment of implementation procedures', 'equivalence' or 'regulatory alignment'. The mobilisation of societal actors, notably through 'buffering' and 'managing permeability' by regulatory officials, influences if suggestions and demands are included into a regulatory cooperation strategy and thus pursued or if they are discarded (IV3). Besides, the mobilisation of societal actors guides the search of regulatory officials for technical information on issues on which regulatory cooperation could be pursued. As 'information exchange' does not constrain the autonomy of regulators both with regard to regulatory policies and implementation procedures, supportive mobilisation of societal actors is not expected to be necessary for the choice and pursuit of 'information exchange'. Supportive mobilisation is, however, expected to be necessary for the choice of the other three strategies, given the information requirements and legitimacy preferences of regulatory officials.

Figure 7 illustrates the relationship between the independent variables and the dependent variable graphically:

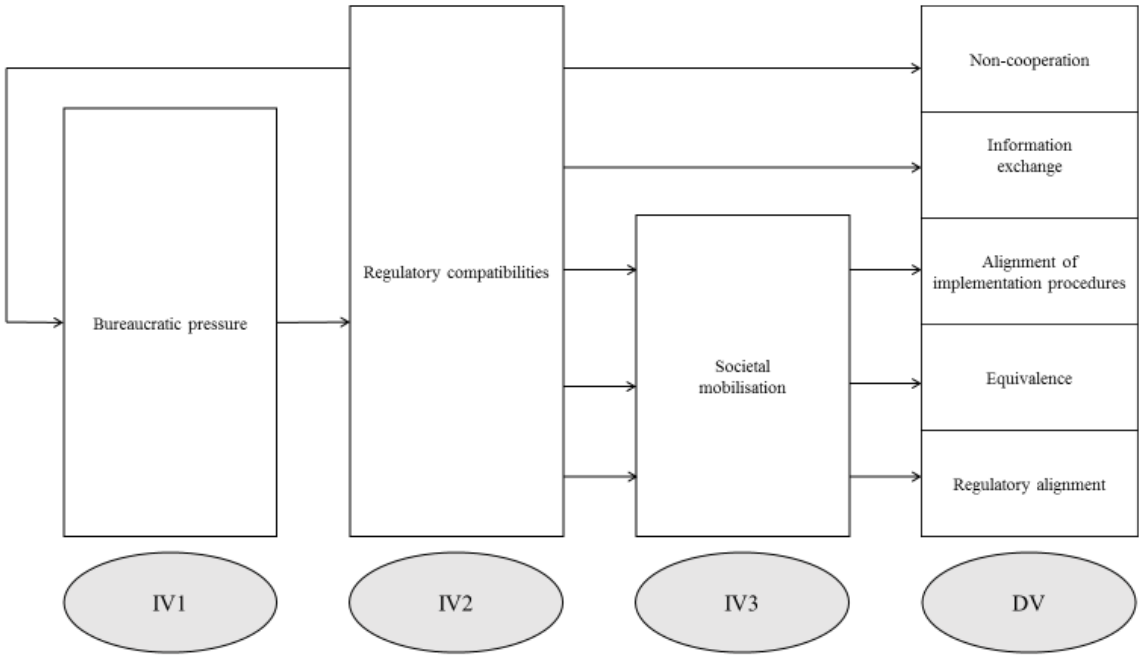


Figure 7: Relationship between the variables

To sum up, this sub-section has deduced the independent variables which explain the presence of variation on the dependent variable of this study, 'bilateral regulatory cooperation strategies'. It has deduced that the independent variable 'bureaucratic pressure' constrains the engagement in regulatory cooperation rather than the maintenance of regulatory competition. The independent variable 'regulatory compatibilities' constrains the 'extent' of regulatory cooperation, i.e. the depth and dimension of bilateral regulatory cooperation at which cooperation is envisaged. The independent variable 'societal mobilisation' constrains the adoption of the strategy in line with regulatory compatibilities. In the next step, the process shaping the choice of a regulatory cooperation strategy shall be operationalised to strategy formation in the European Commission in order to prepare the empirical analysis in chapter 6.

4.4. Operationalising the Inter-relational Institutionalism

The Inter-relational Institutionalism proposes a theoretical explanation for the formation and choice of a bilateral regulatory cooperation strategy. For issues subject to EU-level regulation, the main regulator in the EU is the Commission. At the same time, an increasing number of authors approximate the Commission as the 'executive' or 'government' of the EU and observes a "normalisation of the Commission as the EU's executive" (Wille, 2013; see also Shore, 2011, Egeberg, 2006; Franchino, 2000)[40]. This section operationalises the Inter-relational Institutionalism with regard to the authority of the Commission in bilateral regulatory cooperation and its processes of strategy formation.

A first sub-section (chapter 4.4.1.) describes the Commission's authority in EU regulatory policy-making relative to other EU institutions. A second sub-section (chapter 4.4.2.) looks at how the discretion of technical Commission DGs varies along the different regulatory cooperation strategies delineated in chapter 3.4. Both help understand to which extent the Commission can engage in bilateral regulatory cooperation without the support of other EU institutions. A third sub-section (chapter 4.4.3.) applies the independent variable 'bureaucratic pressure' to the Commission. It identifies the different regulatory sub-actors described in chapters 4.2.1., 4.3.2. and 4.3.4 and shows how Commissioners and other DGs can affect the behaviour of technical officials. A fourth sub-section (chapter 4.4.4.) applies the causal mechanism described in chapter 4.3.3 to decision-making within the Commission and lays down the process of strategy formation. This section will, however, not operationalise the second independent variable, 'regulatory compatibilities'. This will be done at the start of each empirical chapter as regulatory authority structure and the adherence to regulatory principles in the EU and a foreign jurisdiction differ across sectoral regimes and policy fields.

4.4.1. Regulatory authority of the European Commission

This first sub-section begins with a delineation of the Commission's regulatory authority in EU regulatory policy-making to understand to what extent it has authority to accept or recognise regulations or implementation procedures of third countries during regulatory cooperation. In line with the distinction between legislation and regulation in chapter 3.1.3., the adoption of legislation, which in internal market policies mainly follows the Ordinary Legislative Procedure, must be distinguished from the adoption of regulations and rules through implementing and delegated acts. These processes entail different scopes of authority for the Commission. Consequently, they also impose different constraints

[40] Most authors, however, still underline the sui generis character of the Commission and the difficulty to compare it national executives of member states as well as the governments of third countries (e.g. Christiansen, 1997; Follesdal & Hix, 2006).

on the ability of the Commission to change the content or objectives of these policies through regulatory cooperation.

In the Ordinary Legislative Procedure, the Commission enjoys the exclusive right to initiate legislation and to submit a legislative proposal[41]. Yet, the right to take legislative decisions lies with the EP and the Council as co-legislators. The Commission has no authority to vote on the proposal. The Commission proposal first goes to the EP, which may approve, reject or amend it. The (amended) proposal then is passed on to the Council. If the Council agrees with the EP's position, the bill is adopted. In practice, the Commission can steer the discussions between the EP and the Council through informal tripartite meetings between the Commission, the Council and the EP called 'trilogues'. Moreover, it can change the voting rules in the Council if it disagrees with significant amendments introduced into the legislative proposal. However, it cannot vote on the legislative proposal or seek to ensure its adoption through other means than dialogue or persuasion. Similarly, it cannot amend existing legislation without a new legislative proposal which is again subject to approval by the EP and the Council.

In regulatory policy-making through delegated and implementing acts, the authority of the Commission is substantially greater. Through delegated acts, the Commission has authority to supplement or amend primary legislation in its non-essential parts. More precisely, the Commission has authority to adopt delegated acts if a Regulation or a Directive delegates to the Commission the power to adopt non-legislative "acts of general application to supplement or amend non-essential elements of the legislative act". This delegation of authority is frequent in particular in internal market policy that is the subject of regulatory cooperation (Parker & Alemanno, 2014: 10). 'Non-essential elements' are provisions that do not influence the fundamental principles a legislative act, e.g. the choice of a mandatory labelling scheme. The decision which amendments are 'essential' or 'non-essential' are taken by the legislators in the adoption of the underlying legislative act. Since the Lisbon Treaty, the Commission has authority to prepare and adopt a draft delegated act without being obliged to consult committees of national representatives[42]. The Commission presents the adopted delegated act to the EP and the Council for review. If the EP and the Council oppose the delegated act, they must state reasons for their opposition (e.g. ultra vires, breach of a procedural requirement, etc.). Opposition of the EP and the Council may delay the entry into force of the act, but the Commission can still adopt the act even if both institutions oppose it[43].

[41] The following summary builds on Parker and Alemanno (2014).
[42] Before the entry into force of the Lisbon Treaty, the Commission was also legally obliged to consult with committees of member state representatives in the preparation and adoption of 'delegated acts' under the so-called 'comitology procedures'.
[43] In such a constellation, member states may, however, choose not to implement a delegated act adopted by the Commission in opposition to the Council.

Through 'implementing acts', the Commission can implement primary legislation where uniform conditions of implementation are required[44]. The adoption of implementing acts requires that the Commission consults committees of member states representatives. The committee that is chaired by the Commission delivers its opinion by a qualified majority. If the committee is unable to find a qualified majority (for or against), it issues a 'no opinion' and the Commission is free to adopt or withdraw the implementing act in question.

Technical standards in support of EU-level legislation, so-called 'harmonised standards', are developed or provided by the European Standards Organisations (ESOs) CEN (European Committee for Standardisation) and CENELEC (European Committee for Electrotechnical Standards) and ETSI (European Telecommunication Standards Institute). The Commission has authority to designate them as the only providers of European standards and maintains a contractual relationship with them. It elaborates and publishes annual standardisation requests to the ESOs (Egan & Pelkmans, 2015: 8). The Commission has, however, no influence on the voting on the adoption of standards. This is reserved to the members of the ESOs, which are the standardisation organisations of each member state.

In sum, it follows that the Commission has legal authority to engage in regulatory cooperation without the consent of other EU institutions where it is limited to the adoption of delegated acts. Moreover, it can task the ESOs to change European 'harmonised standards' through the inclusion of such requests in the annual standardisation work programmes. Yet, it has no authority to pursue strategies which conflict with existing EU legislation or aim at changing EU legislation without requiring the approval of the Council and the EP through the Ordinary Legislative Procedure. As this makes the 'success' of a regulatory cooperation strategy uncertain, the Commission should not be expected to pursue regulatory cooperation that conflicts with or requires changes in the essential parts of EU legislation[45].

Regulatory authority of the European Commission in regulatory cooperation

This section builds on the insights of the previous sub-section to elaborates how the authority of the Commission in EU regulatory policy-making affects its discretion in the formation of a bilateral regulatory cooperation strategy.

Previous empirical studies confirm that regulatory preferences of the Commission correspond to the regulator preferences theoretically deduced in chapter 4.3.1. On the one hand, they argue that Commission seeks to protect its material interest, i.e. its regulatory autonomy (Thatcher, 2011;

[44] This process used to be referred to as 'comitology', since the exercise of this authority by the Commission required the consultation of committees made up of representatives of the Member States.
[45] At the time of writing, the Commission has not pursued regulatory cooperation which conflicted with or required changes to EU legislation.

Groenleer, 2014; Bach, de Francesco, Maggetti & Ruffing, 2016). Many authors (e.g. Meunier, 2014, 2005; Laatikainen & Smith, 2006) suggest that 'internal cohesiveness' is an important factor for the Commission to enjoy power and thus engage in external governance. On the other hand, authors have underlined the identity of the Commission and its normative orientations of legitimate behaviour as decisive for its behaviour. They propose that the Commission's identity and own experience in market integration leads it to protect the common rules and rule-making procedures of the Single Market against international disciplines (Woolcock, 2005; Young, 2004) and use the Single Market as a row model to address non-tariff trade barriers (Holmes & Young, 2001).

To describe the legal authority of the Commission to engage in bilateral regulatory cooperation, a distinction must be introduced here with regard to the scope of the intended regulatory cooperation. Pelkmans and de Brito (2015) differentiate if regulatory cooperation extends on a single technical regulation and regulatory decision or if it sets up an agreement covering a whole range of products. Examples of the latter are Mutual Recognition Agreements or Veterinary Equivalence Agreements. If the Commission pursues regulatory cooperation on individual regulations or regulatory decisions, it has substantial legal discretion in doing so as long as these decisions remain within the 'non-essential parts' of overarching EU legislation and thus fall under the scope of delegated acts or decisions. If the Commission, however, were to pursue regulatory cooperation covering a whole range of products through the negotiation of an agreement, its legal discretionary authority is limited. It can be argued, though, that the de facto discretion of the Commission in the formation of a strategy is nonetheless considerable. Importantly, the dimension and depth of a strategy that the Commission can pursue within its discretion is not restricted by the scope.

Within its discretionary authority in EU regulatory policy-making that the previous sub-section has delineated, the Commission has legal authority to pursue regulatory cooperation along all the strategies differentiated in chapter 3.3.2. If the technical regulation falls within the non-essential aspects of the overarching legislation, the Commission can harmonise or mutually recognise regulatory requirements within the non-essential aspects through a delegated act, thus pursuing 'regulatory alignment'. Likewise, it can take 'equivalence' decisions through delegated and – in exceptional cases- implementing acts[46]. Moreover, through 'decisions' the Commission can authorise production facilities in third countries for export to the EU, thus certifying their compliance with the conformity assessment requirements of the EU (Weimer & Vos, 2015) and pursuing an 'alignment of implementation procedures'. 'Information exchange' does in many cases not even entail a formal non-legislative decision and thus lies within the discretionary behaviour of the Commission (Chase & Pelkmans, 2015: 10).

[46] To illustrate the applicable EU procedures, see Commission (2017). It lays down the procedures for recognition of non-EU regulatory frameworks in the example of financial frameworks, specifying the 'equivalence' assessment and the 'equivalence' decision. The Commission specifies that "an 'equivalence' decision may take the form of an implementing or delegated act, in accordance with what is envisaged in the corresponding 'equivalence' provision in the basic act."

Agreements that establish procedures for a range of products and legislative decisions, in turn, only to a limited extent fall under the legal authority of the Commission. Agreements promoting 'equivalence' are 'Veterinary Equivalence Agreements' while 'Mutual Recognition Agreements promote an 'alignment of implementation procedures' (see chapter 3.2.). Harmonisation and mutual recognition, both captured by 'regulatory alignment', have come to be negotiated in Free Trade Agreements although the regulatory decision adoption mostly follows the procedures of delegated and implementing acts (Interview 19). These Agreements fall under the Common Commercial Policy and follow the procedure for the negotiation of international agreements[47]. In this procedure, authority is centralised at the EU level[48], but the legal discretionary authority of the Commission relative to other EU institutions is limited. Previous studies have, however, argued that de facto the Commission still enjoys considerable discretion (Siles-Brügge, 2014; Siles-Brügge, 2011; Elsig & Dupont, 2012).

In international negotiations, the Commission has the right to formulate initial negotiating positions and to conduct the negotiations[49]. Under the lead of DG Trade, the Commission initiates the formulation of the EU's strategy in abstract terms, i.e. its negotiating positions. In coordination with other DGs concerned, DG Trade elaborates draft negotiating directives[50]. Yet, the adoption of these negotiating directives is in the responsibility of the Council. DG Trade sends the negotiating directives to the Trade Policy Committee of the Council. The Council, i.e. EU member states, then adopts these negotiating directives, the so-called 'mandate', and thus launch international negotiations[51].

Subsequently, the Commission has authority to conduct the negotiations. In coordination with other DGs concerned, DG Trade specifies the strategy of the EU and elaborates position papers and then textual proposals for individual chapters of an agreement. Lead negotiators are the Trade Commissioner and the DG Trade. Agricultural negotiations are conducted by the Commissioner for Agriculture and the Directorate General for Agriculture. In the sectoral regulatory cooperation negotiations, lead negotiators came from the technical DGs while DG Trade representatives only participated. A special arrangement persists with regard to discussions on sanitary and phytosanitary measures. Here, both Commission representatives of DG Trade and DG Sanco as well as member state representatives participate in the negotiations in the so-called 'Potsdam Group' and 'Roosendaal Group'. This arrangement has been

[47] An exception to this are the Memoranda of Understanding that the Commission has concluded with regulators from a number of third countries, notably the US and Canada. They establish formalised procedures for 'information' exchange between the Commission and third-country regulators (see chapter 3.3.2.). These agreements fall within the discretionary authority (Chase & Pelkmans, 2015; see also Damro, 2005).
[48] The EU holds the exclusive competence on the Common Commercial Policy since the Treaty of Rome (1958). The Treaty of Lisbon extended the scope of the Common Commercial Policy. Yet, agreements including provisions on sensitive sectors, notably audio-visual services, health, and education services, require unanimous ratification in the Council.
[49] The following paragraphs build on Peterson and Young (2014: 80-85) and Woolcock (2010).
[50] The detailed procedure is laid down in the subsequent sub-section.
[51] While the EP has no formal role in this step, it is informed by DG Trade and has sent comments and amendments on the negotiating directives to the Commission, e.g. on the EU-US TTIP and the EU-Japan FTA.

established prior to the competence transfers under the Amsterdam Treaty and has been kept since (Interview 7, Interview 8).

The legal discretion of the Commission in the formulation of a strategy and the conduct of negotiations is constrained by two factors, though. First, on an almost weekly basis the Commission[52] reports to the Trade Policy Committee of the Council[53] and the Special Committee on Agriculture on the progress of the negotiations, shares documents and outlines its agenda for the negotiations. The member states can thus monitor the state of play and progress of the negotiations as well as the conduct of the Commission in line with their preferences. Bilateral links between member states and negotiating partners eliminate the scope for informational advantages of the Commission, which could otherwise be a source of autonomy and discretion (Pollack, 2003: 278; Woolcock, 2010: 389). Since the Lisbon Treaty the Commission also reports to the INTA Committee of the EP.

Second, the Commission does not have authority to adopt the outcomes of the negotiations. The Trade Commissioner signs the agreement and thus decides when negotiations are finished. Yet, the negotiated outcome is ratified by the Council in the Trade Policy Committee and since the Lisbon Treaty also by the EP. Both therefore have the possibility to refuse the ratification of an agreement negotiated by the Commission[54].

Despite these legal institutional constraints on the formation and pursuit of negotiating strategies by the Commission, studies on EU trade policy have proposed that the Commission retains considerable discretion. First, the Commission can anticipate the preferences of different member states and thus seek to reflect specific preferences in the drafting of the negotiating directives. Besides, divisions among member states make it difficult for the Council to adopt a 'tight' mandate that would significantly constrain the Commission's room for manoeuvre. Disagreements among member states have arguably helped the Commission advance its liberalisation agenda (Siles-Brügge, 2014; Conceicao-Heldt, 2010). Second, the Commission presents the negotiated outcome as a bundle to the Council that member states can either adopt or reject, but not amend. For this reason, a non-ratification of a negotiated outcome is usually very unlikely[55]. Third, and crucially, the Commission can structure the information it presents to member states and thus use its argumentative space to persuade member states (Siles-Brügge, 2011). On many issues, member states do not have fixed preferences and therefore do not constrain the

[52] This is mostly DG Trade or DG Agriculture. Only where sectoral regulatory cooperation negotiations are conducted by other DGs, these report to the Council or the EP.
[53] Until the Lisbon Treaty, the Trade Policy Committee was known as the 'Article 133 Committee', reflecting the article 133 of the Nice Treaty upon which the establishment of this Committee was based.
[54] The EP ratifies agreements with a majority of its component members. This process has become formalised with the Lisbon Treaty. Decision rules in the Council depend on whether a specific policy falls within the Common Commercial Policy. Decisions under the Common Commercial Policy require a qualified majority in the Council of Ministers. Yet, member states de facto seek to achieve a consensus even where decision rules only require a qualified majority. Unanimity is still required if policies touch upon areas of mixed competences ('mixity').
[55] This is not to say that non-ratification is impossible. The EP has rejected the ratification of the anti-piracy and intellectual property rights agreement ACTA in 2012 (Dür & Mateo, 2014). The Council has been very close to a non-ratification of the EU-Canada CETA Agreement in 2016.

negotiating space of the Commission (Adriaensen, 2016). This is also true for issues in regulatory cooperation (Interview 4).

In conclusion, this sub-section has elaborated the authority of the Commission in the formation of a regulatory cooperation strategy towards member states in the Council and the EP. It has deduced that the authority of the Commission does not constrain its choice among the regulatory cooperation strategies delineated in this book. The Commission's discretionary authority is high in regulatory cooperation that concentrates on individual regulatory measures. Its legal discretionary authority is limited towards the Council and the EP in the negotiation of agreements that are larger in scope and address a range of products. Yet, the Commission's de facto discretion is often still considerable, given inter alia information asymmetries and collective action problems of the Council and the EP. Crucially, however, while the scope of regulatory cooperation may restrict the discretion of the Commission, it does not constrain the Commission's ability to choose among a regulatory cooperation strategy based on the analytical categories of this book, i.e. dimension and depth.

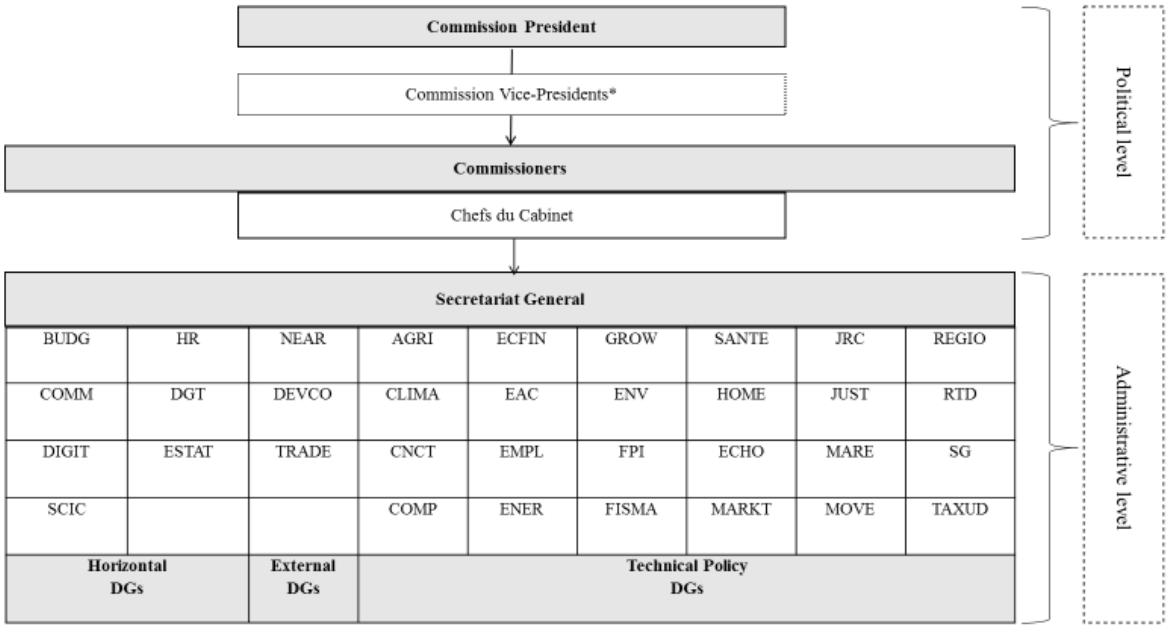
4.4.2. Bureaucratic pressure in the European Commission

This sub-section applies the independent variable 'bureaucratic pressure' to bureaucratic interaction within the Commission. It identifies the different regulatory sub-actors described in chapters 4.2.1., 4.3.2. and 4.3.4. Based on this, it shows how Commissioners and other DGs can direct the behaviour of technical officials.

The Commission consists of an administrative and a political level. The administrative level is divided into several Directorates General (DGs). These, in turn, can be subdivided into 'technical' DGs with policy responsibilities, DGs with responsibilities for external relations and so-called 'horizontal' DGs. All DGs have different mandates. Within each DG, responsibilities are divided among different departments and units. Each DG is led by a Director General. At political level, the Commission is made up of 28 Commissioners whose responsibilities broadly reflect the divisions between the different DGs.

For the clarity of the terminology and the distinction between the political and administrative levels within the Commission, figure 8 offers an overview of the organisation of the Commission. The organisational structure depicted and the names of the DGs and the relevant Commissioners correspond to the organisation of the Commission at the time of the Juncker Commission[56],[57].

[56] Commission Vice-Presidents were for the first time introduced with the Juncker Commission in 2014.
[57] The names of DGs and the responsibilities of Commissioners slightly change with the appointment of new Commissioners. For the DGs and Commissioners which are relevant for the empirical case studies discussed in this book, changes to names of DGs and the responsibilities of the relevant Commissioners are introduced in the corresponding case studies.



Abbrev. DG	DG name	Relevant European Commissioner	Abbrev. DG	DG name	Relevant Commissioner
AGRI	Agriculture and Rural Development	Agriculture and Rural Development	**FISMA**	Fin. Stability, Fin. Services, Capital Markets Union	Fin. Stability, Fin. Services, Capital Markets Union
BUDG	Budget	Financial Programming and the Budget	**SANTE**	Health and Food Safety	Health and Food Safety
CLIMA	Climate Action	Climate Action	**HOME**	Migration and Home Affairs	Home Affairs
CNCT	Comm. Networks, Content and Technology	Digital Agenda	**ECHO**	European Civil Protection, Human Aid Operation	International Cooperation, Human Aid and Crisis Response
COMM	Communication	Communication	**HR**	Human Resources and Security	Inter-Institutional Relations and Administration
COMP	Competition	Competition	**MARKT**	Internation Market and Services	Internation Market and Services
ECFIN	Economic and Financial Affairs	Economic and Financial Affairs	**JUST**	Justice and Consumers	Justice, Fund. Rights and Citizenship
EAC	Education and Culture	Education, Culture And Youth	**MARE**	Maritime Affairs and Fisheries	Maritime Affairs and Fisheries
EMPL	Employment, Social Affairs and Inclusion	Employment, Social Affairs and Inclusion	**MOVE**	Mobility and Transport	Transport
ENER	Energy	Energy	**REGIO**	Regional and Urban Policy	Regional Policy
NEAR	Neighbourhood and Enlargement	Enlargement and European Neighbourhood Policy	**RTD**	Research and Innovation	Research, Innovation and Science
GROW	Internal Market, Industry, Entrepreneurship	Industry and Entrepreneurship	**SG**	Secretariat General	
ENV	Environment	Environment	**TAXUD**	Taxation and Customs Union	Taxation and Customs Union, Audit, Anti-Fraud
DEVCO	International Cooperation and Development	Development	**TRADE**	Trade	Trade
DIGIT	Informatics		**DGT**	Translation	
SCIC	Interpretation		**ESTAT**	Eurostat	
JRC	Joint Research Centre		**FPI**	Service for Foreign Policy Instruments	

Figure 8: Organisation of the Commission at political and administrative level

Based on figure 8, the sub-actors distinguished in sections chapters 4.2.1., 4.3.2. and 4.3.4. can now be identified. Technical officials correspond to the bureaucratic officials of the DG (subsequently: technical DG officials) that is in the lead on an issue[58]. Regulatory leaders are the Commissioner and the Director General leading a DG. Other bureaucratic actors are the DGs which can influence the pursuit of regulatory cooperation in certain context, but which focus on other objectives. In the pursuit of regulatory cooperation, these other bureaucratic actors are officials and the Director General from DG Trade as well as the Trade Commissioner[59]. For analytical simplicity it shall be assumed that preferences of technical officials within a DG overlap to a considerable extent[60].

Commissioners and Directors General are assumed to have slightly different preferences from technical officials (for this assumption see also Elsig & Dupont, 2012: 895). This reflects their lower structural embeddedness in a DG and a lower degree of structural uncertainty that enables them to consider new ideas and work on the basis of personal convictions.

In the administration of day-to-day activities, technical DG officials have discretion in their decision and prioritisation of different issues (Pollack, 2005). Heads of units and department directors report to the leadership at administrative and political level about the administration of these day-to-day activities in two weekly coordination meetings: at administrative level between heads of units, department directors and the Director General and at political level including the participation of the Commissioner. Each meeting is chaired by the Director General of a DG and the responsible Commissioner respectively. Heads of units and department directors can use these coordination meetings with the Director General and the Commissioner to propose issues and tasks themselves. Due to the burden and overload of officials, this is, however, uncommon (see also Pollack, 2005).

Officials from other DGs and Commissioners are likely to have different preferences than the technical DG regulators. Their preferences can be deduced in analogy to the deduction of the preferences of the technical DG regulators in the previous sub-section. Above I have specified that actors' preferences are shaped by subjectively defined material interests and normative orientations. Besides, I have linked the subjective definition of a material interest to the 'mandate' of a regulator. One source of variation in preferences among regulatory actors within the Commission is thus the 'mandate' and the understanding of legitimate behaviour of a DG in the Commission. Another source are normative orientations, influenced by the personal beliefs held by actors. Among the individual regulatory actors specified by

[58] The 'lead', i.e. the competence to draft a proposal, coordinate with DGs and implement a decision, reflects the mandate, or 'missions', of the different DGs. An issue, or 'dossier', is officially allocated to a DG that is subsequently in the lead by a decision of the College of Commissioners.

[59] This operationalisation reflects the distinction by Elsig and Dupont (2012) of three types of bureaucratic actors in trade and regulatory negotiations within the Commission: (1) bureaucratic officials in the lead DG, (2) officials who focus on other objectives (usually from other DGs) and (3) politically appointed agents, i.e. the Commissioners.

[60] Empirical research by Kassim et al. (2013) finding a strong ideational coherence among officials working in a DG supports this assumption.

Elsig and Dupont (2012) above, only politically appointed agents, i.e. Commissioners, can be reasonably expected to have the capability in order to shape the preference of a regulator as an individual[61].

Bureaucratic pressure on regulatory cooperation arises at administrative and at political level within a DG and at political level within another DG. Existing research confirms that for the formation of the agenda, administrative and political leadership is important (Hartlapp et al., 2010: 10). First, in the coordination between the political and administrative level, bureaucratic pressure results from the availability of the Director General from the technical DG and the Commissioner to assume administrative and political leadership. At administrative or political level within a DG, the Director General of the DG and the respective Commissioner can task bureaucratic officials to elaborate a proposal or strategy on a regulatory cooperation issue. The task to identify issues for regulatory cooperation then sets off the strategy formation process outlined in the next sub-section.

Second, in the coordination at political and administrative levels across the DGs, bureaucratic pressure results from a suggestion at political level in DG Trade, notably the Commissioner, to pursue regulatory cooperation through an international agreement rather than through discussions between regulators alone. The pursuit of regulatory cooperation through trade negotiations shifts the 'lead' from the technical DG to DG Trade. This leads to an overlap of internal jurisdictions, which may produce 'turf wars' between different individual Commission Directorate Generals (DGs) over the formation of the Commission strategies (Dijkstra, 2009). In line with the process illustrated in the next section, this suggestion should lead to a task to officials in DG Trade to identify issues for regulatory cooperation. As DG Trade has a different 'mission' than technical DGs, i.e. trade liberalisation, the assessment of the relative costs and benefits of regulatory cooperation likely differs from the -initial status quo- assessment of officials (and administrative and political leaders) of the technical DGs and may cause a different policy preference on regulatory cooperation within DG Trade than within technical DGs (Sapir, 2011).

Bureaucratic pressure at political level in another DG, i.e. pressure exerted by the Trade Commissioner, can thus task officials from the technical DG to elaborate a proposal or strategy on an issue. In the latter case, officials from the DG Trade coordinate with officials from the technical DG to contribute and provide input on the issue, either through informal consultations or formal inter-service consultations. This process will be explained in further detail in the next sub-section. For now, it shall be maintained that both administrative or political leadership within the DG as well as political leadership in another DG, however, constrain the discretion of technical officials and force them to act.

[61] There is a growing literature underlining the influence of personal convictions and ideas on institutional choices of actors, calling itself 'actor-centred constructivism' (e.g. Saurugger, 2013). For a detailed discussion of the influence of the mandate of a regulator, distinguished among different DGs within the Commission, see previous literature (Kassim et al., 2013; Smith, 2013; Trondal, 2012; Frennhoff-Larsén, 2007).

Figure 9 shows the two sources of bureaucratic pressure:

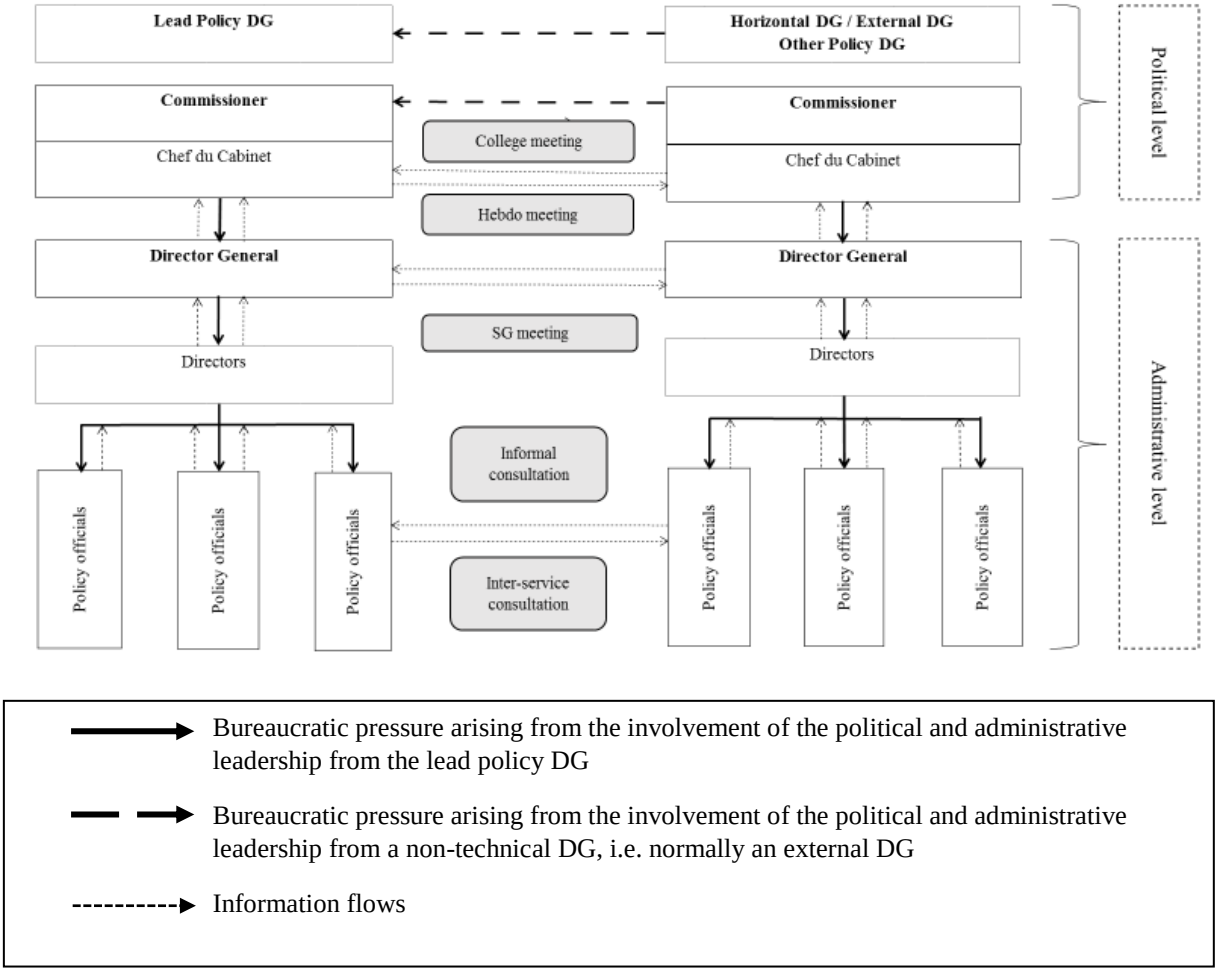


Figure 9: Sources of bureaucratic pressure

Political leadership of the Trade Commissioner and political leadership of the technical DG Director General or Commissioner are thus likely to shift the balance of internal assessments of costs and benefits of regulatory cooperation in favour of regulatory cooperation and thus lead to a collective Commission preference 'regulatory cooperation'. Yet, it cannot be deduced that shifts in the leadership among different DGs and Commissioners can explain the choice among the regulatory cooperation strategies developed in chapter 3.3. The pursuit of regulatory cooperation may occur through any of the forms other than non-cooperation delineated in section 3.4. Hypothesis 1 can therefore be operationalised as follows:

H1a: The presence of bureaucratic pressure from the Director General, Commissioner or Trade Commissioner leads technical lead DG officials to choose 'regulatory alignment', 'equivalence', 'alignment of implementation procedures' or 'information exchange'.

H1b: The absence of bureaucratic pressure leads technical lead DG officials to pursue regulatory competition.

In sum, this sub-section has operationalised the independent variable 'bureaucratic pressure' to specific actors within the Commission. It has shown that administrative or political leadership by the Director General of the technical lead DG, the respective Commissioner or the Trade Commissioner forces technical lead DG officials to act on an issue upon which they may not have acted otherwise.

4.4.3. Conceiving the strategy formation process in the European Commission

This sub-section now applies the causal mechanism described in chapter 4.3.3 to decision-making within the Commission and lays down the process of strategy formation. The Commission's regulatory cooperation strategy can take two forms. It can be a proposal for a 'regulatory alignment' or 'equivalence' decision by means of a delegated act or it can be a negotiating position or textual proposal to be pursued through negotiations on an international agreement. This sub-section therefore distinguishes between strategy formation for regulatory cooperation on individual regulatory measures through delegated acts and implementing acts and regulatory cooperation through the negotiation of international agreements[62].

If coordination between the administrative and the political level within a DG (see chapter 4.4.3) concludes that the Commission should engage in regulatory cooperation, the administrative level within the lead DG begins the work on the Commission's strategy. It does by initiating coordination with officials of other DGs at administrative level to gather information. Besides, it consults with societal actors. The scope of the consultation with societal actors and other DGs depends on the type of decision. For administrative decisions, the responsible unit in the lead DG consults with societal actors on an ad-hoc basis and coordinates with other DGs informally. Additional informal coordination may for instance take place through the Inter-Service Group (Hartlapp et al., 2010: 6). Since the adoption of the 'Better Regulation' agenda in 2002, the Commission additionally commissions external scientific impact assessments on the decision or mandate public consultations (Parker & Alemanno, 2014: 25). As part of the 'Better Regulation' agenda, it is required to launch public consultations with societal actors and commission impact assessments (Parker & Alemanno, 2014: 14). Furthermore, Commission officials may initiate informal consultations with member state representatives in the Council (through the Council Working Groups or the Trade Policy Committee) and MEPs. Importantly, Commission officials consult with or anticipate demands of the foreign regulator.

Technical officials in the lead DG then evaluate the knowledge and information that they have collected through the consultation with societal actors. This information is compared with own information and information obtained through the coordination with other DGs. Technical officials evaluate proposals

[62] Although Memoranda of Understanding on 'information exchange' are also agreements, their nature as non-treaty agreements makes the internal decision-making process equal to regulatory cooperation on individual regulatory measures.

of societal actors (as well as other actors) for regulatory cooperation with regard to expected effects of these proposals to preferences of the Commission. Subsequently, and taking into account the proposals submitted by societal actors and political actors, technical officials then elaborate draft textual proposals for regulatory cooperation.

These draft textual proposals are then shared with other DGs who can comment on the draft textual proposal. For delegated and implementing acts, technical DG officials consult with other DGs through inter-service consultations. Likewise, for international agreements, the lead DG, i.e. DG Trade, coordinates with other DGs through inter-service consultations. In inter-service consultations, the DG which is responsible, i.e. 'in the lead', for a decision initiates the procedure. It is required to seek the approval of all DGs that are concerned by a decision and "have a legitimate interest in the draft text" (Commission, 2000: art. 23(2)). While the lead DG is required to consult the Commission's Legal Service and the Secretariat General, it has discretion in deciding which other DGs it contacts (Hartlapp et al., 2010: 10). If a consulted DG blocks a decision, the lead DG and the blocking DG enter consultations. In practice, however, technical officials from the lead DG share documents with other DGs for comments already in advance of formal inter-service consultations.

Besides, officials as well as administrative and political leaders of the lead DG continue to interact with societal actors. Notably, they employ the mechanisms of 'managing permeability' and 'buffering' outlined in chapter 4.3.4. They mobilise societal actors to provide additional information on comments submitted in the public consultation. Moreover, they mobilise societal actors to raise argumentative pressure in support of their proposed strategy both during and after the inter-service consultations.

As an outcome of these consultations, the proposed strategy is amended or sent to the political level (for an in-depth discussion see Stroß, 2014: 64). At political level, an issue for which no agreement has been possible at technical level, is further discussed. Forums for discussion are the weekly hebdomadaire ('Hebdo') meeting between the heads of Cabinet of each Commissioner, chaired by the Secretariat-General as well as the 'special chef' meetings chaired by a member of the President's cabinet and composed of the relevant sectoral cabinet members responsible for a policy item. Issues which could not be resolved through either of these meetings at political level are sent to College meetings of the Commissioners (Stroß, 2014: 65). The textual proposal, i.e. strategy, is then formally adopted by the College of Commissioners.

Figure 10 shows the process of strategy formation.

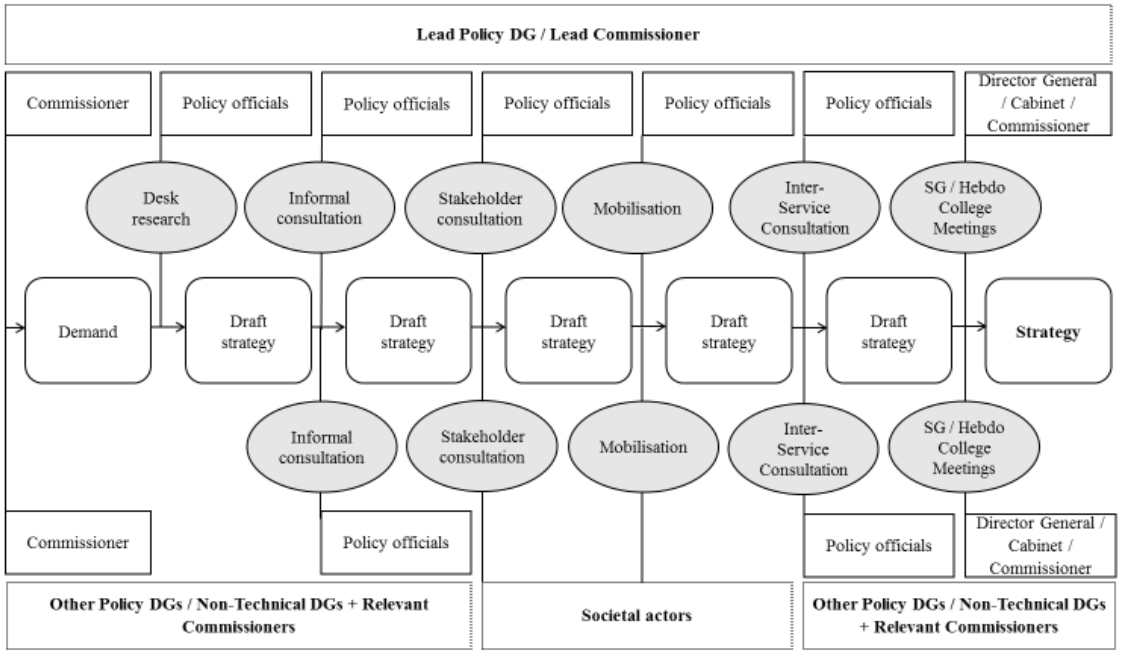


Figure 10: Process of strategy formation within the Commission

The elaboration of the causal mechanism helps to clarify the relationship between the independent variables. The presence of bureaucratic pressure (IV1) initiates the process of strategy formation. Regulatory compatibilities (IV2) then determine which proposals and demands of societal actors and foreign regulators Commission officials take into consideration. Moreover, they guide the search of Commission officials for technical information on issues on which regulatory cooperation could be pursued. Regulatory compatibilities thus constrain the choice among different regulatory cooperation strategies.

4.5. Summary

This chapter has deduced an Inter-relational Institutionalist framework as a theoretical basis to analyse the constraints that a regulator from a large jurisdiction considers in the formation of a bilateral regulatory cooperation. The chapter has discussed actor-centred institutionalism and the New Interdependence Approach as the theoretical foundations for the 'inter-relational institutionalist' integrative framework. It has argued that the conclusions of the New Interdependence Approach that a) rule overlap is an opportunity structure for regulatory actors to enhance their preferences and b) their power is shaped by institutional complementarities between the domestic and international level derive a theoretical foundation for the engagement of a regulator from a large jurisdiction in bilateral regulatory cooperation. It has integrated these conclusions into an actor-centred institutionalism combining rational-choice and sociological-constructivist approaches. The discussion of the first building block of actor-centred institutionalism, 'actor characteristics' has led to the derivation of the independent variable 'bureaucratic pressure' that explains the regulator's choice between cooperation and non-cooperation. The discussion of the second building block, 'actor constellations' has allowed deducing the important two variants of the second independent variable 'regulatory compatibilities', i.e. 'regulatory authority compatibilities' and 'regulatory principle compatibilities'. These are argued to explain its choice among different cooperation strategies, given that it has decided to engage in cooperation. The chapter also deduced a causal relationship between the variables.

The variables will be tested in the empirical part of the book. The independent variable has been operationalised to internal politics in the Commission with three outcomes (no administrative or political leadership / administrative and political leadership by technical lead DG / administrative or political leadership by DG Trade). The important second independent variable 'regulatory compatibilities' has been operationalised dichotomously as 'compatible' and 'non-compatible'. 'Compatible regulatory authority structures' have been understood as a centralisation of authority in both the EU and the third country. 'Compatible regulatory principles' have been defined as the absence of directly conflicting regulatory approaches.

The major benefit of the 'inter-relational institutional' framework is its ability to grasp variation in bureaucratic dynamics and its influence on the engagement in bilateral regulatory cooperation as a form of external governance. At the same time, it contributes to reconcile previously conflicting explanatory approaches into one integrative framework and understand the structural-institutional factors which constrain the Commission's choice among different regulatory cooperation strategies as mechanisms of external governance. The Inter-relational Institutionalism thus helps structure an in-depth empirical analysis of different sectors of EU internal market policy to reveal under which conditions and under which constraints the Commission forms a cooperation strategy in bilateral regulatory cooperation.

The hypotheses that will be tested in four empirical case studies can be summarised as follows:

H1a: The presence of bureaucratic pressure leads regulators to choose 'regulatory alignment', 'equivalence', 'alignment of implementation procedures' or 'information exchange'.

H1b: The absence of bureaucratic pressure leads regulators to pursue regulatory competition.

H2a: If both regulatory authority structures and regulatory principles are compatible, the Commission pursues a strategy of 'regulatory alignment'.

H2b: If regulatory authority structures are compatible, but regulatory principles are incompatible, the Commission pursues a strategy of 'equivalence'.

H2c: If regulatory authority structures are incompatible, but regulatory principles are compatible, the Commission pursues a strategy of 'alignment of implementation procedures'.

H2d: If both regulatory authority structures and regulatory principles are incompatible, the Commission pursues a strategy of 'information exchange'.

H3: If regulatory leaders and regulatory officials succeed to mobilise societal actors in support of the strategy that is in line with regulatory compatibilities, regulators will pursue a strategy in line with regulatory compatibilities.

The next chapter discusses the methodology of this book before chapter 6 begins the empirical analyses.

5. Methodology

Under which constraints the Commission chooses a strategy for bilateral regulatory cooperation is the topic of this book. The EU has developed considerable regulatory capacity in a great number of policy fields and industry sectors, delegated discretionary authority to the Commission to adopt delegated and implementing acts. Besides, the member states have given the Commission discretion in its authority to interact with regulators from third countries as long as this interaction remains within the Commission's discretionary authority. Many of these policy fields and industry sectors are characterised by high economic internationalisation and interdependence with other jurisdictions and are therefore subjects of both multilateral and increasingly also bilateral regulatory cooperation.

This chapter develops the methodology in complement to the theoretical framework deduced in chapter 3 and 4 for the empirical application of the Inter-relational Institutionalism. To test the framework, a comparative case study research design shall be employed. First, the chapter selects the case studies. It presents the universe of third countries with which the Commission has engaged in regulatory cooperation and selects the US as a regulatory cooperation partner based on a 'least-likely' logic for the influence of bureaucratic pressure. Then industry-sectoral regimes are drawn out of the population of industry sectors and EU governance regimes. A sample of four sectoral case studies is selected based on a combination of the 'least-likely' logic and the 'method of difference' on the independent variable 'regulatory compatibilities'. The selected sectoral case studies chemicals, engineering, food safety and ICT are briefly presented. For each of the four sectoral case studies, three sub-cases, i.e. different regulatory cooperation initiatives, are defined to ensure variation on the independent variable 'bureaucratic pressure'. From the history of transatlantic regulatory cooperation initiatives, the New Transatlantic Agenda (NTA), the Transatlantic Economic Council (TEC) and the negotiations over a Transatlantic Trade and Investment Partnership (TTIP) are selected.

Second, the chapter presents the method for data analysis. The within-case analysis examines the Commission's choice of regulatory cooperation strategies for each of the three sub-cases, relying on process-tracing as the main method. Based on the results of the within-case analysis, a cross-case synthesis discusses the identified variables. Third, it discusses the methods of data collection. The document analysis is based on public and non-public documents of the Commission, complemented with analytical publications by think tanks and articles by specialist journals. Moreover, data has been collected through 26 semi-structured expert interviews conducted between 2015 and 2017.

5.1. Comparative case study research design

Explaining the difference in strategies that the Commission aims for in bilateral regulatory cooperation is the object of this book. It thus pursues an 'outcome-centric research design' (Dür, 2007). The ambition of this book is not to make inferences from a sample to a population, but rather to establish the causal mechanism that leads to a specific 'outcome' (Dür, 2007). It thus requires a research design to show that for a set of case studies, theoretically deduced hypotheses validly explain actual empirical phenomena. The following paragraphs lay down why this goal qualifies this study for the employment of a comparative case study research design. A case study shall be understood as a "an intensive study of a single unit for the purpose of understanding a larger class of (similar) units" (Gerring, 2004: 342).

The objective of any scientific study in the social sciences is to make descriptive or causal inferences based on empirical information about the "real world". King, Keohane and Verba (1994) note that both qualitative and quantitative research is based on the logic of inference. A case study is only scientific if it allows drawing conclusions or understanding the world beyond the immediate information collected. 'Descriptive inference takes observations from the world to learn more about unobserved phenomena while 'causal inference' aims at learning about causal mechanisms. Woll (2008: 85-92) further distinguishes between the description of a 'causal mechanism' and 'constitutive mechanism'. Within a causal mechanism, an element A generates an element B. A constitutive relationship implies, in turn, that B exists in virtue of A (Woll, 2008: 88). While this distinction helps to remind a case study researcher of the difficulty to postulate an actual causal relationship between observed factors, it is not taken up by this book. Instead, the notion shall be taken up that any description of a casual mechanism in the social sciences presupposes inferences about the relationship between factors that cannot be proven with ultimate certainty.

The outcome-centric research design makes this study more amenable to qualitative rather than quantitative research methods. This book seeks to trace the chain of causal factors, the causal mechanism which leads to a given outcome. The study of causal mechanisms is difficult with a large-n quantitative design (see Dür, 2007: 155). The latter could rather be used to test the causal mechanism observed by this book across a larger set of cases. Yet, the small number of cases among which a researcher can choose constitutes an additional complexity for the employment of a quantitative research design. The engagement in regulatory bilateral regulatory cooperation presupposes power resources which, for the time being, only few entities in the world can fulfil. Apart from the EU these are the US, Canada, Japan and to a limited extent Korea (see below).

This book nonetheless seeks to employ qualitative methods with the objective to draw causal inference. Case study methods aim at drawing causal inference by discarding powerful alternative explanations

(George & Bennett, 2005: 181). The purpose of a comparative research design is to cover cases that are able to explain variation to be expected from theory. As will be discussed in the following paragraphs, the ability of a comparative case study design to draw causal inference can be enhanced through a process of careful case selection). King, Keohane and Verba (1994) suggest that case selection based on the method of difference reduces the risk of selection bias. The selection of observations "according to the categories of the key causal explanatory variable" (King, Keohane & Verba, 1994: 137) reduces the risk of introducing bias because the selection procedure does not make any statements with regard to the expected outcome of a study.

The units of analysis or cases of Inter-relational Institutionalism are the industry sectoral regimes. Units of analysis can be understood as 'the sort of phenomena that constitute cases in a given research context" (Gerring, 2001: 160) This book thus reflects the delineation of cases based on industry sectors (Woll, 2008; Vogel, 2012) by comparable studies in the past. In contrast to the focus on industry sectors, however, industry sectoral regimes comprise the regulatory policies, i.e. legislation, regulations and standards as well as implementation procedures that govern the authorisation and marketing of goods and services within an industry sector.

The regulatory policies and implementation procedures within an industry sectoral regime constitute the phenomena and elements within a case. This delineation does not suppose that all issues addressed within a sectoral regime are homogenous elements. The adherence to a certain regulatory principle may for instance only apply to some issues within a sectoral regime, but not others (see also chapter 7.2.2.). Yet, a delineation of cases based on industry sectoral regimes can be justified for several reasons: First, regulatory cooperation dialogues are commonly structured around industry sectors. Commission officials that participate in a regulatory dialogue thus usually address several issues within an industry sector, but not from other industry sectors (Interview 21). This also reflects the conclusion of Peterson and Young (2014: 159) that most regulatory cooperation is sector-specific. When strategies for regulatory cooperation are formed, strategies are formed for each sector independently. Possible concessions in discussions are identified within, but not across sectors (Interview 21). In the same vein, Peterson and Young (2014: 159) emphasise that the scope for inter-sectoral trade-offs in regulatory cooperation is small. This ensures that cases identified and delineated are independent. Second, societal actors that are consulted and propose policy demands are organised around industry sectors. Delineating cases on the basis of sectors thus also helps delineating the societal actors that are likely to influence the behaviour of the Commission within a case study. The population of possible cases therefore covers, first, all third countries with which the EU pursues bilateral regulatory cooperation and, second, all industry sectoral regimes.

Selecting the EU as a promoter of bilateral regulatory cooperation

Before the selection of cases for the subsequent empirical analysis is presented, a few arguments shall be put forward on the choice of the EU and the Commission as a promoter of bilateral regulatory cooperation. As indicated above, the universe of potential jurisdictions for which the formation and choice of a bilateral regulatory cooperation strategy can be studied is limited. Yet, the choice to study the formation of a bilateral regulatory cooperation strategy using the example of the Commission can be justified with both theory-driven arguments and empirical observations.

First, the EU holds the power resources that the literature on international regulatory cooperation considers to be relevant for the capacity to externalise domestic regulatory measures (Damro, 2015; Farrell & Newman, 2014; Damro, 2012; Bach & Newman, 2007; see also chapter 2.4). The EU is argued to have a large internal market, have a high regulatory capacity and to show high regulatory stringency (Damro, 2015; Bradford, 2012; Vogel, 2012; Posner, 2010). Second, the literature widely notes that the EU has a normative orientation towards trade liberalisation (Siles-Brügge, 2014; Manger, 2009) as well as towards an externalisation of its norms and rules (Lavenex & Schimmelfennig, 2009; Manners, 2006). Indeed, the argument that the Commission is a regulator with has an outward perspective has given rise to an entire literature on EU external governance (Lavenex & Schimmelfennig, 2009 for a review). This makes the EU a 'most likely' candidate to engage in bilateral regulatory cooperation as the latter aims at both trade liberalisation as well as a ramification and spread of domestic levels of safety, health and environmental protection.

Third, a focus on the EU can also be justified with observations in the specialist literature on regulatory cooperation that no other jurisdiction beside the EU has concluded a similar amount of regulatory cooperation agreements, notably Veterinary Equivalency and Mutual Recognition Agreements (Chase & Pelkmans, 2015; Pelkmans & Brito, 2015). The US which arguably also has a large internal market, high regulatory capacity and high regulatory stringency, has not concluded a similar number of corresponding agreements (see also Ahearn, 2009). A focus on the EU and the Commission to study strategy formation on bilateral regulatory cooperation can therefore be justified both with its power resources and its normative orientations which make the EU a 'most likely' jurisdiction to pursue regulatory cooperation as well as actual data on its engagement in bilateral regulatory cooperation.

Selecting a third country case

Studies that follow an outcome-centric research design seek to discard alternative explanations through a comparative case study design. At the same time, the aim of case selection is to select a representative sample of the population and realise the maximum variance in the variables of theoretical interest (Seawright & Gerring, 2008: 296). This section therefore first creates a list of third countries with which the Commission has pursued bilateral regulatory cooperation at the time of writing.

In line with the description of regulatory cooperation strategies in chapter 3.2, the list of third countries with which the Commission has engaged in bilateral regulatory cooperation can be constructed from the conclusion of Mutual Recognition Agreements, Veterinary Equivalence Agreements and the inclusion of regulatory cooperation provisions in bilateral Free Trade Agreements. Based on information provided by the Commission (2017a, 2017b), at the time of writing the Commission has pursued bilateral regulatory cooperation with the following third countries:

Partner country	**Agreements**
Australia	Veterinary Equivalence Agreement, Mutual Recognition Agreement
Canada	Veterinary Equivalence Agreement, Mutual Recognition Agreements, Free Trade Agreement (CETA)
Chile	Veterinary Equivalence Agreement
Japan	Mutual Recognition Agreements, Free Trade Agreement (JEITA, under negotiation)
Korea	Mutual Recognition Agreement, Free Trade Agreement (KOREU)
New Zealand	Veterinary Equivalence Agreement, Mutual Recognition Agreement
Singapore	Mutual Recognition Agreement
United States	Veterinary Equivalence Agreement, Mutual Recognition Agreements, Free Trade Agreement (TTIP, under negotiation)

Table 7: Overview of EU regulatory cooperation agreements

To test the empirical validity of the theoretically deduced hypotheses through a comparative case study design, selected cases are subjected to especially 'hard' empirical cases. Eckstein (1975) argues that the employment of 'most-likely' or 'least-likely' cases are essential tests for rival theories. The logic of a 'least-likely' case is that if a hypothesis is not valid for this specific case, it is not likely to be valid for all or many other cases. The selection of a third country should therefore constitute a 'least-likely' case

for the explanatory relevance of the independent variable of the theoretical framework. Out of the countries listed above, the US is a 'least-likely' case for the need of bureaucratic pressure to push Commission officials to engage in regulatory cooperation. First, based on the New Interdependence Approach, incentives for regulators to engage in cooperation are high if the level of interdependence between the EU and the third country is high. Interdependence of the EU is arguably largest with the US. The Ecorys study (2016: 108) notes that in 2015 US subsidiaries of EU firms contributed two-thirds of total foreign direct investment in the US. Moreover, it notes that 60% of US imports from the EU and 31% of US exports to the EU were intra-firm or related-party trade (Ecorys, 2016: 113). Second, based on theories of firms' trade preferences, the high degree of intra-industry trade should drive EU firms with US subsidiaries and US firms with EU subsidiaries to prepare joint demands and lobby Commission officials for 'regulatory alignment' (see Eckhardt & Poletti, 2016). Differences in regulations and implementation procedures affect the competitive position of firms as well as the market share of foreign firms (Lütz, 2011: 4).

At the same time, the US is an 'extreme' case for the Commission's pursuit of regulatory cooperation rather than externalisation or functional extensions of EU rules and standards (Lavenex, 2014). The New Interdependence Approach (Newman & Posner, 2015) and the 'Market Power Europe' conceptual framework (Damro, 2015b; Damro, 2012) put forward that the ability of the Commission to externalise EU rules and standards reflects its relative market size and its relative regulatory capacity vis-à-vis the third country. The regulatory capacity of the US is particularly high and considered to be comparable to the one of the EU (Bach & Newman, 2010; Posner, 2010). Moreover, while all countries listed above have sizeable internal markets, the relative market asymmetry in favour of the EU is smallest with the US (Statista, 2017). Interactions between decision-makers and regulators of either jurisdiction are very dense, creating a 'Euro-American regulatory condominium' (Posner, 2009). Considering that the US is an 'extreme' case a third country for bilateral regulatory cooperation, chapter 7.2.4 will discuss the limitations of the generalisability of findings from an examination of regulatory cooperation cases with the US towards other third countries included in the population.

Selecting industry sectoral regimes of EU-US regulatory cooperation as cases

To select among potential industry sectoral regimes, it is necessary to first identify the universe of industry sectors which can be subject to regulatory regimes. The population of industry sectors for regulatory cooperation is derived from the list of sectors in the Single Market distinguished by the Commission (Commission, 2017c) and complemented with the list of sectors delineated by previous studies of regulatory cooperation (Chase & Pelkmans, 2015). The Commission distinguishes the following sectors in its internal market policy as shown in table 8 (next page):

Space/Aeronautics	Automotive	Biotechnology
Chemicals	Construction	Cosmetics
Defence	Engineering	Food / Food Safety
Gambling	Healthcare / Pharmaceuticals	Information and Communications Technology
Maritime	Medical devices	Raw materials
Textiles	Toys	

Table 8: Overview of industry sectors 1

Based on an empirical observation of the EU's engagement in regulatory cooperation with the US, Chase and Pelkmans (2015: 33) add the following sectors. These are displayed in table 9:

Financial services	Aircraft	Transport services

Table 9: Overview of industry sectors 2

Alternatively, the population of cases could be constructed on the basis of policy fields (e.g. Falkner & Müller, 2013). The Treaty on the Functioning of the European Union (TFEU; parts three 'Union Policies and Internal Actions' and five 'External Action') distinguishes the following policy fields as shown in table 10:

Agriculture	Foreign Affairs	Regional Policy	Development
Fisheries	Research	Economic/Monetary Affairs	Health
Security	Education and Culture	Humanitarian Aid	Taxation
Employment/ Social Policy	Industry and Competition	Trade	Energy
Internal Market	Transport	Environment	Justice and Home Affairs

Table 10: Overview of policy fields

Out of these policy fields, only agriculture, health, economic and monetary affairs, industry and competition, internal market and environment are object to technical regulation and thus possible subjects of regulatory cooperation. Moreover, the boundaries of some of these policy fields are diffuse. The regulation of chemicals and automotive thus simultaneously falls into the fields of internal market and environment.

The objective of a comparative case study research is to discard alternative explanations. Rejecting potential alternative explanations increases the internal validity of a finding of a comparative case study, i.e. the explanatory strength of the claim "that the postulated cause-effect relationship is really at work" (Dür, 2007: 161). Case study research frequently reflects the logic of Mill's (1843) methods of

agreement and difference. The method of agreement argues that if only one of several explanatory factors is present in all cases, then this common explanatory factor must be the cause of the outcome. The method of difference takes cases with different outcomes and argues that if all but one factor is present in the cases, the one factor which is absent or different in each case must be the cause of the difference. King, Keohane and Verba (1994: 137) suggest that case selection based on the method of difference reduces the risk of selection bias compared to the method of agreement because the selection procedure does not make any statements with regard to the expected outcome of a study. Ragin (1987: 41) further suggests that after categories of explanatory variables have been defined, observations should be matched to the different categories.

The goal of this book is to explain the constraints on strategy formation and choice in bilateral regulatory cooperation and thus to understand why a regulator such as the Commission chooses different strategies in different regulatory contexts. Potential alternative explanations can thus be discarded if they are present in all cases and take the same value across cases. The literature review in chapter 2 already argued why 'global regulatory capitalism' and 'domestic regulatory culture' approaches taken in isolation struggle to explain the puzzle that motivates this book. The case selection of the subsequent empirical analysis should, however, also discard potential 'international political economy' explanations. For this reason, cases need to be selected which are characterised by dense interactions among regulators in international organisations and international organisations and agreements with judicial enforceability. These would support explanations within this field of literature that underline the influence of international institutions. The sectoral regimes of space/aeronautics, biotechnology, construction, defence, gambling, raw materials and transport services have until present not been subject to substantial regulation within international organisations (for a positive list of sectoral regimes that have been addressed by international organisations see Jorgensen et al., 2011). As table 11 shows, a number of potential cases can be discarded:

~~Space/Aeronautics~~	Automotive	~~Biotechnology~~
Chemicals	~~Construction~~	Cosmetics
~~Defence~~	Engineering	Food / Food Safety
~~Gambling~~	Healthcare / Pharmaceuticals	Information and Communications Technology
Maritime	Medical devices	~~Raw materials~~
Textiles	Toys	Financial services
~~Aircraft~~	~~Transport services~~	

Table 11: Overview of sectoral regimes with international cooperation

Moreover, an explanation supporting the Inter-relational Institutionalism must be able to discard rival Open Economy Politics explanations. Open Economy Politics contributions underline the influence of societal contestation and the aggregation of societal preferences. They stipulate that the ability of state

actors to engage in regulatory cooperation is constrained where the level of societal contestation is high and NGOs leverage resources against the pursuit of regulatory cooperation. To reject an Open Economy Politics explanation, first all sectoral regimes can be discarded that have not been the subject of intensive contestation and thus not subject of politicisation on the issue of regulatory cooperation between business actors and NGOs. The intensity of societal contestation on regulatory cooperation is approximated using the Commission's assessment of societal contestation in its sectoral position papers on TTIP regulatory cooperation published in 2014. All sectors for which the Commission does not 'sensitive or controversial issues' are discarded.

Table 12 illustrates that despite the overall high level of politicisation during the TTIP negotiations, the level of societal contestation has remained relatively low for the automotive, maritime, textiles and toys sectoral (Commission, 2013f). The corresponding sectoral regimes can thus equally be discarded as case studies to test the explanatory strength of the Inter-relational Institutionalism.

~~Space/Aeronautics~~	~~Automotive~~	~~Biotechnology~~
Chemicals	~~Construction~~	Cosmetics
~~Defence~~	Engineering	Food / Food Safety
~~Gambling~~	Healthcare / Pharmaceuticals	Information and Communications Technology
~~Maritime~~	Medical devices	~~Raw materials~~
~~Textiles~~	~~Toys~~	Financial services
~~Aircraft~~	~~Transport services~~	

Table 12: Industry sectoral regimes with politicisation

To substantiate the rejection of alternative Open Economy Politics explanations, second, all sectoral regimes that are not characterised by high volumes of intra-industry trade should be discarded. High volumes of intra-industry trade increase the salience of a sector and thus the likelihood that societal actors mobilise resources proactively to gain access to decision-makers (for a discussion of salience on lobbying see Klüver, 2012; Mahoney, 2007). A proactive mobilisation of societal actors would weaken the argument that bureaucratic pressure is necessary to initiate the formation of a regulatory cooperation strategy. Sectoral regimes should thus be chosen in which underlying industry sectors show high levels of intra-industry trade. Besides, this decision further helps to disregard international political economy explanations that emphasise economic internationalisation. Figure 11 shows EU exports to the US by sales volume in the largest sectors (see next page; for complete data see Annex 3).

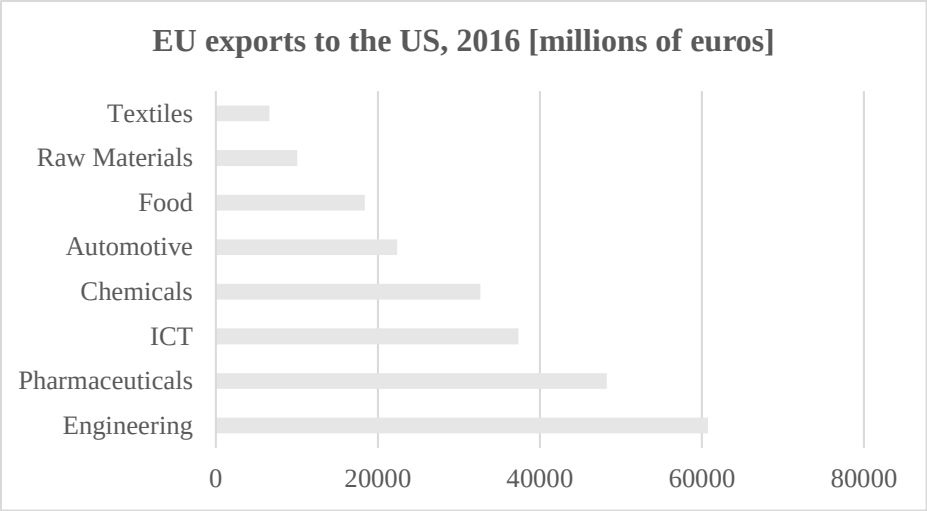


Figure 11: EU exports to the US by sector, 2016

As a result, the relatively low-volume trade sectors medical devices and cosmetics are discarded as shown by table 13.

~~Space/Aeronautics~~	~~Automotive~~	~~Biotechnology~~
Chemicals	~~Construction~~	~~Cosmetics~~
~~Defence~~	Engineering	Food / Food Safety
~~Gambling~~	Healthcare / Pharmaceuticals	Information and Communications Technology
~~Maritime~~	~~Medical devices~~	~~Raw materials~~
~~Textiles~~	~~Toys~~	Financial services
~~Aircraft~~	~~Transport services~~	

Table 13: Industry sectoral regimes with high intra-industry trade

Besides, sectoral regimes within the Commission's internal market policy can be assumed to be those sectors on which the Commission has authority to propose and adopt regulations on the 'non-essential parts' of the corresponding sectoral legislation. This point has been elaborated in chapter 4.4.1. This ensures that the Commission can in principle choose to pursue regulatory cooperation and avoids that the empirical analysis does not yield any results because the Commission is not entitled to form and choose a strategy.

To test the Inter-relational Institutionalism, cases need to be selected to ensure variation on the explanatory variables. As variation on the explanatory variables requires itself an in-depth analysis of the regulations and implementation procedures governing each sector, cases are selected to maximise the likelihood that variation can be observed along the variables deduced in the theoretical framework. Variation must especially be especially ensured on the independent variables which constrain the formation and choice of a bilateral regulatory cooperation strategy.

The Inter-relational Institutionalism puts forward that the choice among bilateral regulatory cooperation strategies is constrained by regulatory compatibilities. It shall not be assumed that regulatory authority structures and underlying regulatory principles are homogenous for all regulatory policies and implementation procedures that govern a sectoral regime. The case studies rather seek to maximise the likelihood that all possible combinations of regulatory compatibilities and their effect on the constraint of the choice of a bilateral regulatory cooperation strategy can be observed. To estimate the likelihood that regulatory compatibilities vary across the sectors, existing literature is used.

Vogel (2012) argues that distinct regulatory principles persist in the EU in the chemicals and food safety sectors because of the EU's reliance on the precautionary principle. Naiki (2007) adds that in the chemicals sector, the EU adopts a distinct allocation of competences between the Commission and private actors. Büthe and Mattli (2011) conclude that in international technical standardisation, shaping notably the engineering sector, the allocation of authority in the EU is distinctly different from the authority on standardisation in the US.

This book therefore chooses the industry sectoral regimes chemicals, engineering, food safety and information and communication technology (ICT) as case studies to apply the theoretical framework. Based on insights of existing literature, these sectors can be broadly matched to the combinations of regulatory compatibilities as illustrated by figure 12:

Regulatory authority structures	**Regulatory principles**	
	Incompatible	**Compatible**
Incompatible	Chemicals	Engineering
Compatible	Food safety	Information and communication technology (ICT)

Figure 12: Regulatory compatibilities and case selection

Case selection based on Mill's methods has been criticised for the omission of potential causal explanatory variables and its inability to account for multiple causation. George and Bennett (2005: 153-160) and Goldthorpe (2000: 49) criticise that in reality cases are not as clearly organised as demanded by theory and may score differently on different explanatory variables. While this problem cannot be entirely eliminated, this book seeks to control for this risk by basing the case selection on a comprehensive synthesis of the preceding literature review. King, Keohane and Verba (1994) criticise that neither of Mill's methods can account for multiple causation as a variable is eliminated if it exerts

its influence only in combination with another variable. In particular if a variable exerts its influence only in combination with another variable, it will be eliminated by Mill's methods. This problem is at least mitigated through systematic process-tracing within the case studies (see chapter 5.2).

Selecting cooperation initiatives as sub-cases

The empirical chapters of this book will analyse the four selected sectoral regimes with regard to the constraints that different Commission actors face in choosing a strategy for regulatory cooperation with the US. Thus, it needs to look at specific initiatives of transatlantic regulatory cooperation for which Commission actors formed regulatory cooperation strategies.

The identification of such sub-cases needs to meet the following criteria: First, cooperation initiatives should cover all four selected sectoral case studies. Second, all cooperation initiatives should involve the mobilisation and consultation of societal actors to ensure positive outcomes on the independent variable 'societal mobilisation' and to allow an observation of the causal mechanism. Third, to test constraints on the formation of a regulatory cooperation strategy, the selection of cases should also reflect variation on the independent variable 'bureaucratic pressure'. The participation of individual Commission actors in line with the delineation of chapter 4.4.2 should therefore vary between the cooperation initiatives.

First, sub-cases should allow the observation of the formation of cooperation strategies in all selected sectoral case studies. This is necessary to keep the context of interaction constant for each sub-case across the sectoral regime case studies. Transatlantic regulatory cooperation between the EU and the US has begun in the early 1990s and since then taken place in different initiatives. Some initiatives were directly linked to other initiatives, creating mechanisms of preparation and oversight. Regulatory cooperation across various sectors was targeted in the New Transatlantic Agenda (NTA) that was linked to the Transatlantic Economic Partnership (TEP; Commission, 2001b; Commission, 2000b), in the High-Level Regulatory Cooperation Forum (HLRCF; Commission, 2005a) complemented by the Transatlantic Economic Council (TEC; Transatlantic Economic Council, 2007a) and in the Transatlantic Trade and Investment Partnership (TTIP) negotiations (Commission, 2013f). In the Positive Economic Agenda (PEA), in turn, regulatory cooperation was restricted to insurance, financial services, public procurement and food regulation (Commission, 2003e). In the TEP, regulatory cooperation was only addressed horizontally, i.e. through the development of Guidelines for Regulatory Cooperation (Commission, 2001b; Commission, 1998).

Table 14 (see next page) summarises the regulatory cooperation initiatives which have been established between the EU and the US. It shows that the HLRCF and the TEC were connected initiatives.

Name	Established	Topics	Organisation
New Transatlantic Agenda (NTA)	1995	Encompassing: 150 goals	Summits: biannual summits of EU and US leaders Senior Level Group: senior government officials from both sides Junior Task Force: technical-level interactions Agendas of different forums do not overlap
Transatlantic Economic Partnership (TEP)	1998	multilateral free trade in the agriculture, industrial tariffs, investment, competition and procurement general government guidelines for effective regulatory cooperation improving reciprocal access to regulatory procedures	Co-chaired by EU Trade Commissioner and US Trade Representative for Europe
EU-US Safe Harbour Agreement	2000	Data privacy	DG Justice US Department of Commerce
Positive Economic Agenda (PEA)	2002	regulatory cooperation in insurance, financial services, public procurement and food regulation	Created out of the TEP Technical-level interactions
Financial Market Regulatory Dialogue	2002	Financial services Financial market regulation	DG Internal Market US Securities and Exchange Commission
High-Level Regulatory Cooperation Forum (HLRCF)	2005	Various sectoral dialogues: insurance, financial services, public procurement food regulation, automobile safety, chemicals, radio and telecommunications	Technical-level interactions Senior-level support Meets ahead of TEC meetings
Transatlantic Economic Council (TEC)	2007	Regulatory convergence in 40 public policy areas, including intellectual property rights, security standards for international trade, regulatory obstacles to investment and financial markets or innovation and technology in health industries	Co-chaired by the Commissioner for Industry and the US Deputy National Security Advisor for International Economic Affairs oversees HLRCF
Transatlantic Trade and Investment Partnership (TTIP)	2013	Horizontal regulatory cooperation: regulatory coherence and Good Regulatory Practices Regulatory cooperation in food safety and animal and plant health (Sanitary and Phytosanitary Measures), engineering (including Technical Barriers to Trade), chemicals, cosmetics, medical devices pesticides, ICT, pharmaceuticals, textiles, automotive vehicles	DG Trade Technical DGs

Table 14: Regulatory cooperation initiatives between the EU and US

Second, to ensure positive outcomes on the independent variable 'societal mobilisation' and to be able to observe variation on this variable over time, the initiatives should involve the consultation and mobilisation of societal actors. Table 15 shows that societal actors from both the EU and the US were involved in both the NTA, the HLRCF and the TEC as well as the TTIP (Commission, 2014l; Transatlantic Economic Council, 2009a; Commission, 2005a; European Council, 1998).

Initiative	**Involvement of societal actors**
New Transatlantic Agenda (NTA)	Transatlantic Business Dialogue (TABD) Transatlantic Consumers Dialogue (TACD) Transatlantic Labour Dialogue (TALD) Transatlantic Environmental Dialogue (TAED) Transatlantic Legislator Dialogue (TALD)
High-Level Regulatory Cooperation Forum (HLRCF) / Transatlantic Economic Council (TEC)	Public consultation in 2004 Group of Advisors: Heads of the Transatlantic Business Council (TABC) and TACD Ad-hoc consultations: business associations, firms, NGOs and academia
Transatlantic Trade and Investment Partnership (TTIP)	Three public consultations Stakeholder meetings at TTIP negotiation rounds TTIP Advisory Council: 14 members from EU business associations and NGOs

Table 15: Involvement of societal actors in regulatory cooperation initiatives

Third, the initiatives should vary as regards the participation of different actors within the Commission to ensure variation in the independent variable 'bureaucratic pressure'. In the NTA, regulatory cooperation was allocated to the Junior Task Force and thus to officials from DGs on technical levels (Commission, 2001b; Commission, 2000b). In the HLRCF and in the TEC, the interactions between Commission and US technical officials were given oversight by senior officials and Commissioners (Transatlantic Economic Council, 2009; Transatlantic Economic Council, 2007a). The TTIP negotiations were prepared by a High-Level Working Group consisting in the EU mostly of officials from DG Trade (Inside US Trade, 2012d). The Commission position papers for the TTIP negotiations were then drafted under the joint lead of DG Trade and officials from the technical DGs (Inside US Trade, 2014f; Commission, 2013f).. The variation in the participation of actors within the Commission across the three cooperation initiatives which involved regulatory cooperation discussions in all sectors selected for the case studies of this book and mobilisation of societal actors can thus be summarised as follows:

This book therefore chooses the NTA, the HLRCF/TEC and the TTIP negotiations as sub-case studies within the sectoral case studies to apply the theoretical framework. Figure 13 shows that these sub-cases can be matched to the variation in bureaucratic participation as follows:

Cooperation Initiative	**NTA**	**HLRCF/TEC**	**TTIP (High-Level Working Group)**
Commission bureaucratic politics	Technical officials in Junior Task Force	Technical officials + Senior-level officials + Lead Commissioners	DG Trade (technical + senior-level) + Technical DG (technical + senior-level)

Figure 13: Variation in bureaucratic participation and case selection

The New Transatlantic Agenda (NTA) launched in 1995 was the first large-scale regulatory cooperation initiative between the EU and the US (Lütz, 2011; Pollack, 2005; Peterson et al, 2005; Peterson & Pollack, 2003; Pollack & Shaffer, 2001; Vogel, 1997; Kahler, 1995). It operated on the basis of biannual Summits of EU and US leaders, namely between the US President and a delegation of EU officials, consisting of the President of the Commission, the rotating Presidency of the Council of Ministers, and the High Representative of the EU for the Common Foreign and Security Policy. The Summit meetings were supplemented by meetings of the Senior-Level Group. Within the latter, high-level officials from both sides held regular meetings. The US Undersecretary of State and Commission Directors General were tasked to oversee the implementation of the work of the Senior-Level Group.

In addition, a Junior Task Force was established to plan targets for the work in regulatory policy cooperation (Lütz, 2011: 6). It comprised technical specialist officials from the Commission Directorates General and the corresponding departments of the US Administration. US regulatory agencies were not part of the process. The Junior Task Force was tasked to remove or manage "behind-the-border non-tariff barriers caused by domestic regulation of issues like product safety, food safety, data protection, and financial services" (Pollack, 2005: 905).

Lower-level EU and US technical officials met in issue-specific working groups and committees. Therein, they exchanged information and established "laundry lists" of issues for the annual Summits (Pollack, 2005: 900) with a view to the harmonisation and mutual recognition of each other's regulations. In support of this work, they consulted notably with the Transatlantic Business Dialogue (TABD)[63]. While in the first years of the NTA consultations often took place on very technical issues

[63] The TABD was an initiative of a group of EU and US chief executive officers (CEOs) which was established just before the launch of the NTA. The CEOs held annual meetings to identify areas for transatlantic cooperation. Moreover, the CEOs met annually with US government and Commission officials and the participants of the annual EU-US Summits. After early successes, the CEOs soon lost interest in the TABD, in particular after they felt that the "low-hanging fruits" had been picked and that neither the EU nor the US could implement the reforms

such as testing and certification procedures, the agenda broadened after 1998 to include issues such as e-commerce and the regulation of capital markets (Commission, 2000b; Commission, 1998). Moreover, officials consulted with the Transatlantic Consumers Dialogue (TACD)[64]. The NTA continued until 2004 when it had led to 33 bilateral, sectoral agreements and 49 dialogue structures at different technical and political levels (Peterson et al., 2005: 10).

The HLRCF was established in 2005 and was active until 2011 (Commission, 2013f). It was created after the adoption of the non-binding set of Guidelines for Regulatory Cooperation and Transparency in 2002 and the adoption of the Roadmaps for EU-US Regulatory Cooperation in 2004 and 2005 (Commission, 2005a; Commission, 2004b; Commission & US Trade Department, 2002). The latter identified priority areas for regulatory cooperation across a range of policy issues. Besides, it committed the EU and the US to establish the HLRCF. The HLRCF included senior-level officials from different Commission Directorates General and US regulatory agencies (Commission, 2005a). On the EU side, it was co-chaired by the Director General of DG Enterprise and the US side by the Associate Administrator of the Office of Information and Regulatory Affairs (OIRA) which is part of the Office of Management and Budget (OMB; Commission, 2006a). Its task was to monitor the progress of the cooperation priorities identified under the Roadmaps and set objectives for the future (Commission, 2006c). For the latter, senior officials met with societal actors in public sessions that were part of the bi-annual meetings (Commission, 2007a).

The TEC was established in parallel to the HLRCF at the 2007 US-EU Summit by President Bush, German Chancellor Merkel and Commission President Barroso (Transatlantic Economic Council, 2007a). It was a ministerial-level body to oversee, guide and accelerate implementation of the work under the HLRCF. Meetings took place bi-annually. The TEC was co-chaired by the EU Commissioner for Industry and the Director of the US National Economic Council (Transatlantic Economic Council, 2007a). On the EU side, the permanent members of the TEC in addition to the EU Co-chair were the Commissioners for External Relations, for Trade and for Internal Market and Services. On the US side, the Secretaries for Treasury, Commerce, Agriculture, Health and Human Services, Labour and the heads of many regulatory agencies attended the meetings (US Department of State, 2007). In 2007, only few Commissioners other than Verheugen supported the TEC process. In particular Environment Commissioner Dimas and Health Commissioner Vassiliou reportedly actively opposed the TEC and

which the TABD had proposed. Besides, as a result of the decreasing interest in the TABD among firms, the TABD after 2002 encountered problems to recruit CEOs for its rotating leadership. The TABD was subsequently relaunched, but sustaining the interest of CEOs still proved difficult as many CEOs struggled to see tangible benefits in the structured dialogue (Cowles, 2005).

[64]The TACD was a networking group for EU and US consumer organisations. Although it suffered from a number of financial difficulties and disagreements in its beginning during the mid-1990s, it succeeded to coordinate positions of EU and US consumer organisations and produced a number of position papers on important issues within its working groups. Authors point out, however, that frustration among members grew as they felt that they did not enjoy the same level of access to the US government or the Commission as members of the TABD (Peterson et al., 2005: 55).

refused to participate in TEC meetings despite the inclusion of "their" issues on the agenda. (US Department of State, 2007). Technical officials from Commission DGs, US government departments and regulatory agencies worked on issues identified for cooperation under the TEC in the time between meetings (Transatlantic Economic Council, 2008). Technical officials, could, however, not make policy decisions (Transatlantic Economic Council, 2009). During TEC meetings, both political representatives and technical officials also met with societal actors, notably the Transatlantic Business Council (TABC), which replaced the former TABD, and the TACD.

The TEC included six pillars, i.e. regulatory cooperation, capital markets integration, investment, innovation, IPR protection and transport security (Transatlantic Economic Council, 2010a). Under the regulatory cooperation pillar, the Commissioners intended to address regulatory impediments in the food, drug, chemical, automotive, and electrical/electronic sectors. TEC members dropped regulatory cooperation issues from the agenda after US Cabinet members criticised that technical issues were not worth of Cabinet-level focus (Transatlantic Economic Council, 2011a; US Department of State, 2009b). Since then, regulatory cooperation shifted to the innovation pillar (Transatlantic Economic Council, 2010a). With the launch of the TTIP negotiations, ministerial-level meetings within the TEC structure stopped (Commission, 2013f).

The TTIP negotiations were prepared by a High-Level Working Group on Jobs and Growth (HLWG) which was chaired by the US Trade Representative and the EU Trade Commissioner (Inside US Trade, 2012d). The HLWG was tasked to identify measures to enhance trade and investment between the EU and the US. To this purpose, it elaborated a report (High-Level Working Group, 2013). DG Trade proposed regulatory cooperation as a major instrument to achieve the increase in trade and investment. In order to identify issues for regulatory cooperation, DG Trade launched a public consultation in 2012, asking societal actors to submit comments and “concrete ideas” how to align regulations in specific economic sectors (Inside US Trade, 2012a). The results of this consultation entered the Report of the High-Level Working Group which was endorsed by both Commission President Barroso and US President Obama in February 2013 (High-Level Working Group, 2013). With the endorsement of the Report, the TTIP negotiations were formally launched. The first round of TTIP negotiations was held in July 2013. 15 negotiation rounds took place until October 2016 (Commission, 2016i). Since then, negotiations are frozen.

The TTIP negotiations were chaired by the EU Trade Commissioner and the US Trade Representative. The negotiations were divided into three equal pillars: market access, regulatory cooperation, and rules. Under the regulatory cooperation pillar, EU and US officials discussed regulatory cooperation in eleven sectors: TBT, SPS, chemicals, cosmetics, engineering, medical devices, pesticides, ICT, pharmaceuticals, textiles and vehicles (Commission, 2013f). Moreover, they negotiated overarching, so-called ‘horizontal’, regulatory cooperation provisions which should apply to all sectors. On the EU side, lead negotiators were both officials from DG Trade and officials from technical DGs (Commission,

2015b). Since the fourth round, both EU and US negotiators met with societal actors at the margins of each negotiation round in stakeholder meetings in which societal actors could present their priorities in brief public presentations (Commission, 2014n)[65].

In sum, this sub-section has selected the cases which will be used and examined in the empirical analysis of the subsequent chapter. It has briefly outlined the reasons why the EU and the Commission are an appropriate object to study the formation of a regulatory cooperation. It has then argued why the US is a 'least likely' case for EU regulators to require bureaucratic pressure in order to initiate the formation of a bilateral regulatory cooperation strategy. Four industry sectoral regimes have then been selected with a view to discard potential alternative explanations and to ensure variation on the independent variable 2, 'regulatory compatibilities'. In a next step, three regulatory cooperation initiatives between the EU and the US have been defined as sub-cases, ensuring variation on the independent variable 1, 'bureaucratic pressure'. Besides, they have been selected to safeguard the possibility of positive outcomes on the independent variable 3, 'societal mobilisation' for all three sub-cases.

5.2. Data analysis

The empirical case studies of this book examine the four selected sectoral regimes by using qualitative case study methods. I argue that case study methods are suitable to understand the complex and dynamic interactions that influence processes of strategy formation in a complex institutional setting such as the EU.

The main research question of this book '*What constrains the Commission's formation and choice of a bilateral regulatory cooperation strategy*?' presupposes that it closely examines the processes of strategy formation that connect the variables of its theoretical framework. It aims at establishing the causal mechanism, understood as "the processes and intervening variables through which an explanatory variable exerts a causal effect on an outcome variable" (Bennett 1997). The processes that influence the strategy formation are crucial to understand the constraints on the Commission's pursuit of bilateral regulatory cooperation. A case study offers the conduct of a detailed and deep analysis.

To examine the collected data, this book relies both on within-case and between-case analysis. Mahoney (2005: 389) distinguishes both based on the level of aggregation. While between-case analysis compares variables between cases in an aggregate, within-case analysis compares within cases in disaggregation

[65] In line with the rules for the conduct of trade negotiations in the EU that have described in chapter 4.4.1, DG Trade and other negotiating DGs also informed Council representatives in the TPC as well as members of the European Parliament in the INTA Committee after each negotiation round and consulted them before upcoming rounds (Commission, 2014, Commission, 2015).

(Mahoney 2005: 389). The sub-cases within the four sectoral case studies are analysed separately to show the interplay of the different independent and dependent variables.

Between-case analysis seeks to establish the causal relationship between the independent variable 'regulatory compatibilities' and the dependent variable. The sectoral regime cases have been selected based on the method of difference to realise a maximum variance on the independent variable 'regulatory compatibilities'. The between-case analysis focuses on finding the distinctive patterns that lead to differences in the constraints on the bilateral regulatory cooperation strategies at which the Commission aims (Yin 2009: 156-160). The generalisability of these findings increases because this book has employed several case studies. As noted in the previous section, the selection of cases based on the method of difference especially enhances the generalisability of the results.

Within-case analyses employ methods with which "hypotheses are evaluated by elucidating intervening processes" (Mahoney 2005: 17). George and Bennett (2005) give pattern-matching, causal narratives and process-tracing as examples of methods for within-case analyses. Among these, process-tracing is arguably the most frequently employed one to establish causal relationships between variables. Process-tracing allows increasing the number of observations and understanding the causal mechanism which links variation in explanatory factors to observed outcomes. It "attempts to uncover what stimuli the actors attend to, the decision process that makes use of these stimuli to arrive at decisions, the actual behaviour that then occurs, the effect of various institutional arrangements on attention, processing, and behaviour, and the effect of other variables of interest on attention, processing, and behaviour (George & McKeown, 1985: 35; in Dür, 2007: 189). The advantage of process-tracing is that it does not only allow determine correlations between variables, but also establishing that there is a causal relationship between the variables. Process-tracing enables inferences about how certain o9utcomes come to happen (Beach and Pedersen 2013: 2). This book thus uses process-tracing for the within-case analyses. It relies on process-tracing notably for the TEC and TTIP sub-cases in which bureaucratic processes are theorised to shape the formation of regulatory cooperation strategies[66].

Beach and Pedersen (2013) distinguish theory-testing, theory-building, and explaining outcome variants of process-tracing. As the goal of this book is to test the causal mechanism theorised by the Inter-relational Institutionalism, it relies on the theory-testing variant of process-tracing. The causal mechanism linking the variables was derived from previous theoretical literature. The use of process-tracing shall thus examine if the theorised mechanism is verified by the empirical evidence.

[66] The difficulty to obtain sufficiently detailed data on the processes of strategy formation during the NTA restricts the use of systematic process-tracing for the first sub-case. At the time, the discretion of technical officials in the formation of specific cooperation strategies and the consequently less complex decision-making processes also make the use of process-tracing less suitable for the first sub-cases.

The combination of between-case and within-case analysis allows this book to first test the hypotheses on the integrated reasoning of the New Interdependence Approach and actor-centred institutionalism and then use the cross-case synthesis of the within-case analyses to substantiate and confirm the findings.

5.3. Data collection

To make inferences, case study methods require reliable data. Data collection refers to methods for collecting reliable evidence, e.g. participant observation, randomised experiments, content analysis or sample surveys (King, Keohane & Verba 1994: 51). The choice of a data collection method needs to reflect the choice of the method of data analysis. For the use of process-tracing in case study research, Bennett and Elman state that "the researcher examines histories, archival documents, interview transcripts, and other sources to see whether the causal process (…) is in fact evident" (2007: 6). This implies that all data that can help to elucidate the constraints relevant for the strategy formation process of the Commission is relevant. The formation of regulatory cooperation strategies is not only a recent process, but has been relevant since the inception of the transatlantic regulatory cooperation in the early 1990s. This book thus needs to rely on both recent and historical documents to understand the constraints considered in the strategy formation process. The data collection combines document analysis with expert interviews. This section will discuss both document analysis and expert interviewing.

Document analysis

One of the methods frequently applied in case study research is document analysis (King, Keohane & Verba, 1994: 51). Document analysis is also an important source of collecting reliable data. The next paragraphs discuss how and which documents were collected for the within-case analyses of this book. They adopt the frequent distinction between primary and secondary sources. A primary source is a document which is created during the process examined whereas a secondary source constitutes an analysis or interpretation of a primary source.

This book is interested in all primary and secondary sources that help it trace the decision-making process for the formation of a strategy in the Commission. This involves documents from first drafts of issues for cooperation written by technical officials in a Commission DG to the adoption of negotiating texts in the College of Commissioners and conclusions of EU-US working groups or Summit meetings. Relevant primary sources are both public documents of the Commission that refer to the strategy that the Commission seeks to adopt in regulatory dialogues with the US and non-public documents that offer background information and explanations of the Commission's choice of strategy.

Public primary documents can be mostly obtained from the website of the Commission. For the Commission's formation of a strategy for regulatory cooperation, the most important public documents are annual Trade Barriers Reports, roadmaps for regulatory cooperation dialogues, the position papers for regulatory cooperation in individual sectors in the TTIP negotiations, textual proposals for the TTIP negotiations and EU-US Summit conclusions. Trade Barriers Reports indicate which regulatory measures the Commission considers as particularly important for potential discussion in regulatory cooperation. The contrast of EU-US Summit conclusions with Trade Barriers Reports and internal Commission documents reveals how and which issues the Commission translated from the definition of trade barriers into demands for regulatory cooperation.

Non-public primary documents of the Commissions which were produced as a preparation or in the context of regulatory cooperation discussions are equally essential. Examples for internal documents are meeting reports, drafts for inter-service consultations and strategic notes sent by the Commission to the Trade Policy Committee in the Council. Usually, internal documents are not accessible to the public and need to be retrieved by researchers by filing an Access to Document request under Regulation 1049/2001. Many internal documents on the TTIP negotiations have, however, been requested by NGOs, especially Greenpeace and the Corporate Europe Observatory, under the Regulation and have subsequently been released to the public on the websites of these organisations. Confidential documents have also been leaked by Members of the European Parliament and members of national parliaments, notably the German Bundestag, and have been placed on platforms such as Correctiv.org. Internal Commission documents on the HLRCF and TEC have been released by the platform Wikileaks. The empirical chapters will refer to these documents.

Secondary sources analysing or commenting the Commission's engagement in regulatory cooperation comprise several kinds of documents. This book obtained essential information from academics and policy-observers following the Commission's pursuit of regulatory cooperation. Important sources were policy papers published by Brussels-based think tanks, e.g. the TTIP series published by the Centre of European Policy Studies. Position papers published by societal actors offered background information on the content of regulations and the design of implementation procedures in the EU and the US as perceived by societal actors. Their use in this book is nonetheless important as descriptions in these position papers also informed Commission officials and offered background knowledge to their decision-making behaviour. Insights into discussions among Commission DGs were further retrieved from articles by the specialist journal 'Inside US Trade'. Information on decision-making in the Commission and its behaviour in meetings with US officials could also be obtained from classified reports of the US government that were released on Wikileaks. Other sources include academic journal articles which examine regulatory cooperation notably within the NTA and regulatory cooperation

between the EU and other third countries[67]. A crucial source were also legal science articles on EU and US regulatory frameworks and policy papers commissioned by the European Commission, notably the Ecorys Impact Assessment studies, as well as International Trade (INTA) Committee of the EP. Secondary sources are referenced in the empirical chapters.

Expert interviews

Case study research further often requires additional 'insider knowledge' that cannot be obtained from document analysis alone, but relies on expert interviews (Cohen, 1999; Leech, 2002). Following Manheim and Rich (1995: 161), 'experts' are understood as those individuals who were directly involved in the process under examination and who have first-hand knowledge that can help to answer the research questions (Manheim & Rich 1995: 161-2). A person is interviewed because of her knowledge of an issue. As this book concentrates on the decision-making that takes place within the Commission, process-tracing needs to consider the views and experiences of the officials who are involved in the formation of the regulatory cooperation strategy. The goal of expert interviews is to 'assist in reconstructing some event or discerning a pattern in specific behaviors' (Manheim & Rich, 1995: 162). Expert interviews are often used in case study research relying on process-tracing because they increase the number of observations and allow shedding light on the actions and decisions that establish the chain of events producing a decision and thus elucidate the functioning of the causal mechanism (Tansey, 2007: 765-66). An interview can thus gain access to information that is otherwise not available. They also enable assuming an 'insider perspective' and gain insights on the importance of individual actors. Moreover, expert interviews allow triangulating inferences that were drawn from document analysis.

By assuming an 'insider perspective', the expert interviews helped structure the research in two ways: First, they allowed better understanding the relevance of regulatory cooperation as a topic. The initial objective of this study was to understand why the EU only reduced some non-tariff trade barriers in its trade liberalisation efforts, but left others in place. Early interviews with both government officials and business representatives indicated that this question was both too broad and abstract to be effectively addressed through a dissertation. Instead, interviewees drew attention to the regulatory cooperation efforts that the Commission was undertaking in the context of the TTIP negotiations and before. Moreover, they stressed that it was much more important to understand the political dynamics that were underlying these efforts than the patterns of business mobilisation shaping traditional trade negotiations.

[67] For a discussion of the use of previous academic literature as observations in process-tracing see (Leuffen, 2007: 157)

Expert interviews thus helped make the research question both more precise and direct it to dynamics which were considered as relevant by policy experts.

Second, the expert interviews guided the search for empirical information already available elsewhere. Little of the information obtained through expert interviews is new or unavailable. Interviews, however, show a researcher what information to look for to understand an issue or a process. Moreover, the interviews clarified which officials and associations are ultimately closely involved in the consultation for and the drafting of position papers and thus the formation of the EU's regulatory cooperation strategy. An internet search of these people helped find documents, including often detailed minutes, of meetings they attended, positions they took in interviews with other researchers or journalists, or even personal or scientific accounts of their reflections on regulatory cooperation interactions in the past.

Frequently employed interview techniques are standardised questionnaires, semi-structured and non-structured, open question interviews (Leech, 2002). Standardised interviews frequently measure political attitudes or specific political behaviour such as voting. Non-structured interviews often take the form of a conversation in which the role of the researcher is comparable to that of an ethnographer. This book builds on semi-structured interviews as a method to carry out expert interviews. Semi-structured interviews aim at grasping the experiences, opinions and perspectives of interviewees. They give interviewees the opportunity to elaborate certain points and share personal reflections and interpretations of an event or process (Marsh & Stoker, 2010: 138). Moreover, interviewees share the relative weight they attach to individual factors for a decision. Despite its embedding in rational-choice literature, opinions and perceptions are important in institutionalist accounts. The technical details, but also the personal observations, reflections and experiences of interviewees help to reconstruct the considerations that led to the development of a specific regulatory cooperation strategy. Semi-structured interviews are thus a suitable technique for the conduct of expert interviews for this book.

Semi-structured interviews rely on an interview guide of building block questions that interviewees respond to freely and in a non-standardised way. The interviewer may change and adapt the order of questions to the interview context and handle the interview guide flexibly. Besides, during the interview the interviewee may add further information or suggest additional topics. Responses of interviewees are not coded or analysed by statistical means.

The interview guides were constructed according to a comparable structure for all interviews even if questions were adapted to both the role and the likely knowledge of interviewees. The following box offers general examples of questions that were asked in most of the interviews (for full interview guides see Annex 2).

- Which processes have contributed to the formation of the Commission's regulatory cooperation strategy in …?
- How were you involved in these processes? How has the agenda of … been set?
- Why did you participate in these processes? What has been your interest?
- Please describe the US regulatory approach on …. How do you think that it differs from the EU approach on this issue?
- Why did you decide to take position … on issue … ?
- Have you changed your position later?
- Which actors in the Commission have contributed to … [inter-service consultations]?
- What have been the positions of these actors?
- How do you assess your ability to influence these processes?
- How have the EP/the Council/societal actors influenced the Commission's decision?
- What other influences have there been?

Many of these questions address sensitive information on intra-institutional relations and relations with US regulators. To ensure that responses would constitute reliable information, interviewees were assured both in the initial contact with the interview request and at the beginning of the interview that their answers would be treated anonymously. To further demonstrate interviewees that their responses would be handled with care, the interviews were not recorded. Instead, extensive notes were taken during the interview. A list of all interviews is provided in the annex. To protect the identity of interviewees, only their affiliation is indicated (Commission / societal actor).

The selection of interviewees for semi-structured expert interviews is crucial. Unlike other interview techniques, expert interviews are not based on random sampling. Instead, interviewees are selected deliberately because of their knowledge. To identify adequate interviewees, this study relied on purposive sampling and snowball sampling (Tansey, 2007: 770). For purposive sampling, research was carried out to identify the units and officials that were responsible for regulatory cooperation within a sector. Rather than selecting several interviewees from the same DG, the selection of interviewees focused on ensuring interviews with officials from all DGs that contributed to the formation of the strategy in the relevant processes. Interviewees were also identified and contacted through the participation in two Stakeholder Dialogues on 24 February 2016 and 13 July 2016 at the margins of the TTIP negotiations. Moreover, through snowball sampling interviewees were asked to suggest persons that could be contacted for the research project.

The number of interviewees who are sufficiently knowledgeable of the processes that influence the formation of the Commission's strategy on regulatory cooperation as well as the factors and technical

issues determining its choice of strategy is limited. In many cases, snowball sampling illustrated that it was enough to speak to one person within a DG to understand how this DG contributed to the Commission's strategy. This study concentrated on obtaining interviews with all relevant interviewees. Substantial time was spent on ensuring that all relevant interviewees could be contacted. In many cases, the frequent travels of Commission officials between Brussels and Washington during the TTIP negotiations made it difficult to contact officials on an issue that was in itself already politically highly sensitive. Moreover, due to the rotation of officials between DGs, EU institutions and even between the Commission and private organisations it proved difficult in some cases to identify interviewees through either purposive or snowball sampling that had knowledge of the Commission's behaviour in regulatory cooperation initiatives before the TTIP negotiations. In a considerable number of cases, however, officials had been working on an issue, even if not always in the same position, for more than 10 years and freely shared their impressions and recollections of regulatory cooperation under the TEC and before.

Almost all interviews were conducted in person. Only in three cases was the interview conducted over the phone. Nonetheless, the level of depth attained in particular on a technically complex and politically sensitive issue was higher in the interviews that were held in person. No conversation was shorter than 30 minutes and interviews lasted mainly between 60 and 120 minutes. In three cases, the interviews lasted three hours and interview partners continued sharing their perceptions and insights after all topics on the interview guide had been addressed.

It proved essential for the conduct of the interviews to demonstrate both professionality and expertise towards interview partners. Several interview partners shared their discontent that despite anonymity requests, previous researchers had not only publicly attributed statements to individual interview partners, but also cited them incorrectly or changed crucial elements of statements. While all interview partners contacted for this book signalled their openness to conduct an interview and their interest in the topic, creating an atmosphere of trust proved a challenge. The decision to take extensive notes rather than recording the conversation noticeably eased the atmosphere in a number of cases. Moreover, demonstrating expertise in the subject was a crucial factor to establishing this trust. Knowing the meaning of 'SDoC' or of a 'Notified Body' was as important as using regionalisation or audits in the appropriate context. In one interview, mistaking terms caused the concentration of the interviewee to drop and required considerable effort to win back the attention of the interviewee. Each interview thus required substantial preparation. Besides, interviewees who had been described as particularly knowledgeable or insightful on regulatory cooperation across sectors were only at the later stage of the research to ensure that they could be approached with sufficient expertise.

The reliance on expert interviews to ascertain the importance of the independent variables must be put into perspective. Extrapolating their relative weight relied on building a 'narrative' or story that linked the insights and perceptions shared by interviewees. The constraints identified in this way rely on

observation. The actual preference of an actor is difficult to identify. Yet, it seems that there are no better research methods to approach this question. Sending out standardised questionnaires would be subject to the same measurement problems in this regard as observations based on expert interviews and document analysis. To ensure the reliability of the responses shared by interviewees, statements of interviewees were triangulated with responses collected in interviews with member state representatives and societal actors. The selection of interviewees for triangulation also followed purposive and snowball sampling. Interviews with societal actors concentrated on representatives of firms and business associations as both purposive and snowball sampling indicated that these were more likely to have the technical knowledge of EU and US regulations and implementation procedures. This technical knowledge was considered as necessary to be able to understand and reconstruct the Commission's decision to choose one rather another strategy regarding a specific issue.

Rules for identifying the number of necessary and sufficient expert interviews are less clear-cut than for standardised interviews. An indicator for the number of interviews to be conducted became the knowledge of the subject. In the last interview conducted for each sector, the responses of interviewees could be often anticipated. Moreover, interviewees confirmed that the most relevant interviewees had been identified and contacted.

In sum, 26 interviews were carried out between 2015 and 2017. Table 3 lists the interviews broken down to governance regimes, government and business representatives, and their level of activity, i.e. at the EU or member state-level (for the full list of interview see Annex 1).

	Chemicals		**Engineering**		**Food**		**ICT**		**Horizontal**		**Sum**
	Gov.	**Business**	**Gov.**	**Business**	**Gov.**	**Business**	**Gov.**	**Business**	**Gov.**	**Business**	
EU	1	1	2	1	2	2	2	2	1	2	16
MS		1	1	1		1			1	5	10
Sum	**3**		**5**		**5**		**4**		**9**		**26**

Table 16: Breakdown of interviews

Nonetheless, in the context of strategy formation for regulatory cooperation a few indicators can be developed. First, early interviews with member state representatives confirmed that strategy formation on regulatory cooperation occurs mainly at the EU level. While member states' support and endorsement of regulatory cooperation is essential for the pursuit of regulatory cooperation by the Commission and its success, member states are usually little involved in the details of strategy formation as long as it involves issues on which EU-level rules already exist. This reduced the necessity to speak to a large number of member state representatives. Second, the number of Commission officials working on regulatory cooperation on a specific issue is relatively small- in many cases position papers are drafted and meetings are attended by two or three people. They are well connected and maintain close working relationships. Quickly, interview partners confirmed that important actors shaping the strategy formation process had been contacted.

5.4. Summary

This chapter has discussed the methodology of this book to employ a case study-based research design. The book combines case selection according to a least-likely logic with the method of difference. Out of eight possible third countries with which the EU has pursued bilateral regulatory cooperation in the past, the United States was selected as a least-likely case for the influence of bureaucratic politics. The method of difference was then applied to select cases based on variations on the independent variable. The cases were selected to ensure variation on the compatibility and incompatibility of regulatory authority structures in combination with the compatibility and incompatibility of regulatory principles while at the same time holding rival explanatory factors constant to discard potential alternative explanations. As a result, four industry sectoral regimes were selected out of a population of 20 industry sectors for in-depth empirical examination in case studies: chemicals, engineering (mechanical and electrical safety), food safety and information and communications technology. Within each case study, three sub-cases were defined to ensure variation on the independent variable 'bureaucratic pressure'. Out of five potential transatlantic regulatory cooperation initiatives, three were selected in line with variation on the independent variable 'bureaucratic pressure' between politico-administrative leadership by DG Trade, politico-administrative leadership by the lead technical DG and no politico-administrative leadership.

The empirical analysis employs with-in case analysis. The main method of data analysis is process-tracing of the strategy formation within the selected case studies. Through a close examination of the processes that lead to the formation of regulatory cooperation strategy, the causal relationship between the factors identified in the theoretical framework is established. A cross-case synthesis compares the findings for the case studies.

Besides, the chapter has discussed the two main data collection methods employed by this book, i.e. document analysis and expert interviews, and has argued why they allow drawing inference from the material collected. The document analysis relies on public and non-public primary documents, including previously unavailable material leaked by NGOs, and secondary documents, including think tank reports, academic studies and policy documents by specialist journals such as 'Inside US Trade'. Expert interviews have built on a semi-structured approach with interviewees selected non-representatively based on their expertise. Document analysis and expert interviews are used to triangulate information on the Commission's choice and formation of a bilateral regulatory cooperation strategy.

The subsequent empirical analysis applies the 'inter-relational institutionalist' framework on the Commission's strategy choice in the industry sectoral regimes chemicals (chapter 6.1), engineering (chapter 6.2), food / food safety (chapter 6.3) and information and communications technology (chapter 6.4). These sectors have been addressed in most of the transatlantic regulatory cooperation initiatives and are also particularly important for the EU's engagement in regulatory cooperation due to their large volumes of intra-industry trade between the EU and the US as well as other third countries. The depth and dimension of regulatory cooperation that the Commission aims at with the US can thus also have repercussions on the setting of global rules and standards beyond the transatlantic relationship. The empirical analysis will show how regulatory compatibilities constrain the Commission's choice of the depth and dimension of regulatory cooperation and bureaucratic politics influences the formation of the regulatory cooperation strategy. The empirical chapters will therefore concentrate on the behaviour of officials within both internal and external constraints.

6. European Commission strategies in transatlantic regulatory cooperation

The main hypothesis proposed by this book is that the choice of a regulatory cooperation strategy is constrained by the compatibility of both regulatory authority structures and regulatory principles between a domestic and a foreign jurisdiction. This hypothesis has been incorporated into an integrative framework, the Inter-relational Institutionalism, which also clarifies the role of and relationship between different political and societal actors. Based on the selection of case studies that has been elaborated in the previous chapter, this chapter puts the explanatory power of the Inter-relational Institutionalism to test. It presents case studies for four industry sectoral regimes that were selected based on maximum variation in the distribution of regulatory case studies. As noted in this previous chapter, this book does not assume that regulatory authority structures and underlying regulatory principles are homogenous for all regulatory policies and implementation procedures that govern a sectoral regime. The case studies rather seek to maximise the likelihood that all possible combinations of regulatory compatibilities and their effect on the constraint of the choice of a bilateral regulatory cooperation strategy can be observed. Expectations for the distribution of regulatory compatibilities between the EU and the US in the chosen sectoral regime case studies have been formed on the basis of previous analyses.

To look at the effect of regulatory incompatibilities for both regulatory authority structures and regulatory principles, this chapter first examines the Commission's choice of regulatory cooperation strategies towards the US in the chemicals regulatory regime (chapter 6.1.). The second case study, transatlantic engineering cooperation, investigates the constraining effects of incompatible regulatory authority structures under compatible regulatory principles (chapter 6.2.). To examine the constraint that exert compatible regulatory authority structures, but incompatible regulatory principles, the third case study looks at the Commission's choice of regulatory cooperation strategies towards the US in the food safety regulatory regime (chapter 6.3). Lastly, the fourth case study, transatlantic ICT cooperation analyses the constraints on the choice of a regulatory cooperation strategies where both regulatory authority structures and regulatory principles in the EU and the US are compatible (chapter 6.4.).

Each case study is developed analogously to facilitate the comparability of the analyses and findings across the four case studies. A first sub-section outlines the scope of the corresponding regulatory regime and identifies major issues for regulation and implementation. Moreover, it presents the level of transatlantic trade flows to prove that goods and services falling within the sectoral regulatory regimes are subject to high levels of intra-industry trade and to show that the EU and US economies are interdependent as regards the regulation of sectoral regime. It also presents major societal actors that shape decision-making within the sectoral regime.

A second sub-section summarises the agreements that have already been taken through international regulatory cooperation within the given regulatory regime. This information is intended to clarify the

context in which Commission officials choose bilateral regulatory cooperation strategies and helps identify and exclude issues within a given regulatory regimes on which Commission regulatory officials may seek to cooperate with their US counterparts.

A third sub-section introduces the distribution of authority structures and identifies the principles to which the Commission adheres in the EU. This sub-section only examines EU-level regulations and implementation procedures to ensure that the Commission has in principle authority to act and cooperate on an issue through transatlantic regulatory cooperation. The presentation of the regulatory regimes does not aim at a comprehensive discussion of the underlying legal framework, but presents the regulatory regime in a reduced, focused manner to identify and indicate regulatory authority structures and regulatory principles. The discussion of the regulatory regime is thus directed at the operationalisation of the independent variable 2 of this book and the preparation of the subsequent analysis of regulatory cooperation strategies. The description of the regulatory regime is based on the status at the time of writing to enable comprehensiveness. As sectoral regulatory regimes evolve, new regulatory policies and implementation procedures build on decisions and experiences of past policies and procedures. The decision to focus the description of the regulatory regime at the time of writing reflects the assumption of this book that changes to individual regulatory policies and implementation procedures rarely overthrow the fundamental authority structures and principles that govern a sectoral regime as a whole.

The fourth sub-section of each case study contrasts the regulatory regime of the EU with the regulatory regime of the US for each selected sectoral regime. Again, the objective of this sub-section is not to offer a comprehensive discussion of the US framework in question. On the contrary, the presentation is directed at an immediate contrast of the EU and US approaches. US regulatory policies and implementation procedures are presented in light of their compatibility with the EU approaches. For the reasons laid down in the previous paragraph, the analysis concentrates on the contrast of EU and US regulatory regimes at the time of writing. The contrast of regimes is intended to elucidate issues on which the Commission may choose to cooperate along the strategies in line with distribution of regulatory compatibilities.

A fifth sub-section formulates expectations for the Commission's choice of regulatory cooperation strategies towards the US in the given sectoral regime. These expectations offer the specific operationalisation of hypothesis 2 for each of the case studies. Expectations are on the one hand formulated with regard to the 'maximum' regulatory cooperation strategy that the Commission is constrained to choose based on the distribution of regulatory compatibilities. On the other hand, they name specific issues within each regulatory regime on which the Commission may cooperate with the US, based on the prior contrast of regulatory regimes.

The sixth sub-section of each case study presents the analysis of the Commission's choice of regulatory cooperation strategies. This part is divided into three sub-parts in line with the definition of sub-cases explained in chapter 5.1. The process-tracing in this sub-section identifies the sequence of activities and

behavioural steps that lead to the formation of a given regulatory cooperation strategy and thus clarifies the relationship between decisions of regulatory officials and the mobilisation of societal actors. Moreover, it presents interview evidence from the perspective of both Commission officials and societal actors on the rationale of Commission officials to aim at cooperation on a specific issue along the chosen strategy.

A seventh sub-section discusses the findings of the empirical analysis of the Commission's choice of regulatory cooperation strategies on specific issues over time. On the one hand, the discussion examines the influence of bureaucratic pressure (IV1) and societal mobilisation (IV3) in each case study on the initiation and formation of a regulatory cooperation strategy. On the other hand, it investigates if the choice of a regulatory cooperation strategy on a specific issue is in line with the expectation that has been developed from the distribution of regulatory compatibilities in the fifth sub-section. A last paragraph in each case study casts a look at potential transatlantic regulatory cooperation within the sectoral regime in the future.

6.1. Commission strategies in transatlantic chemicals cooperation

This section proposes a case study for which existing literature implies that both regulatory authority structures and regulatory principles in the EU and US are incompatible. It is thus a case in which the Commission can be expected to pursue 'information exchange'. This case study covers the Commission's choice of regulatory cooperation strategies in transatlantic regulatory cooperation in the chemicals regime.

6.1.1. Introduction

Chemicals regulations broadly aim at two distinct objectives: the assessment of risks of chemicals to measures to human health and the environment and the management of these risks. Risk management measures pertain to questions of the authorisation or restriction of chemicals. They are subject to regulatory policies as they determine the substances which can be sold and marketed in a jurisdiction and have implications for the level of safety, environmental and public health protection. Policy issues also pertaining to risk management are the classification and labelling of chemicals. The labelling and classification of a chemicals often entails legal effects with regard to the ability to market a chemical and the ability to use a chemical in certain products. Debates have emerged if and to what extent specific substances, e.g. endocrine disruptors, or the use of substances in specific and new applications, e.g. nanotechnology, require distinct regulatory specifications and what these specifications should be. Risk assessment measures, in turn, refer to questions of the evaluation and testing of chemicals. As these are measures that are applied to ascertain and verify if substances fall under the restrictions established by regulatory policies, risk assessment measures fall under the category of 'implementation procedures' defined in chapter 3.1.3.

Due to the internationalisation of the chemicals industry, chemicals regulations extend beyond domestic regulatory boundaries. Chemicals producers and users thus face strong rule overlap and conflicting regulatory requirements as they sell or buy substances across jurisdictional boundaries. In 2013, 25% of safety data dossiers submitted to the EU chemicals database was submitted by non-EU firms (Biedenkopf, 2015: 125). In the transatlantic relationship, Francois et al. (2013) estimate that regulatory differences amount to trade costs of 19.1% for EU exports to the US and 13.6% for US exports to the EU. Only a part of these barriers are tariffs, which between the EU and the US range between 3% and 6%, but for many chemical substances they are already zero. The remaining non-tariff measures reflect

regulatory differences between the EU and the US[68]. Figure 14 shows the development of trade flows between the EU and the US in the chemicals sector between 2006 and 2016[69].

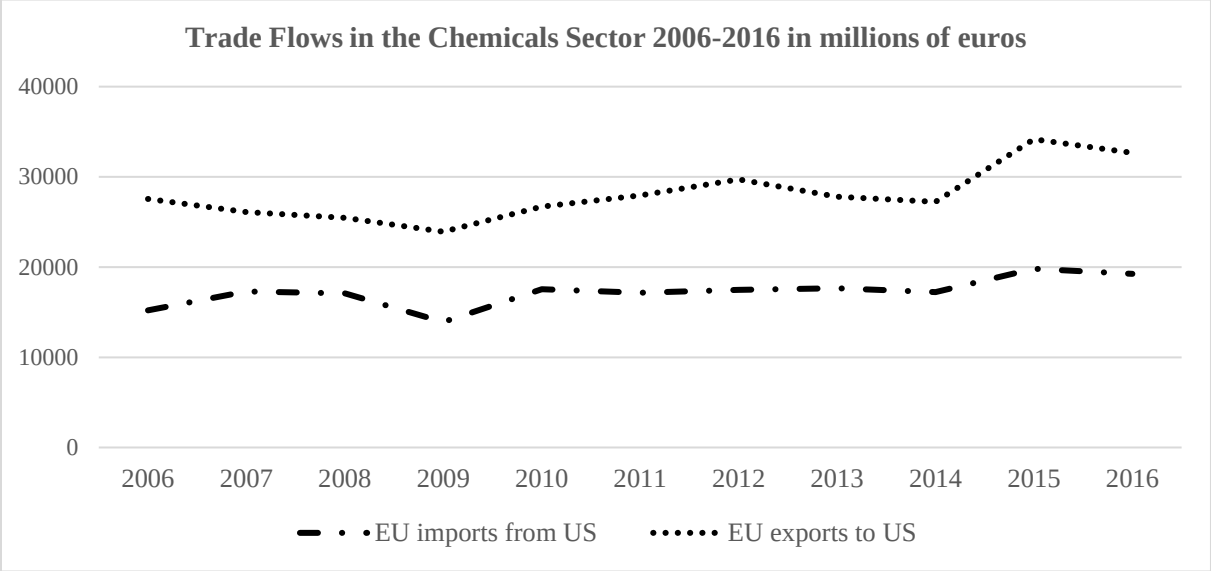


Figure 14: Trade Flows in the Chemicals Sector 2006-2016

Numerous societal actors engage in chemicals regulations. On the business side, lobbying is crucially shaped by large multinational companies which also organise in business associations, notably the EU-level chemicals association Cefic. Due to their transnational operations and their spread of production across global value chains, multinational chemicals firms often organise in both domestic and foreign business associations, including the US business association American Chemistry Council (ACC) at the same time. Chemicals production and trade is, however, also involves the non-negligible participation of SMEs. Due to the risks chemicals potentially present to both the environment and public health, chemicals regulations and their implementation procedures have involved the mobilisation and participation of many NGOs and CSOs, including Chemical Watch, Greenpeace, Friends of the Earth and the EU lead consumer organisation BEUC.

This chapter proceeds as follows: It first outlines the distribution of regulatory authority structures and principles in the EU chemicals regulatory framework and then outlines divergences of the US regulatory framework to the distribution of regulatory authority structures and principles in the EU. It then formulates expectations on the Commission's choice of regulatory cooperation strategies with the US, based on the compatibilities of EU-US regulatory authority structures and principles. The subsequent sections present the regulatory cooperation strategies the Commission pursued in the three phases of

[68] Important barriers to trade are also due to characteristics of substances themselves, including challenges to transport substances over longer distances or explosion risks.
[69] The choice of the time period reflects data availability constraints (Eurostat, 2017).

transatlantic regulatory cooperation delineated in chapter 6.3. and contrast them with the mobilisation of societal actors. The Commission's choice of regulatory cooperation strategy is then contrasted with the formulated expectations and the patterns of societal mobilisation. The final section concludes.

6.1.2. International chemicals cooperation

This section briefly summarises the subjects of regulatory cooperation in international organisations. It offers background and contextual information for the adoption of regulatory principles in both the EU and the US. In line with the theoretical framework developed in chapters 3 and.4, international organisations are, however, not expected to have causal influence on the choice of strategies in bilateral regulatory cooperation.

Regulatory cooperation on chemicals in international organisations has especially concentrated on regulatory within the United Nations Subcommittee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) of the United Nations Economic and Social Council (ECOSOC) Committees and the OECD. Regulatory cooperation on chemicals within UN Committees and the OECD has addressed risk management, including the classification and labelling of chemicals, as well as risk assessment[70].

With regard to risk management, the OECD Secretariat has pushed to seek and define best practices and new methods for risk management, and develop methodologies and joint action with regard to specific chemicals. For chemicals produced in high volumes, the OECD has established a programme in which companies report health and environment information for specific chemicals to the OECD(OECD, 2013a). The EU has accepted that data submitted to the OECD can in principle be used for the registration of chemicals under REACH (Quick, 2011: 281). Yet, it has not changed its methods of risk management in light of risk management methods proposed and elaborated by the OECD. The US has not (yet) accepted data submitted to the OECD as a basis for recommendations to ban substances.

Regulatory cooperation with regard to the classification and labelling of chemicals has been pursued by both the EU and the US through several UN committees. A Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) was initiated by the United Nations Conference on Environment and Development in 1992 as an initiative to promote harmonised criteria for the classification of chemicals according to different hazard categories for health, physical and environmental hazards. The standards were subsequently negotiated and endorsed within different UN committees in the early 2000s, encouraging UN members to implement them by 2008. The respective GHS document, however, only consists of recommendations for states and lays out a 'building block

[70] More informal regulatory cooperation also occurs within the Strategic Approach to International Chemicals Management (Zeitlin, 2011).

approach', which therefore allows differential implementation of the Globally Harmonised System in different hazard classes and categories (Quick, 2011: 277). The EU has followed this 'building block approach', implementing the GHS where it corresponds to its own previous classification of chemicals. It sought to prevent a provision making the implementation of the entire GHS mandatory. The US also sought to prevent making the GHS mandatory, emphasising instead that the adoption of the GHS should remain voluntary (Interview 2).

Concerning risk assessment, regulatory cooperation has been pursued notably by the EU within the OECD under its chemical safety programme(OECD, 2013a). It has supported the OECD in the development of Test Guidelines for the testing of chemicals. Moreover, it has promoted an agreement on principles of Good Laboratory Practices. The development of Test Guidelines for the testing of chemicals and the agreement on principles of Good Laboratory Practices facilitated a binding agreement among OECD members on the Mutual Acceptance of Data (Quick, 2008). The agreement on the Mutual Acceptance of Data obliges signatories to accept chemical safety data from other OECD states and additional seven countries (e.g. India, Brazil, Singapore, South Africa), given that the safety data have been generated based on OECD Test Guidelines and OECD Good Laboratory Practices (OECD, 2013a).

Subsequently, efforts notably of the EU and the US have consisted in determining possibilities of 'burden-sharing' among OECD members notably on the assessment of 'high-production-volume' chemicals. Moreover, the OECD Secretariat has proposed discussions on a harmonisation of industry dossiers for chemicals and review reports for pesticides (Elliott & Pelkmans, 2015: 17).

Although regulatory cooperation within the OECD covers "an impressive range of chemical safety issues" (Quick, 2011: 279), it has not been able to resolve the differences between the EU and the US both with regard to risk management and risk assessment. "Regulatory cooperation in the OECD has overall been good" (Interview 1) and "the US and the EU have been leading in this [the OECD] work" (Elliott & Pelkmans, 2015: 15). However, both the US and the EU have restricted regulatory cooperation through the OECD, albeit to different extents on different issues (OECD, 2013a). Important obstacles persist in the implementation of the OECD Test Guidelines, partly also due to constraints in the capacity of test laboratories in some OECD member states (Interview 1). Overall, regulatory cooperation in an international organisation essentially presupposes that the EU and the US reach an agreement among each other before they can advance regulatory cooperation through the OECD (Interview 1).

6.1.3. EU chemicals regime

This section outlines the distribution of regulatory authority structures and principles in the EU chemicals regulatory framework, both with respect to the regulatory policies anchored in the chemicals framework REACH as well as the Classification, Labelling and Packaging Regulation and the implementation procedures established by REACH.

The development of an EU regulatory framework for the risk management of chemicals reflected Council conclusions from the late 1990s, tasking the Commission to elaborate a coherent chemicals legislative framework. After intense discussions in both the Council and the Parliament, the Regulation, to become known as REACH, was adopted by both the Council and the Parliament in late 2006. REACH centralises EU chemicals regulation, leading authors emphasise that the regulatory framework of the EU is very 'coherent' (Elliott & Pelkmans, 2015: 2)[71]. REACH establishes a three-step approach to placing chemical substances on the EU market: registration, evaluation and authorisation. Under registration, manufacturers and importers of existing and new chemicals have to submit data on the properties of chemicals and their uses in a database with the European Chemicals Agency (ECHA) before they can bring them to the market. This data is used during evaluation to assess the potential risks of chemical substances to human health and the environment. Evaluation follows a prioritisation approach. Authorisation by the Commission is then necessary for substances which have been found during evaluation to pose risks before they can be placed onto the market. Beside formulating the regulatory policy framework for chemicals, REACH establishes the corresponding implementation procedures. It establishes e.g. the type of information that needs to be submitted for substance registration. It further establishes the Community Rolling Action Plan (CoRAP) which specifies that the ECHA and member states need to define risk-based criteria for the selection of substances for prioritised evaluation (Biedenkopf, 2015: 110). Risk management also addresses the classification and labelling of chemicals. On the latter, the EU adopted the Classification, Labelling and Packaging Regulation in 2008, Regulation(EC)1272/2008, which implemented the UN Global Harmonised System(GHS). It implements the UN GHS according to the 'building-block approach', i.e. in hazard classes and categories that were compatible with existing EU classification and labelling rules, but deviated where either UN GHS classes and categories are not part of the EU system or where the UN GHS does not cover categories of the EU system (Quick, 2011: 278)

Under REACH, risk management falls within the authority of the Commission, i.e. the DGs Environment and Grow. The Commission decides on applications for the authorisation of chemicals

[71] While REACH centralises chemicals regulation at the EU-level, Biedenkopf (2015: 108) argues that it reaches beyond EU borders in three ways: First, it extends internal EU processes to non-EU actors. Second, the data concerning the intrinsic properties of chemical substances and possible safer alternatives generated through REACH procedures can be used by non-EU regulators in their own domestic policies. Third, REACH constitutes a model of chemicals regulation that can exert external effects on policy-making processes outside the EU.

through comitology procedures[72] as REACH gives the Commission the authority to authorise or ban substances. Moreover, the Commission has the authority to impose restrictions on chemicals, including but not only for 'substances of very high concern'. In deciding on applications for authorisations, the Commission takes into account the scientific opinion of the European Chemicals Agency (ECHA)'s Committee for Risk Assessment. REACH thus centralises authority for regulatory policies, i.e. risk management for chemicals, at the EU level.

Risk management follows the regulatory principle of the 'precautionary principle'. The Commission has defined that it applies the precautionary principle "where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection" (Commission, 2000: 5). The application of the precautionary principle in the EU is strongly revealed in three aspects, two of which relate to REACH. Reflecting the precautionary principle, REACH first establishes a general obligation to register all substances above a production or sales volume of 1t (with a few exceptions)[73]. Unless producers or importers register substances in the ECHA database, they cannot bring them to the market. Second, the Commission requires that it needs to authorise substances for which the evaluation has indicated potential risks to human health and the environment. In line with the precautionary principle, REACH thus stipulates that substances which may potentially entail hazard are banned from the market unless they are authorised (Elliott & Pelkmans, 2015; Vogel, 2012). For these 'substances of very high concern' (SVHCs), i.e. substances which are 'carcinogenic, mutagenic or toxic to reproduction' or 'persistent organic polluters', REACH demands that they need not only be properly controlled, but also, where economically and technically feasible, be progressively replaced with alternative substances. Besides, REACH specifies that SVHCs can only be authorised if they provide an overall benefit to society. SVHCs are not authorised as substances, but on a firm basis. Third, the classification of substances entails immediate legal consequences. The classification of a substance as a SVHC immediately restricts its use in certain products (regardless of societal implications), e.g. biocides or pesticides. The regulatory principle for chemicals regulatory policies in the EU is thus the precautionary principle.

Risk assessment is coordinated by the EU-level agency ECHA. ECHA also approves testing proposals and adopts the CoRAP. Yet, risk assessments are conducted by member state authorities under a joint division of labour, so that one member state authority is responsible for the evaluation of one specific substance. Member state authorities do not generate test data themselves, but rely on the data submitted by firms. REACH specifies that firms need to submit safety test data to the ECHA database on the internal properties of substances during the registration of chemicals. The distribution of authority for

[72] The authorisation of substances is conducted under comitology procedures with the scrutiny of the EP. Comitology procedures are e.g. also used to set rules on test methods (Biedenkopf, 2015: 113).
[73] This is called the 'no data, no market' approach (Biedenkopf, 2015: 109).

implementation procedures, i.e. risk assessment, in turn, is thus shared between 'government' authorities and private actors and therefore non-centralised.

Risk assessment follows the proportionality principle. Rather than requiring the full test data sheets, it only requires the submission of so-called 'robust summaries' that do not contain potentially confidential business information e.g. on the exact composition of a substance. With the submission of data, firms are required to form 'Substance Information Exchange Forums'. It implies that firms need to form consortia in which firms registering the same substance regulate the allocation of data ownership and costs between them (Kommerskollegium, 2015: 50). This does not exclude that the ECHA demands also complete data sheets in exceptional cases. According to REACH, the ECHA can also request complete data sheets for individual chemical substances and has in a limited number of cases also used this right in the past (on average in one or two cases per year; Interview 1). As a regulatory principle of the implementation procedures, the EU thus applies the proportionality principle.

6.1.4. Contrast of the EU and US chemicals regimes

This section summarises divergences between the EU and US regulatory frameworks for chemicals. It demonstrates that differences exist both with regard to the distribution of regulatory authority structures and regulatory principles. The regulation of chemicals in the US is mostly[74] shaped by the US Toxic Substances Control Act (TSCA) adopted in 1974 and amended in 2015.

In the US, chemicals regulation largely lies within the authority of the Environmental Protection Agency (EPA) (for regulations aiming at environmental protection), but chemicals are also controlled and regulated by the Occupational Safety and Health Agency (OSHA; for regulations aiming at safety at the workplace) and the Food and Drug Administration (FDA) (Interview 1). The authority of the US regulatory agencies is limited. Although the EPA has legal powers to restrict or ban a chemical substance if it poses an unreasonable risk to human health or the environment, its de facto ability to do so is limited. To prohibit or restrict a substance, the EPA needs to demonstrate that this is the least restrictive measure. Moreover, restrictions or prohibitions of chemical substances are subject to legal review. Courts have narrowly interpreted whether a restriction or prohibition is least restrictive. As a result, the EPA de facto in most cases only issues recommendations (Interview 1). Recommendations of the US agencies to restrict substances are subject to legal review. For this reason, authors note that the EPA has in the past effectively struggled to 'ban' hazardous substances (Schwarzman & Wilson, 2011), citing the inability of the EPA to ban asbestos due to company lawsuits under legal review as an example of a certain

[74] In practice, US regulatory agencies use a number of regulatory acts and administrative procedures to restrict the use of chemical substances (Elliott & Pelkmans, 2015).

'under-regulation' (Elliott & Pelkmans, 2015). Under the TSCA, the EPA has only restricted the use of six chemical substances since 1976 (Kommerskollegium, 1976: 47).

The amendment of the TSCA arguably enhances the authority of the EPA to restrict hazardous substances. (Interview 1). According to the amendment, the EPA can request further test data in order to decide on a recommendation to ban or restrict of substances, thus bringing the TSCA closer to REACH (Interview 2). Still, the subject of restrictions to legal review means that the EPA has only limited regulatory authority. Regulatory authority on regulatory policies in the US is thus non-centralised. The distribution of regulatory authority structures for regulatory policies in the chemicals sector between the EU and the US is thus incompatible.

For risk management, i.e. the adoption of regulatory policies, the EPA and other US agencies apply the science and risk principle (Elliott & Pelkmans, 2015; Vogel, 2012). This shows in two important policy aspects: First, US agencies do not have a general registration obligation for substances (Renn & Elliott, 2011). Second, chemicals are allowed for production and marketing unless the EPA or another agency has issued a recommendation to restrict a substance (Schwarzman & Wilson, 2011). If the EPA finds that a chemical presents a risk to human health or the environment, it can adopt regulatory restrictions on the production or marketing of a chemical to eliminate the risk. This is a juxtaposition of the EU's regulatory principle requiring the authorisation of a substance before it is allowed to be produced or sold. As a similarity of principles to the EU, the classification of chemicals also entails legal consequences in the US, i.e. restricting their use in certain products or environments, e.g. at the work place (Schwarzman & Wilson, 2011). The legal consequences of classifications for certain uses differ, though. As classifications may restrict the use of substances of certain products or contexts, the implementation of the international classification scheme (UN GHS) in the US is partial and differs from the EU (Interview 2). Notably, the UN GHS has been implemented by the OSHA, but not by the EPA (Elliott & Pelkmans, 2015). Yet, the application of the science and risk principle in the US creates immediate conflict with the precautionary principle in the EU. The EPA only proposes a restriction for a chemical substance if scientific evidence indicates safety risks for human health or the environment (Vogel, 2012). The Commission can, however, restrict a chemical even if scientific evidence does not clearly indicate safety risks, but is only inconclusive (Interview 3). The regulatory principles of the EU and the US for chemicals regulatory policies are thus incompatible.

The EPA does not delegate the submission of test data to private actors, i.e. firms. Instead, the EPA can determine which test data it uses to evaluate the safety of chemicals[75].If the EPA believes that a substance may pose an unreasonable risk, it can require that the substance be tested. If test data is unavailable, the EPA can mandate firms to conduct tests (EPA, 2017). It can also conduct tests itself to determine the safety risks of chemicals (Interview 2). However, if the EPA wants to restrict a substance,

[75] The EU's reliance on firm safety data is cited by Naiki (2010) as a hurdle for Japanese authorities to adopt REACH. He cites that Japanese authorities did not trust the validity of safety data submitted by producers.

it needs to present the data itself which show that a substance poses heavy risk. To require further information from firms, the EPA needs to demonstrate the risk first. This implies that the EPA must also generate test data itself if companies are unwilling to share data (Kommerskollegium, 2015: 49). Regulatory authority for implementation procedures in the US is thus centralised. As regulatory authority for implementation procedures in the EU is non-centralised, the distribution of regulatory authority structures in the EU and the US incompatible.

For risk assessment, the EPA request complete safety data sheets for the evaluation of the safety risks of chemicals (Interview 1).[76] These safety data sheets contain full hazard and exposure assessments (EPA, 2017). As a side-effect of the submission of full safety data sheets, firms can demand that the EPA treats their data as confidential business information (Interview 2). This contrasts with the treatment of risk assessment by the ECHA which relies on 'robust summaries'. The regulatory principles for implementation procedures in the EU and the US are thus also incompatible.

If the different regulatory systems in the EU and the US offer different levels of consumer health and environmental protection, is nonetheless subject to debate. Some observers both from the EU and the US attribute a higher level of protection to the EU system, as a likely consequence of the higher coherence of the EU's REACH framework and underlining the inability of the EPA to restrict certain hazardous substances (Vogel, 2012; Schwarzman & Wilson, 2011). Others question that there are principle divergences beyond product- and case-specific differences (Elliott & Pelkmans, 2015: 15). The latter refer to the voluntary withdrawals of chemicals by firms under EPA pressure and the effects of tough liability cases on the marketing of chemicals in the US as well as potential 'over-regulation' under REACH without benefits for environmental protection or consumer health. While there is a lack of systemic data comparing levels of protection, studies analysing the regulatory stringency for specific chemical substances find that the level of protection offered in either the EU or the US differs for individual substances rather than systemically across the two jurisdictions (Renn & Elliott, 2011).

[76] The reason for this difference in data policy appears to mostly be linked to differences in resources of EU authorities and the EPA. Indeed, observers argue that the ECHA contents itself with robust summaries rather than complete data sheets because of its limited staff resources.

Figure 15 summarises the contrast of the EU and US chemicals regulatory regimes.

Dimension	Regulatory instrument	Authority distribution	EU	US
Regulatory policies	**Legislation**		REACH Classification, Labelling and Packaging Regulation	Toxic Substances Control Act
	Regulations **Standards**	**Centralised**	<u>Precautionary principle</u> - Authorisation of substances that have been found to pose risks - Restrictions, authorisation of SVHCs on a firm basis, - Legal guillotine clause for specific classifications of chemicals: restricted use in all products	
		Non-centralised		<u>Science and risk principle</u> - no general registration requirement - marketing of substances unless recommendation to restrict - recommendation to restrict requires conclusive scientific evidence - No legal guillotine effects of classifications: restrictions for certain uses and applications
Implementation procedures		**Centralised**		<u>Full data sets:</u> - Risk assessment: Submission of complete safety data sheets
		Non-centralised	<u>Proportionality principle</u> - Risk assessment: Submission of robust summaries	

Figure 15: Contrast of EU and US chemicals regulatory regimes

In sum, this sub-section has compared the distribution of regulatory authority structures and regulatory principles in the EU and the US. It has concluded that the distribution of regulatory authority is incompatible as assessment authority is allocated to the EPA in the US whereas it is allocated to firms in the EU. At the same time, the Commission has authority to authorise substances in the EU whereas the EPA does not have such authority. Moreover, the previous sub-section has summarised that the EU and US follow incompatible regulatory principles, both related to regulatory policies and implementation procedures. Whereas the EU follows the precautionary principle in cases of scientific uncertainty, the US strictly adheres to the scientific risk principle. With regard to assessment, the EU follows a proportionality principle for data submissions whereas the US relies on full data sheets.

6.1.5. Expectations: Commission strategies in transatlantic chemicals cooperation

Based on the contrast of the chemicals regulatory regimes in the EU and the US and the distribution of regulatory compatibilities, this sub-section formulates expectations for Commission strategies on transatlantic chemicals cooperation. These expectations operationalise the hypothesis derived on the influence of regulatory compatibilities on the constraints of a choice of a regulatory cooperation strategy that has been presented in chapter 4.3.2. As bureaucratic pressure within the Commission has already been operationalised in chapter 4.4. and the presence of bureaucratic pressure across the three regulatory cooperation initiatives has been outlined in chapter 5.1., this sub-section will not re-formulate expectations for the influence of bureaucratic pressure. Besides, societal actor mobilisation across the three selected transatlantic regulatory cooperation initiatives has also been outlined in chapter 5.1 and will not restated in this sub-section.

Both in the EU and the US the authorisation or ban of chemicals is subject to legislation adopted by legislatures. As changes to legislation require approval by legislatures and thus lie beyond the regulatory authority of both EU and US regulators, it should be expected that the Commission does not pursue changes to the authorisation or ban of chemicals under REACH and the TSCA[77]. Besides, as the regulatory principles underlying the authorisation or ban of chemicals in the EU and the US are incompatible, it should be expected that the Commission does not pursue an alignment of chemicals authorisations. Likewise, as the classification of chemicals entails conflicting legal implications in the EU and the US, it should be expected that the Commission does not pursue an alignment of chemicals classifications. Moreover, given that the authority of the Commission and the EPA on the authorisation or restriction of chemicals is incompatible, the Commission should neither pursue an 'equivalence' of authorisation decisions. At the same time, as the distribution of regulatory authority on implementation procedures in the EU and the US is incompatible, the Commission should also not pursue an alignment of testing procedures beyond the work that has been carried out in the OECD. Likewise, as regulatory principles for implementation procedures in the EU and the US are incompatible, the Commission should also not choose a strategy to mutual recognise safety data sheets.

Instead, given the incompatible distribution of both regulatory principles and authority structures, the Commission can be expected to choose a strategy with the aim of 'information exchange'. This 'information exchange' should target implementation procedures, i.e. testing procedures and the provision of safety test data requirements, as well as new and emerging issues for regulatory policies.

[77] These expectations do not make statements about the adoption of REACH elements by non-EU actors through learning, emulation or diffusion. Biedenkopf (2015: 128) offers examples of learning and emulation from US Congressional hearings, enhanced data transparency of the EPA as well as the adoption of REACH elements by authorities in Japan and South Korea. Yet, under these processes, regulatory conflicts often do not fully disappear as other jurisdictions do not copy REACH or other EU Regulations one-by-one (Heyvaert, 2009).

6.1.6. Commission strategies in transatlantic chemicals cooperation

This section lays down the Commission's choice of regulatory cooperation strategies during the three regulatory cooperation initiatives selected in chapter 5.1.

New Transatlantic Agenda (NTA)

At the launch the NTA, the initiative of DG Trade to establish the Transatlantic Business Dialogue (TABD) mobilised in particular the EU and US chemicals industries (Quick, 2007). The TABD presented comprehensive proposals for regulatory cooperation entailing both 'equivalence' and an 'alignment of implementation procedures' (see below). Far-reaching joint proposals submitted by EU and US chemicals industry under the TABD raised demands for the Commission to pursue 'equivalence' and an 'alignment of implementation procedures'. The TABD proposed 'equivalence' with regard to low-risk polymers, suggesting that the Commission and its US counterparts negotiate an 'equivalence' agreement (Quick, 2007). Until the Commission presented its White Paper for a EU-level chemicals regulation, both EU and US chemicals industries considered a mutual recognition of the functional 'equivalence' of EU and US regulatory frameworks as in principle possible (Quick, 2011: 254; TABD: 2000). Furthermore, the TABD tabled proposals on the application and use of the classification and labelling of chemicals (Quick, 2007; TABD, 1996). With regard to an 'alignment of implementation procedures', the TABD put forward that the EU and the US should implement the previous OECD Agreements on Good Laboratory Practices and the Mutual Acceptance of Data and negotiate a Mutual Recognition Assessment for test data (Quick, 2011: 250; TABD: 1996). Moreover, it suggested negotiations over Conditional 'equivalence' Agreements on risk assessment. Industry thus sought to align implementation procedures by enhancing mutual understanding and acceptance of the methods used for hazard and risk assessment (Elliott & Pelkmans, 2015: 11).

However, Commission officials from DG Environment and DG Enterprise did not take up these proposals. The administrative and political leadership of both DGs was reluctant to endorse regulatory cooperation in the chemicals sector because it wanted to concentrate administrative resources on the domestic adoption of a coherent EU-level chemicals policy that should replace the previous fragmented system (Quick, 2007; Pelkmans, 2005). In the elaboration of REACH, the leadership of DG Environment and DG Enterprise put only limited emphasis on avoiding trade frictions with the US. One observer notes that the Commission "adopted its [REACH] proposal in full knowledge that it would

violate the cooperation requirements contained in the Guidelines on Regulatory Cooperation" (Quick, 2011: 260)[78].

Commission officials, however, took up demands of the TABD to include exceptions for low-risk chemicals in line with US exceptions at least to some extent into (Elliott & Pelkmans, 2015: 10). Besides, they took into consideration the demand of the TABD that REACH should not a require registration of polymers if component monomers have already been registered and agreed to exceptions for Research & Development chemicals (Quick, 2011: 262). Above all, however, both DGs wanted to protect the EU's regulatory framework and arguably reinforce regulatory competition by adopting a domestic framework that would enhance the regulatory capacity of the Commission.

Despite an "intensive lobbying battle" of the US Administration to influence the design of REACH (Interview 1), the political and administrative leadership of DG Environment and DG Enterprise sought to protect and defend the regulatory autonomy of the Commission. Through the adoption of a coherent and stringent regulatory framework, the Commission crucially wanted to enhance its capacity to shape the design of chemicals regulatory frameworks worldwide (Interview 3). Any regulatory cooperation with the US should not obstruct the ability of the Commission to develop a regulatory framework that would allow it to develop high regulatory capacity. The Commission therefore pursued a strategy of 'non-cooperation'.

At the same time, the administrative and political leadership of DG Enterprise raised that officials improve their understanding of the US regulatory framework for chemicals, the TSCA. To achieve the first, Commission officials invited contributions from the TABD to demonstrate 'compatibilities' between the EU and US chemicals frameworks. Yet, the Commission did not pursue any of the recommendations of the TABD. Quick (2011: 259) criticises that by 2002, none of the TABD recommendations had been implemented. However, DG Environment, DG Enterprise maintained occasional dialogues with the US EPA and pursued, to some extent, 'information exchange', including on envisaged legislative projects. These exchanges were, however, not sustained by demands of the administrative and leadership of either DG. The pursuit of 'information exchange' remained sporadic and "coincidental" (Interview 1).

High-Level Regulatory Cooperation Forum (HLRCF)/Transatlantic Economic Council (TEC)

With the launch of the High-Level Regulator Cooperation Forum, Commissioner Verheugen, the new Commissioner for Industry and Entrepreneurship, emphasised chemicals policy as a priority sector for

[78] The Guidelines on Regulatory Cooperation were adopted by the EU and the US in 2002. They demand regular consultation, exchange of data and information as well as mutual information on envisaged regulations.

regulatory cooperation with the US (US Department of State, 2007; Commission, 2005a). Supported by the administrative leadership of DG Enterprise, Verheugen proposed the institutionalisation of informal exchanges between officials DG Environment, DG Enterprise, the ECHA and the EPA (US Departmetn of State, 2007; Commission, 2006a; Commission, 2005a). Officials should use these informal dialogues to inform each other about legislative and regulatory activities of past months and outline envisaged legislative projects. Moreover, officials should exchange information with regard to specific questions, including the implementation of adopted policies and possible approaches to emerging issues. The Roadmap on Regulatory Cooperation under the HRLCF further outlines the establishment of staff exchanges between Commission officials and officials of the EPA (Commission, 2005b). Starting with 2006, the Commission DGs used these informal dialogues primarily to defend their regulatory policies in REACH. The US EPA and USTR heavily criticised the Commission for its regulatory policies adopted in REACH, arguing they would cause heavy trade frictions between the US and the EU, and sought to push the Commission to align REACH with provisions contained in the TSCA (Interview 1, Interview 2, Interview 3)[79]. Officials from both DG Environment and DG Enterprise responded to the US criticism by defending EU policies and explaining to the EPA why it preferred to maintain regulatory competition (US Department of State, 2007b). They emphasised that REACH did not discriminate against foreign producers because both domestic and foreign producers had to register substances above a production volume of 1t in the ECHA database (Commission, 2007d; Interview 1). At the same time, DG Enterprise and DG Environment wanted to explain the logic and functioning of REACH to their US counterparts with the aim to raise acceptance of the EU approach in the US. In 2007, Commission officials admitted that REACH was flawed in its treatment of imported cosmetic ingredients and offered a pragmatic remedy to mitigate this issue (US Department of State, 2007).

Besides, given the adoption of REACH by the Council and the EP, Commissioner Verheugen encouraged the use of the HLRCF to promote regulatory cooperation in a sector that was characterised by high volumes of intra-industry trade (Quick, 2007). Technical officials in DG Enterprise were therefore tasked to evaluate opportunities for bilateral regulatory cooperation. Both DGs agreed that neither strategies subsumed ‘regulatory approximation’ or ‘equivalence’ of authorisations of chemicals should be the objective (US Department of State, 2008a). This was mainly explained with the divergence of the regulatory approaches encoded in REACH and the US TSCA (Quick, 2011). This initiated consultations especially with the newly established Transatlantic Business Council (TABC) that replaced the TABD.

The TABC lowered its level of ambition and limited itself on demanding an implementation of the UN GHS for the classification and labelling of chemicals and the implementation of the OECD Agreement

[79] The USTR even considered lodging a complaint against REACH under the WTO, but gave up these considerations in 2007 in order not to escalate the discussions with the EU (Interview 2).

on the Mutual Acceptance of Data (Quick, 2007). At the same time, the TABC concentrated on criticising the newly adopted REACH (Interview 1).

Under the continued demands for regulatory cooperation by Commissioner Verheugen and the administrative leadership of DG Enterprise, technical officials took up the proposals of the TABC on both classification and labelling under the UN GHS and on Good Laboratory Practices under the OECD (Commission, 2007b). Neither Commission officials from DG Enterprise nor DG Environment nor their administrative and political leaderships, however, chose to make any commitments on specific outcomes beyond the objectives set within the respective international organisation (Commission, 2007c). Regulatory cooperation should not constrain the autonomy of the Commission to take its own decisions (Interview 2). In particular, the DGs agreed not to pursue an 'equivalence' of US and EU classifications and labels because of the divergent regulatory responsibilities of the EPA and the Commission, but to maintain the existing 'building block approach' of the UN GHS (Interview 2). Besides, the EPA had made clear that it did not want to change its classification system along the guidelines of the UN GHS because it reflected different procedural approaches (Interview 2). Moreover, neither Verheugen nor the administrative leadership of DG Enterprise proposed to pursue attempts to 'align implementation procedures', e.g. through the development of common test methods. Although these issues remained on the agenda of exchanges in the High-Level Regulatory Cooperation Forum, an internal report of the US Department of State from 2009 correspondingly notes "that the discussion of pure chemical issues was […] quick" (US Department of State, 2009a).

When the Transatlantic Economic Council (TEC) was launched in 2007, Commissioner Verheugen again sought to use his role as Co-Chair of the TEC to promote regulatory cooperation on chemicals (Transatlantic Economic Council, 2007b; US Department of State, 2007a). Alongside the 'information exchange' promoted on the ongoing work in the UN on classification and labelling and the OECD work on mutual acceptance of test data, the Commissioner proposed to explore opportunities for regulatory cooperation under the 'innovation' pillar of the TEC (US Department of State, 2007a). Rather than concentrating regulatory cooperation on existing issues, the identification of emerging issues should facilitate cooperation work (US Department of State, 2007b).

With the task to identify issues for regulatory cooperation on emerging issues, officials between DG Enterprise and DG Environment coordinated and identified the development of common risk assessment methodologies for manufactured nanomaterials. Commissioner Verheugen insisted that the Commission should use the TEC to cooperate with the EPA on this issue (Commission, 2007b). Regulatory cooperation with the EPA on an emerging issue should entail a double benefit for the Commission: First, it should contribute to establish procedures that would be considered as appropriate by societal actors in both the EU and the US. The joint development of common assessment methodologies would thus be an instrument to ensure that these would not be subject to special interests in either the EU or the US. Second, it should avoid unnecessary trade barriers and thus enhance business opportunities for chemicals

firms (Commission, 2007b; (Interview 3). DG Enterprise confirmed that nanotechnology would be a sufficiently relevant issue to raise the interest of high-level politicians interacting in the TEC (Interview 1). Exchanges among officials and bureaucratic support by the administrative and political leadership notably of DG Enterprise should help to develop common understandings of methodologies how the safety risks of manufactured nanomaterials could be assessed (Commission, 2007c). If pursued successfully, the development of common test methodologies for manufactured nanomaterials would have led to an 'alignment of implementation procedures'.

The EPA initiated rule-making procedures on the development of common test methodologies for manufactured nanomaterials in 2008. As the notice-and-comment procedure and the subsequent evaluation by EPA officials consumed considerable time, officials in DG Enterprise and DG Environment suggested moving ahead with the development of EU procedures in order not to leave this issue unregulated (Interview 1). The EPA insisted that it wanted to engage with the Commission on this only after its domestic consultations with other agencies on this issue had been completed (Transatlantic Economic Council, 2008). The slow response of the EPA arguably also caused also Commissioner Verheugen to lose interest in regulatory cooperation on chemicals and concentrate available resources elsewhere (US Department of State, 2008a; Interview 2).

After both the political and administrative leadership of DG Enterprise had lost most of their interest in regulatory cooperation with the US on chemicals issues, the administrative and political leadership only raised a few issues at the margins of the annual HLRCF and TEC meetings (Transatlantic Economic Council, 2009; Transatlantic Economic Council, 2008b). In 2009, DG Environment, DG Enterprise initiated discussions with EPA to discuss hazardous substances. (US Department of State, 2009b). Moreover, they encouraged the formalisation of dialogues between the ECHA and EPA. This led to the signature of a Memorandum of Understanding between the ECHA and the EPA in 2010, promoting data and 'information exchange' (ECHA, 2010). Subsequently, officials of both agencies have met once or twice per year, often through video conferences, and exchanged information on which issues they were currently working (Interview 1).

Officials from DG Environment and DG Enterprise maintained 'information exchanges' with the EPA, but did not pursue strategies of 'alignment of implementation procedures'. Beside the 'alignment of implementation procedures' outlined above, this alignment could have potentially also consisted in an alignment of the databases of the ECHA and the EPA through which they each give access to test data to stakeholders (Interview 1). Yet, to protect their autonomy, both the ECHA and the EPA chose to establish their respective platforms in a parallel process with little or no coordination among each other (Interview 2). Besides, the EPA had argued the test data submitted by EU firms as sufficient to take decisions on recommendations for bans of chemical substances (Interview 2). Given this difference in regulatory approaches, DG Enterprise did not consider an alignment of ECHA and EPA databases as sufficiently important to mobilise political resources and push the ECHA to coordinate the establishment

of its platform with the EPA. As a result, data on identical substances disseminated through the website of either the ECHA or the EPA is not available through the platform of the other (Interview 1). The 'information exchanges' which the Commission chose to pursue with the EPA remained informal and non-binding. While both sides were interested in learning about regulatory priorities of the other side, neither the EPA nor DG Environment or Enterprise did not want to make any commitments to use the dialogues to elaborate common work programmes or proposals for joint projects to safeguard their autonomy. Moreover, given different regulatory approaches, possibilities for policy cooperation were considered very small (Interview 1).

To sum up, the Commission used the interactions in the framework of the TEC during the second phase to promote 'information exchange' between Commission DGs, the ECHA and their US counterparts, notably the EPA. It hoped that this 'information exchange' would promote an 'alignment of implementation procedures' within the OECD. The Commission did, however, not promote an 'alignment of implementation procedures' in direct interactions with US officials. At the same time, it defended regulatory competition over the policies shaping the chemicals regulatory frameworks in both jurisdictions and pushed back US demands for 'regulatory alignment' in line with the US TSCA.

Transatlantic Trade and Investment Partnership (TTIP)

With the drafting of the High-Level Working Group Report in 2012 that prepared the TTIP negotiations, the 'lead' in the Commission on regulatory cooperation shifted to DG Trade (Inside US Trade, 2012a). Especially Trade Commissioner de Gucht believed that regulatory cooperation would be an instrument to strengthen the global influence of the EU and facilitate trade in previously unaddressed areas (Interview 3). He therefore tasked officials in DG Trade to identify sectors in which economic gains from regulatory cooperation would be greatest (Interview 1). The focus of DG Trade on chemicals was thus motivated by the search for sectors in which the trading volume was perceived to be particularly large (Interview 1). Chemicals is thus mentioned as one of three priority sectors for regulatory cooperation in the High-Level Working Group Report that the Commission adopted with the USTR in 2012 (High-Level Working Group, 2013).

The focus of Trade Commissioner de Gucht and DG Trade on exploring opportunities for regulatory cooperation in the chemicals sector shaped the public consultation for the launch of trade negotiations with the US. The EU and US industry associations Cefic and ACC were "fast" in elaborating a joint position paper that they presented even before the launch of the public consultation (Interview 1). The Cefic-ACC paper suggests cooperation through an 'alignment of implementation procedures' and 'information exchange'. With regard to 'information exchange', Cefic and ACC put emphasis on "common prioritisation principles and burden-sharing for assessments of high-priority chemicals"

(Cefic & ACC, 2012: 2) and call for "enhanced information-sharing while protecting confidential business information" (Cefic & ACC, 2012: 3). To move towards an 'alignment of implementation procedures', the position paper proposed the "recognition of each other's data and studies and harmonised standards and methodologies for hazard and risk assessment […] for effective burden sharing" (Cefic & ACC, 2012: 2).

DG Trade and DG Grow officials called on Cefic and the ACC to elaborate on their ideas and supply more detailed proposals (Interview 3; Elliott & Pelkmans, 2015: 15). This call arguably reflected two motivations. On the one hand, DG Trade wanted to mobilise business associations to supply more detailed information in order to substantiate the demands of Trade Commissioner de Gucht for regulatory cooperation on chemicals. On the other hand, DG Grow was sceptical in particular with regard to Cefic-ACC calls for the identification of existing barriers for information-sharing (Interview 3).

Subsequently, DG Grow and DG Environment evaluated the proposals submitted by Cefic and the ACC. The focus of the Trade Commissioner on regulatory cooperation on chemicals led to a request for DG Grow[80] and DG Environment to elaborate a joint position paper for the Commission on chemicals regulatory cooperation (Commission, 2013a; Interview 2). The position paper was drafted jointly by technical officials from both DGs with the lead, however, being with DG Grow (Interview 1).They took up industry proposals to pursue 'information exchange' with regard to developing a mechanism for the common prioritisation of chemicals and exchange information on the classification and labelling of chemicals (Commission, 2013a; Interview 2). The Commission's choice to pursue 'information exchange' strongly reflects the priorities formulated by Cefic and the ACC[81]. Yet, both DG Grow and DG Environment were very reluctant to pursue the demands of the chemicals industry related to the 'alignment of implementation procedures' (Interview 2). Officials explained their choice to discard demands on a recognition of each other's data and studies with a double argument. First, whereas the ECHA and the Commission relied on firm data for the evaluation and authorisation of chemicals, the EPA had discretion in selecting data for the assessment of chemicals. This difference in competence made the EPA reluctant to recognise EU data. At the same time, the Commission emphasised that the obligation of firms to supply data should not be undermined (Interview 2). Second, the EPA was reluctant to work with robust test summaries that were supplied by firms to the ECHA database. While the Commission could legally also request full test sheets of firms, it generally considered robust summaries as sufficient to evaluate a chemical. Its limited administrative resources also implied that work with robust summaries with most effective to meet regulatory objectives in the evaluation and authorisation of chemicals (Interview 1).

[80] DG Enterprise was renamed as DG Grow with the entry into office of the Juncker Commission in 2014.
[81] Suggestions to exchange data were also by US stakeholders including the Government Accountability Office in 2013 in a Congressional hearing on the reform of the TSCA, calling the data of the ECHA a valuable resource for the EPA (Biedenkopf, 2015: 126).

In its 2013 position paper on chemicals, DG Grow and DG Environment thus propose three issues for regulatory cooperation on chemicals: First, they suggest cooperating on the prioritisation of chemicals for risk assessment and assessment methodologies. Second, they promote the alignment in the classification and labelling of chemicals. Third, they propose to ascertain possibilities for further information-sharing (Commission, 2013a).

The first and third proposal correspond to the 'information exchange' strategy defined in the typology in chapter 3.3.1. Under the first proposal, the prioritisation of chemicals for risk assessment, the Commission DGs aimed at establishing a mechanism for mutual consultation between EU and US authorities, i.e. the ECHA on the EU and the EPA on the US side, which chemicals should be prioritised for risk assessment (Interview 1). It reflected an expectation especially within DG Grow that a mechanism for mutual consultation could help both the ECHA and the EPA to concentrate their limited resources on the assessment of those chemicals which required an assessment the most (Interview 2). Moreover, DG Grow hoped that a mutual consultation mechanism for the assessment of chemicals would enable the Commission to share burdens with the US regulator and therefore eventually concentrate resources on few substances to ensure high-quality assessment. This would help the Commission to use its resources most effectively with regard to minimising safety risks coming from chemicals (Interview 1). In short, the Commission hoped that the establishment of a mechanism for mutual consultation would enhance both its autonomy and legitimacy. The third proposal to ascertain possibilities for further information-sharing should push officials in the negotiations to consider additional pathways for regulatory cooperation through 'information exchange' and thus convince both the EPA and the Council in the EU that chemicals regulatory cooperation is a beneficial exercise (Interview 1). It avoids, however, aiming at policy or deep forms of cooperation that would constrain the policy autonomy of the Commission.

The second proposal to promote the alignment of the classification and labelling of chemicals equally does not make commitments beyond the pursuit of 'information exchange'. Exchanges among regulators should facilitate "ways of establishing a common list of classification for substances" (Commission, 2013a). The wording avoids, however, a commitment to adopt the UN GHS in full. Both DG Environment and DG Grow officials argued that the existing classification and labelling system in the EU established clear information and were beneficial to EU producers, giving them little reason to change its policies (Interview 2). At the same time, Commission officials reportedly emphasised that the EPA was unwilling to adopt the UN GHS and change its existing practices, notably due to lobbying of pesticide producers in the US (Elliott & Pelkmans, 2014: 10). Further 'information exchange' on the classification and labelling with the EPA would, however, help promote the Commission's approach and insulate it against possible demands for adaptations in the future (Interview 3). The establishment of further 'information exchanges' with the EPA on the classification of chemicals should pave the way

for a commitment of the EPA to implement the UN GHS for a broad range of chemicals within a specified timeframe (Interview 1).

With the presentation of the position paper by DG Grow and DG Environment, DG Trade was arguably reassured that regulatory cooperation on chemicals was a feasible way to facilitate transatlantic trade through the TTIP (Interview 2). Correspondingly, DG Trade invited the representative of the chemicals industry as one of the members of the TTIP Advisory Group (Commission, 2014l). Yet, after the TTIP negotiations had begun, the EU business association Cefic struggled to uphold the coalition with the US association ACC. On the one hand, ACC questioned the benefit of increased 'information exchange' for chemicals producers (Interview 1). Firms were concerned that data exchange between EU and US authorities would lead to a leak or loss of confidential business information, given the different implementation principles regarding data that firms need to submit to regulators (Interview 2)[82]. They requested that firms should be contacted for agreement before regulators should be allowed to pass on confidential business information (Interview 1)[83]. Firms also rejected demands for a further alignment of substance classifications given the legal effects of the classification of a substance as 'carcinogenic' in the EU and the US[84]. The weakening of the transatlantic chemicals business coalition during the TTIP negotiations is most evidently shown by the absence of the ACC from business presentations at stakeholder meetings during negotiation rounds (Commission, 2015n)[85]. Moreover, the ACC published a position paper on the TTIP negotiations in which it called for changes to REACH, a view reportedly not shared by EU chemicals industry (Interview 2)[86]. The ACC also published a position paper within the International Chemistry Council whose policy lines runs largely counter to the joint position paper with Cefic [87](Interview 1).

At the same time, with the launch of the TTIP negotiations, NGOs became very active on chemicals (e.g. BEUC, 2016; Chemicalwatch, 2016; Greenpeace, 2015; Seattle to Brussels Network, 2015; Centre for International Environmental Law, 2014; Corporate Europe Observatory, 2014). Their mobilisation

[82] In the past, criticism with regard to inappropriate protection of confidential business information has been expressed primarily by the ACC that views data-sharing between the ECHA and third-country authorities as a possible threat to the protection of confidential business information.

[83] Observers call into question that data exchange between agencies would still make sense under these conditions. Rather than requesting authorities to exchange data, firms could directly submit their data to the ECHA and EPA (Interview 1; Interview 2). Moreover, the concerns of ACC with regard to confidential business information is likely overstated as existing REACH provisions already allow for the exchange of confidential business information.

[84] While reasons and conditions at present diverge, one could hypothetically eliminate the controversy by upward harmonisation and in case of a divergence always take the more stringent classification. In this case, however, a classification of a chemical as carcinogenic in the US which would not be classified as carcinogenic in the EU could result in a market ban for this chemical in the EU as the identification of a substance as a SVHC automatically bans it from its use in pesticides.

[85] The absence of the US chemicals industry from these stakeholder meetings contrasts with the presence of transatlantic business coalitions across many other sectors (Young, 2016; Commission, 2015; Commission, 2014)

[86] This implies that US chemicals producers did hope to gain leverage on amending at least parts of REACH through the TTIP negotiations.

[87] This decision may be explained with a loss of interest among US chemicals firms in transatlantic regulatory cooperation once they realised that one of their priorities, amending REACH, could not be achieved.

triggered the high politicisation of the chemicals negotiations (Eliasson, 2014). Among the non-business societal actors, only one animal welfare NGO supported efforts of the Commission to enhance information-sharing between EU and US authorities (Humane Society, 2015). Yet, most NGOs strongly mobilised against regulatory cooperation on chemicals as part of a TTIP agreement (especially Greenpeace, 2015; Centre for International Environmental Law, 2014). They directed their criticism mainly at two aspects, that the US would seek to "soften" the provisions of REACH (Corporate Europe Observatory, 2014), and that consultation with US regulators in the future would lead to a "regulatory chill" (Centre for International Environmental Law, 2014). The criticism of NGOs likely reflected suspicions and fears that the exercise of the precautionary principle may become more limited under regulatory cooperation and that the EU may eventually become convinced that its present approach may be overly precautionary. For this reason, some NGO (Greenpeace, 2015) demanded that the Commission exclude the chemicals sector from regulatory cooperation and stop the TTIP negotiations altogether. Besides, the Centre for International Environmental Law (CIEL) warned that 'information exchanges' on the assessment of chemicals could obstruct the process of testing and regulating substances (Inside US Trade, 2014e).

Despite the growing contestation among societal actors, DG Grow in coordination with DG Environment continued to work on the priorities outlined in the 2013 position paper. Emphasis was put on 'information exchange' between the ECHA and EPA. In a non-paper from early 2014, DG Grow outlined four ideas of issues on which it or the ECHA could consult with the US EPA (Commission, 2014a; see also Commission, 2014f): First, it suggested 'information exchange' on the update of the Community Rolling Action Plan (CoRAP) under REACH[88]. Second, it proposed 'information exchange' on the nomination of 'substances of very high concern' (SVHCs) for the candidate list of authorisation. Third, it flagged 'information exchange' on the prioritisation of SVHCs that are to be moved from the candidate list to authorisation. Fourth, it put forward 'information exchange' and involvement of the US EPA on the listing of a substance for restriction in the Commission's so-called 'Registry of Intent' (Commission, 2014a).

The choice of these issues reflected the evaluation of DG Grow and DG Environment officials where 'information exchange' between the ECHA and EPA could contribute most to improve the substance of evaluation data for the Commission. Exchange of information on the identification of chemicals for prioritised assessment would substantiate corresponding decisions of the Commission whose identification of chemicals as SVHC were often controversial (Interview 3). 'Information exchange' would thus enhance the legitimacy of Commission decisions to classify chemicals as priority chemicals

[88] The CoRAP specifies the substances that are to be evaluated over a period of three years. It is established by the ECHA in cooperation with the authorities of member states (ECHA, 2017). In the EU, substances are selected based both on the potential hazard they pose along with exposure and production volumes, then put on what is known as the "community rolling action plan" (CoRAP) list following the opinion of a member state committee. ECHA then conducts a risk assessment. If the risk assessment determines that a substance has not been properly controlled, it could be subject to further scrutiny and restrictions (Inside US Trade,2014a).

for assessment. At the same time, it would help protect the Commission against demands of chemicals producers to re-classify substances (Interview 3).

Although the transatlantic chemicals business coalition had weakened and opposition of many NGOs had grown by 2014, the political and administrative leadership of DG Trade sustained its interest in using chemicals as a case for regulatory cooperation. Besides, the continued demands for regulatory cooperation should help business associations to mobilise firms in support of regulatory cooperation (Interview 1). In the Stakeholder Dialogues, officials from DG Trade and DG Grow criticised NGOs that they did not engage with the substance of their position paper (Commission, 2014m). In particular, they sought to diffuse fears of NGOs that the TTIP negotiations could be used as a vehicle to change REACH[89]. They emphasised that legislation could not be changed without the approval of the Council and the EP. Moreover, the different regulatory approaches in the EU and the US made" a mutual recognition of the frameworks impossible" (EU Chief Negotiator Garcia Bercero, TTIP Stakeholder Dialogue 24 February 2016).

The weakening of the chemicals business coalition contributed to decrease the focus of DG Grow on 'information exchange' with a view to initiate a process for the harmonisation of the classification and labelling of chemicals thus decreased. After DG Grow and DG Environment had taken up exchanges with the EPA, EPA officials made clear that it did not consider the adoption of the UN GHS a priority. This was partly due to lobbying from pesticides firms both US firms and US subsidiaries (Interview 1). Besides, the EPA did not feel that an adoption of the UN GHS would be beneficial for its autonomy[90] .

The insistence of DG Trade to achieve tangible results in chemicals regulatory cooperation led it to propose 'information exchange' and consultation on emerging issues. Upon demands of the US Administration, it asked DG Grow to consider the statements put forward by the USTR on endocrine disruptors[91]. It considered that cooperation on endocrine disruptors could be a test case for 'information exchange' on emerging issues in the future (Interview 3). At the same time, it supported the administrative leadership of DG Grow to encourage the pursuit of envisioned pilot projects with the EPA for the prioritisation of chemicals for risk assessment. DG Grow established a pilot project to see if the EU and the US shared their evaluations of substances to be assessed under a priority. It tasked the ECHA to share its proposed 2015 update of the Community Rolling Action Plan (CORAP) and invite the US EPA for comments (Commission, 2015gl: 13). At the same time, it convinced the US EPA in

[89] Trade Commissioner de Gucht had sent a letter to 116 NGOs in March 2014 to emphasise that REACH would not be changed and the Commission (and neither the US Administration) pursued a strategy to harmonise or mutually recognise the chemicals regulatory frameworks.

[90] With around 17000 employees the EPA does not face the same resource constraints as DG Grow or DG Environment. Reducing the regulatory burden is thus likely to be less a reason to cooperate with regulators from other jurisdictions for the EPA than it is for DG Grow or DG Environment.

[91] Endocrine disruptors are substances believed to interfere with the human neurological system. The Commission proposal foresaw restricting those substances because their dangerous effects were not immediately detectable and cannot be mitigated by restricting exposure (Inside US Trade, 2013e).

the interactions during the negotiation rounds to share its Work Plan Update with the ECHA[92]. The exchange of the CoRAP documents and the EPA Work Plan showed that the ECHA and EPA had an overlap of 17 substances to be evaluated over a period of three years (Commission, 2015g: 13). Under the pilot project, both the ECHA and EPA chose priority substances to be evaluated according to their respective procedures in 2015, four EU member states agreed to participate in the project. The lists of priority substances were compiled without prior coordination. The ECHA published draft updates of its priority list. But the US EPA did not use its opportunity to comment on the priority list (Interview 1). Subsequently, the identification of substances in the EU and the US showed that the EU priority list had no matches with the list of priority chemicals of the US EPA (Commission, 2015g: 13).

By late 2015, hoping to achieve some visible success on chemicals regulatory cooperation, the administrative and political leadership of DG Grow encouraged a continuation of the pursuit of the implementation of the UN GHS (Inside US Trade, 2016c). DG Grow thus set up a pilot project on classification and labelling with the US OHSA, which had already implemented the UN GHS. Under this pilot project, the Commission exchanged lists of substances with ongoing or forthcoming classification with the US Occupational Safety and Health Agency (OSHA) and the National Toxicology Programme (NTP). The Commission and the US National Toxicology Programme showed interest in individual proposals of the other side and commented on them (Commission, 2016: 14). Under a third pilot project, the Commission persuaded the OSHA to prepare a first analysis to compare the content of 'Safety Data Sheets' in the EU and the US (Commission, 2016e: 15).

As DG Trade maintained demands to move ahead with regulatory cooperation including in the chemicals sector, DG Grow and DG Environment elaborated a draft textual proposal for a Chemicals Annex in TTIP. The proposal had been adopted through inter-service consultations and presented on 14 July 2016. The textual proposal lays down the strategy that the Commission chose to pursue in the TTIP. It takes up the initiatives described above, but mainly focuses on the idea to exchange information on the review and assessment of high-priority chemicals. It mentions four main objectives (Commission, 2016e, art. 1.6 (a)-(d) TTIP Chemicals Annex textual proposal; emphasis added by the author):

> "a) *Enhance cooperation on the review and assessment of chemicals of common priority* to enable governments and stakeholders, including in particular small and medium-sized enterprises, to better use their limited resources;
>
> b) *Enhance scientific cooperation* related to *hazard identification and risk assessment methodologies*;
>
> c) *Improve the exchange and/or availability of information and data* generated on chemicals for regulatory purposes, while ensuring the protection of confidential business information;

[92] The US EPA has a similar procedure to the CoRAP under the Toxic Substances Work Plan. (Inside US Trade, 2014a).

> d) *Promote alignment in classification and labelling of chemicals based on the UN GHS* including *inter alia*:
> i. classification and labelling of individual chemicals; ii. identification of differences in the Parties' respective requirements for Safety Data Sheets (SDS)"

The list of objectives demonstrates that the Commission's strategy was the pursuit of 'information exchange'. Its strategy on the assessment of priority substances (Commission, 2016e; art. 6 TTIP Chemicals Annex) entailed that each side "shall inform each other promptly when updating the lists of priority substances foreseen in their respective legislations with a view to allowing the responsible authorities of the other Party to comment on the selection of such priority substances and on the planned timing of their assessments" (art. 6.1 TTIP Chemicals Annex). It underlined, however, that "the responsible authorities of each Party shall conduct assessments of priority substances in line with their respective rules and procedures" (art. 6.3 TTIP Chemicals Annex). Likewise, with regard to risk assessment methodologies, the Commission suggested that "the responsible authorities of the Parties shall inform each other promptly when reviewing their respective methodologies for the assessment of priority chemicals and related scientific issues, in particular those related to hazard and risk assessment" (art. 7.1 TTIP Chemicals Annex). Yet, it emphasised that it did not aim at an alignment of implementation, i.e. assessment procedures, but rather that the Commission and the ECHA should engage in 'information exchange' with the EPA to avoid 'unnecessary' divergences of testing procedures: "Upon request of a Party, the Parties shall enter into discussions when assessment methodologies are reviewed or technical guidance documents are developed or reviewed by either Party, with a view to avoid divergences, where feasible[…]" (art. 7.3 TTIP Chemicals Annex).

With regard to the implementation of the UN GHS, the textual proposal foresees that "each Party shall implement the UN GHS as comprehensively as considered feasible within its respective system […] unless there are specific reasons to apply a different labelling system for particular chemical products" (art. 8.1. TTIP Chemicals Annex). Moreover, the "Parties commit to periodically examine cases in which the building block approach and in-built flexibilities of the UN GHS have led to divergent implementation in the Parties" (art. 8.2 TTIP Chemicals Annex). The Commission thus puts forward that commitments made under the UN GHS should be implemented. Crucially, it does, however, not propose that both sides should consider their classifications as equivalent where either EU or US classifications and labels differ from the UN GHS or they deviate within permitted flexibilities of the UN GHS.[93] At the same time, the Commission does not seek to urge the EPA to adopt the UN GHS or align its classification and labelling schemes with those of the EU. Rather, it pursues a strategy of 'information exchange': "When the responsible authorities of each Party consider to classify individual

[93] This shall not call into question the importance of a further implementation of the UN GHS pursued by the Commission. Both Commission officials and industry representatives underline the tremendous 'progress' a further implementation of the internationally agreed UN GHS would constitute for the alignment of chemicals classifications and labels.

substances, […], in accordance with its respective procedures, they shall give the responsible authorities of the other Party, upon their request, the possibility to express their views within those respective procedures" (art. 8.3. TTIP Chemicals Annex).

Besides, the Commission proposed 'information exchange' through cooperation "on the dissemination of data related to chemicals safety" (art. 9.1. TTIP Chemicals Annex), including the "exchange of non-confidential information among the relevant responsible authorities" (art 9.2. TTIP Chemicals Annex). Finally, the Commission proposed 'information exchange' related to "regulatory initiatives on individual chemicals" (art. 10 TTIP Chemicals Annex) and with regard to "new and emerging issues of common interest" (art. 11 TTIP Chemicals Annex).

6.1.7. Discussion

The previous sub-section has shown that during all three cooperation initiatives, including the TTIP negotiations, the Commission has restricted its choice of regulatory cooperation strategies to 'information exchange'. This sub-section discusses the Commission's choice of regulatory cooperation strategies during the three regulatory cooperation initiatives in view of the hypotheses derived from the Inter-relational Institutionalism. Particular emphasis is put on a contrast of the empirical findings from the previous sub-section with the expectations formulated in section 6.1.5.

The process-tracing conducted for each of the three cooperation initiatives has demonstrated the need for bureaucratic pressure to initiate the engagement in regulatory cooperation and the formation of a regulatory cooperation strategy (Hypothesis 1). During the NTA, bureaucratic pressure on technical Commission officials was low to engage in chemicals regulatory cooperation. Instead, Commissioners and Directors General of DG Enterprise and DG Environment agreed that priority should be placed on the strengthening of the EU chemicals regulatory regime. In line with hypothesis 1, this led to the pursuit of non-cooperation. During he HLRCF and the TTIP negotiations, the presence of bureaucratic pressure from Commissioner Verheugen and Commissioner de Gucht drove technical officials to explore opportunities for transatlantic chemicals cooperation. In the first case, demands of Commissioner Verheugen were reinforced by support from the administrative leadership of DG Enterprise. This led to the pursuit of 'information exchange', notably with regard to classification and labelling of chemicals and emerging issues. Likewise, when bureaucratic pressure decreased during later phases of the TEC, the pursuit of cooperation by technical Commission officials also weakened. The need for bureaucratic pressure to initiate the engagement in regulatory cooperation and the formation of a regulatory cooperation strategy, however, decreased with the TTIP negotiations. Although the insistence of Trade Commissioner de Gucht on regulatory cooperation in chemicals as a high-volume trade sector strongly contributed to the engagement in regulatory cooperation, interview evidence collected for this study

suggests that technical officials themselves considered 'information exchange' an opportunity structure. The presence of bureaucratic pressure rather supported the formation of a strategy because officials could anticipate that their technical counterparts in US regulatory agencies would respond to cooperation offers if bureaucratic pressure was also present in the US. The presence of bureaucratic pressure has, however, not pushed Commission officials another strategy as 'information exchange'.

The empirical finding of the strategies selected under bureaucratic pressure during the HLRCF and the TTIP negotiations confirms the expectations formulated in section 6.1.5. The strategy choice reflected the distribution of regulatory compatibilities between the EU and the US in the chemicals sector (Hypothesis 2).

Arguably most evidently, the Commission has not sought 'regulatory alignment'. On the contrary, it stressed in its initial TTIP position paper that "neither full harmonisation nor mutual recognition seems feasible on the basis of the existing framework legislations in the US and the EU" (Commission, 2013). The Commission invoked three reasons for its choice to maintain 'regulatory competition' between REACH and the TSCA: First, it noted that the REACH review concluded in 2013 did not indicate any need to amend the framework. Indeed, the Commission had been keen on finalising the REACH review before it began the third phase of regulatory cooperation, expecting that both the USTR and US industries might otherwise use the TTIP negotiations to demand changes to REACH (Interview 3). The Commission preferred to show that REACH in its existing form was considered as legitimate by non-business societal actors and also was accepted by chemicals producers. In the TTIP stakeholder dialogues, a Commission official emphasised that "REACH was working well for EU businesses. We don't see a need to change it." (Commission official, Stakeholder dialogue 24 February 2016). Second, it stresses that the US does not share the EU's view that substances should be registered before they can be marketed, a "fundamental requirement under REACH", as evidenced by the absence of a general registration obligation in the draft TSCA proposal (Interview 3). Third, the Commission underlined that the US does not share the EU's view to authorise chemicals rather than restrict them after initial marketing (Commission, 2013). Crucially, a difference stressed concerned the EU's ban of chemical substances it considers as hazardous whereas the US EPA issues recommendations (Interview 1). Without addressing a potential compatibility or incompatibility of regulatory authority structures, the Commission thus emphasised the incompatible regulatory principles with regard to the registration and authorisation of chemicals as reasons not to pursue 'regulatory alignment'.

Likewise, the Commission has not sought to pursue 'equivalence'. 'equivalence' could have been pursued through a recognition of 'equivalence' of chemicals classifications (Interview 2). Yet, the Commission emphasised that an 'equivalence' of classifications would be "difficult" because both in the EU and the US classifications had legal effects with regard to the authorisation or ban of chemical substances for certain uses, i.e. their use in biocides or pesticides (Interview 1). The recognition of a classification according to EU or US law by the respective other side without the legal effect linked to

that classification would thus restrict upon the autonomy of either the Commission or the EPA to authorise or ban a substance. For this reason, it was unwilling to envisage an 'equivalence' of classifications (Interview 1). Instead, the Commission wanted to exchange information for a reduction of divergence of future classifications where these it did not entail legal effects with regard to their authorisation or ban for certain uses. The different regulatory authority structures with regard to the ability of central-level regulators to restrict substances based on their classifications thus contributed to prevent the Commission from pursuing an 'equivalence' of classifications and labels.

Third, the Commission has not pursued an 'alignment of implementation procedures'. The latter could notably have been pursued through an alignment of assessment methodologies for substances or a mutual recognition of test results (Interview 2). Yet, the Commission did not suggest that either of these should be the objective of TTIP negotiations. Interview partners stated that the criteria applied by the Commission and the EPA to consider scientific evidence as relevant for the authorisation and ban of chemical substances differed in the EU and the US, obstructing an alignment of assessment methodologies (Interviews 1, Interview 3). At the same time, the noted that EPA officials were sceptical of tests conducted by firms in certain EU member states, making EPA unwilling to accept evidence produced by such firms as a basis for their decision to ban a chemical substance (Interview 2). Both the divergence of regulatory authority structures, i.e. the allocation of the responsibility to conduct assessments, and the principles followed in the assessment of chemicals stopped the Commission from pursuing an 'alignment of implementation procedures'.

For this reason, the Commission concentrated on pursuing 'information exchange' on chemicals in line with the expectation formulated in section 6.1.5. It is noteworthy that the Commission does not refer to diverging standards or diverging levels of environmental protection and consumer health as reasons for maintaining 'regulatory competition' over the regulatory frameworks (Interview 1, Interview 2, Interview 3).

Yet, the issues covered by the Commission's pursuit of 'information exchange' have expanded over the three phases of regulatory cooperation. While the Commission was reluctant to engage in regulatory cooperation during the first phase and instead sought to reinforce 'regulatory competition' by the adoption of REACH, Industry Commissioner Verheugen pushed officials to pursue 'information exchanges' with the US EPA under the TEC during the second phase. With the beginning of the third phase and the TTIP negotiations under the participation of DG Trade, DG Grow and DG Environment extended 'information exchange' to the assessment of priority chemicals, risk assessment procedures and new classifications of chemical substances. Besides, Commission officials pursued 'information exchanges' on new and emerging issues, notably related to the reform of the chemicals framework in the US and envisaged legislation on endocrine disruptors in the EU.

The choice of issues within the chemicals regulatory regime on which the Commission has pursued 'information exchange' has been shaped by the mobilisation of societal actors (Hypothesis 3). The effect

has been twofold: During the HLRCF and the TTIP negotiations, Commission officials took up proposals of the TABC, Cefic and the ACC to direct the pursuit of 'information exchange' on the assessment of priority chemicals, procedures for risk assessment and the classification and labelling of substances. These issues were in line with regulatory compatibilities between the EU and the US chemicals regulatory regimes. In the case of classification and labelling, industry proposals also built on earlier international chemicals cooperation. At the same time, mobilisation within industry groups for strategies going beyond 'information exchange' failed to influence the strategies pursued by the Commission. This also applies to mobilisation by some NGOs against the pursuit of regulatory cooperation under any strategy during the TTIP negotiations. Still, the influence of Commissioner Verheugen at the launch of the TEC and the participation of DG Trade at the launch of TTIP negotiations have pushed and supported Commission officials to pursue 'information exchange' rather than 'non-cooperation'.

In sum, this section has shown that the Commission has restricted the choice of strategies in transatlantic regulatory cooperation to 'information exchange'. This choice reflects the incompatible distribution of regulatory authority structures related to the assessment of substances and the ability to restrict substances as well as the incompatible regulatory principles related to the registration and authorisation of substances between the EU and the US. It remains to be seen how the changes in the EPA leadership under the Trump Administration will affect the engagement of the Commission in regulatory cooperation with the US EPA. Two scenarios are imaginable: On the one hand, the opposition of the new EPA executive to the regulatory principles pursued by the Commission may discourage the Commission from pursuing regulatory cooperation, given that US EPA responses to previous strategies have been limited. On the other hand, resource costs imposed onto the EPA under the Trump Administration may increase the interest of the US EPA to exchange data with the ECHA and develop coordinated plans for the assessment of priority chemicals. Yet, unless the distribution of regulatory compatibilities changes, it should not be expected that the Commission goes beyond 'information exchange' in regulatory cooperation on chemicals with the US.

6.2. Commission strategies in transatlantic engineering cooperation

This section proposes a case study for which existing literature implies that regulatory authority structures in the EU and US are incompatible, but regulatory principles are compatible at least for some policies. It is thus a case in which the Commission can be expected to pursue an 'alignment of implementation procedures'. This case study covers the Commission's choice of regulatory cooperation strategies in transatlantic regulatory cooperation in the engineering regime.

6.2.1. Introduction

Engineering regulations aim at the mechanical and electrical safety of products to human health and the environment. They thus address issues of mechanical safety, electrical safety, electromagnetic compatibility and explosion protection. Engineering regulations cover products of both mechanical and electrical, and electronics industries. Products can be as diverse as industry machines, household products, hand tools, sports and leisure equipment. Mechanical safety refers to the mechanical aspects of a product and the conditions under which its failure can pose a risk to the user of a product. It thus addresses the design and shape of a product, its potential e.g. to squeeze body parts, its durability characteristics as well as the design of safety components including screws. Electrical safety refers to the potential risk that users of a product experience an electrical shock and thus addresses e.g. the avoidance of current leakage, the strength of electrical insulation. Electromagnetic compatibility describes the ability of a product to function safely in its electromagnetic environment without causing electromagnetic disturbances. Explosion protection refers specifically to the prevention of 'pressure equipment' from explosion during use. Environmental safety invokes especially the functionality of a product under extreme weather conditions and its resistance to corrosion[94].

In many jurisdictions, these issues are regulated by regulatory policies, often legislation, giving guidelines for the human health and environmental safety requirements of a product. Standards offer technical specifications and solutions for producers to meet the human health and environmental safety requirements of legislation for a product. These are usually developed by standards development organisations (SDOs). Implementation procedures address the measures verifying that products conform to the safety requirements of regulatory policies, i.e. the conformity assessment procedures. Moreover,

[94] Specific 'horizontal' environmental regulations may additionally address the production or recycling of a product or its components.

they refer to testing procedures used to assess the conformity of a product with the requirements of regulatory policies.

The engineering industry is highly internationalised, entailing that producers and buyers of products face high rule overlap and conflicting regulatory requirements as they buy or sell engineering products across jurisdictional boundaries. While some engineering firms are large, multinational firms with production sites across many jurisdictions, a high number are small- and medium-sized enterprises with nonetheless a high integration into global value chains and the fragmentation of the production chain into different components. In the transatlantic relationship, Francois et al. (2013) show that technical barriers to trade costs amount to 19.1% for EU exports to the US and 13.6% for US exports to the EU. In particular EU engineering firms are highly competitive, causing EU engineering exports to account for more than 30% of total EU exports to the US in 2012 (Francois et al, 2013). Figure 16 shows the development of trade flows between the EU and the US in the engineering sector between 2006 and 2016[95].

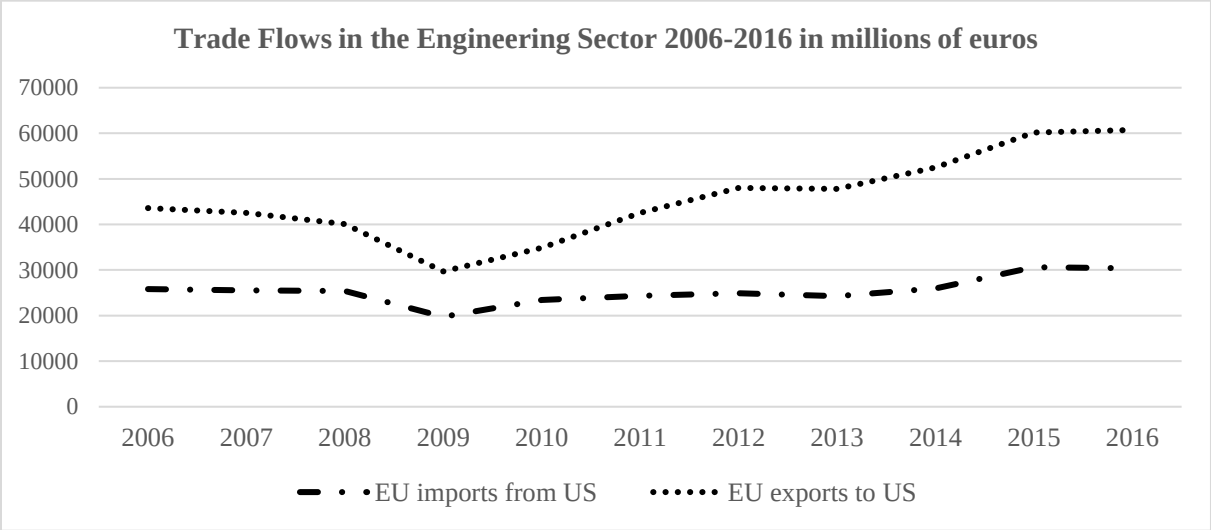


Figure 16: Trade Flows in the Engineering Sector 2006-2016

Both business societal actors and NGOs engage on engineering cooperation. In the EU on the business side, lobbying is crucially shaped by EU-level and German business associations, i.e. Orgalime, VDMA (mechanical safety) and ZVEI (electrical safety). Besides, firms are densely involved in standards development. Standards development organisations may also act as societal actors. Among NGOs, notably the consumers lead organisation BEUC has mobilised on engineering issues.

[95] The choice of the time period reflects data availability constraints (Eurostat, 2017).

This section proceeds as follows: It first outlines the distribution of regulatory authority structures and principles in the EU chemicals regulatory framework and then outlines the incompatibility of US regulatory authority structures and compatibility of regulatory principles. It then formulates expectations on the Commission's choice of regulatory cooperation strategies with the US, based on the incompatibility of EU-US regulatory authority structures and compatibility of regulatory principles. The subsequent sections present the regulatory cooperation strategies the Commission pursued in the three phases of transatlantic regulatory cooperation delineated in chapter 5.1 and contrasts them with the mobilisation of societal actors. The Commission's choice of regulatory cooperation strategy is then contrasted with the formulated expectations and the patterns of societal mobilisation. The final sub-section concludes.

6.2.2. International engineering cooperation

This section briefly summarises the subjects of regulatory cooperation in international organisations. It offers background and contextual information for the adoption of regulatory principles in both the EU and the US. Regulatory cooperation with regard to mechanical and electrical safety in engineering products is addressed by the Technical Barriers to Trade (TBT) Agreement of the World Trade Organisation (WTO) and standardisation within the international standard development organisations International Standardisation Organisation (ISO) and International Electrotechnical Commission (IEC).

The TBT Agreement in its form at the time of writing entered into force after the conclusion of the Uruguay Round in 1995. It does not specifically refer to or address mechanical or electrical safety, but has particular relevance for the engineering sector because the latter is relatively less regulated than other industry sectors (Interview 6). The TBT Agreement specifies that technical regulations and standards must ensure non-discrimination between domestic and foreign products and not treat domestic products more favourably than imported products (art. 2.1 TBT Agreement). While states are free to pursue any objective they consider as appropriate, the TBT Agreement requires them to develop technical regulations and standards which are not more trade-restrictive than necessary to achieve a legitimate public policy objective (art. 2.2. TBT Agreement). Legitimate public policy objectives are enumerated e.g. as environmental or consumer protection. Where 'international standards' exist[96], the

[96] While the EU understands 'international standards' as those standards developed by international standardisation organisations, i.e. ISO and IEC, with international membership, the US understands 'international standards' which are used by firms internationally (Interview 4,6; for further elaboration on the background of the 'international standards' discussion see also Pelkmans, 2015b).
Here it should be noted that for firms, including EU firms, standards promulgated by US standard development organisations, e.g. ASTM, have also become de facto world standards. Firms with transnational activities are used to adopt two standards simultaneously. EU firms use US standards too in products not specifically designed for export to the US due to their claimed high quality and specialisation (Interview 6).

TBT Agreement requires WTO members to use them as a basis for technical regulations, standards and conformity assessment procedures. The use of international standards establishes the presumption that states and jurisdiction conform with their multilateral obligations. Yet, states can adopt measures more stringent measures than international standards in pursuit of legitimate public policy objectives, given that they follow the procedure laid down in the Agreement (WTO, 1995a, art. 2.4 TBT Agreement). Non-discrimination also applies to conformity assessment procedures, implying that conformity assessment procedures need to grant access not less favourably to importers than domestic producers (WTO, 1995a, art. 5.1. TBT Agreement).

Related to engineering products, the ISO develops standards for mechanical safety whereas the IEC develops standards for electrical safety. Besides, related to implementation procedures, the ISO also sets standards for the testing of products to establish conformity assessment. The ILAC (International Laboratory Accreditation Cooperation) sets standards for test laboratories. Moreover, the IAF (International Accreditation Forum) has developed standards for the accreditation of conformity assessment bodies.

Despite regulatory cooperation in these international organisations, differences persist in the regulatory frameworks between countries, including and notably between the EU and the US. First, jurisdictions have rejected the implementation of international standards for a lack of compatibility with domestic standards. Second, they have adopted regulatory policies and implementation procedures beyond international standards to pursue public policy objectives in light with their rights under the TBT Agreement.

6.2.3. EU engineering regime

This section describes the distribution of regulatory authority structures and regulatory principles in the EU. The first part of this section looks at the distribution of authority structures and principles with respect to regulatory policies, the second part at authority structures and principles with respect to implementation procedures, i.e. procedures of conformity assessment and testing.

Regulatory policies shaping engineering regulation in the EU can be divided into legislation and standards. Legislation mostly falls under the ‘New Legislative Framework’ (Regulation (EC) 764/2008 and Regulation (EC) 765/2008), a reform of the so-called ‘New Approach’ in 2008. These have been proposed under the lead of DG Grow. Within the ‘New Legislative Framework’, mechanical safety is regulated in the Machinery Directive (Directive 2006/42/EC), electrical safety in the Low Voltage Directive (2006/95/EC and 2014/35/EU), electromagnetic compatibility in the Electromagnetic Compatibility Directive (2014/30/EU) and explosion protection in the Pressure Equipment Directive (2014/68/EU).

Almost all legislation governing mechanical and electrical safety has been adopted at the EU-level after the establishment of the Single Market. The very few remaining member state laws have been subjected to mutual recognition since 1995.[97] The directives adopted at the EU-level set 'essential requirements' for mechanical and/or electrical safety that engineering products need to meet. Member states have no authority to formulate regulations setting other 'essential requirements'. Technical standards in support of EU-level legislation, so-called 'harmonised standards', are developed or provided by the European Standards Organisations (ESOs) CEN (European Committee for Standardisation) and CENELEC (European Committee for Electrotechnical Standards) [98],[99]. Although the ESOs are private actors, the Commission maintains a contractual relationship with them, based on the General Guidelines for Cooperation (Commission, 2003c), which designates the ESOs as the only providers of harmonised standards, and provides public funding to them. Within the contractual relationship, the Commission elaborates and publishes annual standardisation requests to the ESOs. It notifies stakeholders of its draft standardisation work programmes and invites them for comments on them (Egan & Pelkmans, 2015: 8). The ESOs are hierarchical organisations with the national standards bodies of EU member states are members. Each member state recognises only one singular standards body. Standards are developed in technical committees in which a wide range of stakeholders including SMEs, non-EU firms, consumers, and trade unions participate. Voting rights are, however, restricted to the representatives of the national standards bodies which subsequently adopt standards as 'harmonised standards'. The hierarchical organisation of the EU standardisation system entails an obligation for member state standards bodies to remove and withdraw conflicting national standards once a harmonised standard is adopted (Büthe & Mattli, 2011). At the same time, the Commission requires CEN and CENELEC to verify existing relevant standards in the world before they develop own ones. Through the Vienna and Dresden Agreements from 1991 and 1996 respectively a commitment exists to adopt internationally agreed ISO and IEC as 'harmonised standards'[100].

CEN and CENELEC do, however, not have authority to adopt binding standards. Standards in the EU are only binding if they are directly incorporated into Regulations or Directives. In the so-called 'New Legislative Framework' Directives, i.e. the directives governing mechanical and electrical safety, this is very rare. Yet, CEN and CENELEC standards offer firms a 'presumption of conformity'. On the one hand, if the Commission accepts that a 'harmonised standard' fulfils an 'essential requirement' laid down in a directive, the use of this standard by a firm offers it a 'presumption of conformity' of their

[97] The following paragraphs draw on the illustration in Egan & Pelkmans (2015).
[98] Member state laws in areas of member state competence delegate standard development or provision to national standards bodies.
[99] The role of ETSI as a setter of telecommunications standards is briefly outlined in chapter 6.4. CENELEC develops or provides standards for electrotechnical equipment and components. CEN develops or provides standards for all products not covered by ETSI or CENELEC.
[100] These agreements foresee that new ISO/IEC standards are written jointly with EU standards, with the same European experts participating in international and European Standards Organisations. Egan and Pelkmans (2015: 12) show figures that 72% of CENELEC standards are identical to IEC standards, and 31% of CEN standards identical to ISO ones.

product with the relevant safety and health objectives laid down in the directive. This guarantees the firm free movement of its products within the Single Market. On the other hand, the use of a 'harmonised standard is not mandatory to show compliance with the 'essential requirements' of EU legislation. Producers can demonstrate compliance with the 'essential requirements' through other means, e.g. by developing their own standards[101]. Nonetheless, the authority to formulate 'essential requirements' for mechanical and electrical at the EU-level upon proposal of the Commission and the delegation of the development and provision of standards for the technical specification of these 'essential requirements' means that regulatory authority on regulatory policies in the EU is centralised.

In the formulation of 'essential requirements', the Commission does not seek to eliminate potential risk to human health and the environment that could possibly arise, but pursues the principle to eliminate all risk that can arise under conceivable 'normal' uses of a machine (Interview 2)[102]. The Directives listed above only lay down 'essential requirements', i.e. technical expressions of safety and health objectives that products need to meet (Egan & Pelkmans, 2015: 10)[103]. The regulatory principle followed by the Commission in the proposal of regulatory policies, i.e. directives governing mechanical and electrical safety, is therefore the risk principle[104].

For conformity assessment, the Commission has the authority to propose the content of implementation procedures. However, the procedures themselves are conducted by firms and member state authorities. Product safety is foremost the responsibility of producers. The product directives listed above obliges them to manufacture and place safe products on the market (European Parliamentary Research Service, 2015: 8). Producers thus conduct the conformity assessment themselves. By affixing the CE mark on their product, they affirm that their product complies with the safety requirements. Market surveillance authorities in EU member states monitor products placed on the market and guarantee that products placed on the market comply with the safety requirements of EU legislation (Commission, 2016j: 114-117). Yet, for products requiring conformity assessment through third-party testing, the authority to conduct tests is partially centralised (see the next paragraph). The 'New Legislative Framework' designates conformity assessment bodies (CABs) which are allowed to conduct third-party assessment (European Parliament & Council, 2008). These designated CABs, called 'Notified Bodies', need to be recognised, i.e. accredited, by a member state. To be able to be accredited by a member state, a CAB

[101] For this reason, the Commission underlines that standards remain 'voluntary' even if they are adopted as a harmonised standard (Commission, 2014: 3). A choice not to use 'harmonised standards', however, has implications for the applicable procedures for conformity assessment, leading to higher costs for firms. US business associations and the US Trade Department (USTR) therefore argue that 'harmonised standards' are de facto binding.

[102] This follows the 'economics of regulation' (Egan & Pelkmans, 2015: 9), according to which the elimination of all potentially conceivable risk leads to highly restrictive markets, stifling competition and innovation.

[103] These are also called 'safety, health, environmental and consumer' (SHEC) objectives (Egan & Pelkmans, 2015: 5)

[104] In contrast e.g. to chemicals and food safety, engineering is a relatively lowly regulated sector. This limits the possible presence of regulatory principles.

needs to maintain an office in that member state[105]. Member states agree to mutually recognise the conformity assessments of the 'Notified Bodies' conducted in another member state[106]. If regulatory policies require third-party testing for a product, thus only conformity assessment by a 'Notified Body' gives a firm the certification of conformity with the requirements formulated by regulatory policies. Regulatory authority over implementation procedures in the EU is thus centralised.

For conformity assessment of products with mechanical and electrical safety requirements, the Commission relies on 'Supplier Declaration of Conformity' (SDoC) and, to a very limited extent, 'third-party conformity assessment'(Interview 4). Under SDoC, the declaration of conformity lies in the responsibility of the producing firms. Firms apply the testing requirements for conformity assessment and provide data and technical documentation that their product meets the 'essential requirements' of regulatory policies. For 'high risk' products, the principle for conformity assessment is 'third-party conformity assessment'. The conformity of high-risk engineering products needs to be assessed by a 'Notified Body' in line with the distribution of regulatory authority described in the previous paragraph. The 'third-party conformity assessment' applies e.g. to dangerous machinery and explosion protection in the EU (Interview 6). Products that conform to the 'essential requirements' laid down in regulatory policies and whose conformity to the 'essential requirements' has been tested according to the applicable conformity assessment procedure are allowed to carry the CE mark[107]. Principles for the testing of products to establish conformity assessment are ISO standards, i.e. ILAC (International Laboratory Accreditation Cooperation) standards for test laboratories in firms for SDoC and IAF (International Accreditation Forum) standards for the accreditation of CABs under 'third-party conformity assessment'. Regulatory principles in conformity assessment procedures followed by the EU are thus SDoC and, to a very limited extent, 'third-party conformity assessment'.

6.2.4. Contrast of the EU and US engineering regimes

This section summarises divergences between the EU and US regulatory frameworks for engineering products. It demonstrates that incompatible differences exist mostly with regard to the distribution of regulatory authority structures while regulatory principles are compatible especially for regulatory policies.

[105] This requirement is also known as the 'territoriality' requirement.
[106] Member states are responsible to control a Notified Body if problems are detected in a product certified by 'Notified Body' (Interview 4). In the negotiations of the 'New Legislative Framework', this has been a precondition by certain member states for the mutual recognition of conformity assessments. In exchange for the legal responsibility to control 'Notified Bodies', member states demand that they establish an office in their jurisdiction (Interview 5).
[107] The CE mark states that products conform to EU technical requirements and grants producers free movement of their products in the Single Market.

US regulations on mechanical and electrical safety are made at both the central, sub-central and local level (Interview 6; Orgalime, 2014: 6). Central-level safety regulations are adopted mainly by the Occupational Safety and Health Administration (OSHA) and, less frequently, by the US Consumer Product Safety Commission (CPSC). They exist only if central-level regulatory agencies have been mandated by Congress to develop regulation with a view to regulate a specific safety risk[108]. Otherwise, sub-central safety regulations persist where issues have not been regulated by central-level regulatory policies. These may establish diverging and conflicting safety requirements across states[109].

If OSHA or the CPSC have received mandates, i.e. authority, to adopt central-level safety regulations with regard to a risk or a product, they can only regulate this risk or product within a defined scope. The OSHA does not have authority to regulate safety features of all engineering products brought onto the US market, but regulates the safety characteristics that products must have if they are used within the area of its mandate, i.e. at the workplace[110].

Standards are developed by both accredited and non-accredited standard development organisations (SDOs) and authority is not centralised to eliminate or withdraw competing standards. More than 200 SDOs are accredited in the US, the most important ones of them being former sectoral business associations. The umbrella organisation of US SDOs and the main interlocutor of the ESOs in transnational dialogues, the American National Standards Institute (ANSI), only assumes a coordination and accreditation function for the various SDOs. Besides, ANSI has authority to represent the US in the international standardisation bodies ISO and IEC and thus is a platform for promoting standards internationally. Yet, ANSI does not have authority to develop standards or provide standards itself. Moreover, standards are also set by SDOs, consortia and forums not accredited by ANSI (Egan & Pelkmans, 2015: 9). Likewise, ANSI does not have the authority to adopt or recognise standards and demand a withdrawal of rival or competing standards[111]. The US regulatory framework allows for the

[108] A great number of central-level regulations exist on electrical safety while central-level regulations on mechanical safety are rare (Interview 6; Orgalime, 2014: 6).

[109] If safety issues are regulated by sub-central regulations in a US State or local area, products not complying with the safety requirements of these sub-central regulations cannot be sold in that State or area. Unlike the EU, the US does therefore not have an internal market for all engineering products.

[110] Within its authority, the OSHA may thus restrict the use of 'unsafe' products at the workplace, but it cannot restrict the use of 'unsafe' products outside the workplace, e.g. in private households. As one interview partner described this logic as follows: "Everything can be produced, but not everything can be used." (Interview 6). OSHA regulations may, however, have indirect effects on machines used in households as firms will avoid duplicative production of machines for households and workplace to use economies of scale.

[111] Various SDOs compete over the development of standards. A standard becomes relevant in the US if it is used by many firms. Neither ANSI nor a regulatory agency, however, has the authority to determine which standard is more suitable to meet consumer health and safety requirements.

existence of multiple parallel standards developed by multiple SDOs[112]. In turn, the adoption and implementation of internationally agreed ISO and IEC standards is weak[113].

US agencies, e.g. the OSHA, have, however, authority to develop or adopt standards if they use standards to give technical specifications in regulations. They can 'reference' standards in regulations which makes compliance with these standards binding[114]. When regulatory agencies 'reference' a standard, they can choose any available, i.e. published, standard that they consider suitable for their regulatory objective. Once an agency has selected an already published standard or several standards for incorporation into a regulation, it collects stakeholder comments through notice-and-comment procedures[115]. If they do not find a suitable standard, they also have the authority to set so-called 'government unique standards' themselves[116]. Moreover, agencies have the authority to participate themselves as members in private standards development.

As US regulations on mechanical and electrical safety are made at both the central, sub-central and local level, the authority of central-level regulatory agencies is restricted to specific and narrowly defined mandates and standards are set by both accredited and non-accredited SDOs, regulatory authority in the US is non-centralised for engineering regulatory policies. The previous section has shown, however, that regulatory authority in the EU for engineering regulatory policies is centralised to ensure the functioning of the Single Market. This makes the distribution of regulatory authority structures between the EU and the US incompatible. The authority of the Commission to regulate safety requirements for engineering products in the EU can thus not be extended to the US which only regulates specific risks in specific contexts. Likewise, the Commission has authority to only 'reference' standards – itself a rare practice in the EU- that are 'harmonised' standards. The technical specification of 'essential requirements' through the 'harmonised standards' adopted within the ESOs creates the obligation for member state SDOs to withdraw rival and conflicting standards. This creates a contradiction with the authority of the OSHA to 'reference' multiple and conflicting standards for the technical specification

[112] In practice, however, many prominent standards are developed by only very few independent SDOs. Among these, the American Society of Mechanical Engineers (ASME), the National Fire Protection Association (NFPA), the American Society for Testing and Materials (ASTM) and the Institute of Electrical and Electronics Engineers (IEEE) are arguably the most important ones and are claimed to enjoy a recognised status in many markets internationally (Egan & Pelkmans, 2015: 9).

[113] Reasons for the reluctance of the US to adopt ISO and IEC standards have been widely discussed in the literature (e.g. Büthe & Mattli, 2011; Egan & Pelkmans, 2015: 13). On the one hand, explanations put forward that the EU, represented by all 27 member states, has many more votes than the US with only one vote and that the US thus risked being outvoted by the EU. Yet, with the expansion in membership of the ISO and the IEC this argument has arguably lost track. A second explanation offered is that US agencies choose not to use ISO and IEC standards for 'quality' reasons, given that ISO and IEC standards often represent compromises among their large membership.

[114] Although US agencies incorporate standards into regulation through 'referencing', the relative number of standards incorporated into US public law is argued to be relatively small (Egan & Pelkmans, 2015: 11).

[115] While US agencies make consultation on published standards, the Commission publishes draft standardisation programmes for comment (Interview 5).

[116] In the latter case, however, US regulatory agencies need to justify why they develop a 'government unique standard' if there is an existing private consensus standard (Egan & Pelkmans, 2015: 10)

of safety requirements[117]. Although the distribution of regulatory authority structures on engineering safety is overall incompatible between the EU and the US, it may be compatible in specific cases if the OSHA has the authority to regulate a product for the US market and the product is mainly used in workplaces.

The US Congress and regulatory agencies follow the 'risk principle' in regulatory policies on engineering safety issues (Pelkmans, 2015b). Overall, they seek to regulate those risks which can possibly occur under 'normal' conditions and seek to keep regulation proportional to the intensity of the risk[118]. The practical application of the 'risk principle' in US regulations differs, however, from the application in the EU regulatory policies. While EU directives formulate only 'essential requirements' with regard to safety and health objectives, OSHA and CPSC regulations lay down detailed technical specificities[119]. Interview partners have noted that US agencies and US SDOs sometimes argue that the 'quality' of US standards, i.e. the level of safety risk protection, is higher than the 'compromise' standards agreed on ISO, IEC or within the ESOs (Interview 4, Interview 5), OSHA officials are cited to concede, however, that referenced US standards are functionally equivalent in terms of SHEC objectives to ISO or IEC standards (Orgalime, 2014: 11). Regulatory principles on engineering regulatory policies can thus be considered compatible. The pursuit of comparable regulatory objectives and priorities underlines the compatibility of regulatory principles even if OSHA and other relevant US agencies make technical specifications of safety requirements directly in regulations whereas Commission directives only formulate 'essential requirements'.

With regard to conformity assessment procedures, the OSHA has the authority to designate conformity assessment bodies, so-called 'Nationally Recognised Testing Laboratories' (NRTLs) for mandatory third-party certification. For a long time, the OSHA assigned only Underwriters Laboratories (UL) as an NRTL for third-party certification. Since 2011, OSHA recognises 12 NRTLs[120]. Other agencies, including the CPSC, do, however, not designate specific CABs for third-party conformity assessment. In these cases, firms can choose among all existing CABs for third-party testing. The authority of OSHA to designate specific NRTLs for mandatory conformity assessment makes the distribution of regulatory

[117] Moreover, the authority of agencies including OSHA to set 'government unique standards' and participate in standard development itself contrasts with the delegation of standard development to the ESOs in the EU and the lack of authority of the Commission to participate in standard development.

[118] This offers an explanation why the OSHA has adopted many regulations on electrical, but not mechanical safety.

[119] One interview partner has explained the different application of the 'risk principle' in the EU and the US with the mandate and accountability of US regulatory agencies such as the OSHA. Whereas the Commission has the mandate to ensure a high level of protection from safety risks while simultaneously promoting competition among firms, the OSHA only has the mandate to promote the protection of workers at the workplace. Moreover, the OSHA is liable in judicial review for failures of its regulations to control and eliminate safety risks. When the OSHA thus adopts a regulation, it seeks to eliminate the risk to the highest degree possible to protect workers. It does not consider other implications of the regulation, e.g. for competition among producers (Interview 6).

[120] About 30 state agencies and a number of local agencies, however, continue to recognise only UL. Besides, UL remains in a dominant position because it does not accept the certification of components and parts of other NRTLs (Interview 6).

authority over implementation procedures in the US centralised for the OSHA, but non-centralised in other cases. The centralisation of authority on implementation procedures in the US under the designation of NRTLs is thus compatible with the centralisation of regulatory authority for implementation procedures in the EU.

Like the EU, the US also applies 'Suppliers Declaration of Conformity' (SDoC) and 'third-party conformity assessment' as principles of conformity assessment. Yet, US agencies require third-party testing for many engineering products[121]. At the same time, US agencies do not require that firms put a label on products such as the CE mark to indicate conformity with the essential safety requirements of legislation[122]. Only products whose conformity to regulatory requirements has been assessed by a third party, i.e. a CAB, carry a label in the US (Interview 5). For the accreditation of CABs and the establishment of rules for testing procedures, the OSHA partly relies on international ILAC and IAF standards for some issues, yet also relies on divergent US standards (Pelkmans, 2015b: 15). From an overall perspective, regulatory principles for implementation procedures on engineering products are therefore mostly compatible. Even if the OSHA relies on divergent testing standards for conformity assessment, these do not establish different safety procedures and are therefore in principle compatible. The OSHA and other agencies, however, widely rely on third-party conformity assessment whereas the use of third-party testing in the EU is reserved to dangerous machines and pressure equipment. Regulatory principles for implementation procedures are hence only compatible if both US agencies and the Commission use 'SDoC' or 'third-party conformity assessment' for the same risk or product[123].

To summarise, regulatory policies in the engineering sector in the EU and the US are characterised by compatible regulatory principles, but incompatible regulatory authority structures. The distribution of regulatory authority is incompatible as, unlike in the EU, regulations on mechanical and electrical safety in the US are made at both the central, sub-central and local level and standardisation authority is decentralised. While the Commission has authority to regulate mechanical and electrical safety risks for the entire EU market, the OSHA and the CPSC regulate only specific uses or risks of a product. Besides, central-level regulations in the US are complemented with conflicting sub-central and local regulations. Moreover, whereas the Commission has the authority to task the EU standards development

[121] Even if US regulatory agencies do not require third-party conformity assessment, US firms have signed voluntary agreements to use third-party testing for the assessment of their products' conformity with the regulatory safety requirements. The latter allows firms to defer liability for marketed products in court action on product safety requirements under tort law.

[122] This difference reflects the divergent distribution of regulatory authority. US agencies such as the OSHA or CPSC do not regulate the entire US market, they only regulate the use of products at the workplace or in households respectively. This implies in the words of one interview partner that while "everything is allowed to be sold, not everything may be used" (Interview 6).

[123] The debate about the relative benefits of SDoC and third-party certification has in the view of observers often been "ideological in nature" (Interviews 4,5; Pelkmans, 2015: 28). Interview partners stress that neither principle per se offers a higher level of protection of human health and the environment (Interviews 4,5). Moreover, they stress that producer liability laws in the US make it impossible for firms to sell 'unsafe' products on the markets. Due to producer liability reasons, voluntary commitments exist among firms to use third-party testing e.g for the consumer safety of electrical products, where this is not required by CPSC regulations (Orgalime 2014: 10).

organisations with the elaboration of standards that invalidate conflicting sub-central standards, standards development in the US is decentralised and leads to multiple, conflicting standards. Both the EU and the US, however, adopt the risk principle in the design of regulatory policies on mechanical and electrical safety although the risk principle is applied slightly differently in the EU than in the US. Figure 17 summarises the contrast of the EU and US engineering regulatory regimes.

Dimension	Regulatory instrument	Authority distribution	EU	US
Regulatory policies	**Legislation**	**Centralised**	New Legislative Framework: Machinery Directive, Low Voltage Directive, Electromagnetic Compatibility Directive, Pressure Equipment Directive	e.g. Occupational Safety and Health Act
	Regulations **Standards**	**Centralised**	Risk principle - Elimination of all safety risks that arise under normal circumstances - Regulation of safety risks for specific products	Risk principle - Elimination of all safety risks that arise under normal circumstances Full protection principle - Elimination of all potential safety risks - Regulation of safety risks for specific uses and applications of products
		Non-centralised		Full protection principle - Elimination of all potential safety risks - Regulation of safety risks for specific uses and applications of products
Implementation Procedures		**Centralised**	SDoC: - testing of most products, testing according to ISO standards Third-party conformity assessment: - only high-risk products, testing according to ISO standards IAF: - accreditation of CABs according to ISO standards	Third-party conformity assessment: - as a general rule applies to most products, testing according to US standards US accreditation: - accreditation of CABs and Testing according to US standards or agency monopoly
		Non-centralised		

Figure 17: Contrast of EU and US engineering regulatory regimes

While regulatory authority structures for implementation procedures between the EU and the US are per se incompatible, they can be made compatible. Authority on conformity assessment procedures in the EU is centralised through the designation of 'Notified Bodies', but it is mostly decentralised in the US, unless an agency lists a specific CAB – such as the OSHA in the past. However, an extension of autonomy for both the Commission and the OSHA is possible if the Commission recognises US CABs as 'Notified Bodies' and the OSHA recognises 'Notified Bodies' as NRTLs. Regulatory principles are overall compatible, but incompatible for risks and products for which the Commission assigns SDoC and US agencies assign 'third-party assessment'. Besides, regulatory principles applying to accreditation procedures for CABs and testing procedures to ascertain conformity are overall compatible.

6.2.5. Expectations: Commission strategies in transatlantic engineering cooperation

Based on the contrast of the engineering regulatory regimes in the EU and the US and the distribution of regulatory compatibilities, this sub-section formulates expectations for Commission strategies on transatlantic engineering cooperation. As in chapter 6.1.5, these expectations operationalise the hypothesis derived on the influence that regulatory compatibilities have on constraining the choice of a regulatory cooperation strategy. No separate operationalisations will be presented for the effects of bureaucratic pressure within the Commission and societal actor mobilisation as this has already been done in chapters 4.4.2. and 4.4.3 respectively.

Given that US regulations on mechanical and electrical safety are often developed at state- or regional-level and OSHA and CPSC regulations mostly cover highly specific risks, it should not be expected that the Commission pursues 'regulatory alignment' or 'equivalence' with regard to mechanical or electrical safety regulations. Exceptions to this expectation may apply if the Commission is able to identify a safety regulation which applies to the same product or risk and prescribes the same level of safety protection in the EU and the US. In the latter case, the Commission can be expected to pursue 'equivalence'. Likewise, as standards in the EU are developed under a centralised authority to offer a presumption of conformity whereas the US maintains a competitive system of rival standards, it should not be expected that the Commission chooses 'regulatory alignment' or the recognition of 'equivalence' with regard to standards.

As the compatibility of regulatory authority structures on conformity assessment procedures can in principle be established and regulatory principles are compatible, the Commission can be expected to pursue an 'alignment of implementation procedures' with regard to a mutual recognition of conformity assessments where both the EU and the US require third-party testing. Besides, the Commission can be expected to pursue an 'alignment of implementation procedures' regarding testing procedures where both the EU and the US engineering regulatory regimes require third-party testing. Furthermore, the Commission can be expected to choose an 'alignment of implementation procedures' related to accreditation procedures. At the same time, the Commission should not pursue an 'alignment of implementation procedures' where the EU and US regulatory require establish diverging requirements for the application of third-party testing or SDoC.

The Commission can also be expected to choose 'information exchange' with regard to the development of new electrical safety regulations and standards in support of these regulations.

6.2.6. Commission strategies in transatlantic engineering cooperation

This section lays down the Commission's choice of regulatory cooperation strategies during the three regulatory cooperation initiatives selected in chapter 5.1.

New Transatlantic Agenda (NTA)

During the NTA, the Commission pursued an 'alignment of implementation procedures' in line with the expectation derived in section 6.2.5. DG Trade opened negotiations on six Mutual Recognition Agreements (MRAs) in 1995 with the US Trade Department (USTR), one of which covers electrical goods (Pelkmans & de Brito, 2015: 3). DG Trade was driven by optimism that the negotiation of the MRAs would pave the way to lower the "a quick route to lowering the costs of EU/US TBTs" (Egan & Nicolaidis, 2001: 891). The optimism of DG Trade also persuaded DG Industry and its Commissioner. Both hoped to realise a double benefit with the negotiation of the MRAs. First, they held the belief that the MRA would be an easy way to facilitate and promote trade including in engineering products (Egan & Nicolaidis, 2001: 893; see also Peterson et al, 2005). In this regard, DG Trade and later also DG Industry not only noted the motto of the TABD supporting the negotiation of the MRA ("one standard, one test, approved everywhere"), they greatly welcomed it (Commission, 2000a). In their view, the MRA would create significant benefits for EU firms and should therefore be supported (Commission, 2001a)[124]. Second, DG Industry held the belief that a mutual recognition of conformity assessment that would facilitate transatlantic trade would also enhance the support of firms and especially member state authorities for the EU's own internal system of a mutual recognition of conformity assessment (Commission, 1998). At the time of the NTA, especially authorities and CABs in Northern member states were sceptical that CABs across the EU delivered the same level of safety protection for consumers (Interview 4). The recognition of the EU's model by the US was thus also seen by the Commission as a way to reduce opposition to the EU's conformity assessment system within the Internal Market[125]. The negotiations were successfully concluded in 1998.

The MRA followed the notion to reduce trade restrictions resulting from conformity assessment procedures in the TBT Agreement. It established that for electrical products requiring 'third-party conformity assessment' in the EU and the US[126], EU member state authorities accept the results of conformity assessment procedures conducted in the US according to the regulatory requirements of the

[124] This can be read as an indicator that the Commission promoted the MRA to enhance its legitimacy.
[125] The hope to reduce opposition of member state authorities and CABs suggests that the Commission also used the MRA to enhance its autonomy.
[126] The MRA thus did not cover electrical products whose assessment with regulatory requirements was subject to Suppliers' Declaration of Conformity (SDoC) in the EU.

EU. Likewise, it established that the OSHA accepts the results of conformity assessment conducted in the EU according to the regulatory requirements of the US (Commission, 1999)[127].

Kept out of the negotiations on the MRA, the OSHA, however, considered the 'quality' of the designation for CABs for conformity assessment in the EU as unsatisfactory (Interview 4). It therefore rejected EU designations of CABs and began conducting on-site reviews of CABs in the EU starting in 1999 to evaluate their ability to assess conformity with regulatory requirements. At the same time, the OSHA refused to accept the results of conformity assessments conducted in the EU. After it continued to refuse implementing the MRA on electrical goods negotiated between DG Trade and the USTR, the Commission officially suspended the Agreement in 2004 (Interview 5)[128]. Moreover, at the time it considered the OSHA principle to require 'third-party conformity assessment' for most electrical products as "excessively burdensome" (Interview 5) because it regarded the safety risk emanating from most electrical products to human health as very low.

Technical officials in DG Industry came to suspect the OSHA of protectionism for an industry in which trade statistics implied that the EU had a competitive advantage over the US (Interview 5). Frustrated about the failure to align implementation procedures through the MRA, the support for regulatory cooperation at the 'political' level of the Commission slowed down (Pelkmans & de Brito, 2015: 6). Where regulatory cooperation in the engineering sector should thus still take place, this had to occur in the Junior Task Force. Both Egan and Nicolaidis (2001) and Pollack (2005) offer reasons why technical officials did not further pursue regulatory cooperation at the technical level. First, regulatory cooperation was considered a burdensome process with resources of DG Industry officials bound in the preparation of the New Legislative Framework Directives. Second, after the failure of DG Trade and DG Industry to negotiate an MRA that would be implemented by the OSHA, officials did not consider it worthwhile to invest their limited time resources into a process that was unlikely to deliver tangible results. Their 'legitimacy' towards both firms and consumers in the EU was arguably better ensured by investing resources into the New Legislative Framework Directives. Technical officials thus did not pursue any further bilateral regulatory cooperation with the US during the NTA (Interview 5)[129].

[127] For an in-depth description of the negotiations leading to the conclusion of the MRA see Egan and Nicolaidis (2001)

[128] Besides, the Commission was dissatisfied with the degree of US market access the MRA gave to EU producers of electrical goods.

[129] Pelkmans (2015: 20) interprets the refusal of the OSHA to implement the MRA and the Commission's suspension of the MRA as an indication of a lack of trust between both regulators. He argues that neither side made efforts to appreciate the choice of each side to choose SDoC and 'third-party conformity assessment' respectively. Moreover, he argues that the OSHA's decision to inspect CABs in the EU demonstrates the high level of mistrust OSHA had in tests conducted by EU CABs.

High-Level Regulatory Cooperation Forum (HLRCF)/ Transatlantic Economic Council (TEC)

At the beginning of the HLRCF in 2005, technical officials and senior-level bureaucrats did not consider engineering products as a priority sector for regulatory cooperation and did not mention it in the Roadmap for Regulatory Cooperation (Commission, 2005a). This changed when in 2007, the HLRCF was superseded with the TEC. Industry Commissioner Verheugen who co-chaired the TEC for the EU, insisted that the Commission also take up regulatory cooperation on engineering again (US Department of State, 2007; Interview 5).

Mobilisation of societal actors in support of regulatory cooperation in the engineering sector was scarce. The TABC who provided business input to the TEC rather focused on regulatory cooperation in other sectors, such as cars (US Department of State, 2007; Interview 14). Engineering industries were only represented by a few large firms comprising engineering departments, e.g. Siemens (Interview 6). To promote regulatory cooperation as means to trade liberalisation and better regulatory policy-making, the Commissioner had to task his DG to identify issues for regulatory cooperation itself. This search was guided by an assumption that for electrical goods, US standards resembled EU standards. In line with the prediction in chapter 6.2.5., senior-level officials in DG Enterprise sought to implement the demands of Commissioner Verheugen by seeking regulatory cooperation through an 'alignment of implementation procedures'. This alignment should, however, this time not be sought through a mutual recognition of conformity assessment procedures, but an alignment of the conformity assessment procedure itself (Commission, 2006c).

In 2007, DG Enterprise submitted a proposal to the OSHA to accept SDoC for low-risk electrical goods, i.e. those governed by the Low Voltage Directive in the EU. In the statement, it argued that "third-party conformity assessment of "low-risk electrical and electronic products […] imposes unnecessary additional costs and market-entry barriers on exporters of these goods" (OSHA, 2008)[130]. The Commission emphasised that certain products lay outside the scope of this request and the Commission continued to require the third-party conformity assessment for them[131]. In meetings with the OSHA, DG Industry sought to explain why it relied on SDoC as a principle for conformity assessment of low-risk electrical products and to persuade the OSHA of its benefits (Interview 5). Moreover, it supplied statistics to the OSHA on compliance failures of self-certified low-risk electrical products, provided by the authorities in member states responsible for market surveillance[132]. The OSHA rejected the request of the Commission in a long 'Notice' in 2010 (OSHA, 2010). First, it argued that the statistical data

[130] For the OSHA's full request of information and a summary of the Commission's request see (OSHA, 2008)
[131]This included e.g. electrical equipment for use in an explosive atmosphere (OSHA, 2008).
[132] Yet, the Commission could not rely on systematic accident statistics and across-the-board statistics from market surveillance itself (Pelkmans, 2015: 22) as the EU approach does not offer incentives to collect such systematic information (Interview 4). Besides, the Commission does not have the organisational resources to collect corresponding statistics itself or conduct annual inspections.

submitted by the Commission failed to demonstrate that the SDoC used in the EU achieved the same level of protection than the third-party certification in the US. Second, it claimed that the EU system to select a conformity assessment procedure based on proportionality and cost-benefit considerations was incompatible with its own mandate for the elimination or reduction of risk for the safety of workers[133] (Pelkmans, 2015b: 21).

DG Enterprise responded to the OSHA, rejected the interpretation of the OSHA that its application of SDoC as a principle of conformity assessment was overall incompatible with the risk principle[134]. In exchanges with the OSHA during the TEC, DG Enterprise officials emphasised that the statistics submitted by the Commission to the OSHA did not allow inferences why compliance failures in the case of self-certified low voltage electrical products had occurred (see Pelkmans, 2015b: 21). It put forward that compliance failures could not only be the result of product failures, but also be due to inappropriate paperwork, inappropriate conduct of workers or consumers or indeed the safety of the products (Interview 5; Pelkmans, 2015b: 21). Instead, the argument that had been developed in internal coordination meetings within DG Enterprise was that there was no systematic statistical evidence that self-certified products of suppliers were more likely to show product failures and thus cause safety risks to human health than products whose conformity assessment was assessed by third-party testing (Interview 4)[135]. Essentially, DG Industry argued that the SDoC principle was compatible with the third-party testing principle in the US for low-risk electrical products. In response to the OSHA Notice, the Commission did, however, not further seek to persuade the OSHA to align its implementation procedures with those of the EU in the framework of the TEC. On the contrary, it began to think internally how it could reduce the compliance failures detected by the OSHA and improve inspections and market surveillance by member state authorities (Interview 4).

Given the renewed failure to achieve an 'alignment of implementation procedures', support at the 'political' level of the Commission for regulatory cooperation once again dropped by the time of 2009 (Transatlantic Economic Council, 2009a). Technical officials in DG Enterprise were also reluctant to pursue regulatory cooperation in the absence of political support in the HLRCF (US Department of State, 2009b). An 'alignment of implementation procedures' now seemed difficult to achieve, given that the OSHA had opposed to implement both the MRA and to adopt SDoC. Moreover, the fragmentation of regulatory authority in the US in the engineering sector made officials reluctant to adopt a different regulatory cooperation strategy and attempt policy cooperation. The Ecorys (2009) study had signalled Commission officials that important trade barriers in the engineering sector were not federal regulations,

[133] The assessment of an 'incompatibility' between the risk principle applied by the Commission and the OSHA should be read as a perception and interpretation of the OSHA.
[134] I have described that the risk principle characterises the adoption of regulatory policies in the EU (see chapter 6.2.3).
[135] Interview partners (Interviews 4,5) noted that where product failures were detected in the EU during market surveillance by member state authorities, these were often found in products tested through third-party conformity assessment.

but State-level regulations (Interview 4) . Potential attempts towards policy cooperation with the OSHA were thus seen as non-beneficial to EU societal actors, given that 'equivalence' or 'regulatory alignment' would offer only limited market access to EU firms (Interview 18). The lack of mobilisation of engineering associations during the TEC was unable and unwilling to dispel this impression.

At political level in the Commission, regulatory cooperation remained, however, a priority. Agenda-setting by Commissioner Verheugen and senior-level officials sought to address the divergence in EU and US technical standards that firms had indicated as an important trade barrier in the Ecorys (2009) study. Regulatory cooperation was thus seen by the administrative and political leadership of DG Enterprise as an instrument to enhance the legitimacy of the Commission towards societal firms, notably engineering firms many of which were SMEs (Interview 5). In light of the Commission's inability to align implementation procedures on conformity assessment with the OSHA, the administrative and political leadership of DG Enterprise tasked officials to look for alternative means to facilitate transatlantic trade not only, but also in engineering products. They proposed to consider 'information exchange' on standardisation in view of the divergence in standards used in the EU and the US in support of legislation (Commission, 2011a)[136]. Commissioner Verheugen supported this proposal for enhanced 'information exchange' between the European standardisation organisations (ESO) and the coordinator of US standard development organisations, ANSI (Transatlantic Economic Council, 2010). DG Enterprise and the Commissioner presented their strategy to pursue 'information exchange' on standards for discussions in the TEC (Commission, 2010; Inside US Trade, 2010b). At the December 2010 meetings of the TEC and the High Level Regulatory Cooperation Forum, the Commission reached an agreement with the US Department of State to formulate joint improvements to each side's processes for the use of voluntary standards in regulation (Commission, 2011a). Upon the Commission initiative, the EU and US negotiated a joint document, "Building bridges between the US and EU standards systems" in November 2011 (Commission, 2011a). In the document, the Commission and the US Department of State agreed to enable and facilitate 'information exchange' in processes of the use of voluntary standards in regulation[137]. Furthermore, both sides gave a political commitment to encourage the ESOs and the American National Standardisation Institute (ANSI) to strengthen transparency and facilitate comments by stakeholders on draft standards (Commission, 2011a: 3)[138].

[136] As pointed out in chapter 6.2.4, the divergence in EU and US standards results from the use of multiple, competitive standards in the US, the decentralised distribution of regulatory authority, allowing sub-central regulatory agencies to 'reference' standards, many of which are US standards and not ISO or IEC standards, and the authority of OSHA to 'reference' any standard, including non-ISO or IEC standards, in its technical regulations.
[137] The US State Department gave a political commitment to instruct federal agencies to consider international standards when developing regulatory measures, consistent with their procedures (Commission, 2011a: 3).
[138] Itself, the Commission agreed that in its standardisation requests to the ESOs, it would instruct them to consider "consensus standards developed through an open and transparent process and that are in use in the global marketplace".

Transatlantic Trade and Investment Partnership (TTIP)

With the drafting of the High-Level Working Group Report in 2012 that prepared the TTIP negotiations, the 'lead' in the Commission shifted to DG Trade. Yet, engineering was not a priority sector for DG Trade when the High-Level Working Group Report was finalised and the TTIP negotiations were launched in 2013 (High-Level Working Group, 2013). Engineering products were only addressed in general through the position paper on Technical Barriers to Trade (TBT). While there was no disagreement within DG Trade that a potential TTIP should have a chapter on TBT[139], the consideration of the engineering was not a priority (Interview 6).

DG Trade organised the public consultation for the launch of FTA negotiations with the US (Inside US Trade, 2012d). The German engineering associations VDMA and ZVEI participated in this consultation (Commission, 2012c). Yet, unlike e.g. in the chemicals sector, they did not present a joint position paper with a US engineering association (see ZVEI, 2015; VDMA;.2013) Subsequently, DG Trade officials evaluated the contributions of business associations and NGOs to the consultation. In coordination with DG Grow officials, but under the lead of DG Trade they drafted a position paper on TBT (Interview 4, Interview 5, Interview 6).

DG Trade published a position paper on TBT on 16 July 2013 (Commission, 2013b). In the paper the Commission chose issues in line with a strategy to pursue an 'alignment of implementation procedures'. DG Trade and DG Grow officials thus proposed to agree on common criteria to be applied when either side introduced new conformity assessment rules (Commission, 2013b: 6). This should enhance the consideration of these criteria as appropriate by regulators in other countries, but also by societal actors within the EU (Interview 5). Moreover, Commission officials suggested an alignment of accreditation processes of conformity assessment bodies (CABs), seeing "some merit in encouraging the greater use of the ILAC and IAF agreements to facilitate the mutual recognition of accreditation certificates" (Commission, 2013b: 6). Commission officials hoped that the spread of ILAC and IAF standards for the accreditation of CABs would substantiate support within member states for EU rules on the accreditation of CABs. Moreover, an alignment of accreditation procedures for CABs would make it easier for EU CABs to sell their services in the US and thus support trade.

Beside an 'alignment of implementation procedures', the Commission also chose to pursue 'information exchange'. The choice of issues for 'information exchange' covers mainly the adoption of regulatory policies, notably regulations and standards. The proposals for 'information exchange' on regulatory policies build on previous documents, i.e. the 'Guidelines for EU-US Regulatory Cooperation and

[139] The inclusion of a TBT Chapter was also important to protect the 'template' for EU FTAs. 'Template' considerations were particularly important for the TTIP as DG Trade envisioned extending a potential TTIP to other third countries or at least use certain chapters as templates for negotiations with other third countries.

Transparency' (Commission & USTR, 2002) and the 'Building bridges between the US and EU standards systems' (Commission, 2011a). With regard to technical regulations, the Commission chose to persuade the OSHA to enhance transparency and exchange information for the development of coherent future regulations (Commission, 2013b: 4). This would make it easier for EU firms and NGOs to anticipate future OSHA regulations and at the same time help avoid technical differences that obstruct transatlantic trade (Interview 4). Regarding standards, officials put forward to encourage SDOs in the EU and US to develop joint standardisation work programmes. The position paper proposes to 'link' the standardisation systems notably through the encouragement and consideration of an "exchange of technical information between expert committees in the development of standards" (Commission, 2013b: 5). This link would offer a triple benefit to the Commission: First, it would reduce the likelihood that technical specifications of regulatory requirements would differ between the EU and the US, thus reducing adjustment costs for EU firms seeking to export to the US. Second, it would promote the spread of EU standards and thus support their consideration as appropriate by societal actors in the EU and outside the EU. Third, it would reduce political pressure by foreign governments on the Commission that considered the EU standardisation system as closed and protectionist (Interview 5).

The choice of implementation procedures to be aligned thus reflects results and failures of the previous transatlantic regulatory cooperation initiatives. The Commission, however, neither proposed a mutual recognition of conformity assessments nor an adoption of SDoC as a conformity assessment procedure for low-risk engineering products (Commission, 2013b). The OSHA had made clear to Commission officials that it did not consider an adoption of SDoC as appropriate to ensure a high level of consumer safety (Interview 5). At the same time, the Commission arguably wanted to prevent an open discussion on the respective benefits of SDoC and third-party conformity assessment in the EU. CABs were starting to lobby the EP, but also member state representatives that third-party conformity assessment was able to provide a higher level of consumer safety (Interview 4; for the argument of CABs see VdTÜV, 2014). Both officials in DG Trade and DG Grow were sceptical of this argument, pointing out that most incidents of product failure and thus higher consumer safety risk in the EU had occurred in products which had been subject to third-party conformity assessment (Interview 4, Interview 5, Interview 6). Moreover, both DG Trade and DG Grow wanted to avoid a discussion that would subsequently raise costs for firms through domestic pressure to introduce third-party conformity assessment without potentially raising the level of consumer protection (Interview 6).

After the publication of the position paper, DG Trade began in early 2014 to mobilise engineering associations to provide input to discussions on TBT within the Commission. Moreover, they should help to raise societal support for the conduct of the TTIP negotiations. NGOs, but also some business associations representing small- and medium-sized enterprises (SMEs), notably from Germany, openly questioned that a potential TTIP agreement would offer benefits to small firms (for a discussion see

Götz, 2018). The important role played by SMEs in the engineering industry subsequently led DG Trade to focus mobilisation efforts on the engineering industry (Commission, 2014c).

The request of DG Trade to engineering industry to provide technical input led to the publication of a series of position papers by the EU-level engineering association Orgalime (Orgalime, 2016; Orgalime, 2015; Orgalime, 2014). Many of these position papers reflect or are translated versions of position papers published by the German engineering associations VDMA and ZVEI (ZVEI, 2015; VDMA, 2013). In its position papers, Orgalime raises mostly demands aiming at an 'alignment in implementation procedures' and 'information exchange'. With its 2015 position paper, it also makes suggestions for a limited 'regulatory alignment' and 'equivalence' (Orgalime, 2015). Regarding an 'alignment in implementation procedures' with regard to the accreditation of conformity assessment bodies. It encouraged the Commission to demand a "NRTL mutual recognition system" based on the European accreditation system (Orgalime, 2014: 5)[140]. Moreover, Orgalime proposed an alignment of testing procedures (Orgalime, 2014: 6). At the same time, it warned against an immediate mutual recognition of conformity assessment procedures as it viewed that this would be disadvantageous to EU industries (Orgalime, 2014: 6). Proposals for 'information exchange' aim at the establishment of a "transparent system […] including notifications of planned developments" (Orgalime, 2014: 4). This notification system should be built on the practices of the EU standardisation system (Interview 6)[141].

Orgalime also presented vague proposals which implied a one-sided 'equivalence' of standards. This one-sided 'equivalence', however, only concerned the 'referencing' of ISO and IEC standards in addition to US standards in technical regulations of the OSHA[142],[143]. Orgalime warned, however, against a two-sided mutual recognition or equivalence of 'harmonised standards' in the EU with US standards[144]. Moreover, Orgalime in 2016 presented a comprehensive list of mechanical safety, electrical safety and explosion protection technical regulations (Orgalime, 2016) which it considered as possible for 'regulatory alignment' or 'equivalence'.

[140] The 2014 position paper once again praises the "liberal nature of the successful European market access system" while Orgalime in its 2013 and 2015 position papers outlines the heavy and costly forms of conformity assessment in the US with the de-facto monopoly of UL (Orgalime, 2015; Orgalime, 2014; Orgalime, 2013).

[141] Orgalime highly praises the openness, transparency and predictability of the EU standardisation system, while heavily criticising the decentralised standardisation system of the US which "makes it difficult for European companies […] to participate in the development of standards […] and results in the need to purchase standards from more sources" (Orgalime, 2014: 5-6).

[142] In the long term, only standards developed in close connection with ISO and IEC should be used for compliance with EU and US legislation (Orgalime, 2014: 6).

[143] The approximation of NEMA and Orgalime positions on standardisation likely reflect the increasingly frequent adoption of IEC standards in the US after 2010. The latter, in turn, indicates concerns of US industry that their international competitiveness suffers if US standards differ from IEC standards (Pelkmans, 2015b: 23; Interview 6).

[144] US businesses would then be able to use US standards as a presumption of conformity with EU requirements while EU firms would still need to go through third-party certification in the US. The latter would give US producers immediate access to the EU market, given that US standards would thus qualify for compliance with 'essential requirements', and could self-certify their products. EU firms, however, would still have to pay for 'third-party conformity assessment' in the US (Interview 6).

Moreover, NGOs mobilised against regulatory cooperation on engineering products, especially the European Environmental Citizens Organisation for Standardisation (2016) and the German Social Accident Insurance (DGUV; 2014). They warned that a "mutual recognition of standards" would lower the level of health and safety protection and implied that the Commission should therefore pursue 'regulatory competition'.

Demands for an 'alignment of implementation procedures' were then also raised by EU conformity assessment bodies (CABs), notably Verein der TÜV (2014). The CABs demanded a mutual recognition of conformity assessment bodies and a mutual recognition of conformity assessments which would apply in sectors enumerated in a 'positive list' third-party conformity assessment (VdTÜV, 2014: 8). This list contains engineering products currently not subject to third-party conformity assessment in the EU, such as machines or low-voltage electrical products. The position paper also outlines demands for the accreditation of CABs without, however, explicitly requiring an accreditation based on ILAC and IAF standards. Instead, VdTÜV promoted a mutual recognition of accreditation, based on the accreditation rules of the country of origin, and laid down the establishment of a centralised accreditation body in both the EU and the US as a possible long-term objective. Yet, CEN and CENELEC (2013) urged Commission negotiators not to accept US requirements for specifically applicable conformity assessment procedures and work towards the elimination of these requirements. The objective of the Commission should be to achieve 'equivalence' for the recognition of conformity assessment bodies where recognition, i.e. accreditation, follows internationally recognised practices (CEN & CENELEC, 2013: 9)

Subsequently, DG Trade began to concentrate its efforts to 'align implementation procedures' on the accreditation of CABs for third-party conformity assessment. DG Trade emphasised that the OSHA should recognise conformity tests of CABs accredited according to IAF standards (Commission, 2015b). It argued that US standards for the accreditation of CABs did not invoke different principles than IAF standards. A recognition of tests conducted by CABs that were accredited according to other than US accreditation standards would therefore not undermine the 'quality' of accreditations demanded by the OSHA in the US. The differences in accreditation procedures between the Commission and the OSHA rather reflected different bureaucratic practices[145](Interview 5). Both DG Trade and DG Grow agreed that key to aligning accreditation procedures would be a separation of functions between SDOs and CABs in the US (Commission, 2015d)[146]. Besides, the OSHA had the regulatory authority to designate

[145] Likewise, the Commission also demanded the elimination of duplicative testing requirements for components by restricting the reassessment of components for the certification of final products (art. 7.5 Commission TTIP TBT Proposal).

[146]art. 7.3 Commission TTIP TBT Proposal. Some US SDOs also conduct conformity assessment. This allows them developing standards which designate them as the only CAB able to conduct the corresponding conformity assessment. If the OSHA 'references' a standard developed by a SDO which also conducts conformity assessment, it may create a monopoly for conformity assessment with the relevant 'referenced' standard.

CABs that it considered as capable of conducting third-party conformity assessment[147]. Aligning accreditation procedures would help to reduce the high costs of third-party certification for EU exporters (Interview 4). From the perspective of DG Trade, it would thus enhance the legitimacy of the Commission.

At the same time, DG Grow began to examine whether it could technically accredit US CABs as 'Notified Bodies' for conformity assessment in the EU and thus also align accreditation procedures in this way (Interview 5; Commission, 2015d). DG Grow officials presented the CETA Protocol to USTR and the OSHA, seeking to persuade them that this could be a template for recognising US CABs for testing and certification for the EU market (Interview 5; see also Commission, 2016f). Besides, officials sought to learn if accreditation practices of the OSHA as well as other agencies, e.g. the CPSC, could provide an equivalent solution for the enforcement of product safety rules of products certified by CAB (Interview 5)[148]. Both approaches were intended to enhance the consideration of appropriateness of the EU accreditation system for CABs that at the time of writing continues to be the subject of criticism by some member state authorities. This would enhance the legitimacy of the Commission's system.

Yet, especially DG Trade officials rejected demands of the USTR for a mutual recognition of conformity assessments until accreditation procedures had been aligned (Interview 4). They emphasised that a mutual recognition of conformity assessments[149] remained its objective for the long-term (Interview 4, Interview 5, Interview 6). The reason for the pursued sequencing in the 'alignment of implementation procedures' was mostly a tactical one. The experience of the failed MRA had shown that such regulatory cooperation would not be beneficial to EU firms unless the Commission succeeded to break the monopoly of certain US CABs on third-party conformity assessment first (Interview 6). Given that the designation of CABs was well within the authority of the OSHA, the Commission needed the bargaining leverage to ensure that regulatory cooperation would enhance its legitimacy with regard to societal actors, notably EU firms[150].

Simultaneously, DG Grow pushed back emerging demands of the USTR for an 'equivalence' of EU and US standards (Interview 4). Moreover, it rejected USTR demands for an alignment of EU and US standardisation procedures (Interview 5). In the Commission's view, the latter would have undermined the centralised distribution of regulatory authority on standardisation in the EU (Interview 5)[151]. The

[147] Interview partners underlined that the decision of the OSHA to break the monopoly of UL in 2012 and appoint 12 CABs as designated CABs demonstrated the authority of OSHA to take these decisions (Interviews 4,5,6).
[148] The Commission emphasised explaining the relevance of the 'territoriality' rule for the designation 'Notified Bodies' given that member state authorities in which a CAB is territorially placed have obligations to control accredited CABs.
[149] This is the regulatory cooperation strategy pursued with the MRAs during the first phase.
[150] Mutual recognition of conformity assessments was also a strong interest of the USTR (Interview 4).
[151] In chapter 4.1.2., I have excluded the necessity of institutional change as a consequence of a regulatory cooperation strategy. The demand of the US is thus arguably more 'far-reaching' than the strategies pursued by the Commission. This acknowledgement raises potential limitations of the theoretical model derived in chapters 3 and 4 with regard to its transferability to other regulators than the Commission.

Commission emphasised that an 'equivalence' of standards[152] would give US standards the basis for a presumption of conformity with 'essential requirements' defined by EU legislation (Interview 4)[153]. Likewise, DG Grow pushed DG Trade to reject US demands to change the EU standardisation system itself. Notably, it rejected US demands that the Commission establish an obligation for CEN and CENELEC to involve US experts in the standards development process, underlining that unlike US agencies, it did not have authority to establish rules for SDOs (Commission, 2015e; Commission, 2016f).

The European Standardisation Organisations (ESOs) began to mobilise against the demands of the USTR. They fended off demands of the USTR for a "mutual recognition", i.e. 'equivalence', of US and EU standards (CEN & CENELEC, 2014: 2)[154]. Their warnings notably reflected fear that national standards bodies could potentially also demand greater individual authority and demand the recognition of national standards in parallel to harmonised standards (Interview 4). Especially DG Grow was wary of the recognition of US standards as it could undermine the centralised distribution of standardisation authority in the EU (Interview 4). In the view of the Commission, this would challenge the integrity of the Single Market (Interview 6). Moreover, the recognition of rival or competing standards in addition to 'harmonised standards' would undermine the authority of the ESOs to demand the withdrawal of conflicting standards (Interview 5; Commission, 2016h). Both the ESOs and Commission DGs feared that SDOs in member states could raise claims to regain authority over the development of standards (Interview 6). As a consequence, it would also undermine the autonomy of the Commission to issue standardisation requests in support of regulatory requirements and accept ESO standards as technical specifications of regulatory requirements.

Instead, DG Grow officials sought to address the demand of the US for an alignment of standards by proposing reinforced 'information exchange' between the ESOs and US SDOs (Commission, 2016h). In the view of the Commission, enhanced 'information exchange' between the ESOs and US SDOs could promote using existing standards of the other side rather than developing own standards and thereby help align standards (Interview 5, Interview 6). This proposal built on the 'information exchange' established among the ESOs and ANSI through the 'Building Bridges' document (Commission, 2011a). In this regard, DG Grow sought to persuade US negotiators that enhanced information exchange between EU and US SDOs would already facilitate mutual access of technical experts (Interview 5; Bundesministerium für Wirtschaft und Energie, 2014: 8).

[152] This refers to equivalence as understood by the USTR.
[153] This implies that in addition to an incompatible distribution of regulatory authority, equivalence of standards would also be incompatible with the implementation principles of the EU.
[154] CEN and CENELEC warned that an 'equivalence' of standards would undermine 'SHEC' objectives, fragment the EU market, reduce opportunities for stakeholders to participate and create unbalanced market opportunities favouring US firms. Moreover, 'equivalence' would undermine their authority to withdraw conflicting national standards.

Moreover, the ESOs promoted proposals for reinforced 'information exchange'. They proposed to Commission negotiators to promote improving transparency of the US standardisation system by publishing information on draft standards and thereby enable participation of stakeholders- including ESOs- in the development of standards (CEN & CENELEC, 2013: 7)[155]. Commission officials took up this suggestion and put forward that US SDOs publish their planned standardisation work and open it up for comments by other actors, including the Commission[156]. In exchange for possibilities to comment on planned standardisation activities of US SDOs, DG Grow officials offered that they would establish a commitment for ESOs to consider existing US standards when it issued standardisation requests for ESOs to develop or provide standards (Interview 4, Interview 6). Moreover, they offered that the Commission publish drafts of its annual standardisation work programmes and its standardisation requests so that stakeholders, including US regulators, could comment on them (Interview 5; Commission 2016h)[157].

During 2015, DG Trade officials continued to demand input from the engineering industry and encouraged it to present joint EU-US industry positions on provisions beyond a TBT Chapter. By late 2014, the EU engineering association Orgalime was, however, able to present a joint position paper with the US association of electrical equipment manufacturers (Orgalime & NEMA, 2014)[158]. Although demands expressed in the joint position paper remained vague and without specific policy prescriptions, DG Trade used it to promote further regulatory cooperation through the TBT negotiations. This encouraged DG Grow to reinforce efforts on an already previously proposed issue, i.e. 'information exchange' between the Commission and the OSHA (Commission 2016h). DG Grow officials thus proposed a change in the notification practices of the OSHA and other agencies for the development of technical regulations and the referencing of standards in technical regulations. This should include the possibility to receive feedback from regulators of the other side and the possibility to give written replies to these comments and the ability of regulators to communicate with each other during the comments procedures (Interview 5). The Commission demanded that the OSHA and other US agencies should make public their intention to 'reference' a standard in a technical regulation to allow stakeholders, including EU regulators, to comment on the preselection of standards for referencing (Commission, 2016h; Commission, 2015e). Interview partners noted that 'information exchange' could facilitate the ability of the Commission to persuade the OSHA to consider internationally agreed or EU 'harmonised

[155] They also underline that bilateral exchanges between EU and US SDOs should not weaken incentives for US SDOs to seek cooperation in ISO and IEC (CEN & CENELEC, 2013:7), argued by Büthe and Mattli (2011) to be preferred venues for the ESOs.
[156] Commission, 2014; art. 6.2 TBT textual proposal
[157] In reality, this offer did not propose to change existing procedures in the EU. It has been a practice of the Commission to publish draft standardisation programmes and requests for comments.
[158] The difficulty of Orgalime to develop a joint position paper with a US association reflects not only a lack of overlapping preferences, but also, if not mainly, the organisational structure of US engineering associations. While EU industries are organised hierarchically in horizontal associations representing the various subsectors of the engineering industry, US industries are represented in a fragmented manner through subsector associations without, however, an overarching horizontal association. The difficulty for Orgalime to present a transatlantic business position thus at least partly reflects collective action problems within the US industry (Interview 6).

standards' when it selects standards for referencing in technical regulations (Interview 4, Interview 5). They stressed that inviting other actors, including other regulators such as the Commission, for comments on envisaged technical regulations would not affect or restrict the ability of OSHA or another agency to adopt technical regulations that reflected its public policy objectives[159] (Interview 5). Higher transparency by introducing a notification for envisaged regulations would thus not restrict the autonomy of an agency[160]. However, the exchange of technical data during the preparation of technical regulations could help agencies make their regulations 'better' and strengthen them in the view of a judicial review of their regulations (Interview 5)[161]. At the same time, the Commission could gain limited access to the preparation of rule-making procedures in the US and demonstrate its willingness to address concerns of societal actors.

Until 2015, especially DG Grow officials had been reluctant to put forward proposals for 'equivalence' or an 'alignment' of regulations. It feared that the limited centralisation of authority on regulations in the US could open the way to calls that such alignment provided asymmetric benefits to US firms and support for calls in member states for sub-central regulations (Interview 6). At the same time, DG Trade noted the results of the Ecorys study (2009) that diverging EU and US regulations posed adjustment costs for EU SME exporters. DG Grow lacked, however, the technical knowledge on which issues OSHA technical regulations posed trade problems for EU exporters, but ensured the same level of protection as the essential requirements formulated in EU directives. Moreover, it did not have information on which issues OSHA had the authority to formulate regulations for the US market (Interview 5). DG Trade thus mobilised engineering industries to put forward proposals on which issues the pursuit of 'equivalence' would be feasible. In a comprehensive position paper on regulatory cooperation, Orgalime listed individual EU and US regulations in the areas of mechanical safety, electrical safety and pressure equipment that DG Grow could consider for 'equivalence' (Orgalime, 2016). Although NGOs continued to mobilise against regulatory cooperation on engineering products, especially the European Environmental Citizens Organisation for Standardisation (2016) and the German Social Accident Insurance (DGUV), DG Grow agreed to evaluate and consider these proposals (Interview 6). It did not exclude any more that it would also pursue 'equivalence' or 'regulatory alignment' on very limited issues (Interview 5; Commission, 2015e). It acknowledged that 'equivalence' could be a means to facilitate trade while 'regulatory alignment' could also reinforce the autonomy of the Commission to avoid particularistic policies. DG Grow refused, however, to make a commitment to

[159] In line with this terminology of this dissertation, information exchange is thus without regard to the compatibility of 'regulatory principles' that a US agency a foreign regulator adopt.
[160] Correspondingly, the Commission only included a 'best endeavours' statement, i.e. giving discretion to deviate, in its TBT textual proposal that EU and US should ensure compliance with referenced standards remains voluntary for manufacturers to demonstrate conformity with regulatory requirements (Commission, 2014; art. 6.5 TBT textual proposal).
[161] The Commission hoped that enhanced information exchange during the preparation of technical regulations would help to reduce 'unnecessary' divergences between EU and US technical regulations on issues in which the EU and the US followed the same regulatory principle (Interview 5).

address 'equivalence' on any of these regulations within the TTIP negotiations themselves as it first wanted to ascertain the OSHA's competence on these regulations as well as the level of protection provided by these regulations (Interview 5). Yet, until the TTIP negotiations were put on freeze in January 2017, the Commission did not select specific issues or regulations for 'equivalence' or 'regulatory alignment' (Commission, 2016l; Commission, 2016i; Commission, 2016d).[162]

Under demands of DG Trade to present a regulatory cooperation proposal on engineering, DG Grow in coordination with DG Trade elaborated a textual proposal for a regulatory cooperation chapter on engineering based on the discussions between 2013 and 2016. This proposal was adopted by the College of Commissioners in June 2016 and then presented to US negotiators on 15 July 2016 (Commission, 2016d). In substance, the textual proposal for an engineering chapter reflects the draft textual proposal for a TTIP chapter on TBTs adopted by the College and presented in March 2014 (Commission, 2014). The textual proposal summarises the strategy of DG Grow with regard to engineering regulatory cooperation.

The textual proposal lists a number of broader issues that the Commission may consider for regulatory cooperation with the US in the future:

> "The Parties shall co-operate […] on the following areas: a) mechanical and electrical safety, b) marking requirements, including safety signs and labels, c) exhaust emissions from non-road mobile machinery, d) energy efficiency, e) food contact materials used in equipment, f) electromagnetic compatibility (electromagnetic disturbance and immunity to electromagnetic disturbance), g) interoperability of equipment." (Commission, 2016d; art. 5.1 TTIP Engineering Annex Textual Proposal).

Likewise, related to conformity assessment procedures "the Parties shall co-operate […] aiming at avoiding unnecessary duplication of testing and administrative burden." (Commission, 2016d; art. 5.2 TTIP Engineering Annex Textual Proposal).

The Commission's TTIP Engineering textual proposal, however, avoids specific commitments on regulatory cooperation on specific issues. The TTIP TBT proposal that complements the Commission's strategy on engineering regulatory cooperation (Interview 4, Interview 5) underlines that the Commission restricts its choice of regulatory cooperation strategies to an 'alignment of implementation procedures' and 'information exchange':

With regard to an 'alignment of implementation procedures', the Commission demanded that regulatory agencies should abolish enlisting only one CAB for third-party conformity assessment and avoid dominant positions of CABs (Commission, 2015f, art. 7.5(a), 7.7 TTIP TBT Proposal)[163]. Moreover, it

[162] This suggests that DG Grow agreed to search for issues and technical regulations for possible 'equivalence' or 'regulatory alignment' as a 'trust-building exercise'. Rather than promoting 'equivalence' or 'regulatory alignment' in the context or during the TTIP negotiations, the Commission sought to initiate exchanges with the OSHA to identify areas in which 'equivalence' or 'regulatory alignment' could structurally be possible.

[163] The Commission in essence proposed that the OSHA align the structure of conformity assessment procedures in the US to the distribution of regulatory authority structures in the EU, if it has the regulatory authority to do so.

proposed that both the Commission and OSHA should review their conformity assessment procedures to "move progressively towards the least burdensome possible procedures commensurate with the risk that the underlying technical regulations are intended to address (Commission, 2015f; art. 7.1 TTIP TBT Proposal). It thus encouraged a movement in selected conformity assessment procedures towards Suppliers' Declaration of Conformity. The textual proposal, however, left out the idea expressed in the 2013 position paper to agree on common criteria for the choice of an appropriate conformity assessment procedure and to mention internationally agreed standards as a basis for conformity assessment. Besides, it does not explicitly promote the accreditation of CABs based on the ILAC and IAF standards.

Moreover, DG Trade and DG Grow emphasised 'information exchange' in the textual proposal. With regard to 'information exchange' on technical regulations, the textual proposal specifies that the EU and US "shall provide information regarding the objectives of, legal basis and rationale for, a technical regulation or conformity assessment procedure, that the Party has adopted or is proposing to adopt" (Commission, 2015f; art. 5.2(a) TTIP TBT Proposal). Related to 'information exchange' on standards, the Commission proposed to encourage SDOs to cooperate more closely and exchange information[164], thereby provide early notification of planned standardisation work and publish drafts for public comments (Commission, 2015f; art. 6.2 TTIP TBT Proposal)[165].

6.2.7. Discussion

The previous sub-section has laid down that during all three cooperation initiatives, including the TTIP negotiations, the Commission has mostly restricted its choice of regulatory cooperation strategies to an 'alignment of implementation procedures'. This sub-section discusses the Commission's choice of regulatory cooperation strategies during the three regulatory cooperation initiatives in view of the hypotheses derived from the Inter-relational Institutionalism. Particular attention is put on the analysis of the expectations on the constraints on regulatory cooperation formulated in section 6.2.5.

The process-tracing of the formation of the regulatory cooperation strategies within the three selected transatlantic cooperation initiatives confirmed the influence of bureaucratic pressure on the engagement of Commission officials in bilateral regulatory cooperation (Hypothesis 1). During the NTA, when bureaucratic pressure was low or even absent, Commission officials largely refrained from the

The competition among CABs which are, however, 'enlisted' by the regulator resembles the 'Notified Bodies' working in the EU.

[164] The Commission presents 'information exchange' as a means to "facilitate (b) the harmonization of standards based on mutual interest and reciprocity, according to modalities to be agreed directly by the standardization bodies concerned, (c) the development of common standards, and (d) the identification of suitable areas for such cooperation on new technologies." (Commission, 2015f: art 5.3 Commission TTIP TBT Proposal)

[165] US agencies do not publish draft standardisation requests. They rather choose standards autonomously for 'referencing' in technical regulations and subsequently publish chosen standards for notice-and-comment (Interview 5).

engagement in regulatory cooperation. An exception to this is the negotiation of the MRA on electrical goods. As the MRA was, however, initiated and negotiated under the leadership of DG Trade, it supports the relevance of bureaucratic pressure through the involvement of non-technical, non-regulatory DGs to begin the engagement in regulatory cooperation. During the HLRCF; the Commission's engagement in regulatory cooperation largely followed from demands of Commissioner Verheugen who tasked technical officials to explore opportunities for regulatory cooperation also in the engineering sector. The importance of bureaucratic pressure on the formation of a regulatory cooperation strategy is also revealed by the subsequent decline in the pursuit of regulatory cooperation by DG Enterprise officials. In the latter case, bureaucratic pressure by the political and administrative leadership slowed down after the OSHA refusal to accept SDoC. The engagement in engineering cooperation during the TTIP negotiations also underlines the need for bureaucratic pressure to initiate strategy formation. Interview evidence collected for this book and reports of TPC meetings suggest, however, that in the engineering case, bureaucratic pressure by DG Trade on DG Grow followed from demands of member states, notably Germany and Spain on DG Trade to explore opportunities for cooperation on the engineering regulatory regime. While this does not invalidate the hypothesis that bureaucratic pressure initiates strategy formation, it recalls that traditional principal-agent relations may continue to play a role even where the discretionary authority of the 'agent', i.e. the Commission as a regulator, is high.

The empirical finding of the strategies selected under bureaucratic pressure during the NTA, HLRCF and the TTIP negotiations again confirms the expectations formulated in section 6.2.5. The strategy choice reflected the distribution of regulatory compatibilities between the EU and the US in the engineering sectoral regime (Hypothesis 2).

Chapter 6.2.6. has shown that the Commission has mostly refrained from 'regulatory alignment' or 'equivalence'. Instead, in line with the expectations of chapter 6.2.5, the Commission has chosen to pursue the strategies 'alignment of implementation procedures' and 'information exchange'. 'regulatory alignment' through a harmonisation of standards should rather be pursued through international organisations and agreements (Interview 4). Besides, the Commission did not suggest the 'equivalence' of standards which are currently used as technical specifications for essential requirements of EU legislation or referenced in US regulations. The lack of OSHA authority to regulate notably mechanical safety has been mentioned by all interview partners as a main reason why the Commission did not promote 'regulatory alignment' (Interview 4, Interview 5, Interview 6). Moreover, the fragmentation of the US standardisation system and the persistence of competing standards have been cited as reasons why the Commission did not promote an 'alignment' or 'equivalence' of standards (Interview 4, Interview 5)[166].

[166] In its TBT position paper on TTIP, the Commission stressed that it wanted to "allow each [the EU and the US standardisation system] to maintain its distinctive character" and instead to "improve links between the two systems" (Commission, 2013b: 4).

Only during the TTIP negotiations the Commission began to contemplate persuading the OSHA to consider the development of common or coherent technical regulations in the future. The Commission suggested that common or coherent technical regulations could be developed "where neither side has regulations in place" (Commission, 2013b: 3). It is in this sense that the Commission welcomed the list of engineering industry of mechanical safety, electrical safety and explosion protection issues on which it could pursue 'regulatory alignment' and 'equivalence'. It does, however, not call into question the explanatory validity of the regulatory compatibilities framework. On the contrary, the absence of an observable strategy to promote 'regulatory alignment' or 'equivalence' in engineering until the time of writing supports the interpretation that the Commission used the list as an indication on which issues it could enhance 'information exchange' with the OSHA to potentially consider policy cooperation in the future. The consideration of regulatory policy cooperation in the future suggests, however, that there are risks and products within the engineering regulatory regime for which the distribution of regulatory authority is compatible so that policy cooperation is a feasible strategy.

The Commission's choice to pursue an 'alignment of implementation procedures' reflects the compatibility of regulatory principles. The compatibility of regulatory principles for policies indeed led to the pursuit of an 'alignment of implementation procedures' in line with the expectations of chapter 6.2.5. within all three cooperation initiatives. In conformity with the expectation formulated in chapter 6.2.5, with the MRA under the NTA, Commission officials promoted a mutual recognition of conformity assessments where engineering regulatory regimes required third-party testing both in the EU and the US. Moreover, also in line with the expectation formulated above, the Commission promoted a mutual recognition of accreditation procedures and an alignment of testing procedures.

Yet, beyond the expectations formulated in chapter 6.2.5., the implementation procedure for which the Commission pursued alignment varied across the three initiatives. This variation in the implementation procedure for which the Commission has chosen to pursue alignment has been argued to reflect tactical considerations in the negotiations. The Commission thus rejected the idea of incorporating or extending the existing Mutual Recognition Agreements (MRAs) negotiated during the TTIP negotiations, stressing that the divergence of the substantive requirements underlying the conformity assessment has not become smaller (Commission, 2013: 6). As laid down in chapter 6.2.6, the Commission feared that a mutual recognition of conformity assessment would create asymmetric benefits for firms located in the US as long as the OSHA did not respond to Commission demands on testing procedures and the recognition of CABs.

Besides, counter to the expectation formulated above, the Commission chose to promote the adoption of SDoC as a conformity assessment procedure by the OSHA in the second phase. Exchanges with the OSHA after the request to extend SDoC and the response of the OSHA arguably changed the opinion Commission officials held about the compatibility of implementation principles for conformity assessment. As a consequence, the Commission argued that it did not seek to promote SDoC during the

third phase any more (Commission, 2013b: 6). These observations do, however, not invalidate hypothesis 2, but rather state that in addition to regulatory compatibility reflections, tactical considerations may play a role in decisions regarding the specific issue to which a regulatory cooperation shall apply.

As in the chemicals case study, the choice of issues within the engineering regulatory regime on which the Commission has pursued the 'alignment of implementation procedures' has been shaped by the mobilisation of societal actors (Hypothesis 3). The promotion of a mutual recognition of accreditation procedures and the alignment of testing procedures reflects corresponding demands by Orgalime and the ESOs. Besides, the decision to propose an 'alignment of implementation procedures' supposedly also reflected proposals of firms participating in the TABC. The provision of technical information and expertise also shaped the content of other regulatory cooperation strategies. The issue-related content of Commission strategies on 'information exchange' and potential 'regulatory alignment' thus reflected issues proposed by Orgalime and the ESOs.

The Commission's rejection of proposals of societal actors shows that this has occurred where societal actor demands were either not in line with regulatory compatibilities or violated tactical considerations of the Commission aiming at the creation of benefits for many societal actors in the EU. For the second reason, the Commission has not taken up demands of CABs during TTIP for a mutual recognition of conformity assessment procedures. For the first reason, the Commission chose to address the deviation of US standards from ISO and IEC standards by promoting enhanced 'information exchange' between EU and US SDOs and enhanced 'information exchange' between the Commission and OSHA in the development of technical regulations. Discussions with the OSHA should serve as a 'trust-building measure' rather than realise 'regulatory alignment' during the TTIP negotiations. Likewise, the Commission acknowledged the warnings of NGOs against a "mutual recognition of standards". It did, however, not choose 'regulatory competition' because it argued that its ambitions reflecting an 'alignment of implementation procedures' and 'information exchange' would not lead to the lowering of health and safety levels feared by NGOs[167].

Furthermore, the process-tracing reveals the causality between regulator activities and societal actor mobilisation. Both interview evidence and the temporal sequence of statements show that societal actor mobilisation was mostly reactive. Activities of the engineering associations to draft position papers in which they indicated potential issues for regulatory cooperation as well as the elaboration of joint position papers with US engineering associations followed after Commission officials expressed demands to business associations for specific technical knowledge.

[167] Remark made by Commission negotiator Garcia Bercero at the TTIP stakeholder dialogue on 24 February 2016 in Brussels.

The high degree of technical complexity of the engineering regulatory regime and the low degree of large-scale regulatory innovation in this sectoral regime makes it unlikely that Commissioners and Directors General will invest bureaucratic pressure to demand engineering cooperation under regulatory dialogues. Moreover, the difficulty encountered by Orgalime and VDMA to form a transatlantic business alliance further decrease chances that they will maintain mobilisation on engineering cooperation when bureaucratic pressure is low. At the same time, the extensive position paper and the list of potential issues for regulatory cooperation may offer guidance to regulatory officials once a future Commissioner and/or Director General will reconsider transatlantic engineering cooperation.

6.3. Commission strategies in transatlantic food safety cooperation

This section proposes a case study for which existing literature implies that regulatory authority structures in the EU and US are compatible, but regulatory principles are incompatible for many policies. It is thus a case in which the Commission can be expected to pursue 'equivalence' according to the Inter-relational Institutionalism. This case study covers the Commission's choice of regulatory cooperation strategies in transatlantic regulatory cooperation in the food safety regime.

6.3.1. Introduction

Food safety policy refers to the regulation of the production and marketing of food for the protection of human, animal, and plant health. Regulatory issues in food safety concern the hygiene of food, the use of additives, residue limits of pesticides and veterinary drugs as well as food contamination (Hristova, 2013: 58). Issues of food safety are delineated from issues of food security and food quality (Josling & Tangermann, 2015a). While food security denotes the availability and affordability of (basic) food, food quality refers to the provision of information to consumers in order to allow an informed choice. Food quality regulations thus address questions of labelling, animal welfare or the geographical origin of a product[168]. While food safety is subject to extensive cooperation in international organisations (see below), engagement on food quality is relatively low. In view of the objective of this book to examine the regulatory cooperation strategies of the EU in case studies where cooperation in international organisations is dense, the following discussion will concentrate on regulatory cooperation on food safety issues. In practice, the delineation in particular between food safety and food quality is not always clear, and regulatory conflicts between the EU and the US have in the past especially emerged where the attribution of an issue to food safety or quality has been contested between both sides (Josling & Tangermann, 2015a: 164).

Firms affected by questions of food safety are both farms, food processors, and retailers. Especially farms, but also many food processors tend to be small- and medium-sized enterprises with their production usually concentrated at one site, notwithstanding the existence of large multinational corporations notably among food processors and retailers. Nonetheless, EU food producers are highly integrated into global value chains, relying on imports for animal feed or fertilisers in the case of farms or agricultural imports in the case of food processors. Similarly, both EU farms and food processors sell their output on global markets, either to processors or through retailers also to end consumers outside

[168] The use of Geographical Indications to indicate the origin of a product from a particular city or region is an example of the EU's policy on food quality.

the EU. Figure 18 shows the development of trade flows between the EU and the US in the food sector between 2006 and 2016[169].

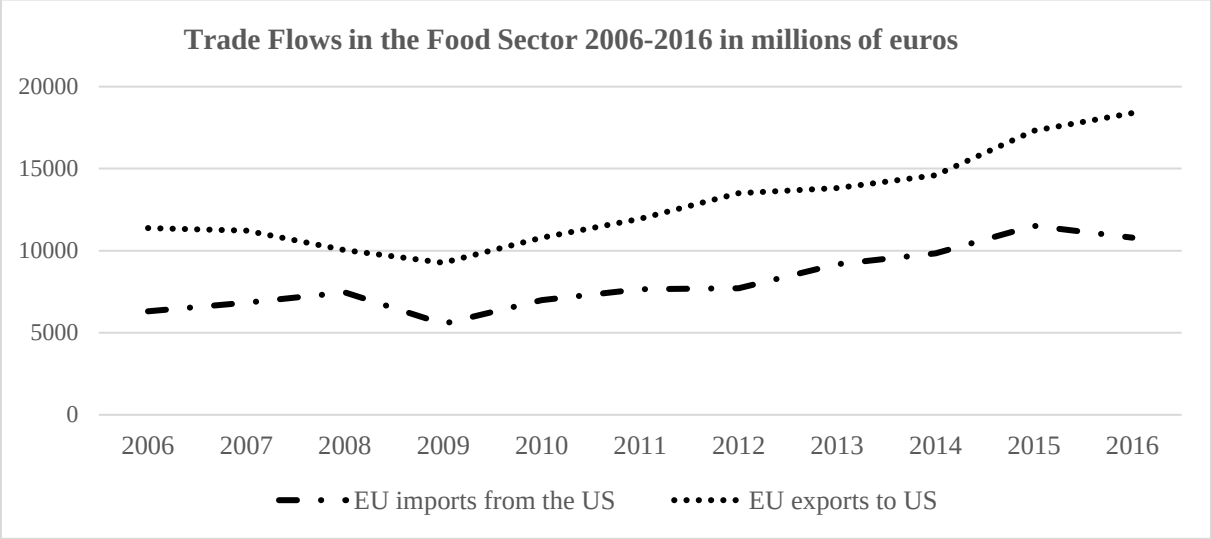


Figure 18: Trade Flows in the Food Sector 2006-2016

In the EU on the business side, lobbying is crucially shaped by the EU-level sub-sectoral agricultural associations, i.e. notably Freshfel (fruit producers), UECBV (meat producers) and Eucolait (dairy producers), as well as the horizontal farmers' association Copa-Cogeca, and to a lesser extent, the food producer association FoodDrinksEurope. EU business associations did not, however, succeed to form transatlantic coalitions with US business associations. Non-governmental and civil society organisations were also highly active. Through the Transatlantic Consumer Dialogue (TACD), EU and US consumer protection organisations succeeded to present a common lobbying position.

As shown by figure 18, the EU is a net exporter of food products to the US. EU exports to the US are high in produced foods, e.g. meat preparations, cheese and olive oil) whereas the US has a trade surplus in agricultural commodities, including meat, fruits, vegetables and nuts). The graph below illustrates the balance of EU-US trade in different food products. Impact assessments conducted for the purpose of TTIP negotiations estimate that non-tariff measures (NTMs) raise the price of EU imports to the US by 51.3% and US imports to the EU by 48.2% (Fontagné et al., 2013).[170]

Regulatory policies on food safety specify the requirements of the food allowed to be sold on a market, including requirements for the hygiene of food, the use of additives, the allowance of residue limits of pesticides and veterinary drugs in food products. Implementation procedures refer to the criteria

[169] The choice of the time period reflects data availability constraints (Eurostat, 2017).
[170] For a list of NTMs identified through a large-scale business survey see Ecorys (2009).

determined to assess the hygiene of a product, the inspection of businesses to ascertain compliance with regulatory requirements, the authorisation of businesses for export or import, the issuance of certificates to indicate compliance. Although not a food safety issue in the narrow sense, analysts also add procedures to identify and control animal diseases such as BSE and avian flu to food safety issues, including so-called regionalisation decisions of authorities to restrict animal movements from an infected region and zoning decisions to contain infected animals within a defined zone.

This chapter will first lay down the regulatory policies and implementation procedures set and defined by the EU. It will then describe regulatory cooperation on policies and implementation procedures established through and within international organisations and institutions. A subsequent section presents divergences between the EU and the US in regulatory policies and implementation procedures based on a survey of the academic literature. The following two sections will describe the strategies that the EU, represented through the Commission, has employed to seek regulatory cooperation with the US.

6.3.2. International food safety cooperation

Cooperation on food safety in international organisations arguably begins with the establishment of the Codex Alimentarius Commission (Codex), a standard-setting body jointly established by the World Health Organisation and the Food and Agriculture Organisation, in 1963. The Codex develops standards, codes of practice, recommendations, and guidelines in permanent expert committees which focus on e.g. food additives, pesticide and veterinary drug residues, food labelling, food hygiene, and animal health. Yet, Codex standards are non-binding and only become effective when they are transposed into domestic law.

International regulatory cooperation on food safety became more legally binding and enforceable with the adoption of the "Agreement on the Application of Sanitary and Phytosanitary Measures" (SPS) under the WTO. The SPS Agreement specifies the conditions under which domestic food safety measures are justified to interfere with international trade. It is legally binding as it subjects governments' violations of their obligations to the WTO Dispute Settlement Mechanism. The SPS Agreement confirms the right of governments to "take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health." Yet, it requires governments to build such measures on the principles of "scientific evidence", "risk assessment", "appropriate level of protection", "harmonisation" and "'equivalence'" (WTO, 1995b). The agreement combines US and EU requests.

In line with US demands during the SPS negotiations, the agreement requires "scientific evidence" for the adoption and maintenance of food safety measures (Poli, 2004). Moreover, it requires "risk assessment" to "determine the appropriate level of protection", thus emphasising the inclusion of economic cost-benefit considerations into the comparison of alternative food safety measures. While it

allows governments to deviate from international standards and adopt a higher level of protection, the agreement requires that governments give a scientific reason for their decision, reflecting US demands (Hristova, 2013: 62). EU demands are, in turn, reflected in provisions specifying that where scientific evidence remains insufficient, governments may adopt measures on "the basis of available pertinent information". These provisions have been interpreted as a reference to the precautionary principle although it is not explicitly mentioned (Josling & Tangermann, 2015a: 172).

In the SPS Agreement, the EU and the US realised their shared preferences for the establishment of the concepts of 'equivalence'" and harmonisation. Following the principle of "harmonisation", the agreement requires WTO members to base their sanitary and phytosanitary measures on international standards, referring specifically to Codex standards in the case of food safety. The domestic transposition of Codex standards offers governments a presumption of conformity with their WTO obligations. Moreover, the agreement encourages the use of "'equivalence'", proposing that WTO members "shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own. […], if the exporting Members objectively demonstrates to the importing Member that its measures achieve the importing Party's appropriate level of sanitary or phytosanitary protection."

Attempts of the EU member states[171] in 1997 to externalise the use of the precautionary principle and the consideration of "other legitimate factors" to standard-setting procedures in the Codex mostly failed. The US rejected the request of EU member states that international standard-setting should be possible even in cases of scientific uncertainty and thus to incorporate the precautionary principle, arguing that precaution was already included in risk assessment. Besides, the US argued that the precautionary principle was not recognised or elaborated in international law (Hristova, 2013: 64; Poli, 2004). The eventual working principles of 2003 lay down that standards can only be developed if there is sufficient scientific certainty. Under uncertainty, Codex should only adopt codes of practices. EU member states, in turn, and against the preference of the US which had advocated a science-only approach to standardisation, succeeded to incorporate a reference to "other legitimate factors" into the Procedural Manual of Codex for the development of standards of food safety standards. Yet, this reference remains general, vague and subject to restrictions, notably that "other legitimate factors" cannot override scientific evidence (Hristova, 2013: 66).

With the adoption of the Cartagena Protocol on Biosafety in 2000 (see Oberthür & Gehring, 2006), the EU succeeded to establish an alternative multilateral framework governing trade in GMOs, seeking to ensure an adequate level of protection in the transfer, handling and use of GMOs. Besides, it could incorporate both the "precautionary principle" and other legitimate factors" into the Protocol. Authors argue that the adoption of Cartagena Protocol gave rise to legal pluralism as the relationship between

[171] The Commission only became a full member of Codex in 2003 after its application for membership in 2001.

the SPS Agreement and the Biosafety Protocol remained unclear (Delreux, 2012; Wouters et al., 2012; Vogel, 2012).

With regard to implementation procedures, the SPS Agreement defines standards on regionalisation and zoning procedures during the outbreak of an animal disease in a WTO member state, giving authorities, however, discretion in taking more stringent measure if they deem that appropriate.

Subsequent international cooperation between the EU and the US centred on the development of standards in the Codex, and to a lesser extent with regard to GMOs, also the OECD. In Codex, the EU adopted an active role and facilitated the agreement on international standards even where the eventually adopted standards deviated from EU requirements. In these cases, the EU promoted the adoption of standards setting lower residual limits than the residual limits previously agreed in the EU to facilitate an agreement. Alternatively, it chose to set deviating residual limits from internationally agreed standards in domestic regulations afterwards (Young, 2011). In few cases, the EU decided to prevent the adoption of a standard by delaying the decisions. Only in very few cases, among them the prominent ractopamine case (see below), the EU sought to block a decision.

6.3.3. EU food safety regime

This section outlines the distribution of regulatory authority structures and principles in the EU food safety regulatory framework, both with respect to the regulatory policies anchored in the General Food Law (Regulation EC/178/2002) and the Regulation on Good Hygiene Practices (EC/852/2004) and the implementation procedures established by the Official Food and Feed Controls Regulation (EC/854/2004).

The division between risk management and risk assessment to delineate regulatory policies from implementation procedures can mostly also be applied to the regulatory framework on food safety. While risk management falls within regulatory policies, implementation procedures address mainly the assessment of safety risks. The development of the EU food safety framework followed the Commission's adaptation of the 'New Approach' which allowed it to expand both the scope and depth of EU food safety legislation. After the food scandals related to mad cow disease and dioxins in food products of the late 1990s and early 2000s, comprehensive food framework laws were adopted in the early 2000s. Before, food safety had been regulated under a system of comprehensive mutual recognition of member states' national food safety laws in reflection of the Cassis de Dijon judgement of the European Court of Justice (Hristova, 2013: 59).

The General Food Law specifies that food and feed imported into the EU must comply with EU requirements, conditions that are recognised as equivalent to EU requirements by the EU, or requirements laid down in specific agreements between the EU and third countries. The Regulation on

Good Hygiene Practices specifies the responsibility of businesses for ensuring the compliance with hygiene requirements. After the food safety scandals of the late 1990s and 2000s, the competence to propose and administer legislation governing food safety was shifted from DG Agriculture to the DG Health and Consumer Protection, renamed as the Directorate General for Health and Consumers, or DG Sanco. Exceptions to this persist in risk management with regard to the authorisation of genetically modified organisms (GMOs). Until 2015, member states could not block the application of a GM authorisation by the Commission, but in practice delay its implementation (see Josling & Tangermann, 2015a: 198)[172]. Yet, a reform in 2015 allows individual member states to ban the sale of EU-authorised GM varieties, now making regulatory policies non-centralised. Except for the authorisation of GM varieties, regulatory authority on food safety regulatory policies is thus centralised in the EU.

The General Food Law specifies that in risk management, EU food safety measures should be adopted on the basis of risk assessment, giving consideration to other factors under specified and clearly defined conditions. The General Food Law regulates all stages of the food production process from feed production to food processing and distributing, also known as the 'farm-to-fork' approach, and thus requires the traceability of products along the production and distribution chain (Hristova, 2013: 60)[173]. The application of the Hazard Analysis Critical Control Point (HACCP) system reflects the 'traceability principle' (Interview 7). As a policy consequence of the farm-to-fork approach, the EU has banned the use of certain 'pathogen reduction treatments' (PRTs) or anti-microbial washes in slaughterhouses, arguing that this covers up "unsatisfactory practices at an earlier stage" of the production process (Josling & Tangermann, 2015a: 177). PRTs banned in the EU has notably concerned the use of chlorine washes in poultry as well as the use of lactic acid in beef. Instead, the EU has adopted animal welfare legislation which it sees as enhancing animal hygiene, thus also enhancing food safety. Moreover, the General Food Law also the Commission to rely on other principles, notably the 'precautionary principle', on issues in which scientific advice is inconclusive or not available. In the understanding of the Commission, recourse to the precautionary principle is possible where "potentially dangerous effects deriving from a phenomenon, product or process have been identified, and […] scientific evaluation does not allow the risk to be determined with sufficient certainty" (Commission, 2000: 1). The precautionary principle applies e.g. to the regulation of GM varieties, in particular with regard to their

[172] Under the authorisation process until 2015, the Commission proposed a decision to the Council committee in charge on the authorisation of a GM variety based on the results of the scientific investigation by the EFSA. Member states in the Council could, however, challenge the decision of the Commission, following comitology rules. If the Council and appellate committees could not agree on a position, the Commission could still approve a variety, although it was not obliged to do so. Once approved, member states could not block the application of a GM authorisation by the Commission, but in practice delay its implementation.

[173] Food-producing firms in the EU are thus required to follow the Hazard Analysis and Critical Control Points (HACCP) system developed within the Codex Alimentarius.

cultivation. The EU allows the non-authorisation of GM varieties for cultivation if scientific evidence leaves uncertainty regarding the risk of the product[174].

Aside from the 'risk assessment' principle, regulatory policies on food safety in the EU are thus shaped by the 'traceability' and the 'precautionary principle'. [175]

The Official Food and Feed Controls Regulation specifies the implementation procedures for controlling compliance with the safety requirements, i.e. the control and inspection procedures, as well as the risk assessment procedures for ensuring compliance of importers with safety requirements. It also specifies procedures for the approval of pre-export checks by third-country authorities. The General Food Law delegates the conduct of risk assessment and the provision of a scientific opinion to an independent scientific agency at the EU level, the European Food Safety Authority (EFSA), under the realm of DG Sante. The EFSA is mandated to conduct risk assessment and give scientific opinions to inform the Commission and member states on food safety measures, including the development of international food safety standards in Codex (Weimer & Vos, 2015: 60)[176]. Under the Official Food and Feed Controls Regulation, audits and the authorisation of agricultural businesses in third countries for imports into the EU lies with EU Food and Veterinary Office (FVO) under the control of DG Sante. The FVO carries out official controls, i.e. inspections and audits, in third countries to verify compliance and/or 'equivalence' with the EU food safety requirements[177]. The Commission can also designate bodies in third countries, so-called 'competent authorities', for pre-export checks in the third country to verify compliance, i.e. establish a 'unilateral' recognition of conformity assessment[178](Weimer & Vos, 2015:

[174] With regard to the regulation of GMOs, the application of these regulatory principles has arguably not always been entirely consistent. Due to conflicts among member states, the Commission established a de facto moratorium on the authorisation of new GMOs in 1997. Moreover, some member states implemented national bans on certain GM varieties for cultivation although the Commission had authorised them for cultivation in the EU as a whole, following a positive scientific assessment of the EFSA. Both measures later triggered complaints by the US under WTO rules (see below). Most GM products authorised for sale in the EU are varieties of maize, soybeans, rapeseed, sugar beets, cotton and potatoes. In effect, only one GM variety (maize MON810) can currently be planted commercially in the EU, most of which is cultivated in Spain. More recently, the stance of the Commission against GMOs has shifted towards a risk-based approach with the Low Level Presence Regulation from 2009, referring to the marketing of GMOs in animal feed, which now allows the minimal presence of non-approved GM material in approved GM products at a level of 0.1%.

[175]Some authors (e.g. Hristova, 2013: 64) have added another regulatory principle to the EU regulatory framework, namely the consideration of 'other legitimate factors'. While they lack a precise definition, authors often understood considerations about the technological need, consumer attitudes, environmental concerns, socio-economic sustainability and animal welfare as these 'other legitimate factors'. Other authors, however, question whether these considerations are part of the food safety framework or should rather be counted to the framework on food quality (Josling & Tangermann, 2015: 179).

[176] While the EFSA absorbed previous scientific committees on food, animal nutrition, veterinary measures, and measures related to animal health and welfare, member states still held on to their national health and safety agencies.

[177] Weimer and Vos (2015: 55) emphasise that these controls in practice are not only of a top-down nature. FVO officials also engage in dialogue and deliberative exercises with federal or local authorities of third countries as well as exporting businesses during their missions to third countries. Even when a third country body has been recognised as a competent authority to establishment conformity of products with EU safety requirements, the FVO maintains deliberative interactions with these bodies, also to ensure their effectiveness in determining compliance.

[178] The establishment of a 'unilateral' recognition of conformity assessment follows comitology procedures.

56). Risk management in the case of a pest crisis in a third country is captured under the Rapid Alert System for Food and Feed (RASFF). After notification of a serious risk detected in food or feed by a third country authority, the Commission can decide on measures to be taken by third-country authorities, e.g. pre-export checks, and additional import checks.

Inspections of agricultural businesses in member states are conducted by member state authorities. Member state authorities thus also authorise EU businesses for export. However, the FVO is tasked to ensure the proper implementation and enforcement of EU food safety laws and undertakes market surveillance. It audits the ability of member state authorities to conduct effective control and to this purpose also inspects individual premises itself to ensure that legal requirements are met. Regulatory authority over implementation procedures is thus centralised with regard to risk assessment of substances, audits of inspections and the authorisation of imports. It is also centralised with regard to the inspection of businesses and the authorisation of businesses for exports although member state authorities conduct the inspections and authorisations.

The risk assessment of food products is based on scientific evidence, with the EFSA as a provider of scientific advice to the Commission and member states[179]. Import controls reflect the risk of a product to human, animal or plant health. Put simply, the higher the risk of a product for human, animal or plant health, the stricter the import controls (Weimer & Vos, 2015: 55). A large number of food products considered to be low-risk are therefore not subject to systematic border controls (Interview 8; Weimer & Vos, 2015: 55; Alemanno, 2011)[180]. For the inspection and audits of agricultural businesses in third countries, the FVO focuses less on inspecting individual businesses, but rather controlling the effectiveness of the regulatory system as a whole (Weimer & Vos, 2015: 63). When the Commission finds that a third country has an effective control system in place, it designates third country bodies as 'competent authorities' and allows them to determine which firms are to be included in the list of establishments approved for export to the EU[181]. If subsequent FVO audits and inspections find ineffectiveness of the control system of a third country, FVO reports can form the basis for restrictive measures of the Commission against that third country. In implementation procedures the Commission thus follows two regulatory principles, the 'risk principle' and the 'systems-based approach'.

This section has established that both regulatory authority on regulatory policies and implementation procedures in the EU is centralised. While regulatory policies follow the regulatory principles 'scientific

[179] The selection of scientific evidence by the EFSA for risk assessment has in the past often been contentious (Interview 11). Risk assessment is conducted by a Working Group comprising EFSA members and scientists that assesses 'available scientific information', drawing on data supplied by member states, research institutes and firms (Dreyer & Renn, 2009: 71-82).

[180] In the case of an animal disease in a third country, the EU follows 'regionalisation' based on internationally agreed standards, thus restricting imports only from the region (not country) affected in line with measures of third-country authorities.

[181] Third country 'competent authorities' issue export certificates that indicate presumed 'equivalence' with EU safety requirements. The EU reduces the frequency of full border checks for these products.

risk assessment', 'traceability' and the 'precautionary principle', implementation procedures follow the 'risk principle' and the 'systems-based approach'.

6.3.4. Contrast of the EU and US food safety regimes

This section summarises divergences between the EU and US regulatory frameworks for food safety. It demonstrates that compatibilities exist with regard to the distribution of regulatory authority structures while regulatory principles are mostly incompatible.

Most US food safety regulations are federal regulations (Josling & Tangermann, 2015a: 167). Depending on the regulatory issue, these are adopted by the US Department of Agriculture (USDA; for meat, poultry and eggs), by the Food and Drug Administration (FDA; for all other foods) or the Environmental Protection Agency (EPA; for the use of inputs including fertilisers). The new framework food safety legislation adopted in 2011, the Food Safety Modernisation Act (FSMA), does not substantially change this division of competences, but strengthens the role of the federal agencies vis-à-vis producers. On issues on which US federal states do or cannot agree on the need to issue a mandate for a federal agency to develop federal regulation, the federal states have also adopted state-level regulations themselves, such as restrictions of the use of GMOs and other biotechnology in food products or provisions on animal welfare (Josling & Tangermann, 2015a: 183). Yet, the majority of food safety regulations are adopted by federal agencies (Josling & Tangermann, 2015a: 184). This makes the distribution of regulatory authority for regulatory policies centralised. The distribution of regulatory authority in the US and the EU for regulatory policies are therefore compatible.

US regulatory agencies follow the principle that food safety regulation should reflect the results of scientific risk assessment. The FSMA has strengthened the reliance on scientific risk assessment in the development of food safety regulations. Moreover, it emphasises the importance of a risk-based approach, in order to concentrate available regulatory resources on the containment of the greatest risks. Scientific risk assessment thus is inter alia reflected in the US milk rules defined by the 'Grade A Pasteurised Milk Ordinance' of the FDA. Other regulatory principles beyond the reliance on scientific risk assessment are, however, not applied at least in federal US regulations. The latter thus neither officially recognise the 'precautionary principle' nor specifically mention 'other legitimate factors' as a basis for the development of food safety regulations. As a consequence, biotechnology and genetically modified products are not subject to other treatment than 'conventional' food products[182]. Similarly, where scientific evidence is inconclusive, US agencies do not and are not allowed to ban substances as

[182] The FDA is responsible for approving new plant varieties in food use and requires safety testing by the firm introducing the variety. The USDA needs to review the test results, considering the effects of variety on the safety of other crops and animals. The EPA oversees the incorporation of pesticide genes into the variety. (Dabroska-Klosinska, 2015).

a result of scientific uncertainty. This explains the permission to use growth-enhancing hormones in the US, such as beef hormones or ractopamine for pigs[183].

Moreover, US regulations neither consistently follow the 'farm-to-fork' or 'traceability' approach. On the contrary, US regulations concentrate on ensuring the 'safety of the end product', thereby often – put simplified- 'sterility'. This principle explains the use and requirement of anti-microbial pathogen reduction treatment in meat, e.g. the use of chlorine washes to treat chicken or the use of lactic acid to wash beef. Equally, it is responsible for the bans of certain raw milk cheese produced in the EU. US central-level regulations thus follow the 'scientific risk assessment' and 'safety of the end product' principles. With the reform of US food safety law, however, the FSMA requires that US food producers develop and implement plans that track the handling steps of food[184] (Interview 7). This can be considered as a partial adoption of the 'traceability' principle. As demonstrated above, the Commission's adoption of the 'precautionary principle' is incompatible with the 'scientific risk assessment' principle pursued by the USDA and the FDA. Moreover, its 'traceability' principle is incompatible with the 'safety of the end product' followed by US agencies.

With regard to implementation procedures, registrations and inspections of agricultural businesses are carried out by the FDA (for non-meat producing farmers) or the FSIS, a service under the auspices of the USDA (for meat producing farmers). Related to the authorisation of agricultural businesses for import, the Food Safety Modernisation Act of 2011 has expanded the scope of third-party certification of businesses in third countries (Interview 8). The Food Safety Modernisation Act allows the authorisation of businesses for import by recognising accreditation bodies which accredit third-party auditors to certify foreign food facilities and imports (Egan & Pelkmans, 2015: 8). Risk assessment in the US is also conducted by federal agencies although producers also often supply their assessment data to the agencies. Moreover, agencies have discretion in choosing which scientific evidence they prefer to use for assessing the safety of a product[185]. Regulatory authority on implementation procedures in the US is thus centralised. This makes the distribution of regulatory authority structures in the EU and the US compatible.

Related to implementation procedures, the FDA and FSIS also conduct inspections of agricultural businesses based on the perceived risk of a product. In inspections, the FDA and the FSIS thus also follow the 'risk principle'. Interview partners have noted, however, that both the FDA and FSIS conduct extensive border controls (Interview 7). Moreover, the FSMA requires that all businesses register

[183] Despite growing scientific evidence that the use of antibiotics in animal raising has contributed to the growth of disease-resistant bacteria, the US agencies have not yet enacted regulation restricting the use of antibiotics beyond medical treatment, but only relied on voluntary guidelines and limits on the use of drugs. The lack of regulations on the use of antibiotics, however, also reflects the long time needed to adopt regulations in the US due to notice-and-comment procedures (Interview 7).

[184] At the time of writing, the FDA has mandatory requirements for traceability for juice and the USDA for meat.

[185] Observers thus criticise that the discretion of US agencies in risk assessment with regard to the selection of scientific evidence can be politically controlled and that risk assessment is thus not entirely independent (Interviews 7,8).

individually with the responsible agency. This applies to agricultural businesses producing fruit that need to register individually every two years with the FDA and to meat-producing firms that need to register with the USDA[186]. Moreover, the FDA conducts audits of individual businesses and does not recognise entire systems (Interview 7). In implementation procedures, while the US therefore relies on the 'risk principle' for audits and inspections. it does not rely on the 'systems-based approach' for the authorisation of businesses for import and export. This makes the regulatory principle for inspections and audits adopted in the EU and the US compatible, but incompatible for import authorisation.

Figure 19 summarises the contrast of the EU and US food safety regulatory regimes.

Dimension	Regulatory instrument	Authority distribution	EU	US
Regulatory policies	**Legislation**		General Food Law Regulation on Good Hygiene Practices	Numerous Acts Since 2011: Food Safety Modernisation Act
	Regulations **Standards**	**Centralised**	Risk assessment principle - Scientific testing of food products Precautionary principle - Non-authorisation of GM varieties and other technology under inconclusive scientific evidence Traceability principle - Ban of pathogen reduction treatments and anti-microbial washes	Risk assessment principle - Scientific testing of food products
		Non-centralised		
Implementation Procedures		**Centralised**	Risk principle - Import controls according to the risk of a product Systems-based approach - Audits and inspections of third-country businesses on a system-basis, designation of competent authorities in third countries	Risk principle: - Import controls according to the risk of a product (but in practice extensive border controls) Individual registration of businesses - Audits of individual businesses, no recognition of entire systems
		Non-centralised		

Figure 19: Contrast of the EU and US food safety regulatory regimes

In sum, this section has shown that regulatory authority structures in the EU and the US are compatible while regulatory principles are incompatible[187]. Moreover, regulatory authority structures are compatible with regard to implementation procedures whereas regulatory principles are compatible for inspections and audits and incompatible for import authorisations.

[186] The FDA and the FSIS adopt changes in import approvals through rule-making. As these require notification of proposed rules and consultation of stakeholders through a process of notice-and-comment, implementation procedures in the US require substantially more time than implementation procedures in the EU where the Commission can rely on implementing acts (Interviews 7,9).

[187] Authors do, however, not attribute a fundamental difference in the level of health and safety protection provided by either regulatory system (Josling & Tangermann, 2015; Vogel, 2012). Although the EU system is considered by some as the more stringent one (Vogel, 2012), others call into question that it is systematically more precautionary than the US food safety system (e.g. Egan & Pelkmans, 2015).

6.3.5. Expectations: Commission strategies in transatlantic food safety cooperation

Based on the contrast of the food safety regulatory regimes in the EU and the US and the distribution of regulatory compatibilities, this sub-section formulates expectations for Commission strategies on transatlantic food safety cooperation. As in chapters 6.1.5 and 6.2.5., these expectations operationalise the hypothesis derived on the influence of regulatory compatibilities on constraining the choice of a regulatory cooperation strategy. No separate operationalisations will be presented for the effects of bureaucratic pressure within the Commission and societal actor mobilisation as this has already been done in chapters 4.4.2. and 4.4.3 respectively.

Crucial elements of the EU and US food safety regulatory regimes are subject to legislation and thus require the approval of legislatures in both the EU and the US to change them. This concerns decisions on the authorisation of modern agricultural technologies (including cloning) and fundamental changes on the cultivation of GM varieties and hormone treatments of live animals. As these issues lie outside the regulatory authority of the Commission, it should not be expected that the Commission pursues changes to authorisation of modern agricultural technologies, cultivation of GM varieties and hormone treatments through regulatory cooperation. At the same time, it should be expected that the Commission will seek to exclude demands from the third country (in this case study the US) from regulatory cooperation discussions as this would entail the involvement of other decision-makers in the EU and thus reduce its discretionary authority within the regulatory cooperation process.

Moreover, food safety regulations elaborated and adopted by central-level regulators both in the EU and the US reflect incompatible regulatory principles with regard to the reliance on the precautionary principle and the traceability principle. Where these incompatible regulatory principles have an immediate effect on regulation, it should be expected that the Commission will choose to maintain regulatory differences and competition. This concerns in particular regulations on the use of growth-promoting hormones, i.e. ractopamine in pigs and the use of beef hormones. It also refers to the authorisation of pathogen reduction treatments for beef and chicken in the EU and the authorisation of certain raw-milk cheeses for marketing in the US. For these issues, it should be expected that the Commission chooses not to pursue ‘regulatory alignment’.

For regulations under the authority of the Commission which only underlyingly reflect the precautionary principle and traceability principle (as part of the EU food safety regulatory regime), but where existing regulations do not explicitly state one of the principles, the Commission can be expected to pursue regulatory cooperation if the level of safety cooperation for consumers is not reduced. This concerns notably food safety regulations for pesticide residuals in fruits as well as bacteria presence levels for

milk and dairy products. For these issues the Commission can be expected to choose 'equivalence' as a regulatory cooperation strategy[188].

Regulatory authority structures in the EU and the US are compatible with regard to implementation procedures. Moreover, regulatory principles are compatible related to inspections and audits of agricultural businesses. For these issues, the Commission can be expected to pursue an 'alignment of implementation procedures'. Besides, regulatory principles shaping decisions on import approvals can be argued to be non-conflicting. The Commission can thus additionally be expected to pursue an alignment of import approval procedures.

Notwithstanding the distribution of regulatory compatibilities, the Commission can be expected to pursue 'information exchange'. 'Information exchange' should concern the development of regulations on new, emerging issues in the food safety regime such as anti-microbial resistance[189].

6.3.6. Commission strategies in transatlantic food safety cooperation

This section lays down the Commission's choice of regulatory cooperation strategies during the three regulatory cooperation initiatives selected in chapter 5.1.

New Transatlantic Agenda (NTA)

Transatlantic regulatory cooperation on food safety began with the negotiations of a Veterinary 'equivalence' Agreement in 1991. Under the lead of DG Agriculture, Agriculture Commissioner MacSherry initiated the negotiations of Veterinary 'equivalence' Agreements with the US, Canada and New Zealand. The negotiation of these Veterinary 'equivalence' Agreements was embedded within a larger initiative of MacSherry and DG Agriculture to facilitate trade through the negotiations of bilateral cooperation agreements that were promoted by the SPS Agreement under negotiation in the WTO (Josling &Tangermann, 2015a: 180).

DG Agriculture officials thus sought to negotiate an agreement with the US that would establish the procedures to establish 'equivalence' of sanitary measures. The agreement would allow the recognition that individual products and establishments are not subjected to the specific standards of the importing

[188] In addition, it can be expected that the Commission it should be expected that the Commission does not pursue 'equivalence' with regard to standards adopted in Codex, but not implemented by either the EU and the US due to more stringent domestic requirements as for these cases the assessment of the maintenance of the level of protection is likely negative.

[189] Anti-microbial resistance describes the resistance of humans to antibiotics against bacterial infections as a result of a high use of antibiotics in animals among agricultural producers.

country. The EU and the US would accept measures as equivalent as long as they meet the level of public and animal health protection required of the domestic industry. To ensure 'equivalence', domestic authorities assess the overall production hygiene and the ability of the importer to deliver an effective inspection system (Commission, 1997a). In the Veterinary Equivalency Agreement, the EU and US agreed on a list of animal products for which they recognise each other's measures as achieving the importing party's appropriate level of sanitary protection. To this purpose, the Commission convinced the US to incorporate the definition of 'equivalence' of the WTO SPS Agreement (Interview 8). Except for fish, the highest possible 'equivalence' was, however, granted to very few products immediately (USDA Foreign Agricultural Service, 2005).

DG Agriculture officials, however, refused to recognise the 'equivalence' of US sanitary measures for chicken and beef that were subjected to pathogen reduction treatments. The Commission maintained "that the veterinary discussions are about public health and its protection. While veterinary measures have trade implications, this should not be the main concern" (Commission, 1997a). They noted that the approach of the US to achieve food safety through pathogen reduction treatment conflicted with the requirement for EU producers to ensure food hygiene through rearing conditions in agricultural establishments. DG Agriculture defended the Commission against criticism of the USDA that the EU's ban of pathogen reduction treatments was scientifically unjustified protectionism, notably the use of chlorine washes for chicken and the use of lactic acid for beef. DG Agriculture insisted on maintaining the respective regulatory approaches[190]. A conclusion of the negotiations was facilitated, if not enabled by US concerns over the implications of the BSE crisis. The USDA then demanded an agreement on certificates of compliance with international food safety standards rather than a resolution of the different approaches to risk management. The Veterinary Equivalence Agreement was concluded in 1999.

After the outbreak of the BSE crisis in 1999, lead authority in the Commission was shifted to DG Sanco. DG Sanco also represented the EU in the Joint Committee of the EU-US Veterinary 'equivalence' Agreement[191]. Within the Joint Committee, DG Sanco and the USDA and FDA could have determined the 'equivalence' of sanitary measures for further products that were not yet covered by the 'equivalence' list (Josling & Tangermann, 2015a: 182). However, DG Sanco officials criticised that the list of products considered as equivalent was highly asymmetrical. While the Commission recognised a considerable number of US animal products as equivalent, the USDA and FDA showed almost no flexibility in recognising EU animal products as equivalent (Interview 7). Moreover, the political and administrative leadership of DG Sanco did not consider regulatory cooperation with the US as a

[190] Besides, DG Agriculture pursued discussions with US authorities, notably the USDA and the FDA. These discussions between the EFSA, the Commission and US authorities that aimed at 'information exchange' focused notably on responses to the BSE crisis and attempts to resolve regulatory disputes (Pérez & Dudley, 2016; Dabroska-Klosinski, 2014).

[191] Moreover, DG Sanco represented the Commission in Codex.

priority[192]. DG Sanco did thus not resume work to evaluate which US animal products would qualify for 'equivalence'. No further products were added to the list until 2002. The Veterinary Agreement was thus essentially "dysfunctional" (Interview 7) [193].

With regard to food safety, DG Agriculture pursued a strategy of 'equivalence', given that evaluations showed both EU and US sanitary measures achieve the same level of protection. Given the lack of political and administrative leadership and in response to a lack 'equivalence' granted to EU products by the USDA and FDA, DG Sanco later shifted towards 'regulatory competition'.

High-Level Regulatory Cooperation Forum (HLRCF)/Transatlantic Economic Council (TEC)

With the launch of the HLRCF in 2005, DG Sanco resumed efforts on transatlantic regulatory cooperation on food safety (Commission, 2005b). The administrative leadership and senior-level officials in DG Sanco as well as the political leadership of DG Agriculture had proposed to consider regulatory cooperation on food safety under the Regulatory Cooperation Roadmap (Commission, 2005a). Demands of the administrative leadership of DG Sanco and DG Agriculture for regulatory

[192] In parallel, DG Sanco and DG Trade were in a number of trade disputes with the USDA at that time. DG Sanco sought to export EU regulatory principles to the international level against regulatory principles adopted and defended by the US. This concerns notably the recognition of the precautionary principle also by the US. Here, the Commission sought to establish a rival regime through the Cartagena Protocol (Hristova, 2014; Josling & Tangermann, 2015, Dabroska-Klosinski, 2014). On other issues, the Commission defended itself against complaints of the USDA. This concerned two complaints of the US under the WTO Dispute Settlement Mechanism, i.e. on the maintenance of the ban to use growth-promoting hormones in beef ("*EC-Beef Hormones case"*; Demortain, 2012) and the moratorium on authorisations of genetically modified organisms (2003) and the imposition of bans by certain member states on the cultivation of GMOs (*EC-Biotech case*).
On the use of six growth-promoting hormones in beef, the EU maintained its ban established in 1985 against suspicions that these were detrimental to human health, despite the ruling of the WTO panel that the EU's decision was against existing scientific evidence. The US, supported by a number of beef-producing countries such as Canada, implemented retaliatory sanctions. The Commission, however, maintained its position and upheld its ban of beef hormones, arguing that its decision was justified as a provisional measure because the scientific evidence available was insufficient. In the GMO case, the Commission slowly restarted GMO authorisations in 2004 for a short period, but did not change its policies nor its regulatory principles regarding the authorisation of GMOs for either cultivation or marketing. neither changed its policy with regard to the authorisation of GM varieties. The WTO panel ruling had agreed with the US complaint that the moratorium on GMO pre-market approvals for marketing as well as the member state bans on cultivation were taken without scientific risk assessment and thus violated the obligations of both the EU and the member states under the SPS Agreement. The Commission argued that the possible health effects of modified crops are scientifically uncertain and that its caution with regard to the approval of imports is therefore justified. The WTO ruling, however, remained procedural in its argument and was either unable or unwilling to evaluate the substantive issues of scientific uncertainty and the risks of GMOs.

[193] There is arguably one exception to this: Following the inspections of businesses by the FVO in the US and its exchanges with businesses and authorities and the reports the FVO delivered to the Commission, the Commission established risk-based approval for US slaughterhouses in its Food Hygiene Package from 2004, thus expanding the implementation procedures it applied to businesses in the EU also to businesses in the US (Interview 7). The expansion of the risk-based approach to US businesses without demands for reciprocity can be seen as an indication that the Commission and the FVO trusted in the ability of US authorities to control the hygiene of slaughterhouses (Weimer & Vos, 2015: 66). With regard to the expansion of risk-based approval to US slaughterhouses, the Commission thus pursued an 'alignment of implementation procedures', building on the use of persuasion and learning.

cooperation on food issues, including food safety, led to ad-hoc consultations between DG Sanco officials and societal actors. The purpose of these consultations was to identify issues on which regulatory cooperation would help EU producers to export to the US. Especially EU milk and beef producers complained about a lack of access to the US market (Interview 7, Interview 9).

Under the administrative leadership in DG Sanco, DG Sanco officials began in 2003 to resume work in the Joint Committee of the Veterinary Agreement and encourage the FDA to recognise EU animal products as equivalent, DG Sanco resumed evaluations of US animal products for 'equivalence' already in 2004 (USDA Foreign Agricultural Service, 2005)[194]. Commission officials hoped that this would facilitate trade for EU exporters and at the same time help to decrease US pressure to change existing EU standards on products proposed for 'equivalence' by the USDA and FDA. DG Sanco thus recognised 'equivalence' for US gelatine in 2003, boneless beef in 2005 and fish in 2006 (Interview 7, Interview 9).

Moreover, at the margins of the TEC, DG Trade under Trade Commissioner Brittan began engaging with the USTR on food safety trade irritants on an ad-hoc basis (Commission, 2007e). DG Trade officials thus mobilised and consulted with representatives of producer groups in the Market Access Group (Interview 10). They were interested to learn on which issues the Commission should seek regulatory cooperation with the US to create export opportunities for EU producers. Producer groups in the EU argued that the relatively higher level of regulation in the EU put them at a competitive disadvantage vis-à-vis US producers (Interview 8, Interview 10). DG Trade thus coordinated positions with DG Sanco based on the issues raised by EU producers.

As a result of this coordination, DG Trade put particular emphasis on the re-establishment of beef imports from the EU which were banned from the entire EU after the outbreak of BSE in the UK(Commission, 2008; Commission, 2007e)[195]. While the ban had initially not caused political tension as also some EU member states had closed their national markets to beef imports from the UK, the maintenance of that ban subsequently became considered as a trade barrier by the Commission (Commission, 2008). The Commission underlined that the World Animal Health Organisation had upgraded the status of EU member states to "negligible risk" (Commission, 2007d; Commission, 2007e).

Moreover, both DG Trade and DG Sanco officials agreed that US milk rules make market access to EU milk producers for dairy products, notably milk and fresh, perishable milk products, almost impossible

[194] Moreover, the Director General of DG Sanco pushed for a Memorandum of Understanding with the FDA that was signed in 2006 (Interview 8; Pérez & Dudley, 2016). This Memorandum of Understanding should incorporate existing exchanges between the DG Sanco, the EFSA and the FDA on the exchange of scientific information into a more formalised framework. It represents a pursuit of 'information exchange'.

[195] For elaborations on the Commission's position on beef exports to the US see (Commission, 2014i; Commission, 2012).

(Commission, 2008)[196]. DG Sanco officials argued that the requirements specified under the Grade A PMO are based on the specific conditions of production and processing plants in the US. Although defined differently, the Commission argued that EU standards on milk and fresh milk products achieve an equivalent level of protection (Interview 7, Interview 8).

With the launch of the TEC in 2007, inter-service consultations put pressure on DG Sanco to reconsider its position with regard to pathogen reduction treatments on meat (Commission, 2007e). Under the TEC, the lead had shifted to DG Grow and Commissioner Verheugen who co-chaired the TEC meeting for the Commission. Health Commissioner Kyprianou was opposed to regulatory cooperation on food safety in the TEC and according to US reports initially refused to participate in the meetings (US Department of State, 2007a). However, the US Administration had demanded from the Commission to address its concerns on food safety as a commitment before the US would consider engaging in regulatory cooperation on other issues with the EU (US Department of State, 2007a). The USDA criticised in particular that US chicken producers could not export chicken to the EU because of the EU ban on pathogen reduction treatment, i.e. the use of chlorine washes (US Department of State, 2007b). In the subsequent inter-service consultations and discussions between Commissioners in the College, other DGs, notably DG Trade and DG Enterprise, but also Commissioner Verheugen put pressure on DG Sanco and Health Commissioner Kyprianou to revise their positions (US Department of State, 2008a). The Commissioner and other DGs did not want to threaten regulatory cooperation that would result in more effective regulations and trade facilitation because of the issue of chicken washes. With the change of lead under the TEC and the pressure created by the other DGs, DG Sanco eventually gave in to US demands in 2008. DG Sanco agreed to accept the use of chlorine washes for pathogen reduction treatment in chicken in 2008 (Johnson, 2012)[197]. The Commission proposal was, however, rejected by the Council of Ministers[198].

Frustrated about the failure to achieve 'equivalence' for milk and dairy products and EU beef with the US by 2008, the administrative leadership of DG Sanco looked for new issues for regulatory cooperation DG Sanco and DG Trade officials increased their consultations with societal actors in the EU. Important interlocutors were UECBV, Freshfel and Eucolait (Interview 7, Interview 9, Interview 10). They drew particularly attention to difficulties to export their products to the US due to US import approval procedures (Commission, 2009). DG Sanco officials took up this point from agricultural producers. The administrative leadership of DG Sanco criticised the US that for meat products EU member states

[196] For explanations of the Commission's position on access of EU milk and dairy producers to the US market see Commission, 2013d; Commission, 2016c: 5, Commission, 2014f; Commission, 2012e.

[197] The agreement of DG Sanco to authorise the use of chlorine treatment in chicken was a strategic one. Its strategic purpose was to enable discussions with the US Administration on regulatory cooperation in the framework of the TEC. Interview partners outlined that in 2008, there was no movement within the Commission, in particular DG Sanco, the recognise the adequacy of pathogen reduction treatments for safeguarding food safety in principle (Interviews 7,9).

[198] For a comprehensive review of the Commission's decision on the permission of chlorine treatment of chicken in 2008 see (Johnson, 2012).

needed to submit applications for import approval procedures per product per country (Commission, 2009: 44). The US should, however, not differentiate among producers within the EU as their products could circulate freely within the Single Market. DG Sanco thus demanded that the US should recognise the EU as a 'Single Entity' (see also Commission, 2012)[199]. It hoped that the recognition of the EU as a Single Entity would substantiate the authority of the DG Sanco over the Single Market and increase its international recognition as the regulator in the EU on food safety. This would increase the power of DG Sanco in both domestic regulation as well as the representation of the EU in international forums. With the adoption of the US Food Safety Modernisation Act (FSMA) in 2011, DG Sanco thus similarly demanded that the FDA authorise the EU as a 'Single Entity' for imports of fruits, notably apples and pears[200] (Commission, 2012).

In order to underline its authority in regulation and strengthen its regulatory autonomy towards member state authorities, the administrative leadership of DG Sanco tasked officials to identify additional issues for cooperation. Officials noted the frequency of audits and inspections of the FDA and APHIS of businesses in the EU. Senior-level officials believed that an acceptance of audits and inspections conducted by EU authorities by US authorities would not only facilitate exports of EU producers to the US, but also strengthen the acceptance of the EU auditing system among sceptical member state authorities within the EU. DG Sanco thus encouraged the the FVO engaged in regular exchanges with US officials, including an exchange of officials, to persuade US authorities that EU authorities were capable of controlling EU businesses to a level equivalent to the US (Weimer & Vos, 2015). As a consequence, the US authorities should reduce the frequency of inspections of EU businesses (Interview 7, Interview 8). The Commission also sought to persuade the US that in the adoption of the Food Safety Modernisation Act in 2011, it recognise the Commission as a body being able to audit exporting businesses in the EU for compliance with US food safety requirements (Interview 7; Egan & Pelkmans, 2015: 8; see also Commission, 2012)[201].

By 2009, the Commission, however, had failed to achieve 'equivalence' for its priorities, notably dairy products (Josling & Tangermann, 2015a: 169; Commission, 2009). Besides, it failed to achieve recognition as a 'Single Entity' to enable exports of fruits and meat. By 2012, only Spain was authorised for exports of apples and only Lithuania could export beef (Interview 7; Commission, 2012).

To summarise, the Commission thus continued to pursue 'equivalence', concentrating on 'equivalence' for EU beef, milk and dairy products. To pursue 'equivalence', DG Sanco complemented more formalised exchanges between the Commission, EFSA and the FDA of scientific data through the MoU

[199] If the EU is recognised as a 'Single Entity', producers from all countries within the EU who are authorised for export by the Commission can export their products.
[200] DG Sanco criticised that for many fruit products, the US maintains a 'positive list approach' for the approval of fruit for import, meaning that only products analysed for pests by the US plant health authorities and approved as safe can enter the US market (Josling & Tangermann, 2015: 180).
[201] The Commission subsequently considered this achievement as a "successful example of good regulatory cooperation" (Commission, 2012f).

with bargaining and offers of reciprocity in the recognition of 'equivalence'. Upon consultations with societal actors, notably agricultural producers, the Commission also pursued an 'alignment of implementation procedures', demanding that the US move towards a risk and systems-based approach for import approval procedures for meat and fruits and a recognition of the EU as a 'Single Entity'. In response to the proposals of EU agricultural producers, DG Sanco thus proposed an adoption of its own systems-based approach for US import approval procedures for meats and fruits and the recognition of the EU as a 'Single Entity'. DG Sanco rejected, however, the adoption of US standards, exporting its own standards or promoting 'regulatory alignment', e.g. on pathogen reduction treatment.

Transatlantic Trade and Investment Partnership (TTIP)

With the preparation of the TTIP negotiations, the 'lead' in the Commission shifted to DG Trade. In 2012, before the launch of the TTIP negotiations, DG Trade agreed with the USTR to exchange mutual concessions in what was called a "stock-taking exercise" (Inside US Trade, 2012a, 2012b). The USTR had demanded the resolution of food safety issues as a precondition for the consent of the US to the launch of trade negotiations (Interview 8). Under its lead, DG Trade thus coordinated issues the Commission should demand in this stock-taking exercise with DG Sante. Subsequently, DG Trade demanded that the US lift its import ban on EU beef, given that also the WHO had found in 2010 that the risk of BSE in EU beef was "negligible" (Interview 8). All EU producers which were not affected by BSE restrictions should thus be able to export beef to the US.

In exchange for its demand to the US to allow the import of EU beef, DG Trade agreed to demands of the USTR to recognise the use of lactic acid to wash beef[202],[203]. After intense internal discussions, DG Sanco authorised the use of lactic acid for the cleaning of beef. It followed a mandated scientific risk assessment by the EFSA that its use was safe for human health. Moreover, it argued that lactic acid also occurred naturally in beef and did therefore not amount to a non-natural treatment such as chlorine washes. Interview partners agreed that the EU's move on the issue of lactic acid was "revolutionary" (Interview 7, Interview 8)[204].

DG Trade insisted that a potential agreement should include a chapter on regulatory cooperation on food safety measures given the importance of non-tariff measures obstructing trade in food products between

[202] Note that the use of lactic acid constitutes a pathogen reduction treatment and is therefore opposed to the regulatory principle followed by the Commission to ensure food safety through a 'traceability' of food products.
[203] Moreover, the USDA demanded that the Commission authorise the use of tallow. DG Sanco also responded to this demand and presented a technical solution that would US producers to export tallow to the EU (Inside US Trade, 2012b). However, US producers and the USDA did not accept the technical solution presented by DG Sanco and demanded instead that the Commission adopt the regulatory approach of the US.
[204] DG Trade did not want to risk an agreement of the US government to the launch of TTIP negotiations by putting forward demands in this "stock-taking exercise" which the US government could consider as "excessive".

the EU and the US. Trade Commissioner de Gucht and DG Trade officials thus demanded to include a chapter on sanitary and phytosanitary measures (SPS) into a potential TTIP agreement. The public consultation for the launch of FTA negotiations with the US should help identify issues that were considered important by societal actors.

For the 2013 stakeholder consultation of the Commission on TTIP, Copa-Cogeca and FoodDrinksEurope conducted an 'internal stock-taking exercise' in which they attempted to compile a list of regulatory barriers in the US for EU exporters (Copa-Cogeca & FoodDrinksEurope, 2013). Yet, only Bundesverband der Ernährungsindustrie (BVE), the German member association of FoodDrinksEurope subsequently included demands for 'regulatory alignment' in its position paper (Bundesverband der Ernährungsindustrie, 2014). Its position paper states suggestions that the Commission should seek 'regulatory alignment' on low-level presence of non-authorised GM varieties in food products and cooperate with its US counterparts on emerging issues, including the use of nanotechnology in food (Bundesverband der Ernährungsindustrie, 2014)[205].

NGOs, in turn, warned in particular of a perceived threat of a regulatory "race-to-the-bottom" if the Commission agreed to a mutual recognition of regulations that would undermine the regulatory principles of the EU, which they connect to a higher level of food safety as well as animal health. Notably, they warned that regulatory cooperation on food safety in TTIP could undermine the application of the precautionary principle in the EU, "lower" standards in food labelling and undermine the ban of pathogen reduction treatments, whose existence NGOs considered linked to the traceability principle of EU food safety regulation (e.g. BEUC, 2013; Greenpeace, 2013). NGOs and CSOs saw little to no potential benefits of regulatory cooperation to raise the level of food safety (and animal health) in both the EU and the US.

Subsequently, DG Trade and DG Sante elaborated and jointly drafted a position paper (Commission, 2013a). Both DG Trade and DG Sante emphasised that this position paper – as well as the subsequently elaborated draft textual proposal- was drafted "in a spirit of cooperation" in contrast to conflicts between DG Trade and DG Sante over food safety cooperation in the past.

Following the consultation with societal actors, the Commission indicated in its position paper on SPS that it published in July 2013 (Commission, 2013a) that it wanted to include a mechanism for 'equivalence' for further animal products in the SPS Chapter. DG Sanco and DG Trade officials agreed to concentrate initial discussions with US negotiators on 'equivalence'. They criticised that EU agricultural producers could not sell milk and fresh dairy products in the US due to the 'Grade A PMO Ordinance'(Commission, 2014i; Inside US Trade, 2014d);[206]. For this reason, DG Trade in coordination

[205] The position paper does, however, not add evidence why 'regulatory alignment' would uphold the level of health protection provided by the EU and the US.

[206] The Commission reiterated its view that the 'Grade A PMO Ordinance' was a "non-tariff barrier" (Commission, 2016: 6) as its technical specificities were based on production practices in the US and did not reflect concerns for a higher level of protection. On the contrary, the Commission emphasised that US dairy producers producing

with DG Sanco proposed 'Grade A' dairy products produced in the EU to be recognised as equivalent by the FDA. France, the Netherlands and Ireland then applied for the determination of 'equivalence' for its 'Grade A dairy products' by the US (Commission, 2016n: 10). With regard to milk and dairy products, the EU thus continued to pursue 'equivalence'.

Yet, the discussions with the USDA and the FDA soon showed DG Trade officials that the FDA rejected the proposal of the Commission for an 'equivalence' article in TTIP (Commission, 2014g). Subsequent exchanges revealed that the FDA rejected this article because it implied for the FDA that it should allow the import of a product without further certification (Inside US Trade, 2014h). The Commission clarified that equivalence did not entail that products should be imported without further certification (Commission, 2015c). Rather, equivalence implied that EU exporters could export all products for which the FDA had determined equivalence without a demonstration that they complied with all technical US food safety requirements. The Commission thus sought to persuade the FDA of the benefits of its equivalence approach (Interview 8). Subsequently, the FDA agreed to determine equivalence of the dairy systems in France, the Netherlands and Ireland and conducted audits (Commission, 2016n: 11).

In 2013, discussions between DG Trade and DG Sanco also centred on the question how the Commission should position itself with regard to USTR demands for an approval of another pathogen reduction treatment, i.e. chlorine to wash chicken (Josling & Tangermann, 2015a: 181). Although EU business associations considered the benefits of pathogen reduction treatments to achieve a higher level of food safety, they did not take a position on this issue in the TTIP negotiations (Interview 7, Interview 9).

DG Trade officials continued to mobilise societal actors in support of its objective to use regulatory cooperation as an instrument to liberalise trade (Corporate Europe Observatory, 2014). Both DG Trade, but also DG Sante received numerous comments from societal actors and engaged in numerous exchanges with both agricultural producers and NGOs. Besides, especially EU producer groups actively participated in stakeholder dialogues (Commission, 2014n). Business lobbying with a view to regulatory cooperation was subsequently dominated by the sub-sectoral associations, notably Freshfel, Eucolait, UECBV (Interview 9, Interview 10). DG Trade and DG Sante also engaged with numerous NGOs (Corporate Europe Observatory, 2014). However, both in public statements and at the Stakeholder Dialogues officials criticised that NGOs failed to engage with the food safety objectives defined by the Commission in its position paper (Interview 7, Interview 8, Interview 9, Interview 10, Interview 11). It can be argued that NGOs appear to confuse the concepts of 'equivalence' and 'regulatory alignment', arguing against 'equivalence' on the basis that this would trigger a "downward" 'regulatory alignment'.

according to the 'Grade A PMO Ordinance' struggled to meet food safety requirements of the EU as the level of consumer health protection of EU dairy standards was at least as high, if not higher (Interview 8, 11).

The demands of firms and business associations, however, concentrated on simplifying import approvals and ensuring approval for dairy products, fruits and beef for export to the US (Eucolait, 2014; Freshfel, 2013; UECBV, 2013). Noteworthy is the absence of EU business demands for 'regulatory alignment' on food safety (both "trading up" or "trading down"). They did not demand an expansion of the precautionary principle to the US nor advocated a 'regulatory alignment' on specific emerging issues (Interview 2). Despite interactions with respective US business associations, EU business associations did not succeed to form alliances and formulate common position papers[207]. Instead, EU agricultural producers thus put emphasis on a pursuit of an 'alignment of implementation procedures'[208],[209]

While pursuing its objective to negotiate a mechanism for 'equivalence', DG Trade now reinforced its concentration on the establishment of a single approval procedure for imports, thus reflecting demands of business associations for an 'alignment of implementation procedures' (Commission, 2015b). The single approval procedure for import became a core objective of DG Trade for the TTIP negotiations (Commission, 2015c). Especially DG Sante emphasised the importance that the EU should be recognised as a a 'Single Entity'. It argued that that agricultural products authorised in the EU could circulate freely within the Single Market. The Commission would monitor that products authorised for the Single Market complied with the food safety requirements formulated by the EU food safety regime (Interview 7)[210].

Moreover, in accordance with consultations with EU producer groups, the Commission began to increasingly emphasise during the negotiations that the US APHIS authorise fruits produced in the EU for export to the US and eliminate additional control measures (Commission, 2015b). This concerned notably apples and pears, but also citrus fruits, apricots and peaches (Interview 8; Commission, 2016: 10). Several member states subsequently applied for import approval of fruits in the US. Also with regard to fruits, the Commission thus pursued an 'alignment of implementation procedures'.

Subsequently, however, the APHIS only approved Spain for export of citrus fruits and apricots. Moreover, it authorised Lithuania for export of apples. Although APHIS published draft rules for the

[207] One explanation for this is that especially sub-sectoral food associations in the US focus on service provision to their members and do not engage in interest representation to the same extent as business associations in the EU (Interview 9). At the same time, interactions were overshadowed by concerns of regulatory cooperation over implications on immediate trade flows. One interview partner stated that it "takes time and trust for both sides to find common positions on this" (Interview 10).

[208] It is noteworthy that business associations put less emphasis on the recognition of the EU as a 'Single Entity'. Interview partners from business associations noted instead that the Commission's strategy to be recognised as a 'Single Entity' was inevitably difficult to achieve, given the responsibility of member state authorities for inspections of businesses and hesitations among member states themselves to recognise the EU as a 'Single Entity'.

[209] UECBV (2013) adds that under trade liberalisation EU producers may be disadvantaged due to higher animal welfare standards in the EU, but does not demand 'regulatory alignment' of animal welfare regulations as an objective of the TTIP negotiations.

[210] Beside the facilitation of trade flows, the Commission's emphasis on the recognition of a 'Single Entity' was in the view of one interview partner motivated by its preference to be recognised by the US as the responsible authority for the control of food safety requirements in the EU (Interview 10). The practice of the FDA to authorise member states individually for export to the US signalled to the Commission that authority on export authorisation lay with the member states, a signal that the Commission wanted to dispel.

approval of apples from other EU member states in January 2015, it did not approve additional member states for export during the same year[211] (Interview 10; Commission, 2016n: 10). Several interview partners expressed frustration about the lack of approvals of member states for exports. They also shared their opinion that the reluctance of the FDA or APHIS to authorise EU products for import were "political and not technical" (Interview 7, Interview 8). Likewise, the FDA continued to inspect businesses in the EU at a high rate (Interview 7, Interview 9). This undermined the efforts of the Commission to achieve a mutual recognition of inspections through the TTIP negotiations. Again, interview partners shared their perception that the motivation of the FDA for the high rate of inspections was "political and not technical".

With the priority of DG Trade to negotiate a SPS Chapter, DG Sante also emphasised the importance of another issue raised previously. DG Sante underlined that the US FSIS and FDA recognise the audits conducted by the FVO in the EU and the inspections carried out by the member state authorities as a determination of import authorisations (Commission, 2016f; Commission, 2015e). The recognition of the audits and inspections conducted by the FVO and member state authorities respectively should help to "eliminate redundant control measures" (Commission, 2016l). At the same time, it should underline the autonomy of the Commission in controlling implementation procedures in the EU (Interview 10).

Commission officials emphasised that EU and US authorities had already long mutually inspected their businesses and could thus build up a certain level of mutual trust in the inspections and audits of the other side[212]. Interview partners suspected the high frequency of inspections of EU businesses by the FDA and FSIS was mostly a "political rather than a technical issue" (Interview 7). With regard to the establishment of a single approval procedure and the pursuit of a mutual recognition of inspections and audits, the Commission thus shifted towards pursuing an 'alignment of implementation procedures' in the TTIP negotiations.

Besides, the entry into office of Health and Food Safety Commissioner Andriukaitis[213] began to push for a regulatory cooperation article on anti-microbial resistance in a TTIP agreement (Commission, 2014k). The selection of this issue reflected an expected double benefit: On the one hand, it should address concerns of NGOs that regulatory cooperation would create downward pressure on regulations, but not lead to a higher level of protection for consumers. On the other hand, the Commission also sought to commit itself to regulatory work on an issue that was subject to controversial debates among domestic producer groups (Interview 10).

[211] Interview partners noted the commitment of US Ambassador Froman to support an approval of Polish apple exports to mitigate the effect of the Russian embargo in 2015. Yet, they criticised that the Ambassador's commitment did not accelerate the approval procedure of the APHIS. On the contrary, they reported that APHIS prolonged the comment period during the notice-and-comment procedure after the publication of the draft rule that would have approved Polish exports.

[212] Interview partners noted that the socialisation among the FVO with the FDA and APHIS in this regard.

[213] Commissioner Andriukaitis has an academic background in medicine and is thus reported to have personal affiliations to the issue of Anti-Microbial Resistance.

While especially DG Trade had demonstrated some willingness to accommodate demands of the USDA and US producer groups at the beginning of the negotiations, it subsequently arguably chose to delay decisions on issues pursued and promoted by the US (Commission, 2016l). At the beginning of the TTIP negotiations in 2014, the Commission had abolished the moratorium on GM approvals and accelerated authorisation procedures of GM varieties for marketing in the EU (Commission, 2014i)[214]. The constraint in bargaining space then concerned US demands for an authorisation of pathogen reduction treatments beyond chlorine washes for chicken (Josling & Tangermann, 2015a: 173) in line with EU procedures. The USDA had submitted a request to the EFSA to ascertain if the use of peroxyacid, a 'natural' alternative to chlorine washes, would be safe for human health (Inside US Trade, 2014h). The EFSA confirmed the safety of peroxyacid for humans (Inside US Trade, 2014h). The Commission initiated a comitology procedure to assess the authorisation of the treatment (Commission, 2016n: 3). Yet, at the time of writing, a decision on the authorisation was still pending. It can be argued that the Commission chose to delay a decision, given that an authorisation would deliver substantial market access for chicken. One interview partner noted that the Commission through this delay avoided giving in to a crucial USDA demand (Interview 9). Once the USDA had achieved market access for chicken cleaned with pathogen reduction treatments, it would be even more difficult for the EU to obtain concessions from the US on regulatory cooperation priorities of the Commission[215].

Moreover, DG Trade and DG Sante mobilised NGOs to engage with their position papers to enhance the legitimacy of their objectives and demands. The TACD in a 2016 joint EU-US position paper comprehensively commented on the Commission's textual proposal for an SPS Chapter (TACD, 2016b) . In the paper, the TACD states it is not in principle opposed to an 'alignment of implementation procedures', yet underlines that both the EU and the US make available "the adequate resources to implement the right to regulate and an appropriate level of protection" (TACD, 2016b: 3). The TACD warns that an 'alignment of implementation procedures' should not lead to an inclusion of non-experts into the implementation of food safety regulations. Instead, the TACD proposes an 'alignment of implementation procedures' on risk assessment and the publication of audit verification results (TACD, 2016b: 5), requiring to make the data that regulators use for risk assessment public. Lastly, it states that an 'alignment of implementation procedures' on animal welfare is insufficient, at the same time, however, considering a 'regulatory alignment' of animal welfare regulations based on EU principles "unenforceable" (TACD, 2016b:9).

[214] The acceleration of the authorisation of GM varieties followed existing EU procedures (see chapter 6.3.3.). The Commission did not alter or amend authorisation procedures to increase the scope for bargaining with the US. It, however, decisively rejected US demands for an alignment in the corresponding implementation procedure, i.e. the US demand to introduce the 'notice-and-comment' procedure applied in the US (Interview 8).

[215] The interview partner noted that both the Commission and producer groups were well aware of the benefits of pathogen reduction treatments to consumer health, notably to address salmonella infections. Rates of salmonella infections in the EU demonstrated that the pursuit of the traceability principle was insufficient to ensure a very high level of consumer protection.

By end 2016, however, the Commission had not succeeded to persuade the FDA of its 'equivalence' approach. Moreover, the FDA had not concluded the 'equivalence' determinations for the applicant member states France, Netherlands and Ireland on milk products (Commission, 2016n: 10).

Under demands of DG Trade to present a regulatory cooperation proposal on SPS issues, DG Sante in coordination with DG Trade elaborated a textual proposal for an SPS chapter based on the discussions in 2012 and 2013. This proposal was adopted by the College of Commissioners in 2014 and then presented to US negotiators on 29 September 2014 (Commission, 2014h). Upon the initiative of some member states in the Council (notably Denmark and Sweden) and demands by Health Commissioner Andriukaitis DG Sante elaborated an article anti-microbial resistance to include in the textual proposal (Interview 7; Commission, 2014k). This article was adopted in College in September 2015 and presented to US negotiators on 19 October 2015 (Commission, 2015i). The textual proposals summarise the strategy of the Commission regarding food safety regulatory cooperation.

With regard to 'equivalence', the Commission follows the language of the SPS Agreement and proposes that "the importing Party shall accept sanitary and phytosanitary measures of the exporting Party as equivalent to its own if the Party objectively demonstrates to the importing Party that its measures achieve the importing Party's appropriate level of protection." (Commission, 2014h; art. 9.1 SPS TTIP Textual Proposal).

With regard to conformity assessment, the Commission effectively demanded a mutual recognition of conformity assessment, putting forward that EU and US authorities shall "recognise each other's competent authorities as responsible to ensure that establishment, facilities and products eligible for exports meet the applicable sanitary or phytosanitary requirements of the importing Party." (Commission, 2014h; art. 8.1 SPS TTIP Textual Proposal). Moreover, "the importing Party shall accept establishments or facilities that were authorized and listed by the exporting Party without re-inspection, third party certification or any other additional guarantees." (Commission, 2014h; art. 8.2 SPS TTIP Textual Proposal).

Besides, and also with regard to implementation procedures, the Commission sought to align auditing procedures, putting forward that "audits shall follow a systems-based approach" (Commission, 2014h; art. 11.1 SPS TTIP Textual Proposal). Besides, it sought to move towards a mutual recognition of audits and verifications, proposing that "the importing Party shall endeavour to rely on audits and verifications undertaken by the competent authority of the exporting Party." (Commission, 2014h; art. 11.3 SPS TTIP Textual Proposal).

Related to anti-microbial resistance, the article that the Commission proposed sought to establish an enhanced 'information exchange' and an exchange of implementation procedures. The Commission suggested "to create a Technical Working Group, consisting of expert level representatives, with a dedicated work plan under the Joint Management Committee of this Chapter on reduced use of

antibiotics in animal production to combat antibiotic resistance" (Commission, 2015i; art. 21.1 SPS TTIP Textual Proposal). The Technical Working Group shall "facilitate the exchange of information, expertise and experiences in the field of antibiotic resistance and animal production" (Commission, 2015i; art. 21.2 SPS TTIP Textual Proposal). Besides, it shall "support the development of a harmonised system for surveillance of antibiotic resistance, and a harmonised system for collection and analysis of data on the use of antibiotics in animal production […]." (Commission, 2015i; art. 21.2 SPS TTIP Textual Proposal).

In sum, during the TTIP negotiations, the Commission continued to pursue 'equivalence' notably with regard to beef, milk and dairy products. A lack of success on 'equivalence' and the lobbying by societal actors, especially EU agricultural producers, in favour of a single import approval procedure contributed to a shift in emphasis of the Commission towards an 'alignment of implementation procedures', both with regard to import approval procedures, inspections and Anti-Microbial Resistance.

6.3.7. Discussion

The previous sub-section has laid down that during all three cooperation initiatives, including the TTIP negotiations, the Commission has 'at maximum' restricted its choice of regulatory cooperation strategies for food safety issues to 'equivalence'. Especially during the TTIP negotiations, however, the Commission has shifted its emphasis from 'equivalence' to an 'alignment of implementation procedures'. This sub-section discusses the Commission's choice of regulatory cooperation strategies during the three regulatory cooperation initiatives in view of the hypotheses derived from the Inter-relational Institutionalism. Emphasis is put on the analysis of the expectations on the constraints on regulatory cooperation formulated in section 6.3.5.

Similar as in the previous case studies, the process-tracing of the formation of food safety cooperation strategies within the three selected transatlantic cooperation initiatives confirmed the influence of bureaucratic pressure on the engagement of Commission officials in bilateral regulatory cooperation (Hypothesis 1). It may, however, be added that bureaucratic officials have maintained regulatory cooperation especially under strategies of 'information exchange' once regular, institutionalised meeting forums such as the Joint Committee were in place. Across the three regulatory cooperation initiatives, the engagement of DG Sanco/Sante officials in regulatory cooperation has been crucially shaped by the presence of bureaucratic pressure. During the NTA, the negotiation of the Veterinary Equivalency Agreement still fell under the lead of DG Agriculture and was embedded under a wider initiative of Commissioner MacSherry. Subsequently, when DG Sanco assumed the lead for food safety within the Commission, DG Sanco officials mostly did not engage in regulatory cooperation as bureaucratic pressure was absent. The absence of bureaucratic pressure followed a perception across all levels within

DG Sanco that the existing achievements under the Veterinary Equivalency Agreement asymmetrically favoured the US. During the HLRCF and TEC, DG Sanco was pushed into cooperation by DG Enterprise, and notably Commissioner Verheugen, although the political leadership of DG Sanco was largely opposed. As a response, DG Sanco increased its search for issues that could be addressed in regulatory cooperation and that would be beneficial for DG Sanco and societal actors in the EU. With the launch of the TTIP negotiations, DG Trade and Trade Commissioner de Gucht pushed for regulatory cooperation on food safety issues to facilitate trade, thus again driving DG Sanco to identify issues for cooperation. Importantly, the interest of Health Commissioner Andriukaitis in anti-microbial resistance promoted the inclusion of a corresponding article on regulatory cooperation on this issue into the Commission's SPS Textual Proposal. In parallel, however, already at the end of the NTA senior-level officials in DG Sanco encouraged the engagement in regulatory cooperation through a resumption of work in the Joint Committee of the Veterinary Equivalency Agreement. Similarly, senior-level officials supported the 'information exchange' between the Commission, EFSA and FDA.

The empirical finding of the strategies selected under bureaucratic pressure during the NTA, HLRCF and the TTIP negotiations for the most part confirms the expectations formulated in section 6.3.5. The maximum strategy choice reflected the distribution of regulatory compatibilities between the EU and the US in the food safety regime (Hypothesis 2). For reasons to be discussed further below in this sub-section, the Commission shifted the emphasis of its food safety cooperation choices to an 'alignment of implementation procedures' during the TTIP negotiations.

As predicted in chapter 6.3.5, the Commission excluded regulatory cooperation on a) issues which are subject to legislation and thus requires the participation of legislatures in the EU and the US and b) issues for which incompatible regulatory principles would prevent a 'regulatory alignment'. This has been evidenced e.g. by the Commission's rejection of e.g. US demands for 'regulatory alignment' on GMOs during the NTA as well as the rejection of USDA demands for 'regulatory alignment' on beef hormones and the use of ractopamine in pigs during the HLRCF and TTIP. The same applies to some extent to the decision of the Commission to reject US demands for an alignment of pathogen reduction treatment regulations[216]. Interviewees confirmed that the Commission's rejection of demands for approximation or regulatory change reflected diverging understandings of Commission officials from US officials what constituted an appropriate regulatory response to the specific policy problem. Correspondingly, at the launch of the TTIP negotiations, these issues were described as 'non-negotiables' by officials of both DG Trade and DG Sanco (Commission, 2014i; Commission, 2012).

[216] Especially DG Sanco/Sante for a long time rejected the application of pathogen reduction treatments as it considered it incompatible with the traceability principle (Interview 7, Interview 8). This has reportedly somewhat changed at the time of the TTIP negotiations. In addition to compatibility considerations, DG Sante rejected US demands for an authorisation of pathogen reduction treatments for chicken as they felt this would give US demanders asymmetrical market access to the EU without similar gains for EU producers.

In line with the predictions of the Inter-relational Institutionalism, the Commission's choice for 'equivalence' followed from compatible regulatory authority structures, but incompatible regulatory principles between the EU and the US. The choice for 'equivalence' has been demonstrated by the Commission's choice to pursue 'equivalence' for citrus fruits and 'Grade A' milk as well as the recognition of 'equivalence' for further products, including boneless beef and almonds. While the recognition of some EU and US products as functionally equivalent extended the geographical effect of technical EU regulations, it at the same time protected existing EU regulations against pressure by domestic and foreign societal actors for regulatory change. Besides, DG Sanco could facilitate trade for EU exporters and thus enhance its legitimacy towards EU firms. In line with predictions, Commission officials collected scientific evidence to determine that the level of protection especially for consumers under status quo regulations in both the EU and the US was functionally equivalent.

Although on many issues regulatory principles in the EU and the US are incompatible, the Commission officials promoted an 'alignment of implementation principles' after bureaucratic pressure arose during the HLRCF and the TTIP negotiations. According to a narrow operationalisation of the Inter-relational Institutionalism, the incompatibility of regulatory principles should obstruct the choice for an 'alignment of regulatory principles'. However, the interview evidence stated in the sub-section above confirms the more refined and 'wider' operationalisation of the Inter-relational Institutionalism conducted in chapter 6.3.5. Commission officials sought to verify that the principles guiding the design of implementation procedures in the US did not establish conflicting objectives to those adhered to in the EU. Scientific evidence as well as socialisation with US officials through interactions and staff exchanges played an important role. The Commission's choice to promote a mutual recognition of conformity assessment as well as a mutual recognition of audits and verifications during the TTIP negotiations provide illustrative examples. At the same time, the decentralisation of executive competences for implementation procedures in the EU to member state authorities required the Commission to convince US authorities that the decentralisation of authority did not imply that it had no control over the effectiveness of implementation in the member states.

As in the previous two case studies, the choice of issues within the food safety regulatory regime on which the Commission has pursued 'equivalence' as well as the maintenance of that strategy relative to 'lower dimension' strategies has been shaped by the mobilisation of societal actors (Hypothesis 3). First, societal actors have been crucial in proposing issues for which 'equivalence' could be pursued. The issues on which the Commission has sought regulatory cooperation with the US were strongly influenced by demands (or the absence of those demands) of societal actors. Second, mobilisation of societal actors has been crucial to maintain the choice for 'equivalence'. After the mobilisation of EU producers and exporters concentrated on demands for import authorisations during the TTIP negotiations, DG Trade and subsequently also DG Sante reduced their focus on 'equivalence' and concentrated additionally on achieving an 'alignment of implementation procedures'. Indeed, since the

beginning of regulatory cooperation with the US on food safety, the Commission has reduced initial ambitions and shifted from seeking 'regulatory alignment' through an expansion of the precautionary principle and a recognition of its GMO policies to seeking 'equivalence' of specific products in the TTIP negotiations. The strong emphasis of EU business to obtain import approvals of EU products and thus market access encouraged the Commission to insist on an 'alignment of implementation procedures' in the TTIP negotiations. The Commission's formation of a regulatory cooperation strategy reflects the mobilisation and proposals put forward by societal actors as the Commission seeks to ensure that its pursuit of regulatory cooperation is considered as legitimate and appropriate by societal actors. At the same time, EU business associations did until the freeze of negotiations in 2017 not succeed to form transatlantic coalitions with US business associations in support of deeper regulatory cooperation strategies.

Third, demands of societal actors for either 'regulatory alignment' or regulatory competition have failed to shape the strategy choices of Commission. Associations that advocated – albeit vaguely- deeper regulatory cooperation such as food processors (Bundesverband der Ernährungsindustrie, 2014) failed to shape the Commission's choice of a regulatory cooperation. This also applies to US agricultural and food processor associations that demanded an authorisation of GMOs and the use of beef hormones.

While transatlantic regulatory cooperation on food safety issues has been difficult across all regulatory cooperation initiatives, the identification of new and emerging issues such as anti-microbial resistance likely helps to prolong cooperation between Commission, FDA and other US agency and service officials. Frequent and dense exchanges between EU and US officials may moreover enable information exchange on food safety issues not yet covered by regulatory cooperation, e.g. the use of nanotechnology in food packaging. Lower mobilisation by NGOs on issues such as pathogen reduction treatments may encourage business associations to propose these issues for 'equivalence' where specific pathogen reduction treatments are in line with the EU traceability principle. At the same time, the difficulty to address long-standing divergences of implementation procedures even under bureaucratic pressure in the TTIP negotiations, makes it unlikely that either administrative leaders or business associations will mobilise in support of these issues for regulatory dialogues.

6.4. Commission strategies in transatlantic ICT cooperation

This last empirical section on the Commission's choice of strategies in transatlantic regulatory cooperation in the sectoral regime information and communication technology (ICT) proposes a case study for which existing literature implies that regulatory authority structures and regulatory principles in the EU and US are compatible at least for some policies. It is thus a case in which the Commission can be expected to pursue 'regulatory alignment'.

6.4.1. Introduction

ICT policies refer to the regulation of the provision of products or services using ICT. While the definition of ICT itself is contested, many studies follow a definition of the OECD which puts emphasis on the functionality of a product. The OECD has proposed that "ICT goods must either be intended to fulfil the function of information processing and communication by electronic means, including transmission and display, or use electronic processing to detect, measure and/or record physical phenomena, or to control a physical process" (OECD, 2008a: 5).

Attempts to structure ICT policies into sub-issues distinguish between ICT content, access to ICT, ICT services, and ICT infrastructure (OECD, 2008a). ICT content policies refer to legislation on copyright, ICT-specific intellectual property such as software patents and content protection through encryption. ICT access policies regulate the accessibility of ICT products to different persons, access of ICT to innovative solutions, notably e-health, and end user information on ICT products. They also include standards on technology such as cloud computing or the Internet of Things. ICT services policies formulate rules on e-commerce, online marketing, e-payment solutions and the digital identity of consumers. They also address questions of data protection and privacy. Besides, they establish rules on service provision across borders through data localisation requirements or commitments to free data flows. ICT infrastructure policies include rules on Internet regulation, notably rules on net neutrality, and the regulation of digital platforms such as Google, Amazon or Facebook, e.g. through rules on intermediary liability.

Only policies on ICT access and services, however, address questions of consumer protection. At the same time, only policies on technological accessibility, end user information, access technology and e-payment solutions also entail technical regulations and standards comparable to the regulation of products discussed in the previous sectors and give a regulator authority to adopt regulations or mandate standards. The focus of this chapter will therefore be on regulatory cooperation strategies related to ICT accessibility, end user information, access technology and e-payment solutions.

Questions of data protection and privacy are closely related to these issues as ICT accessibility and access technology involves the transfer and processing of data. Yet, regulatory frameworks on data protection commonly do not give regulators authority to formulate technical regulations or issue standards. Data protection is thus unlikely to be the object of regulatory cooperation strategies as the regulations studied in the previous empirical case studies. Besides, data protection at least in the EU follows distinct regulatory principles and authority structures that differ substantially from regulation of ICT access technology. For the sake of clarity, the authority structures and principles on data protection will be briefly discussed in the next sections. Yet, to ensure analytical conciseness and avoid excessive complexity, the analysis of the Commission's choice of regulatory cooperation strategies will concentrate on the ICT access issues listed above and their conformity assessment procedures. Figure 20 shows the development of trade flows between the EU and the US in the food sector between 2006 and 2016[217]

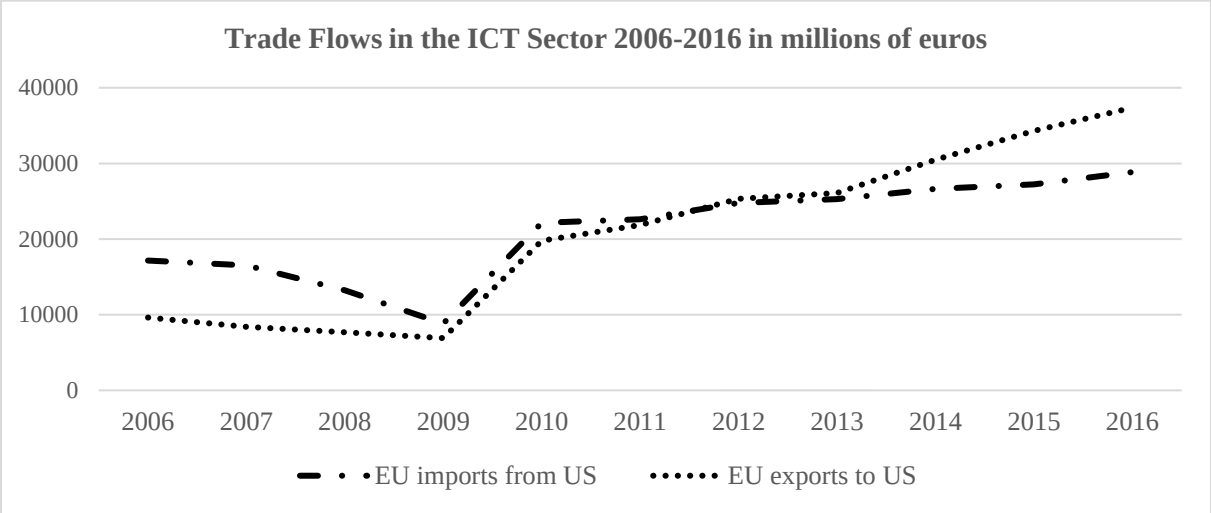


Figure 20: Trade Flows in the ICT Sector 2006-2016

On the business side, lobbying is crucially shaped by the EU-level business association, Digitaleurope, as well as a number of other associations and ad-hoc coalitions. NGOs engaging in advocacy work on ICT issues are both the consumer protection associations organised in BEUC as well as emerging digital rights NGOs such as European Digital Rights (EDRi).

This chapter proceeds as follows: It first outlines the distribution of regulatory authority structures and principles in the EU ICT regulatory framework and then outlines the incompatibility of US regulatory authority structures and compatibility of regulatory principles. It then formulates expectations on the

[217] The choice of the time period reflects data availability constraints (Eurostat, 2017). For the period between 2010 and 2017, OECD data on trade in ICT services has been added to the Eurostat data on trade in ICT goods.

Commission's choice of regulatory cooperation strategies with the US, based on the compatibility of EU-US regulatory authority structures and regulatory principles. The subsequent sections present the regulatory cooperation strategies the Commission pursued in the three phases of transatlantic regulatory cooperation delineated in chapter 5.1. and contrast them with the mobilisation of societal actors. The Commission's choice of regulatory cooperation strategy is then contrasted with the formulated expectations and the patterns of societal mobilisation. The final section concludes.

6.4.2. International ICT cooperation

This section briefly summarises the subjects of ICT regulatory cooperation in international organisations. It offers background and contextual information for the adoption of regulatory principles in both the EU and the US. Regulatory cooperation with regard to ICT access and services is addressed by the World Trade Organisation (WTO) through the General Agreement on Trade in Services (GATS) from 1995 and the Information Technology Agreement (ITA) agreed in 1996 and expanded in 2015 and standards are developed within the International Telecommunications Union (ITU). Regulatory cooperation is also promoted by the OECD and within the Internet Governance Forum (IGF).

The GATS Agreement forms the legal basis for the liberalisation of trade in services, including ICT services. Crucially, it also lays down the legal basis for the exception for data protection from services liberalisation. Article XIV GATS underlines the right of GATS signatories to adopt and enforce laws and regulations, including data protection related to the processing and dissemination of data. The ITA has abolished tariffs on ICT products including computers and telecommunications equipment while its expansion stipulates avoiding the duplication of conformity assessment, promotes the use of international standards and encourages the reliance on e-labelling. International standards for telecommunications equipment are developed within the ITU.

Regulatory cooperation in the OECD has addressed many of the issues shaping ICT policies which have been presented in the introduction to this section: In 2014, the OECD has formulated Principles for Internet Policy Making (OECD, 2014). It has put forward policy guidance related to specific ICT policies, including Policy Guidance on Digital Content, Policy Guidance for Protecting and Empowering Consumers in Communication Services, Policy Guidance on Online Identity Theft and Policy Guidance on Convergence on Next Generation Networks. Moreover, recommendations have been formulated with regard to Consumer Protection in e-Commerce and E-Commerce. Already in 1980, the OECD proposed Privacy Protection and Trans-Border Data Flow Principles (OECD, 1980), reviewed in 2013 in the OECD Privacy Guidelines (OECD, 2013c).

Within the Internet Governance Forum (IGF), a global, multi-stakeholder platform, regulators have discussed questions relating to all ICT issues with societal actors, including the technical and academic

community. The IGF has been established in 2006 and has held annual meetings since then (Interview 13). Issues discussed range from network neutrality to platform responsibility and the Internet of Things.

Despite regulatory cooperation in these international organisations, differences persist in the regulatory frameworks between countries, including and notably between the EU and the US. Jurisdictions have not always adopted international standards. Moreover, regulatory cooperation in the OECD and in particular within the IGF has remained limited to informal discussions and non-binding policy guidelines.

6.4.3. EU ICT regime

This section describes the distribution of regulatory authority structures and regulatory principles on ICT access and services in the EU. The first part of this section looks at the distribution of authority structures and principles with respect to regulatory policies, the second part at authority structures and principles with respect to implementation procedures, i.e. procedures of conformity assessment.

The regulatory framework for ICT access only began to arise during the period of investigation of this book. At the time of writing, the ICT access framework consists of the Radio Equipment Directive from 2014 (2014/53/EU), repealing the Radio & Telecommunications Equipment Directive from 1999 (1999/05/EC). The Radio Equipment Directive is a 'New Legislative Framework", i.e. it specifies 'essential requirements' that ICT access goods need to meet with regard to health and safety objectives. The technical specifications are then provided by means of 'harmonised standards' (see chapter 6.2.3). Most of these 'harmonised' standards correspond to IEC or ITU standards. Related to accessibility, notably the Regulation on Electronic Instructions for the Use of Medical Devices from 2012 (Commission Regulation 207/2012) and the Directive on the Accessibility of the Website and Mobile Applications of public sector bodies (2016/2102) have relevance. The Regulation on Electronic Instructions for the Use of Medical Devices authorises and regulates electronic labelling ('e-labelling') on medical devices, but restricting its application to consumer instructions for use. End-user information is also addressed by the mandated standard on e-accessibility, making ICT accessible to persons with disabilities through the M376 standards mandate. The corresponding standard was published by ETSI in January 2014. Moreover, it increasingly addresses standards on data technologies, cloud computing and the Internet of Things[218],[219].

[218] Related to ICT access is also the Regulation on Open Internet Access that establishes provisions on net neutrality and banning blocking and throttling of internet content and giving users full and open Internet regardless of their connection. The Regulation stipulates, however, exceptions for providers of 'specialised services (e.g. IPTV, video-on-demand or business-critical data-intensive cloud applications; Commission, 2016).

[219] ICT access goods are also affected by 'horizontal' legislation that specifies the energy use or recycling of ICT products. Examples are the Ecodesign Directive, the Regulation on Hazardous Substances, the Waste of Electrical and Electronic Equipment as well as REACH (Kommerskollegium, 2015: 38).

These measures are flanked with the EU's privacy framework, notably the Data Protection Directive from 1995 (Directive 95/46/EC) and the General Data Protection Regulation (Regulation 2016/679) adopted in April 2016, replacing the previous Data Protection Directive[220]. The General Data Protection Regulation (GDPR) follows the seven privacy sub-principles defined within the OECD Privacy Protection and Trans-Border Data Flow Principles in 1980. Specifically, it requires that data collectors need provide notice to data subjects when data is being collected, to collect and use data only for the purpose stated, not to disclose data with the data subject's consent, to inform data subjects as to who is collecting data, to offer data subjects access to their data and to enable data subjects to hold data collectors accountable. However, it exceeds OECD guidance by requiring consent to data collection to be explicit, requiring that data collection remain proportionate, establishing a right for data subjects to delete data and 'be forgotten' in the online environment and by introducing a right for data subjects to information how their data is handled. Like the Data Protection Directive, the GDPR regulates the transfer of corporate data to third countries, requiring that these are only permitted if the third country can ensure an adequate level of protection.

Implementation procedures include the conformity assessment procedures for ICT access products[221], and the procedures to ascertain the compliance of services and technology with privacy provisions. Conformity assessment procedures for ICT access products are specified by the General Product Safety Directive. Compliance procedures with privacy provisions are specified by the e-Privacy Directive and the GDPR.

Directives and regulations on ICT access and services have been developed by DG Connect[222] whereas ICT products have been proposed by DG Grow. The lead authority on data protection lies with DG Justice[223]. 'Harmonised standards' in support of e.g. the Radio Equipment Directive as well as technical standards on ICT access are set by the European Telecommunication Standards Institute (ETSI). Although ETSI is a private actor, the Commission maintains a contractual relationship with it (see chapter 6.2.3), and designates it as the only provider of harmonised ICT standards[224]. ETSI does not only have the member state standardisation organisations as its members, but also firms (unlike non-EU firms) and other societal actors with full voting rights[225]. Yet, the use of 'harmonised standards' in ICT policy is (at the time of writing) relatively scarce. Instead, the Commission supports the use of standards

[220] For a comprehensive overview see Savin and Trzaskowski (2014).
[221] For a more detailed description of conformity assessment procedures see chapter 6.2. Conformity assessment procedures for engineering.
[222] DG Connect was called DG Information Society before 2012.
[223] The 'harmonised standard' on e-accessibility has been mandated by DG Employment. Its involvement in ICT regulatory policies in this case is, however, exceptional (Interview 13).
[224] If ICT standards are to be used in electrotechnical equipment, they may also be developed within CENELEC.
[225] ETSI currently has more than 800 members, among them the well-known large ICT multinational firms as well as small- and medium-sized enterprises. It is thus considered to be more open to participation of non-SDO actors than CEN and CENELEC.

developed within industrial consortia to promote industrial development. Regulatory authority on ICT policies is thus centralised at the EU level for the issues examined in this section[226].

The Radio Equipment Directive, Regulation on Electronic Instructions for the Use of Medical Devices and the Directive on the Accessibility of the Website and Mobile Applications of Public Sector Bodies concentrate on regulating the function of the incorporated technology rather than individual products. By regulating the function technology rather than adopting product-by-product prescriptions, the Commission seeks to enable ICT and its interoperability across products to the greatest extent possible while ensuring a high level of consumer protection. In regulatory policies on ICT access, the Commission thus follows the 'functionality principle'(Interview 12).

The GDPR, in turn, refers to privacy as a fundamental right that prevails over competing interests, underpinned by the fundamental Right to Privacy as enshrined in the Charter of Fundamental Rights (Renda & Yoo, 2015: 31; Hartzog & Solove, 2014). The incorporation of this principle is primarily demonstrated by the requirement formulated in the GDPR to make consent to data collection explicit, to remain data collection proportionate, to establish a right for data subjects to delete data and 'be forgotten' in the online environment and to introduce a right for data subjects to information how their data is handled. With regard to data protection, the Commission thus adopts the 'privacy as a fundamental right' principle.

The Commission has the authority to propose the content of implementation procedures. However, the procedures themselves are conducted by member state authorities. These conduct market surveillance for ICT access products, guaranteeing that they comply with safety and labelling requirements[227]. The national supervisory authorities of member states, i.e. 'Data Protection Authorities', have the authority to implement the EU data privacy framework. Data Protection Authorities must approve data collection which poses high risks to the personal rights of data owners, i.e. 'data subjects'. Moreover, the Data Protection Authorities hear and investigate complaints of privacy violations and impose sanctions[228]. Since the adoption of the GDPR, regulatory authority over implementation procedures in the EU is thus centralised for both ICT access conformity assessment and privacy implementation.

For the conformity assessment of ICT access products, the Commission prescribes that these do not pose high risks to safety and human health to warrant the additional costs of third-party conformity

[226] Regulatory authority is, however, non-centralised notably for a number of ICT content and services policies. This includes ICT content protection through encryption which remains the competence of EU member states due to its foreign policy relevance related to cybersecurity. Regulatory authority is also non-centralised with regard to data localisation where the Commission has not (yet) proposed EU legislation restricting localisation requirements for data.

[227] The full list of member state authorities responsible for market surveillance can be retrieved from (Commission, 2016j: 171-177).

[228] The Data Protection Authorities cooperate among each other and advice the Commission on data protection within the Article 29 Working Party. The latter is replaced with the European Data Protection Board under the General Data Protection Regulation.

assessment. The Commission thus makes producing firms responsible for the declaration of conformity Firms apply the testing requirements for conformity assessment and provide data and technical documentation that their product meets safety and health requirements. The regulatory principle for implementation procedures that the Commission thus applies is Suppliers' Declaration of Conformity Assessment (SDoC).

The application of the 'collective redress principle' for the implementation of privacy provisions stipulates that effective enforcement requires that not only individuals, but also qualified associations can bring actions to court on behalf of individuals. The 'independent implementation' principle foresees that enforcement of data privacy is conducted by an independent supervisor rather than a government authority. Companies collecting data must implement measures which meet the principles of data protection by design and default and thus demonstrate compliance with the General Data Protection Regulation. Yet, the Data Protection Authorities must approve data collection which poses high risks to the personal rights of data owners (named "data subjects"). With regard to the latter, the GDPR has enhanced the judicial and administrative remedies available to Data Protection Authorities to impose sanctions for non-compliance.

6.4.4. Contrast of the EU and US ICT regimes

This section summarises divergences between the EU and US regulatory frameworks for ICT access and services. It demonstrates that compatibilities exist both with regard to the distribution of regulatory authority structures and regulatory principles for ICT access regulatory policies.

Similar and often in parallel to the EU, the regulatory framework for ICT access in the US only emerged during the course of the investigation period of this book. At the time of writing, the US regulatory framework is highly fragmented and consists of a large number of Congress Acts and Agency Rules (Interview 13). Among them, the Open Internet Order adopted in 2015 (Renda & Yoo, 2015) establishes rules prohibiting blocking, throttling and paid prioritisation of ICT services[229]. The E-Label Act adopted in 2014 allows manufacturers of radio-frequency devices to use electronic labelling. With regard to standardisation on e-accessibility, the US Access Board has proposed to revise the S508 standard[230]. At the time of writing, the US did not have legislation regulating the standardisation for cloud computing, the Internet of Things or data technologies. Privacy regulatory policies in the US are also highly

[229] Yet, counter to the EU, there are neither existing Acts nor discussions to adopt policies regulating digital platforms including Google, Facebook or Amazon in the US (Renda & Yoo, 2015: 13).
[230] In reference to Section 508 of the US Rehabilitation Act

fragmented. Privacy regulatory policies, e.g. the Electronic Communications Privacy Act from 1986[231], only apply to certain sectors or the regulation of privacy in specific applications.

Congress Acts have mandated central-level, i.e. federal, agencies to adopt rules on ICT access and ICT services. These rules, e.g. the Open Internet Order, and regulations on e-labelling in line with the E-Label Act are adopted by the Federal Communications Commission (FCC). Sub-central regulators have no authority to adopt regulatory policies on these issues. At the time of writing, the authority of US agencies to regulate ICT services and access is comparable in scope to the Commission[232]. Moreover, the FCC has authority to make standards in support of regulation mandatory by 'referencing' them. Although the FCC has the authority to 'reference' standards in support of legislation, it has at the time of writing rarely done so (Interview 14)[233]. Numerous standard development organisations (SDOs) develop standards on ICT in the US, in many cases ad-hoc forums and industry-led consortia such as the Industrial Internet Consortium (Interview 15)[234].The standard on e-accessibility is one of these exception as it is referenced in the Telecommunications Accessibility Guidelines of the US Access Board. Mostly, industry consortia often adopt standards by international organisations and working groups, e.g. the W3C. Firms participate in these working groups with the same representatives as in US consortia (Interview 15)[235]. The distribution of regulatory authority for regulatory policies in the US is thus centralised and compatible with the distribution of regulatory authority in the EU. The distribution of authority for standard development on emerging ICT technology is non-centralised for both emerging IC technologies in both the EU and the US and therefore equally compatible.

With regard to privacy, in turn, the Federal Trade Commission (FTC) has no authority to adopt comprehensive privacy regulation. Instead, the FTC is only mandated to adopt privacy rules for specific sectors or purposes (Hartzog & Solove, 2014). For other sectors and purposes, privacy rules are subject to self-regulation by private actors, mostly firms. Regulatory authority in the US is thus non-centralised for the adoption of regulatory policies on privacy. This makes the distribution of regulatory authority incompatible with the EU.

The FCC adopts regulations based on the function of the technology rather than product-by-product rules. The E-Label Act concentrates on regulating the function of the incorporated technology rather

[231] The Electronic Communications Privacy Act has been amended several times, including crucially the US PATRIOT Act in 2001.
[232] Renda and Yoo (2015: 35) predict that this may change in the future as the Commission considers proposing legislation for which the FCC has no authority to adopt regulation, e.g. on the regulation of digital platforms and restrictions on the Internet of Things.
[233] As the pace of innovation in the ICT industry is high, the FCC seeks not to 'reference' standards which would make them mandatory and thus slow down innovation.
[234] This contrasts with the authority on standards development in the US engineering sector, in which many standards are set by former business associations and now accredited SDOs.
[235] As the FCC rarely 'references' standards in support of regulation, mandatory standards that clash with 'harmonised standards' in the EU are very rare (Interview 15). Additionally, also the Commission rarely mandates the development of standards in support of legislation before standards have already been provided by industry-led consortia. Where 'harmonised standards' on ICT exist, they therefore often reflect or are identical with prior industry-developed standards (Interview 14).

than the product onto which the electronic label is attached. By regulating the function technology rather than adopting product-by-product prescriptions, the FCC seeks to enable an interoperability of electronic labels across different products. The same logic applies to standards on e-accessibility. The regulatory principle of the FCC for ICT access is thus 'functionality principle', making regulatory principles for ICT access policies compatible.

In contrast, the FTC does not adopt the 'privacy as a fundamental right' principle adopted in the EU. Instead, the FTC views privacy as a tradable commodity that users can exchange in return for better ICT services. As a consequence, the FTC has not adopted comprehensive privacy regulation similar to the GDPR of the Commission[236]. Instead, privacy provisions are mostly specific to certain applications or users of ICT. Regulatory principles are thus incompatible between the EU and the US with regard to privacy.

The FCC has authority to set the rules for conformity assessment procedures. It tasks Telecommunication Certification Bodies to conduct the market surveillance of ICT access products on its behalf, guaranteeing that they comply with safety and labelling requirements (FCC, 2015). Enforcement of US privacy provisions is within the authority of the FTC. The FTC hears and investigates complaints against violations of privacy regulations and has authority to impose sanctions (Cline, 2014; Renda & Yoo, 2015: 24). Moreover, it sets the criteria and definitions of privacy violations to enforce privacy rules[237]. Regulatory authority on implementation procedures is centralised with regard to conformity assessment for ICT access products and the enforcement of sectoral privacy provisions, making the distribution of regulatory authority structures for implementation procedures compatible between the EU and the US.

With regard to regulatory principles for implementation procedures, the FCC shares the application of 'Suppliers' Declaration of Conformity (SDoC)' for the conformity assessment of ICT access products. In 2013, it abolished the requirement to assess the conformity of ICT access products through 'third-party conformity assessment' and adopted the SDoC principle followed by the Commission. As a result of the introduction of SDoC, the FCC has since then also begun to implement market surveillance procedures for products that were self-certified by producers (Commission, 2016). Regulatory principles have therefore become compatible with the adoption of SDoC in 2013.

[236] Yet, authors argue that the US government in principle recognises the privacy sub-principles established by the OECD in 1980 and implemented by the EU in its privacy regulatory framework. The Consumer Privacy Bill of Rights released by the Obama Administration in 2012 consists of seven principles (individual control, transparency, respect for the context in which the data is being collected, security, access and accuracy, focused collection (minimisation), and accountability) which echo those of the EU GDPR. Industry-commissioned legal comparisons of EU and US privacy framework argue that the two are "essentially equivalent" (Sidley, 2016).

[237] Renda and Yoo (2015: 22) stipulate, however, that the criteria and definitions applied by the FTC are not clear, arguing that there is "a significant space for a clarification of FTC powers."

The FTC does, however, not share the 'collective redress procedure' of the Commission for the enforcement of privacy provision[238]. Moreover, it neither shares the 'independent implementation' principle for the enforcement of privacy rules and rejects the underlying idea of the 'independent implementation' principle that implementation should also be safeguarded regarding attempts of state actors to violate privacy. Regulatory principles for privacy implementation between the EU and the US are thus incompatible. The latter can, however, be made compatible if the FTC agrees to accept the principle of 'collective redress' for EU data subjects[239]. Figure 21 summarises the contrast of the EU and US ICT regulatory regimes.

Dimension	Regulatory instrument	Authority distribution	EU	US
Regulatory policies	**Legislation**	**Centralised**	Radio Equipment Directive Directive on the Accessibility of the Website and Mobile Applications General Data Protection Regulation	FCC Title 47 Regulations Numerous Acts: e.g. Open Internet Order, E-Label Act, Electronic Communications Privacy Act
	Regulations **Standards**	**Centralised**	Functionality principle: - Regulation by function: ensure high interoperability with high consumer protection Privacy as a fundamental right: - Right for data subjects to delete data and 'be forgotten' in the online environment, right for data subjects to information how their data is handled	Functionality principle: - Regulation by function: ensure high interoperability with high consumer protection Privacy as a tradable commodity: - No fundamental right to privacy, application-specific privacy provisions
		Non-centralised		-
Implementation Procedures		**Centralised**	Suppliers' Declaration of Conformity: - Testing of products by firms according to IEC standards, market surveillance by MS authorities Collective redress principle: - not only individuals, but also qualified associations can bring privacy violations to court on behalf of individual	Suppliers' Declaration of Conformity: - Testing of products by firms according to IEC standards, market surveillance by the FCC Public law enforcement of privacy: - no collective redress
		Non-centralised		

Figure 21: Contrast of the EU and US ICT regulatory regimes

[238] In a public remark, FTC Commissioner Rosch argued in 2011: "It is that no matter what the EU does in the realm of collective redress, this effort may be misguided because the underlying premise is flawed. I would suggest that a system of private competition remedies is not needed to supplement public law enforcement. Indeed, a private enforcement system may in fact hinder, rather than help, the public authorities in their enforcement of competition laws." (FTC, 2011: 2-3)

[239] In this case, the Commission would, however, still have to recognise the FTC as an independent body.

To sum up, this section has shown that regulatory authority structures and regulatory principles in the EU and the US are compatible with regard to ICT access and services, specifically with regard to e-labelling and e-accessibility. Moreover, regulatory authority structures are compatible with regard to their implementation procedures. The adoption of SDoC by the FCC in 2013 has also made regulatory principles for implementation procedures compatible. Regulatory authority structures and regulatory principles are, however, incompatible with regard to privacy regulatory policies. While authority structures are compatible for privacy implementation procedures, their underlying regulatory principles are incompatible[240].

[240] See, however, the remark in the preceding paragraph.

6.4.5. Expectations: Commission strategies in transatlantic ICT cooperation

After the contrast of the ICT regulatory regimes in the EU and the US and the distribution of regulatory compatibilities, this sub-section formulates expectations for Commission strategies on transatlantic food safety cooperation. These expectations concentrate on operationalising the hypothesis derived on the influence of regulatory compatibilities on constraining the choice of a regulatory cooperation strategy. No separate operationalisations will be presented for the effects of bureaucratic pressure within the Commission and societal actor mobilisation.

Many issues in the ICT sector are addressed by legislation both in the EU and the US, including net neutrality, privacy and e-commerce. To change this legislation in the context of 'regulatory alignment' the Commission either requires the consent of both the Council and the European Parliament or the US Congress. As both are potentially difficult to obtain and both EU and US legislators are likely to introduce amendments into Commission proposals, the Commission should be expected to refrain from pursuing 'regulatory alignment' on issues addressed by legislation.

Based on the constellation of regulatory compatibilities, the Commission can be expected to pursue 'regulatory alignment' on issues within the ICT regulatory regime. Issues within the regulatory authority of the Commission which reflect compatible EU and US regulatory principles include regulations on spam and malware protection, regulations on e-labelling, mandates on e-accessibility and e-health standards and, during the TTIP negotiations, also mandates on standards for cloud computing and the Internet of Things. The Commission can thus be expected to pursue 'regulatory alignment' on those issues in accordance with the mobilisation of societal actors in favour of regulatory cooperation on these issues.

Beyond the pursuit of 'regulatory alignment', the Commission can also be expected to pursue an 'alignment of implementation procedures' on market surveillance procedures for ICT products since the adoption of SDoC by the FCC. Given the incompatible distribution of regulatory authority and regulatory principles with regard to privacy provisions, the Commission should pursue 'information exchange' only. As authority for implementation procedures is, however, distributed compatibly, it may pursue an 'alignment of implementation principles' if it considers that regulatory principles are compatible for the privacy regulations adopted by the FTC. Moreover, the Commission can be expected to pursue 'information exchange' on emerging issues and legislative projects for which the compatibility of EU and US regulatory authority structures and regulatory principles is still unclear. Yet, to reduce analytical complexity, the following process-tracing of the formation and pursuit of regulatory cooperation within the ICT regime will concentrate on the formation of 'regulatory alignment' strategies, notably on the issues presented in the preceding paragraph.

6.4.6. Commission strategies in transatlantic ICT cooperation

This section lays down the Commission's choice of ICT regulatory cooperation strategies during the three regulatory cooperation initiatives selected in chapter 5.1.

New Transatlantic Agenda / Transatlantic Economic Partnership (NTA/TEP)

Under the responsibility of DG Information Society, the Commission initiated transatlantic regulatory cooperation on ICT issues began with discussions on telecommunication and mobile TV standards and e-commerce. ICT access was not discussed, mainly, however, because regulatory work on this issue had not started yet. The launch of the TEP under the NTA led then Information Society Commissioner Bangemann to task officials to elaborate how DG Information Society could use the TEP for priorities within its policy responsibilities (Interview 13).

Commission officials then consulted with societal actors in the framework of the Transatlantic Business Dialogue (TABD). EU and US ICT firms, in 1996 mostly telecommunications firms, however, struggled to find joint positions. They were at odds with each other over the in their view insufficient degree of liberalisation and market access in the other respective other jurisdiction (Renda, 2009). At the same time, other ICT firms did little to lobby the Commission on regulatory cooperation as trade flows on ICT were already high in the absence of regulatory cooperation (Renda, 2004). Moreover, Commissioner Bangemann was reluctant to maintain insistence on using regulatory cooperation with the US on ICT issues to resolve regulatory conflicts.

In the TEP Action Plan adopted by the Commission and the US Department of Commerce (US DOC) in 1997, DG Information Society, in coordination with DG Trade, thus decided to advance only the ongoing work between the EU and the US in the WTO (Commission, 1998). It put forward that the Commission and US DOC "will consult to ensure the implementation of the WTO work programme on the trade-related aspects of electronic commerce, including the examination by the relevant Councils and committees of the aspects identified in the work programme" (Commission, 1998: 4). In a separate Summit Statement, it clarified that the Commission would engage with the US DOC in "bilateral review and discussion" on the following issues: "elimination of unnecessary legal and regulatory barriers; promotion of voluntary standards that enhance interoperability, innovation, and competition; implementation globally of WTO basic telecommunications commitments" (Commission, 1998: 12). Yet, DG Information Society officials did not define specific legal or regulatory barriers in the Action Plan and the Summit Statement that could be eliminated. On the contrary, the formulation remained vague to accommodate for flexibility in the review of e-commerce issues and maintain autonomy in the

future review of EU e-commerce rules. Indeed, the strategy of DG Information Society for the discussions on e-commerce was to pursue 'information exchange'.

When Liikanen replaced Bangemann as Commissioner for the Information Society, the interest of the Commissioner in the engagement of regulatory cooperation changed. Liikanen thus tasked the establishment of an institutionalised 'information exchange' between DG Information Society and its US counterpart, the US Economic and Energy Bureau (EEB) (Interview 13). As a result, he launched the Information Society Dialogue in 1999. The dialogue should become an exchange forum for policy work and the development of the ICT markets in the EU and the US (Commission, 2000a)[241]. The Information Society Dialogue would be an opportunity to engage in 'information exchange' not only on ongoing and envisaging policy work, but also discuss the development of ICT industries in a sector that was developing fast (Lewis, 2001).

In 2000 and 2001, officials and the administrative and political leadership of DG Information Society, notably Commissioner Liikanen, consulted with industry representatives from the TABD and the TACD to identify issues for 'information exchange' with the US EEB in the Information Society Dialogue. The TABD was evidently not interested in the occupation of the Information Society Dialogue's agenda with discussions on planned legislation on e-commerce. Instead, it pushed DG Information Society to discuss regulatory differences that caused EU IT firms problems of market access in the US. These included diverging mobile TV standards between the EU and the US and US telecoms regulation (TABD 2000). The TACD put forward proposals on e-commerce and e-privacy, demanding the Commission and the US government "develop rules to ensure that commercial electronic communications can only be sent out with prior affirmative consent of the consumer addressed." (TACD, 2001: 6). TACD implicit demands for 'regulatory alignment' on e-commerce and e-privacy lacked detail technical prescriptions and failed to shift discussions. Correspondingly, DG Information Society rejected the TACD's implicit call for 'regulatory alignment' on e-commerce and replied to the TACD that it had proposed "a harmonised opt-in approach to unsolicited commercial e-mail throughout the EU. The proposal is currently being discussed by the European Parliament and the Council" (TACD, 2001: 6). DG Information Society also rejected discussing regulatory cooperation on e-commerce in the context of the Information Society Dialogue. Instead, it chose to keep discussions with the US EEB and the FCC on e-commerce ad-hoc (Commission, 2001b; Commission, 2000b). DG Information Society, in coordination with DG Enterprise, sought to avoid making substantive policy commitments on e-commerce in order to retain its autonomy in the domestic legislative process that was still ongoing in 2000 and 2001. Maintaining policy autonomy at this stage was important for all involved Commission DGs (Lewis, 2001). Observations by Renda (2005) support this view. He notes that the Commission only sought ad-hoc interactions with the US Administration after it had presented its legislative proposal

[241] DG Information Society, i.e. DG Connect, is usually represented by its Director General and the Heads of Units in charge of the topics that are put on the agenda by the Director General.

on e-commerce for discussion in the Council and the European Parliament (Renda, 2005). In a 2000 report on the TEP Action Plan, the Commission notes that "both sides have found that ad hoc contacts on specific subjects is for the time being the most adequate way forward" (Commission, 2000: 16). Besides, DG Information Society officials took up the criticism expressed by EU telecommunications firms in the TABD that the liberalisation of the US telecommunications market was incomplete (Renda, 2005). At the same time, DG Information Society defended the decision of the EU to mandate the development of a standard on mobile TV rather than leaving the emergence of a standard to industry competition (Commission, 2001b; Commission, 2000b; see also Renda, 2005).

In sum, while the interest of Commissioner led to the establishment of the Information Society Dialogue in 1999, neither the administrative nor political leadership of DG Information Society before or subsequently pushed for precise policy commitments through the TEP (or, for that sake, the Information Society Dialogue). On the contrary, both officials and the DG's leadership were evidently concerned that policy commitments could restrict the Commission's autonomy in its future and ongoing legislative work. At the same time, the absence of demands for regulatory cooperation by firms and (to a limited extent) NGOs did not give DG Information Society any reason to expect that its legitimacy vis-à-vis societal actors would increase if it engaged in regulatory cooperation. Moreover, the attention of DG Trade to ICT was low as trade in ICT goods (but not ICT services) was generally high (Renda, 2005). the Commissioner to the use Information Society Dialogue for anything but the explanation and justification of domestic policy choices subsequently was low (Renda, 2005). Business proposals failed to make suggestions on a 'regulatory alignment' on e-commerce or mobile TV standards. Neither with regard to e-commerce nor mobile TV standards did the Commission thus pursue any other strategy than 'information exchange'.

High-Level Regulatory Cooperation Forum (HLRCF)/Transatlantic Economic Council (TEC)

With the launch of the HLRCF in 2005, a focus on new issues for ICT cooperation resulted from changes internal to the Commission. Accompanying the entrance of a new Commissioner, Commissioner Reding, the outlook of the Commission on ICT cooperation slightly changed.

Rather than continuing the discussions on mobile TV standards and e-commerce, Commissioner Reding proposed to address new, emerging issues. A Commission Report from 2005 notes that "more intensive upstream co-ordination would help further to prevent unjustified divergences and foster the development of innovative technologies on both sides of the Atlantic." (Commission, 2005a: 10). Moreover, it proposes that EU-US coordination "should seek to prevent abuses which reduce the potential of these technologies for all users, for example by co-operating to cut down spam and contribute to the fight against additional threats such as 'spyware' and other forms of 'malware'. (Commission, 2005a: 10).

Nonetheless, EU and US telecoms firms struggled to find common positions and advance issues for regulatory cooperation. By 2005, the EU telecoms industry mainly gave up on seeking to introduce the DVB-T standard for mobile TV in the US. At the same time, trade between the EU and US in ICT was growing and many firms, most of them transnational firms with operations both in the EU and US, found ways to cope with regulatory differences (Renda, 2007). The newly set up Transatlantic Business Council (TABC), replacing the TABD, did not push for the inclusion of ICT as a priority sector for regulatory cooperation in the framework of the TEC either (Interview 13).

As a result, DG Information Society did not propose any specific ICT issues in the inter-service consultation for regulatory cooperation in 2005. ICT issues were absent from the HLRCF Regulatory Cooperation Agenda (Commission, 2005b). US internal reports show that Commissioner Reding, responsible for Information Society, was not invited to the first high-level TEC meeting (US Department of State, 2007).

With the second TEC meeting in 2007, Industry Commissioner Verheugen who co-chaired the TEC on behalf of the EU extended invitations for participation to further Commissioners including Information Society Commissioner Reding (Transatlantic Economic Council, 2007b; US Department of State, 2007). Internal US reports imply that Commissioner Verheugen pushed for common work on the TEC's 'innovation' pillar after 2005 (US Department of State, 2007b). His shift to the 'innovation' pillar reflected fears that a strong focus of the TEC on policy differences between the EU and the US would prevent successful regulatory cooperation and preclude measurable successes of the TEC (US Department of State, 2008). Rather than aiming at an alignment of existing regulatory policies or implementation procedures, Verheugen under the 'innovation' pillar of the TEC sought to explore possibilities for 'regulatory alignment' in the future.

Verheugen and Reding decided to set up two so-called 'lighthouse' projects for EU-US cooperation (Transatlantic Economic Council, 2007b). Officials from DG Enterprise and DG Information Society were tasked to identify possible issues for the pursuit of these lighthouse projects (US Department of State, 2009a). The choice for these lighthouse projects reflected inter alia considerations for regulatory projects that would be under the competence and control of the Commission and a central-level US regulatory agency to ensure effective implementation and follow-up of the strategy (Commission, 2006). Moreover, the project should build on previous work (US Department of State, 2007b).

At the same time, the Commission wanted to look for an issue on which the 'regulatory approaches' of the EU and the US would be relatively similar to avoid a repetition of failed regulatory cooperation attempts in the past. Instead, they should provide the basis for regulatory cooperation on bigger innovation issues (Commission, 2006c). The subsequent inter-service consultations suggested that ongoing exchanges of the Commission with the US on e-accessibility and planned regulatory work on e-health would meet these criteria. Towards US representatives in the TEC, the Commission therefore

proposed to establish lighthouse projects on e-accessibility and e-health (Transatlantic Economic Council, 2008) [242].

The choice for e-accessibility reflected the shared objective of DG Enterprise and Industry and DG Information Society to cooperate with their US counterparts on the use and interoperability of ICT standards. Joint work on e-accessibility was thus seen as a way to persuade the US of the value of developing joint standards to achieve interoperability (US Department of State, 2008). Previously, the US–EU's Standards Dialogue on e-Accessibility, launched in 2004, had formulated the objective to harmonize their ICT accessibility standards in terms of how digital products can be made accessible to persons with disabilities[243]. To promote a harmonisation of e-accessibility standards, the Commission and the US DOC agreed in 2005 to develop work plans and time tables (Commission, 2005b: 3). In 2005, under the lead of DG Employment, the Commission issued Mandate M376, which led ETSI to set up a Joint Working Group that included US experts. The Commission restricted the mandate, however, first on the development of a standard for the accessibility of ICT products for public procurement (Commission, 2006b: 5). At the same time, in 2006 the US Access Board promised to review its standards for information technology covered by Section 508 (S508) of the Rehabilitation Act. The US Access Board agreed to invite the Commission to participate in the relevant advisory committee.

Commissioner Reding and DG Information Society complemented these work plans with additional mutual exchanges. Within the framework of the Information Society Dialogue, DG Information Society officials organised two workshops on e-accessibility, one on public procurement and one on conformity issues related to the accessibility of ICT products and services (Commission, 2006b: 5). Moreover, DG Information Society organised a study tour to understand how US agencies determine and demonstrate that ICT products conform to requirements, with a view to coordinate conformity assessment for e-accessibility (European-American Business Council, 2011b). Besides, DG Information Society officials sought to mobilise societal actors in support of regulatory cooperation on e-accessibility (European-American Business Council, 2011b).

Subsequently, officials from DG Employment, DG Information Society and DG Enterprise participated in the advisory committee of the US Access Board on the review of the S508 standard for e-accessibility. Under the lead of DG Employment, the Commission finalised the mandate to ETSI to develop a standard on accessibility requirement and an assessment of suitable testing and conformity schemes for accessibility of ICT products to be used in public procurement and agreed to the participation of the US government in the execution of the Commission's mandate (M376) by ETSI (Commission, 2007b: 4).

After the mandate had been issued in 2007, focus at the political level in the Commission on e-accessibility was gradually lost. Commissioner Verheugen and DG Enterprise began to focus on other

[242] Outside ICT, 'lighthouse projects' have been set up in the area of e-vehicles and biotechnology (Commission, 2008).
[243] The following paragraph is based on the description of Zero Project (2016). /

issues such as e-vehicles (Inside US Trade, 2010a). The harmonisation process for e-accessibility took longer than Commission officials as well as the political level had expected because the accessibility standard would be legally binding as a 'referenced' standard in the US while in the EU it would remain voluntary (Interview 13; European-American Business Council, 2011b). At the same time, the US DOC considered issues such as the harmonisation of e-accessibility standards as too technical to merit high-level political attention (US Department of State, 2009b). After Commissioner Verheugen shifted his political focus to other issues for regulatory cooperation and the US DOC indicated its unwillingness to discuss e-accessibility at high-level TEC meetings, the intensity of the coordination between technical Commission officials from DG Employment and the US Access Board declined (Transatlantic Economic Council, 2011; Transatlantic Economic Council, 2010).

The second TEC 'lighthouse project' encouraged by Commissioners Verheugen and Reding in 2007 focused on e-health. Again, the focus on e-health had been the outcome of inter-service consultations among Commission DGs. The choice to focus on e-health reflected the earlier establishment of the EU co-funded project epSOS2 and potential regulatory work of the Commission on this issue in the future (Commission, 2010: 13). E-health was considered a potential test case for the establishment and implementation of globally interoperable IT standards (Commission, 2010: 4). The long-term objective of the project was to achieve a mutual recognition of electronic patient records (Commission, 2010: 4).

Through the mutual recognition of electronic patient records, the Commissioners reportedly hoped to realise a double benefit: First, the joint work of the Commission with the US HHS should promote the work towards best practice solutions on global IT standards (European-American Business Council, 2011a). The Commission should maintain, if not enhance its autonomy from individual firms and organisations and instead develop solutions that would be beneficial for businesses as well as patients (Interview 13). Second, the mutual recognition of electronic patient records should deliver templates for the development and implementation of globally interoperable IT standards beyond electronic patient records that would facilitate trade in ICT goods and services for firms and access to ICT for consumers (Interview 15; Commission, 2010). The regulatory cooperation work should therefore also enhance the Commission's legitimacy towards both firms and consumers.

In order to ensure that societal actors would support the Commission's lighthouse project on e-health, DG Information Society officials consulted with societal actors, especially firms that were already involved in the Commission co-funded project epSOS2 (Commission, 2010: 6). Moreover, officials sought to raise awareness among business associations and firms for the e-health work to substantiate the support of the TEC and gain additional technical input (European-American Business Council, 2011a). These consultations have been sustained throughout the work of the TEC (Interview 13).

In 2006, DG Information Society officials had held joint workshops with the US Health and Human Services (US HHS) officials on patient safety to prepare the mutual recognition work on electronic patient records. Information Society Commissioner Reding closely followed the preparation of the

workshop and reportedly underlined the difficulty for small medical providers in the US to switch from paper to electronic patient records (US Department of State, 2007a). As an outcome of the meeting, Commission officials participating in the workshop underlined the "difficulty of the task which presents numerous challenges" (summarised in Commission, 2010: 14). Nonetheless, Commissioner Reding supported and sustained the regulatory cooperation process. Upon her support and the support of the administrative leadership of DG Information Society, technical working groups of Commission officials and US officials on interoperability and certification of e-health record systems had already been established in 2006 (Commission, 2006a: 2). Besides, Commissioner Reding demanded that updates on the mutual exchanges between DG Information Society officials and US HHS officials be included in annual meetings in the framework of the TEC (Transatlantic Economic Council, 2009b; Transatlantic Economic Council, 2008; Transatlantic Economic Council, 2007). At the margins of TEC meetings in 2007, 2008 and 2009, Commission officials continued to meet with societal actors. The Commission report from 2010 notes that the joint work of DG Information Society with the US Health and Human Services (HHS) began attracting the attention of EU-US business that followed the TEC, especially through the TABC (Commission, 2010).

In 2010, upon the initiative of Commissioner Reding and supported by the new Information Society Commissioner Kroes, the Commission, represented by Commissioner Kroes and US Health Secretary Sebelius signed a Memorandum of Understanding (MoU) with regard to e-health in which they formally agreed to cooperate on the interoperability of e-health records. They also used the signing of the MoU to ask for a submission of a report within one year including concrete steps towards achieving interoperability of e-health records (Commission, 2011c: 13).

The harmonisation of standards for ICT accessibility and the mutual recognition of electronic patient records constitute examples of 'regulatory alignment'. The roll-out of the work plan above demonstrate that especially the political leadership of DG Information Society sought to achieve this 'regulatory alignment' through frequent technical exchanges among officials to create a dense web of interactions and the mutual participation of experts in the respective standardisation committees.

Encouraged by the successes of the coordination between Commission DGs and the US Access Board and the US HHS in the TEC, DG Information Society expanded the range of issues discussed in the Information Society Dialogue. An expansion of issues was also facilitated by a shift in the lead in the US from the US EEB to the FCC in 2006. The FCC was closer in mandate and regulatory focus to DG Information Society than had been the US EEB. At the same time, the FCC had centralised regulatory authority on many ICT issues that were also of interest to DG Information Society. In 2007, DG Information Society and the FCC set up a dialogue with a view to cooperate on regulatory approaches relating to software-defined radio and ultra-wideband technology (US Department of State, 2007a: 5). Moreover, the EU and the US held a joint workshop on spam enforcement. Rather than promoting an 'alignment of implementation procedures' within their own jurisdictions, they took the issue to the

OECD and there contributed to the adoption of corresponding initiatives (Commission, 2007b). In 2011, DG Information Society and the FCC launched a second dialogue in the framework of the Information Society Dialogue on cloud computing. Within this dialogue the Commission and the FCC focused on understanding the respective regulatory approaches and on standards and certification issues for the cloud (Commission, 2013f: 5). Although Commissioner Kroes supported the establishment of these dialogues, she did not demand that their establishment should be connected to the achievement of specific regulatory outcomes. On the contrary, in view of the limited resources of the DG and potential regulatory work on cloud computing in the future, DG Information Society should retain its discretion to promote an appropriate regulatory response. She therefore did not push for the support of any other regulatory cooperation strategy than 'information exchange' on these issues.

In sum, during the HLRCF and the TEC the Commission's strategy to harmonise EU and US standards for ICT accessibility and to mutually recognise electronic patient records demonstrate its strategy to pursue 'regulatory alignment'. At the same time, the expansion of issues discussed under the Information Society Dialogue show its continued reliance on 'information exchange'.[244]

Transatlantic Trade and Investment Partnership (TTIP)

With the preparation of the TTIP negotiations in 2012, the lead in the Commission shifted to DG Trade. In 2012, however, ICT regulatory cooperation was not a priority of the Commission (Interview 14, Interview 15). E-commerce and electronic data flows were neither mentioned in the final report of the High-Level Working Group nor in the Council negotiating directives specifying objectives for the Commission in TTIP (High-Level Working Group, 2013; Chase et al., 2016: 16). The Commission also does not list ICT in its list of priority sectors for regulatory cooperation (Commission, 2013f). The choice of DG Trade not to make ICT a priority sector for regulatory cooperation under the TTIP can be explained twofold: First, the EU already had a forum for 'information exchange' and discussion with the US, namely the Information Society Dialogue (Interview 13). Second, e-commerce and data flows were not considered contentious issues between the EU and the US (Interview 13; Chase et al., 2016: 16).

Nonetheless, the public consultation organised by DG Trade in 2012 for the preparation of the TTIP negotiations mobilised also societal actors from the ICT sector to elaborate suggestions for issues to be

[244] A the TEC meeting in April 2011, the Commission endorsed with the US "Trade Principles for ICT Services", underscoring their common commitment to transparency, open networks and network access, free cross-border data flows, personal data protection, avoiding data localisation requirements, limiting foreign ownership restrictions, calling for independent regulatory authorities, liberal licensing and authorization processes, and promoting interconnection" (Commission, 2011). The Trade Principles have, however, not been discussed in this section as they did not include an agenda for regulatory cooperation and a work plan to align the respective regulatory policies and/or implementation procedures.

addressed in the negotiations. Digitaleurope formed a transatlantic coalition and presented a joint position paper with the US ICT association ITI. In the position paper, Digitaleurope and ITI pushed DG Trade to also pursue regulatory cooperation in the ICT sector (Digitaleurope & ITI, 2013). The joint position paper contained demands and proposals with regard to standardisation, ICT access and end user information (e-accessibility, e-health, e-labelling), data flows, anti-localisation, encryption and cooperation on standards development on the Internet of Things (Digitaleurope & ITI, 2013). For e-labelling, Digitaleurope proposed the acceptance of an optional electronic labelling on Radio and Telecommunication Terminal Equipment through the TTIP (Digitaleurope & ITI, 2013: 7). Besides, Digitaleurope and ITI suggested that the EU should identify ICT standards, also developed by industry consortia, that already are voluntary US standards and that could be directly referenced in public policies (Digitaleurope & ITI, 2013: 8).

The demand of Digitaleurope and ITI for ICT regulatory cooperation led to exchanges between DG Trade and industry societal actors (Interview 12, Interview 13, Interview 14, Interview 15) in which DG Trade (both Trade Commissioner de Gucht and technical officials) demanded a clarification of the objectives industry thought DG Trade should pursue in the TTIP negotiations with regard to regulatory cooperation. Especially in 2012 and 2013 Digitaleurope emphasised regulatory cooperation with regard to ICT access (Interview 13, Interview 16).

At the same time, the contestation of NGOs contributed to a high politicisation of discussions in the ICT sector, it did not substantially alter the regulatory cooperation strategies pursued by the Commission. Their engagement concentrated on the issues of data privacy and consumer protection in e-commerce (Beuc & European Digital Rights, 2016; TACD; 2016a; European Digital Rights, 2015; Netzpolitik, 2014; TACD, 2013; TACD; 2012).

With the submission of proposals for regulatory cooperation by Digitaleurope, DG Trade began reconsidering its approach to regulatory cooperation on ICT issues (Interview 14). In late 2013, as regulatory cooperation in the priority sectors of DG Trade began showing obstacles (see chapter 6.1.6), DG Trade officials again consulted with societal actors to understand if regulatory cooperation on ICT issues could be extended beyond the work on e-accessibility and e-health in the framework of the TEC (Interview 16). It was then that DG Trade and especially Trade Commissioner de Gucht came to see ICT as a 'row model' for regulatory cooperation it wanted to promote with the TTIP negotiations (Interview 15).

In parallel to the TTIP negotiations, the work on e-accessibility and e-health initiated in 2005 had continued to be addressed in annual meetings in the TEC framework throughout 2012 and 2013. With regard to e-accessibility, the Commission, under the lead of DG Employment, provided regular updates of the work in the Working Group that also included US experts. The US Access Board launched consultations after advanced notices of proposed rule-making in 2010 and 2011. The Advisory Committee of the US Access Board which was tasked to update the requirements of the S508 standard

also included EU experts (Interview 13). By 2014, the ETSI Working Group succeeded to develop a first 'harmonised standard' on e-accessibility (Commission, 2016l)[245].

With regard to e-health, with the endorsement of Commissioner Kroes, DG Information Society launched a 'EU-US Roadmap on e-Health' with the US HHS in 2012. Under the Roadmap, DG Information Society officials and US HHS officials should foster standard development to promote transnational interoperability of e-health information and communications technology (Commission, 2013d). A Commission Report from 2013 emphasises the importance of a close inclusion of stakeholders and the "creation of an innovative collaborative community of public- and private sector entities" in which "input from stakeholders is welcome" (Commission, 2013g). Besides, the Commission promoted the identification of "thought leaders and champions from both the EU and the US" to guide the development of standards enabling interoperability (Commission, 2013g).

De Gucht and DG Trade thus initiated consultations with societal actors to explore issues that could be addressed in a sectoral annex chapters on ICT issues within a TTIP agreement. Digitaleurope and ITI had also suggested e-accessibility and e-health as issues on which the Commission should attempt to pursue harmonisation and mutual recognition (Digitaleurope & ITI, 2013). Subsequently, Commissioner De Gucht tasked DG Trade officials to coordinate the elaboration of a position paper for an annex on ICT regulatory cooperation.

The position paper was drafted under the lead of DG Grow with the participation of DG Connect and DG Trade[246]. DG Grow indicated four issues on which it wanted to "explore opportunities" for regulatory cooperation: interoperability, e-accessibility, e-health and e-labelling (Commission, 2014e). Regulatory cooperation was particularly promoted by Digital Commissioner Kroes[247] (Inside US Trade, 2014f). DG Trade also pushed for the pursuit of regulatory cooperation, but wanted to avoid provisions on regulatory cooperation in a Chapter on Digital Trade (Interview 12, Interview 13)[248]. Yet, DG Trade officials emphasised that ICT regulatory cooperation should not undermine the ability of DG Trade to liberalise digital trade (Interview 12). For this reason, it wanted to avoid provisions on issues such as net neutrality, data protection or ICT access cooperation from the Digital Trade Chapter. DG Connect, in turn, was keen on anchoring EU policies on net neutrality in such a Digital Trade Chapter (Interview

[245] As noted above, this standard should, however, only apply on the accessibility of ICT products under public procurement.

[246] While DG Connect and DG Trade jointly drafted the negotiating texts of the E-commerce and Telecommunications Chapter, with DG Trade in the lead, DG Grow was in the lead for the position paper and a potential text on ICT regulatory cooperation (Interview 12).

[247] Subsequently, officials from DG Connect wanted to introduce provisions on recently adopted policies, notably net neutrality, into the TTIP negotiations. As both the EU and the US have adopted policies on net neutrality with, however, different scopes, a provision on net neutrality does not yet regulatory cooperation according to the understanding of this book.

[248] The Chapter on Digital Trade would be subject to state-to-state dispute settlement and thus entail a higher enforceability than the provisions on regulatory cooperation negotiated under the Regulatory Cooperation pillar of a potential TTIP agreement. DG Trade thus had to anticipate making greater concessions in exchange for provisions in a Digital Trade Chapter than for provisions in a separate Regulatory Cooperation Chapter that would not be subject to the same enforceability through state-to-state dispute settlement.

12). DG Grow was open to discussing further ICT cooperation on specific issues within the TTIP, given that it would not be bound to any deadlines through the discussions (Interview 12). The position paper was published in June 2014. It contained four objectives: a) to increase cooperation on e-labelling, b) to increase cooperation on e-accessibility, c) to increase cooperation on interoperability and d) "to set common principles for certifying ICT products, especially for encoding and decoding information" (Commission, 2014e) The position paper did, however, not specify a precise strategy for cooperation.

As a result of the coordination among the DGs and the publication of the position paper, regulatory cooperation on ICT access through the projects on e-accessibility and e-health were now also raised and discussed by Commission officials at the margins of the TTIP negotiations (Commission, 2015d). Especially on e-health, DG Connect officials used the high-level political attention under the TTIP negotiations to advance the work on the roadmap. DG Connect and HHS officials compared patient summary specifications across EU and US to assess the decisive factors for interoperability (Commission, 2014d). They published recommendations on the structure and the content of an International Patient Summary (IPS) standard in a White Paper by 2014 (Interview 13). Moreover, DG Connect officials and US HHS promised to promote and advance this IPS standard, hoping that it could facilitate cross-border exchange of health data (Commission, 2014d).

As the TTIP negotiations continued through 2015 and 2016, momentum on ICT regulatory cooperation was slowly lost (Interview 13). While ETSI published the 'harmonised standard' on e-accessibility in public procurement in 2014[249], the US Access Board had not completed to revise the S508 defining the accessibility characteristics of ICT products that US agencies need to procure. DG Employment, however, did not want to wait for the completion of the US standards revision and instead moved ahead with the proposal of a European Accessibility Act[250] (Interview 13; Interview 15). Interview partners stated that an obstacle for the completion of the US standard and subsequent cooperation was that the standard would be mandatory in the US while it would remain voluntary in the EU (Interview 13, Interview 15).

With regard to e-health, DG Connect continued discussions on a mutual recognition of electronic patient health records. Although a mutual recognition would not lead to transatlantic flows of patient data, DG Connect officials began devoting time to explaining US HHS officials the sensitivity of data flows (Interview 13). Due to the sensitivity of data privacy in particular to DG Just, DG Connect was reluctant to initiate further steps towards mutual recognition before a revised data privacy arrangement between the EU and the US had been established (Interview 13).

Digitaleurope shifted its emphasis in public statements and in consultations with DG Trade officials on the certification of encryption products, i.e. source code, and data flows (Digitaleurope, 2014a; Interview

[249] This standard is the EN 301 549.
[250] The Commission presented a proposal in 2015 for a European Accessibility Act includes the possibility of using standards as guidance to facilitate conformity by industry.

15). This shift reflected the observation that the Commission was already working on e-accessibility and e-health in the continuation of the TEC (Interview 15). Besides, Digitaleurope also underlined the importance of aligning standards. Digitaleurope did not, however, give prominence to cooperation on the Internet of Things during meetings with the Commission (Interview 12, Interview 14).

At the same time, the TACD demanded 'regulatory alignment' on e-commerce (TACD, 2013)[251]. The TACD did, however, not advocate the adoption or transfer of either the EU or US regulatory framework, but instead called for an updating and improvement in the regulatory frameworks of both sides. NGOs, however, mostly continued to lobby against ICT regulatory cooperation through 2014, 2015 and 2016, arguing that regulatory cooperation on these issues would undermine the EU's data privacy regime (TACD; 2016a; European Digital Rights, 2015; Netzpolitik, 2014). The TACD had already demanded in 2013 that the EU and US first "agree on common data privacy standards outside of the proposed TTIP negotiations". (TACD, 2013: 2). DG Just (and ostensibly also other Commission DGs) shared the assessment of EDRi and BEUC that the old Safe Harbour agreement did not provide an adequate level of protection and that "enforcement was one of its main flaws" (TACD, 2016a: 2) (Interview 12). Interviewees noted, however, that DG Just had already considered a revision of the Safe Harbour Agreement in 2010 before TTIP lobbying began (Interview 12). Moreover, despite opposing demands by NGOs, DG Trade and DG Just did not give up their intention to include a proposal on free data flows in an eventual text (Interview 12; Interview 14).

Until the TTIP negotiations were frozen in November 2016, the Commission did not publish a draft textual proposal on ICT regulatory cooperation. Two explanations account for this: First, the new Digital Commissioner Oettinger put less priority on promoting regulatory cooperation than his predecessor Kroes (Interview 15). Second, Digitaleurope shifted its lobbying focus towards including a provision in a TTIP agreement that would safeguard free data flows between the EU and the US and towards a successful conclusion of the negotiations on the Privacy Shield (Interview 14)[252]. This reduced the pressure on Commission officials to pursue regulatory cooperation within the context of the TTIP negotiations.

However, in spring 2016 DG Trade officials held informal consultations with DG Connect and DG Grow (Interview 13) on a non-public draft textual proposal for 'Digital Trade' that to a limited extent also contained regulatory cooperation provisions. DG Trade shared the draft textual proposal on 'Digital Trade' with member state representatives in the TPC in July 2016. Together with a non-public document

[251] The TACD demanded e.g. to ensure coherence in the treatment of unsolicited electronic commercial communications, to ensure non-discriminatory consumer protection for all digital products, to improve consumer protection from misleading advertisement and unfair online practices, update copyright rules and improve consumers' rights to dispute resolution and redress (TACD, 2013b).

[252] Consequently, the Commission stressed that it wanted to exclude data protection from TTIP and seek an agreement with the US enhancing the enforcement of data protection of EU data subjects in the US in parallel to the TTIP negotiations. Thus has led to the negotiation over a Privacy Shield (Bendiek & Schmieg, 2016; Inside US Trade, 2016d).

distributed to member state representatives and the INTA Committee of the EP in March 2016 (Commission, 2016n), the draft Digital Trade Chapter reveals the strategy of the Commission on ICT regulatory cooperation in the TTIP negotiations. The 'Digital Trade' consolidated provisions previously spread across different Chapters into one text (Interview 14)[253]. On e-accessibility, the Commission re-iterated its strategy to achieve 'regulatory alignment'. However, 'regulatory alignment' should only be considered once the US Access Board had published its e-accessibility standard. The Commission noted that it would mandate a re-examination of the 'harmonised standard' afterwards the to see if the EU standard could be aligned (Commission, 2016n: 17). Interviewees noted, however, the Commission did not take up the proposal of Digitaleurope to engage in a broader exercise to harmonise standards because it does not have authority to prescribe standards to ETSI and refused to undermine the authority of ETSI to be the exclusive developer or provider of standards (Interview 12, Interview 14)[254],[255].

On e-health, the Commission likewise continued to propose 'regulatory alignment' based on the e-health Roadmap from 2012. The 'Tactical State of Play' document underlines that the Commission's strategy adopted under the TEC in the view of officials and the administrative and political leadership is the "the appropriate one" (Commission, 2016n: 16). However, DG Connect and DG Grow underlined the pursuit of a mutual recognition of electronic health records should not be subjected to the timetables of TTIP negotiations (Interview 12; Commission, 2016n: 17). Besides, despite the efforts towards 'regulatory alignment', the distinct regulatory approaches of each side should be respected (Commission; 2016: 17).

At the same time, the Commission did not begin discussions on e-labelling as it had considered in the position paper on ICT regulatory cooperation published in 2014. The FCC had adopted the E-Label Act in 2014, allowing manufacturers of radio-frequency devices to use electronic labelling rather than physical labels on the equipment. The reluctance of the Commission had less to do with a perception among officials that regulatory principles on this issue would be incompatible[256]. Rather, officials emphasised that an extension of e-labelling to other equipment than medical devices was not a legislative priority for the Commission at the time, given its focus on other legislative projects (Interview 15; Commission, 2016n: 16). Yet, the Commission agreed to maintain 'information exchange' with the FCC

[253] Interview partners acknowledged that the presentation of a textual proposal on 'Digital Trade' was delayed by the lack of consensus within the Commission on its position regarding data flows. While DG Connect and DG Trade support a provision in a Digital Trade Chapter that would commit the Commission to maintaining free data flows, DG Justice opposed such a commitment as long as the renegotiated data protection framework with the US had not been implemented and confirmed (Interview 12, Interview 14).

[254] Besides, the position paper of Digitaleurope and ITI does not offer a 'green list' of US SDOs or consortia whose standards should be considered in particular by EU SDOs for the development or adoption of ICT standards.

[255] Digitaleurope could also not substantially influence the strategy choice of the Commission with regard to the development of joint standards for the Internet of Things. The joint position paper only states that "coordination between the EU and the US with regard to the nascent Internet of Things would be commendable". (Digitaleurope & ITI, 2013: 2) Yet, it does not list any specific issues on which the Commission should seek coordination beyond information exchange in the Information Society Dialogue.

[256] On the contrary, interview partners from both the Commission and business associations stated that the EU and the US were "very similar on this" (Interview 12, Interview 13, Interview 14, Interview 15).

on e-labelling. It would, however, only intensify these exchanges in the context of a broader project on e-compliance (Commission, 2016n: 16).

Moreover, the Commission decided not to make commitments on regulatory cooperation with regard to another issue proposed by Digitaleurope, i.e. e-trust and authentication services. On this issue, under the lead of DG Connect the Commission was in the process of revising and developing its own legislation at the time of the TTIP negotiations[257]. DG Connect officials sought to ensure that its discretion to adopt legislation would not be restricted under any commitment in the TTIP text (Interview 13). At the same time, DG Connect noted the importance of exchanging information and legislative best practices with the US on this issue (Interview 12) [258]. For this reason, the Commission only laid down in a textual proposal for the TTIP e-commerce Chapter that it would seek to discuss the recognition and facilitation of interoperable cross-border electronic trust and authentication services (Commission, 2015h)[259],[260].

In sum, for the TTIP negotiations, the Commission' continued to pursue its strategy to harmonise EU and US standards for ICT accessibility and to mutually recognise electronic patient records demonstrate its choice to pursue 'regulatory alignment'. Nonetheless, the reluctance to pursue 'regulatory alignment' on issues on which it was simultaneously pursuing own legislative projects or that were not a legislative project at the time of the discussions showed its parallel reliance on 'information exchange'.

[257] The improvement of consumer protection under e-commerce is one of the core objectives of the Digital Single Market.

[258] On other issues still, the Commission chose not to make any commitments in TTIP at the time of writing. This concerned notably provisions on free data flows, data localisation as well as net neutrality. On these issues, the Commission thus decided to maintain 'regulatory competition'.

[259] The Commission also sought to align implementation procedures with regard to conformity assessment of ICT products. After the FCC had accepted suppliers' declaration of conformity applied by the EU as the adequate conformity assessment procedure, the EU aimed at further aligning implementation procedures by cooperating on market surveillance. The perceived compatibility of underlying regulatory principles has been argued to be the basis for this alignment. Yet, the Commission wanted to rely on mutual learning and persuasion strategies given that it was uncertain to what extent the market surveillance approaches of the FCC and the EU authorities would be compatible. Within the context of TTIP, only a framework for cooperation should be established (Commission, 2016: 15).

[260] The Commission also continued information exchanges in annual meetings under the Information Society Dialogue. Information exchange concentrated on legislative work and market developments. The Commission concentrated notably on the Digital Single Market and the issue of cloud computing standards, emphasising its interest to cooperate with the US on the development of standards and conformity certificates for the cloud to avoid the emergence of trade barriers. Moreover, DG Connect used the Dialogue to clarify its position in favour of prohibiting data localisation requirements for servers. It did not, however, seek to set up roadmaps or workplans towards the joint development of standards or certificates (US Department of State, 2015).

6.4.7. Discussion

The previous sub-section has laid down that since the HLRCF/TEC, the Commission has begun to choose 'regulatory alignment' as a regulatory cooperation strategy for issues within the ICT regulatory regime. This sub-section discusses the Commission's choice of regulatory cooperation strategies during the three regulatory cooperation initiatives in view of the hypotheses derived from the Inter-relational Institutionalism. Particular attention is put on the analysis of the expectations on the constraints on regulatory cooperation formulated in section 6.4.5.

A comparative analysis of the formation of the regulatory cooperation strategies across the three selected transatlantic cooperation initiatives reveals the influence of bureaucratic pressure on the engagement of Commission officials in bilateral regulatory cooperation (Hypothesis 1). During the NTA, bureaucratic pressure was largely absent, especially in the beginning under the leadership of Commissioner Bangemann. Officials from DG Information Society thus mostly contributed to the TEP initiatives with proposals to take forward already ongoing under the WTO. Yet, the lack of bureaucratic pressure contributed to the persistence of formulations which remained vague and failed to make precise commitments on ICT issues. This changed somewhat with the entry into office of Commissioner Liikanen who proposed and accompanied the establishment of the Information Society Dialogue. Yet, as illustrated in the previous section, DG Information Society officials did not use the dialogue to pursue regulatory cooperation beyond 'information exchange'. This can be linked to the lack of bureaucratic pressure to pursue regulatory cooperation, especially beyond 'information exchange' during the NTA.

The formation of a regulatory cooperation strategy and the engagement in 'regulatory alignment' began with the invitation of Commissioner Verheugen to Commissioner Reding to participate in the TEC. The subsequent establishment of the two lighthouse projects on e-health and e-accessibility corresponds to the demands and commitment of both Commissioners to use these issues within the ICT regulatory regime to advance transatlantic regulatory cooperation. The need for bureaucratic pressure to initiate the formation of a regulatory cooperation strategy and to pursue 'regulatory alignment' is further underlined by the engagement in ICT regulatory cooperation within the TTIP negotiations. During the negotiations, bureaucratic pressure emanated both from the political leadership within the technical DG, i.e. Commissioner Kroes, as well as the involvement of DG Trade. While reluctant to include ICT cooperation as a priority sector at the launch of the negotiations, Commissioners de Gucht and Malmström later encouraged and pursued regulatory cooperation in the ICT sector as they realised that ICT cooperation could be easier to achieve than in other sectors. Bureaucratic pressure thus drove the formation of a regulatory cooperation strategy and the choice of 'regulatory alignment' during both the TEC and the TTIP negotiations.

The empirical finding of the 'regulatory alignment' selected under bureaucratic pressure during the TEC and the TTIP negotiations supports the expectations formulated in section 6.4.5. Indeed, the choice for 'regulatory alignment' only in the ICT sectoral regime among the case studies examined in this book is in line with the distribution of regulatory compatibilities between the EU and the US in the ICT regime (Hypothesis 2).

The interview evidence gathered for the purpose of this book suggests that regulatory centralisation in both the EU and the US was essential because the pursuit of 'regulatory alignment' relied on dense and frequent consultations between Commission officials and their US counterparts, especially officials from the FCC. At the same time, it underlined that compatibility of regulatory principles was crucial. On the one hand, the Commission chose the two 'lighthouse projects' on e-accessibility and e-health because it knew that neither side had yet implemented policies or adopted principles that would make an alignment difficult (Interview 13). On the other hand, they were chosen because discussions under the Accessibility Standards Dialogue had signalled to the Commission that both the EU and the US "shared similar thinking on these issues". Indeed, subsequent meetings demonstrated to Commission officials that both the EU and the US "were very similar on this" (Interview 13).

Yet, 'regulatory alignment' was 'only' chosen by the Commission with regard to e-accessibility and e-health, but not e-labelling and e-authentication. This indicates that compatible regulatory authority structures and principle do not inevitably lead the Commission to pursue 'regulatory alignment'. Rather, the process-tracing conducted in section 7.4.6. implied that the Commission's choice to pursue 'regulatory alignment' depended on the support of the responsible Commissioner and the absence of ongoing domestic legislative activities in parallel to regulatory cooperation discussion. The personal endorsement of the TEC by Commissioner Verheugen thus drove the Commission's establishment of the 'lighthouse projects' on e-accessibility and e-health. Moreover, the support of Commissioner Kroes contributed to maintain the Commission's pursuit of 'regulatory alignment' on those lighthouse projects even after the US leads on the TEC had found them too technical to deserve high-level political attention. At the same time, ongoing parallel domestic legislative activities also restricted the willingness of Commission officials and Commissioners alike to pursue 'regulatory alignment' on those issues at least until domestic legislation had been completed. This has been the case with the reluctance of the Commission to commit to definite 'regulatory alignment' on e-accessibility until the European Accessibility Act had been adopted. Moreover, the Commission was reluctant to begin 'regulatory alignment' on e-authentication before the corresponding consumer protection provisions had been adopted under its Digital Single Market programme. Legislative autonomy may also deter the Commission from pursuing 'regulatory alignment' under a given timeframe or timetable if this would entail domestic legislative activity on an issue that the Commission does not consider a legislative priority at the time, as suggested by potential 'regulatory alignment' on e-labelling. On all these issues, the Commission instead chose to pursue 'information exchange', at least during the time of writing.

Furthermore, the process-tracing has shown that the mobilisation of societal actors in line with the distribution of regulatory compatibilities has led technical officials to choose 'regulatory alignment' (Hypothesis 3). The relevance of societal mobilisation is evidenced most clearly by a contrast of the mobilisation of societal actors during the NTA and TTIP. During the NTA EU and US ICT firms and business associations were mostly at odds with each other over the design of mobile TV standards. In contrast, Digitaleurope and ITI formed an alliance during the TTIP negotiations and jointly presented a position paper with demands reflecting issues of compatible authority structures and principles within the authority of the Commission and its US counterparts. The invitation of the Commission to societal actors to propose issues for regulatory cooperation also illustrates that it seeks to pursue 'regulatory alignment' there where it delivers benefit to societal actors.

At the same time, the failure of societal actors to include an issue in their demands and position papers contributes to the absence of this issue from the scope of the 'regulatory alignment' strategy formed by the Commission. This conclusion is also in line with hypothesis 3. Indeed, the Commission's demand to societal actors to support discussions for 'regulatory alignment' shows that it hesitates to pursue 'regulatory alignment' without their support. It is shown by the initial absence of joint EU-US standards on the Internet of Things as an issue for 'regulatory alignment'. Interview evidence demonstrated that absent demands of societal actors for this issue strongly contributed to the focus of Commission officials on other issues (Interview 12). Mobilisation of societal actors also fails to affect the choice of a regulatory cooperation strategy if societal actors do not formulate demands sufficiently specific to guide the Commission's focus. The lack of technical detail provided by Digitaleurope and the TACD for 'regulatory alignment' on Internet of Things standards or e-commerce legislation offer examples for the second.

Moreover, and also in line with hypothesis 3, societal actors cannot push or force the Commission to pursue regulatory cooperation. As shown in the previous case studies, the ability of societal actors to demand regulatory cooperation is constrained by regulatory compatibilities. Besides, it is also constrained by the Commission's insistence to preserve its autonomy in simultaneously ongoing domestic legislative projects. For this reason, mobilisation of societal actors for 'regulatory alignment' has failed to expand beyond the Commission' pursuit of regulatory cooperation beyond the lighthouse projects on e-accessibility and e-health. The embedding of regulatory cooperation into the TTIP negotiations, in turn, did not lead to an expansion of 'regulatory alignment' to further issues.

The continuation and expansion of 'regulatory alignment' on ICT access issues is unclear at the time of writing. On the one hand, the Commission has increasingly expanded the agenda for 'information exchange' under the Information Society Dialogue with the FCC. The compatible distribution of regulatory authority entails that the Commission may well consider and propose additional issues for 'regulatory alignment' once it has concluded legislative activities ongoing at the time of writing, e.g. on e-labelling or e-authentication. On the other hand, the increasing adoption of divergent legislation in the

EU and the US on ICT issues, e.g. on net neutrality, may promote the establishment of new, incompatible regulatory principles. Moreover, continuing internal discussions within the Commission on the treatment of international data flows may make both Commission officials and Commissioners to move ahead with 'regulatory alignment' issues that involve data flows, even if the issue for which 'regulatory alignment' is considered does not require itself data flows. In addition, potential divergent regulatory frameworks in the future and the adoption of regulatory principles in the EU that are incompatible with those in the US may be supported by preferences among EU telecommunications, software and Internet firms to regain competitive advantages over US firms through the establishment of regulatory differences.

7. Conclusion

The examination of the factors which constrain the engagement in regulatory cooperation and the choice of a regulatory cooperation strategy has been the objective of the preceding empirical case studies. The four sectoral regime case studies have shown that the choice of a regulatory cooperation strategy is relatively consistent even if the macropolitical context changes. They have found that the strategy which the Commission as the regulator examined in this book chooses and employs on issues within a given sectoral regime is consistent across different cooperation initiatives. This finding reinforces the initial assumption motivating this book that the choice of a cooperation strategy is constrained by structural factors. These structural factors, i.e. the compatibility of regulatory authority structures and regulatory principles, have been theoretically refined and empirically tested by this book.

This chapter draws conclusions about the explanatory strength of the Inter-relational Institutionalism deduced theoretically in the first part to account for the constraints on the choice of a bilateral regulatory cooperation strategy examined in the empirical case studies in the second part of this book. A first section summarises the main results of this book (chapter 7.1.). A second section carries out a comparative analysis of the case studies. To this purpose, it discusses the influence of the three independent variables on the formation and choice of a regulatory cooperation strategy, based on the findings from the four empirical case studies investigated in this book. It then discusses limitations to generalising the findings from the four case studies beyond the analysis of bilateral regulatory cooperation of the EU with the US in the selected cases. Here, this book re-considers the specificity of the sectoral regimes chosen, the specificity of the US as a partner for regulatory cooperation to the EU, the ability to infer from bilateral to international regulatory cooperation as well as the specificity of the EU and the Commission in particular as an actor in bilateral regulatory cooperation (chapter 7.2.). A third section assesses the contributions of this book. It outlines its contributions to theories of the constraints of domestic (regulatory) institutions on the engagement of ‘state actors’ in international cooperation. Furthermore, it describes the contribution which the findings of this book offer with regard to the hopes business actors place in bilateral regulatory cooperation and fears articulated by NGOs. To this end, it looks at effects of bilateral regulatory cooperation that is constrained by the compatibility of regulatory institutions (as well as the presence of bureaucratic pressure and mobilisation by societal actors) on safeguarding and strengthening the level of consumer safety, public health and environmental protection as well as promoting administrative efficiency (chapter 7.3). A final section provides a brief summary of this book (chapter 7.4.).

7.1. Summary of the main results

This book has raised the puzzle why a regulator with high regulatory capacity from a jurisdiction with a large internal market such as the Commission does not use its power resources in international regulatory cooperation to try and externalise domestic regulatory measures and standards to third countries through bilateral regulatory cooperation. From this puzzle it has deduced the research question which factors constrain the formation and choice of a bilateral regulatory cooperation strategy of a state or jurisdiction with high regulatory capacity such as the Commission.

Four sectoral regime case studies from transatlantic regulatory cooperation between the EU and the US have empirically tested the Inter-relational Institutionalism which has been theoretically deduced from an integration of the New Interdependence Approach and actor-centred institutionalism.

The case studies have offered ample evidence that the existence of bureaucratic pressure to cooperate, raised by either a politically appointed such as a Commissioner or top-level officials from a non-technical bureaucratic body such as DG Trade, initiates the formation of a bilateral regulatory cooperation strategy. Due to different bureaucratic roles and mandates, politically appointed Commissioners and non-technical DGs have more often seen bilateral regulatory cooperation as an opportunity structure to enhance the Commission's autonomy and legitimacy than technical officials. If Commissioners and non-technical DGs raised bureaucratic pressure to initiate cooperation, the discretion of technical officials to determine their own priorities was reduced and they followed the priorities set by Commissioners, non-technical DGs. The need for bureaucratic pressure to initiate the formation of a regulatory cooperation strategy has, however, been weaker for the pursuit of 'information exchange'.

The case studies have further confirmed that the compatibility of regulatory institutions between the domestic and the foreign jurisdiction constrains the subsequent choice of regulatory officials among different bilateral regulatory cooperation strategies. Once bureaucratic pressure had initiated the priority to cooperate internationally, the specific EU regulatory institutions constrained technical Commission officials in their choice of a regulatory cooperation strategy across four all sectoral regimes studied. The case studies showed that both the compatibility of EU regulatory authority structures and regulatory principles with US regulatory institutions constrained the choice of Commission officials of a bilateral regulatory cooperation strategy. As the distribution of regulatory compatibilities within individual sectoral regimes stayed mostly constant over time, the 'maximum' regulatory cooperation strategy chosen by Commission officials did not change across different regulatory cooperation initiatives. The interview evidence confirmed that Commission officials only saw regulatory cooperation as an opportunity structure to avoid adverse political intervention to regulation if it did not undermine either

the Commission's domestic regulatory authority or its adherence to institutionalised regulatory principles.

Process-tracing within the individual case studies has laid down that societal mobilisation is essential to ensure that regulatory officials would promote and politically appointed officials would adopt a regulatory cooperation strategy in line with regulatory compatibilities as their actual strategy. The case studies have revealed that mobilisation of societal actors not only helps Commission officials to obtain technical knowledge and expertise of issues within the sectoral regimes on which they can pursue regulatory cooperation. They have also shown that societal mobilisation is necessary because it provides Commission officials with an indication that societal actors approve of their pursuit of regulatory cooperation. Societal actor mobilisation thus also gives legitimacy to the decision of regulatory officials to adopt a specific regulatory cooperation strategy. The process-tracing has demonstrated that societal actor mobilisation has mostly been reactive upon initiative of the Commission. At the same time, the case studies have shown that societal actor mobilisation cannot push Commission officials to pursue regulatory cooperation 'beyond' the constraints of regulatory compatibilities.

7.2. Comparative analysis of the case studies

This section discusses the hypotheses formulated in chapter 4.3 in light of the evidence gathered from the four sectoral case studies in chapter 6 through a comparative case analysis. It will first discuss the influence of bureaucratic pressure on the engagement of technical regulatory officials in regulatory cooperation. Subsequently, it will discuss the effect of the compatibility of both regulatory institutions, regulatory authority structures and regulatory principles, on constraining the choice of a regulatory cooperation strategy. Moreover, it will re-examine the role that societal actors play in the formation of a regulatory cooperation strategy.

7.2.1. Bureaucratic pressure

The findings of all empirical case studies support the hypothesis that the pursuit and uptake of regulatory cooperation is initiated within the Commission. They confirm hypothesis 1 that the launch of regulatory cooperation is the result of changes in power dynamics within the Commission. Hypothesis 1 stated that shifts in access among different DGs and Commissioners to collective preference formation influence the choice between 'regulatory competition' and 'regulatory cooperation'. The gathered evidence found that demands of Commissioner and the DG Trade for regulatory cooperation changed if Commission officials considered engaging in any strategy of regulatory cooperation or if they chose to maintain regulatory competition. To substantiate their demand, both Commissioners and the DG Trade have

mobilised societal actors. Especially where institutionalised exchanges exist, technical Commission officials have, however, also pursued 'information exchange' in the absence of changes in internal power dynamics. Nonetheless, demands of Commissioners or the DG Trade have been important for the pursuit of 'regulatory alignment', 'equivalence' or an 'alignment of implementation procedures'.

In all four case studies, the process of strategy formation for the pursuit of regulatory cooperation with the US began with demands for regulatory cooperation by the competent Commissioner or corresponding demands of DG Trade. Commissioner demands were particularly important during the NTA and the TEC, but also during the TTIP negotiations. The evidence presented in the case studies citing interview partners from all sides strongly underlines this point. Likewise, the empirical case studies offered clear evidence that the participation of DG Trade in the adoption of Commission strategies initiated the engagement in regulatory cooperation by technical officials. The involvement of DG Trade for the initiation of regulatory cooperation was mostly relevant during the TTIP negotiations. Although the role identified for DG Trade confirms hypothesis 1, the evidence underlining the role of DG Trade in supporting the uptake of regulatory cooperation was less clear cut than for Commissioners. The ICT case study suggests that DG Trade wanted to ensure that regulatory cooperation did not overlap and create unfavourable issue linkages with its other priorities before asking technical DGs to explore opportunities for regulatory cooperation (Interview 12). The case studies do not allow for a sufficient differentiation between the influence of the competent Commissioner and the participation of DG Trade on the pursuit of regulatory cooperation by the technical DG officials. Any conclusions therefore need to remain indicative. Yet, it can be concluded that the engagement in regulatory cooperation in 2005 under the TEC largely occurred without the contribution of DG Trade. Here the role of the Commissioners and especially Industry Commissioner Verheugen was pivotal. The demands of DG Trade for regulatory cooperation during the TEC supported the formation of regulatory cooperation strategies, although arguably not to the same extent across all sectors. In the latter case, regulatory cooperation came to be pursued where competent Commissioners at least did not oppose regulatory cooperation. In any case, an indicative conclusion is that the involvement of DG Trade does not appear to be essential for technical officials to pursue regulatory cooperation rather than maintain regulatory competition. This indicative conclusion should, however, be examined in additional research beyond the scope of this book.

The case studies also revealed that the same causal mechanism is at work when Commissioners and DG Trade push technical DGs to engage in regulatory cooperation. During each of the cooperation initiatives examined, either the sectoral Commissioner or during TTIP the Trade Commissioner proposed the launch of high-level discussions with US counterparts with the aim to establish institutionalised regulatory cooperation. To substantiate their claims, they mandated the establishment of public consultations and dialogues with societal actors. These consultations and dialogues mobilised EU societal actors to connect with US societal actors and propose issues on which regulatory cooperation

would create benefits for societal actors. Moreover, they mandated the publication of scientific studies to identify from a legal perspective on which issues EU and US regulatory systems had the potential for overlap (Egan & Nicolaidis, 2001). The process-tracing indicated many issues across all case studies and across all phases on which technical officials did not pursue regulatory cooperation or would not have pursued regulatory cooperation in the absence of Commissioner pressure or demands of DG Trade. Indeed, the interview evidence offered in the case studies provides ample illustration that technical Commission officials hesitated to pursue regulatory cooperation. Reasons stated in the interviews confirm findings of prior research by Pollack (2005): the workload of Commission officials and the fear that regulatory cooperation would distract resources from the fulfilment of other regulatory and legislative tasks (Interview 1, Interview 7, Interview 9, Interview 10, Interview 15). In addition, interview partners stressed that Commission officials were sceptical towards regulatory cooperation with the US in particular as US regulators had not seriously engaged with regulatory cooperation proposals of the Commission in the past.

The hypothesis that bureaucratic pressure is necessary to initiate the formation of a regulatory cooperation should, however, be refined in view of the finding that Commission officials pursued 'equivalence' in the Joint Veterinary Committee in the food safety case and 'information exchange' e.g. under the Information Society Dialogue in the ICT case. In these instances, technical officials have engaged in strategy formation and the pursuit of regulatory cooperation without demands of the competent Commissioners or pushes for regulatory cooperation by DG Trade. Moreover, interview partners across all competent DGs involved in the chosen sectoral case studies stated that by the time of the TTIP negotiations they had come to "appreciate the value of regulatory cooperation in principle" (Interview 1, Interview 7).

Based on the findings from the case studies, technical Commission officials indeed have over time increasingly chosen to engage in bilateral regulatory cooperation also in the absence of bureaucratic pressure, especially in cooperation by means of 'information exchange'. This finding confirms the assumption of the New Interdependence Approach that sub-state actors including regulators increasingly perceive rule overlap between jurisdiction as an opportunity structure. 'Information exchange' allows technical officials to maintain their discretion and avoid conflicts between domestic and foreign regulatory objectives as a result of regulatory cooperation. At the same time, however, interview evidence suggested that 'information exchange' has been sporadic and ad-hoc and has not been used in a 'strategic' way (Interview 2, Interview 14). 'Information exchange' on ICT issues through the Information Society Dialogue is an exception to this as in this instance, 'information exchange' has been embedded in an institutionalised structure which has been created upon bureaucratic pressure in the first place. Moreover, if technical officials engaged in regulatory cooperation in the absence of bureaucratic pressure, they mostly restricted their choice of regulatory cooperation to 'information exchange'. The pursuit of 'equivalence' through the Joint Veterinary Committee constitutes an exception. But in this

instance again, regulatory cooperation has been embedded in an institutionalised structure that had been previously established upon bureaucratic pressure.

In view of the finding that technical Commission officials engage in 'information exchange' out of their own initiative and in the absence of bureaucratic pressure, the theoretical underpinning for the reluctance of officials to engage in regulatory cooperation in the absence of bureaucratic pressure must be refined. The workload of technical officials and the burden that the conduct of bilateral regulatory cooperation additionally poses on officials (Pollack, 2005) remains a valid explanation. It supports the notion that 'information exchange' pursued by technical officials is sporadic rather than systematic. Yet, interview evidence suggests an additional explanation why bureaucratic pressure is necessary to initiate the formation of a regulatory cooperation strategy. Bureaucratic pressure in the EU entails that Commissioners and Directors General or even Heads of State or Government from the member states raise regulatory cooperation as a priority in exchanges with their counterparts from a third country. This, in turn, is likely to entail that the foreign counterparts of the technical officials receive bureaucratic pressure themselves to engage in cooperation with the Commission. If foreign technical officials act under bureaucratic pressure from foreign bureaucratic leaders or the foreign political leadership, they are less likely to reject or ignore the proposals of Commission officials for the engagement in regulatory cooperation. Responses of foreign officials to strategy proposals of the Commission, in turn, lower the perception among technical Commission officials that bilateral regulatory cooperation is an additional burden on their workload which may entail little tangible benefit for themselves.

The emphasis of this book on bureaucratic pressure as the main initiator of regulatory cooperation must not be read as a claim that bureaucratic officials and politically appointed officials can act in insulation from democratically elected legislatures. Indeed, as noted in chapter 4.4.3., in the EU the Commission densely interacts with member state representatives in the Council, notably through the TPC, and since the entry into force of the Lisbon Treaty on an equal basis also with members of the European Parliament. As the Commission reports to both bodies on regular basis and is tightly monitored by both in its transnational interactions[261], it cannot act against the preferences and priorities of majorities in either body. Its discretion is even further constrained where it relies on both for the ratification of international agreements. Moreover, the Commission uses both bodies to obtain technical guidance on issues on which it can or cannot pursue regulatory cooperation. The strong language against any changes to the European chemicals framework REACH in the resolution of the European Parliament on TTIP (European Parliament, 2015) would have made any negotiation difficult even if the Commission had considered discussions with the EPA on REACH. Likewise, the emphasis of member states in the TPC on embracing regulatory cooperation on engineering issues (Interview 16, Interview 18) arguably supported the elaboration of corresponding position papers. Statements in favour of regulatory

[261] During the TTIP negotiations, the Commission reported to the TPC and the INTA Committee before and after each negotiation round (Interview 16).

cooperation by officials in the Council and members of the EP also strengthened the perception among Commission officials that their pursuit of regulatory cooperation was legitimate (Interview 18). Endorsement of regulatory cooperation by the European Council arguably serves a similar purpose (for the role of the European Council in the EU's international interactions see Wessels, 2016).

The argument put forward by the Inter-relational Institutionalism is rather that in practice, neither officials in the TPC nor members of the EP or the European Council systematically demand the pursuit of regulatory cooperation on specific issues. Interview evidence collected for this study has repeatedly supported this conclusion (e.g. Interview 1, Interview 7, Interview 16). Where the Council, EP or European Council have referred to regulatory cooperation, their references have remained vague or general. Moreover, the process-tracing has revealed that support by members of these bodies has followed earlier demands for regulatory cooperation by Commissioners. One interviewee summarised the role of the Council and the EP in sector-specific regulatory cooperation as follows:

> "They were neither in favour nor against. At most, they were observant and wanted to see what we could get out of the [sector-specific talks]" (Interview 4).

Thus, in sum, in all four case studies, the formation of a regulatory cooperation strategy and the uptake of regulatory cooperation has resulted from demands and power dynamics within the Commission. Demands of competent Commissioners and DG Trade for the uptake of regulatory cooperation are particularly important for the pursuit of 'regulatory alignment', 'equivalence' and an 'alignment of implementation procedures'. The demands of Commissioners or DG Trade for technical officials to engage in regulatory cooperation did, however, not lead to the pursuit of a strategy that lies outside the constraints of regulatory compatibilities. In the absence of demands for regulatory cooperation, technical officials mostly choose to maintain regulatory competition for the reasons already stated in previous literature. The finding that technical officials increasingly engage in 'information exchange' even in the absence of bureaucratic pressure refines hypothesis 1, but does not reject it. Rather, it is an important confirmation of the validity of the New Interdependence Approach and its assumption that regulators increasingly see the international level as an opportunity structure. Yet, this book has been able to show that both the pursuit of deeper or higher dimension strategies and the pursuit of systematic 'information exchange' presuppose bureaucratic pressure.

7.2.2. Regulatory compatibilities

The findings of the empirical case studies support hypothesis 2 that the Commission's choice of regulatory cooperation strategy - other than regulatory competition - reflects institutional conditions, i.e. the compatibility of regulatory authority structures and regulatory principles in the EU and the US. Hypothesis 2 stated if regulatory authority structures and regulatory principles are compatible, the Commission pursues a strategy of 'regulatory alignment'. If regulatory authority structures are compatible, but regulatory principles are incompatible, the Commission pursues a strategy of 'equivalence'. If regulatory authority structures are compatible, but regulatory principles are incompatible, the Commission pursues a strategy of 'alignment of implementation procedures'. If both regulatory authority structures and regulatory principles are incompatible, the Commission pursues a strategy of 'information exchange'. The contrast of the case studies shows that the compatibility of EU and US regulatory institutions indeed determined the limits of regulatory cooperation that the Commission would pursue. It did, however, not pre-determine the choice of regulatory cooperation strategy per se.

As predicted by the case selection, this book only identified the pursuit of 'regulatory alignment' in one of the four empirical case studies, i.e. ICT. This is also the only sector chosen in the case selection in which I identified both compatible regulatory authority structures and compatible regulatory principles in the EU and the US. Interview evidence confirmed that both the distribution of competences and the regulatory approaches were decisive for the Commission in its behavioural choice. Interview partners responded that the Commission chose to pursue the harmonisation of e-accessibility standards and the mutual recognition of electronic patient records because officials knew that their interlocutor had authority to implement the alignment. Their decision was reinforced by the knowledge that the alignment would not be contravened by rival decisions of other federal or state-level regulators. Moreover, interview evidence indicated that the Commission decided to pursue 'regulatory alignment' on these issues because they knew that both the Commission and the US regulators "followed the same thinking" (Interview 13). The interviews thus confirm the relevance of both authority structures and principles for the Commission's strategy. The ICT case study has also shown that 'regulatory alignment' is demanding for the Commission. Both the Commission and their US counterparts seek to protect their respective discretion in taking decisions on related issues in the future while ensuring that the 'regulatory alignment' does not undermine their pursuit and protection of the regulatory objectives that they are tasked to achieve.

Similarly, as predicted by the case selection, this book identified the Commission's pursuit of 'equivalence' on issues within the food safety sector. This is the sector chosen in the case selection in which regulatory authority structures are compatible, but regulatory principles incompatible. Interview partners explained that harmonisation or mutual recognition were not the objective of the Commission

in this sector because "the EU and the US had completely different ways of regulating things". Nonetheless, cooperation would be possible because the Commission and its US interlocutors both had competence to adopt and recognise regulations on these issues (Interview 7, Interview 8). To ensure that regulatory cooperation would not lead to a lowering of safety, health or environmental protection, the Commission provides the US with scientific evidence that the level of protection in both systems is equivalent and demands the same from FDA and the USDA for their 'equivalence' proposals. In contrast to 'regulatory alignment', it can therefore be concluded that the pursuit of 'equivalence' does not presuppose that regulatory principles are compatible. The pursuit of 'equivalence' in the engineering sector since the last rounds of the TTIP negotiations shows that this hypothesis cannot be reversed. Indeed, the Commission may pursue 'equivalence' even if regulatory principles are de facto compatible. As 'equivalence' is easier to achieve for the Commission than 'regulatory alignment', both actors within the Commission and societal actors may propose 'equivalence' rather than 'regulatory alignment' strategies. This increases the likelihood that the Commission can successfully realise an outcome within a defined time period. This refinement does, however, not disprove the hypothesis that the Commission will pursue 'equivalence' where regulatory authority structures are compatible, but regulatory principles incompatible.

At the same time, confirming the predictions of the case selection, I observed the pursuit of an 'alignment of implementation procedures' for implementation procedures in the engineering sector. This is the sector in the case selection in which there are incompatible regulatory authority structures[262], but regulatory principles are compatible. Interview partners outlined that the Commission hesitated to pursue 'equivalence' or 'regulatory alignment' strategies because of the distribution of authority structures i.e. "because the distribution of competences in both systems is very different" (Interview 6). Statements that the level of protection achieved by both EU and US safety standards and the identification of certain risks was very similar encouraged the Commission, however, to explore possibilities for regulatory cooperation in order to facilitate trade. This indicated that regulatory principles are compatible and were also perceived as compatible by Commission officials. For this reason, the Commission pursued what it considered to be a way to facilitate trade without harming EU consumers or firms and constraining its own regulatory autonomy.

Two observations have been made across the case studies that may appear to violate hypothesis 2c with regard to the pursuit of implementation procedures. First, interview partners emphasised that the Commission's pursuit of an 'alignment of implementation procedures' strategies was accompanied by the demonstration that the implementation of the alignment would not be questioned by the partial non-centralisation of conformity assessment in the EU. The subsequent explanations showed, however, that an incompatibility of regulatory authority structures does not constrain the pursuit of an 'alignment of

[262] Note that regulatory authority structures are not incompatible for all issues. There are indeed a number of electrical safety issues for which the US OSHA has authority to set regulations and thus has compatible regulatory authority with the Commission (see chapter 6.2.3).

implementation procedures' as long as the Commission can demonstrate that the non-centralisation does not undermine the reliability and quality of the enforcement of the overarching regulatory policies. This difference to the requirement of compatible authority structures for 'equivalence' and 'regulatory alignment' implies that regulators are relatively more open to give up discretion on enforcement as long as they can be ensured that effective implementation will take place. In the engineering section, I have referred to this demonstration as the 'construction and establishment of compatible authority structures'.

Second, an 'alignment of implementation procedures' was also pursued by Commission officials during the TTIP negotiations in food safety although I have argued before that regulatory principles in this sector are incompatible. Interview partners explained, however, that while regulatory approaches differed on the design and content of actual policies, the EU and the US shared thinking on the design of implementation principles[263]. This made it possible for Commission officials to expect that US authorities would also certify compliance with regulatory requirements according to the same thinking as in the EU. This construction of the like-mindedness in the food safety sector, however, involved, substantial persuasion efforts, while the alignment of implementation procedures was immediately pursued in the engineering sector.

Despite these two additions from the empirical case studies, hypothesis 2c can thus also be confirmed. In view of the evidence collected in the food safety case study, it may be refined stating that 'an 'alignment of implementation procedures'' may also be pursued if regulatory principles diverge, but regulators share a like-mindedness in the determination of conformity. Moreover, for analytical clarity, it should be added that the Commission pursues an 'alignment of implementation procedures' under incompatible authority structures if it can be additionally constructed that the incompatibility does not undermine the effective enforcement of the implementation procedures. Both refinements do, however, not alter the institutional condition that the Commission will pursue an 'alignment of implementation procedures' if regulatory principles are compatible or can be constructed to be compatible for implementation procedures while this strategy does not presuppose a compatibility of regulatory authority structures.

Ultimately, and confirming theoretical expectations, 'information exchange' persisted in the chemicals sector. In this sector, centralised and non-centralised authority structures prevail in the EU and the US and the regulatory approaches show conflicting goals. In line with hypothesis 2d, the Commission did not pursue any other regulatory cooperation strategy than 'information exchange' on different chemicals issues across the three phases. Interview evidence stressed that both the differences in competences and the differences in regulatory approaches impeded regulatory cooperation in any other form. 'Information exchange' was also chosen in all other sectors studied, from engineering to ICT. This suggests that the institutional condition of hypothesis 2d should be read as a negative one, i.e. the pursuit of 'information

[263] In the food safety section (chapter 6.3.), I have described this point under 'implementation principles'.

exchange' does not require that either regulatory authority structures or regulatory principles are compatible. Indeed, Commission officials have chosen to pursue 'information exchange' on issues in other sectors to maintain their regulatory discretion on final decisions and to avoid taking decisions that would violate their overarching regulatory objectives. Interview evidence showed, however, that Commission officials nonetheless chose to exchange information to prevent the adoption of unnecessary divergent decisions across jurisdictions. This choice reflected the fear that divergent decisions would allow firms to engage in regulatory arbitrage and put pressure on regulators to weaken the stringency of regulatory requirements for competitive reasons. The chemicals case study underlines, however, that information exchange is the only possible strategy if regulatory authority structures and regulatory principles are incompatible.

Besides, the comparison of the regulatory cooperation strategies pursued within individual sectors across the three regulatory cooperation initiatives shows that the Commission has not pursued a strategy that 'exceeds' the depth and dimension of regulatory cooperation given by the constraints of the regulatory compatibilities. Comparisons across different cooperation contexts suggest that the Commission has varied the specific issues on which it has pursued a particular regulatory cooperation strategy. Moreover, they imply that the Commission has increased the number of issues on which it has sought regulatory cooperation with the US in parallel. It is this increase in issues pursued in parallel that has probably induced authors (e.g. Shaffer, 2016) to speak of an increase in regulatory cooperation over time. The contrast of the case studies examined in this book stresses, however, that this increase in issues must be analytically separated from the depth and dimension of regulatory cooperation chosen for related issues, which has remained constant[264].

While the distinction between regulatory authority structures and regulatory principles allows a clear delineation of the constraints on the choice of a regulatory cooperation strategy, it is admittedly not always easy to apply in practice. On the one hand, overarching regulatory principles are not always clearly identifiable and need to be established through an analysis of legal comments or interviews with regulators and legislators to understand the motivation underlying given regulatory policies. On the other hand, especially regulatory principles are often employed inconsistently in domestic regulation within a given sectoral regime. The inconsistent application of the precautionary principle in the EU chemicals and food safety regimes is a good example for this[265]. Legislation and regulations on different issues

[264] This statement does not preclude that the Commission may choose another dimension or depth of regulatory cooperation after it or the US has reformed domestic institutions and aligned them with those of the other side. These reforms would also change the distribution of regulatory compatibilities. Such fundamental reforms are, however, rare especially in established regulatory systems for a number of reasons (for a theoretical discussion of such reasons see Mahoney & Thelen, 2010). Anecdotal evidence from the reform of the US chemicals and food safety reforms referred to in the corresponding case studies of this book supports this conclusion.

[265] Emerging EU regulation on the use of nanomaterials (Elliott & Pelkmans, 2015) as well as on the use of nanomaterials in food packaging (Josling & Tangermann, 2015) only to some degree follow the precautionary principle (see also Beuc, 2016 and CIEL, 2014) for a critique of the Commission's arguable negligence of the precautionary principle in these cases.

within a sectoral regime are adopted at different points of times under the lead of different individuals and majorities in the legislature. As a consequence, guiding regulatory principles underpin specific regulations and even legislation to different degrees. Moreover, regulations on different issues within a sectoral or policy regime may conflict with each other. For analytical simplicity, these clashes within domestic regulatory regimes and the inconsistent reflection of overarching regulatory principles in specific regulations or the design of implementation procedures have been somewhat neglected in this book. This decision can be justified with the argument that at least apparent conflicts between domestic regulations will be revised by legislatures or be challenged by courts so that mostly more hidden or ambiguous conflicts between domestic regulations and inconsistent applications of regulatory principles persist.

In sum, the empirical case studies have shown that at least in the cases analysed, institutional conditions, i.e. regulatory compatibilities, constrain the Commission's choice of regulatory cooperation strategy. The compatibility of regulatory authority structures constrains the choice for regulatory cooperation on regulatory policies or implementation procedures only. The compatibility of regulatory principles constrains the depth of regulatory cooperation both on both regulatory policies and implementation procedures. The strategies chosen by the Commission across the four sectoral regimes analysed in this book have confirmed the expectations for the influence of regulatory compatibilities on strategy choice. Moreover, they have shown that the choice for 'information exchange' is independent of regulatory compatibilities and is also employed by the Commission where both regulatory authority structures and regulatory principles between the EU and a third country are incompatible. As a refinement to these hypotheses, it should be emphasised that institutional conditions, i.e. the compatibility of regulatory institutions, are maximum constraints on the depth and dimension of regulatory cooperation strategy. Commission officials may and in practice do choose to pursue less deep or 'only' implementation procedure cooperation and thus deviate from this 'maximum' constraint.

7.2.3. Societal actor mobilisation

The empirical case studies have shown that societal actor mobilisation is crucial for regulatory officials to adopt a regulatory cooperation strategy in line with regulatory compatibilities. Hypothesis 3 can thus also be confirmed. The influence of societal actor mobilisation is particularly relevant for the adoption of a bilateral regulatory cooperation strategy which goes beyond 'information exchange', i.e. an 'alignment of implementation procedures', 'equivalence' and 'regulatory alignment'. This sub-section first summarises the interview evidence on reasons for the importance of societal actor mobilisation for the formation of a regulatory cooperation strategy. Then it looks at factors which increase the likelihood that societal actors can influence the choice of a regulatory cooperation strategy. Besides, it revisits the

limits of societal actor mobilisation to influence the choice of a regulatory cooperation strategy and discusses regulatory cooperation in the absence of societal actor mobilisation.

In particular the ICT and food safety case studies have shown that societal actor mobilisation in support of regulatory cooperation on specific issues is essential to drive regulatory officials to engage in regulatory cooperation on this issue. Both interview partners from the Commission and societal actors confirmed that societal mobilisation followed invitations to contribute from the Commission. To substantiate the sequence of mobilisation, interview partners also indicated several mobilisation difficulties among societal actors that stood in the way of actively lobbying the Commission officials. First, member firms did not see regulatory cooperation as a priority and instead encouraged business association officials to pursue other priorities instead (Interview 3, Interview 10). Second, EU and US firms and even EU and US subsidiaries of the same firm disagreed over the proposals that should be raised towards the Commission (Interview 2, Interview 14, Interview 15). Third, EU and US business associations in principle shared an interest in forming a transatlantic business coalition, but struggled to identify common priorities or maintain a joined coalition (Interview 1, Interview 9, Interview 10).

Technical guidance and the supply of information is one reason why societal actor mobilisation is relevant. It can, however, not account for the relevance of societal actor mobilisation alone. In particular with regard to transatlantic regulatory cooperation, a number of scientific studies are available that list non-tariff measures which obstruct trade between the EU and the US (e.g. Francois et al., 2012; Ecorys, 2009). If regulatory officials only relied on societal actor mobilisation for the provision of information, they should have required mobilisation less by the time of the TTIP negotiations when information was widely available. Interview evidence suggests, however, that especially during the TTIP negotiations, Commission officials mobilised societal actors in support of regulatory cooperation. Indeed, the food safety case study showed that the Commission eventually chose not to consider ‘equivalence’ on certain issues such as ‘natural’ pathogen reduction treatments or anti-microbial resistance because societal actors did not mobilise in favour of it. Similar examples were cited in the ICT case study, e.g. with regard to the joint development of standards for the Internet of Things. This demonstrates that apart from the provision of information, societal actor mobilisation is relevant for the formation of a regulatory cooperation strategy because it gives legitimacy to the pursuit of regulatory cooperation. In other words, regulatory officials faced with uncertainty understand mobilisation in support of regulatory cooperation as an indicator that societal actors consider the behaviour of the regulator as legitimate. As a result, the mobilisation of societal actors in support of regulatory cooperation is not restricted to business actors. Yet, business actors support cooperation more frequently than NGOs because of the benefits they expect from trade liberalisation.

The analysis of the patterns of societal actor mobilisation across the four sectoral regime case studies and across the three regulatory cooperation initiatives demonstrates that societal actors are in a better position to shape the formation of a regulatory cooperation strategy if they form a transnational alliance

with similar societal actors in the foreign jurisdiction. A transnational alliance of societal actors helps to raise similar demands and present similar proposals in both the domestic and foreign jurisdiction. Domestic regulatory officials are then more willing to engage in regulatory cooperation if they expect that their foreign counterparts will respond positively to their demands and suggestions. The mobilisation of societal actors across jurisdictional boundaries, especially where rules overlap, supports the positive response of foreign officials to domestic initiatives. Foreign officials equally seek to maintain legitimacy towards their constituencies. The engineering case study has shown that Commission officials have requested Orgalime and VDMA to elaborate joint positions before they were willing to present a textual proposal for engineering cooperation to US officials in the TTIP negotiations. The chemicals and ICT case studies have shown that overlapping firm membership in Cefic and the ACC as well as in Digitaleurope and ITI has facilitated the emergence of a transnational business coalition. At the same time, the weakening of the chemicals industry coalition in support of 'information exchange' demonstrates that overlapping firm membership does not guarantee the maintenance of a transnational coalition. However, a systematic analysis of the patterns of transnational societal mobilisation goes beyond the scope of this book and forms the subject of separate future research.

Moreover, the food safety case study implies that regulatory officials also take up suggestions and demands of societal actors even if these do not succeed to form a transnational coalition. Indeed, the consideration of their demands may by itself correspond to the preferences of regulators to use interdependence as an opportunity structure and expand their legitimacy.

The case studies have similarly shown that societal actors have not been able to alter the constraints on the choice of a regulatory cooperation strategy. Across the four empirical case studies, societal actors have not been able to lobby the Commission to pursue regulatory cooperation to a depth or dimension which is not within the constraints of the regulatory compatibilities. Interview partners have noted business demands for 'regulatory alignment', notably in the chemicals and food safety case studies during the NTA and TEC (Interview 2, Interview 11). By the time of the TTIP negotiations, demands of societal actors have become more aligned with the distribution of regulatory compatibilities. Correspondingly, interview partners have underlined that societal actors learned to propose more 'realistic' and 'feasible' issues and objectives for regulatory cooperation (Interview 2, Interview 3, Interview 6, Interview 10, Interview 12). This potential learning or alignment of regulatory priorities over time corresponds to recent insights from the EU lobbying literature that societal actors are more successful if they 'frame' their demands in light of the discourses employed by the Commission (Mahoney & Klüver, 2015). At the same time, societal actors have not been able to stop the Commission from pursuing regulatory cooperation. On the contrary, policy documents and interview evidence have shown that the Commission chose to convince societal actors that its regulatory cooperation ambitions neither infringe upon the decision and participation rights of legislators or societal actors in the EU nor undermine its regulatory objectives (Interview 1, Interview 7, Interview 12).

The argument that this book makes with regard to the influence of societal actor mobilisation thus differs substantially from the role that Open Economy Politics ascribes to the role of societal actors. For the latter, societal contestation constrains the autonomy and policy space of government and other state actors (Peterson & Young, 2014; Lake, 2009; Young & Peterson, 2006; Milner, 1997). In accordance with the Inter-relational Institutionalism, the capacity of government and state actors to 'buffer' societal demands and give slightly preferential access to societal actors whose preferences correspond to their own ones enhances their autonomy and policy space under contestation[266].

Hypothesis 3 needs to be refined with regard to the adoption of an 'information exchange' strategy. For the latter, Commission officials have formed corresponding strategies even in the absence of societal actor mobilisation. The frequent informal exchanges e.g. between DG Environment, the ECHA and the EPA as well as between DG Sante, the EFSA and the FDA underline this point (ECHA, 2017; Maier, 2008). Unlike the other strategies, 'information exchange' does not constrain the autonomy of regulatory officials even if it offers a lower use of interdependence as an opportunity structure than the other strategies. In the absence of societal mobilisation, however, interviewees have added that these exchanges often remain ad-hoc (Interview 1, Interview 12).

In sum and crucially for this book, the empirical case studies have confirmed hypothesis 3 that societal mobilisation leads regulatory officials from the Commission to adopt a suggestion for regulatory cooperation as a strategy. Societal mobilisation offers technical expertise and guidance to regulatory officials on which issues within a regulatory regime they can cooperate with a third country or jurisdiction. Moreover, it assures them that societal actors consider their pursuit of regulatory cooperation as legitimate. Hypothesis 3 needs to be slightly refined for the choice of 'information exchange' which regulatory officials readily choose even in the absence of societal actor mobilisation.

7.2.4. Limitations of the comparative case design

This section discusses the limitations of the findings of this book with regard to their reliability, validity and wider generalisability. Limitations pertain both to methodological issues and the case selection. Methodological limitations can be discussed from the perspective of the reliability and validity of the findings. Limitations towards a wider generalisation reflect the case selection and thus the omission of potential other cases (Leuffen, 2007: 157). This section begins with a discussion of the limitations regarding the reliability and validity of the findings before examining the scope for their wider generalisation.

[266] The limits to buffering are reached, however, where societal actor mobilisation becomes so large that ignoring the demands of these actors would itself undermine the legitimacy of the regulator (Eliasson, 2014). This argument does thus call into question the constraining effect of politicisation, including on regulators (Zürn, 2015).

Limitations with regard to the reliability of the findings shall be discussed in light of the reliance of this book on a qualitative approach and expert interviews. Reliability limitations potentially exist because interview data is subject to subjective interview factors that may impede the replication of the same statements and observations by other researchers. The collection of data depended on the availability of potential interview partners for an in-depth conversation as well as their perception of my trustworthiness and expertise. The information and observations shared by interview partners are at least in part contingent on the level of trust between researcher and interview partner. Moreover, they depended on contextual factors outside the influence of the researcher, including the time constraint of the interview partner on the day that the interview was conducted. It must therefore be acknowledged that these contextual influences on the interview situation impose constraints on the replicability of the data by other researchers. Nonetheless, other researchers can at least obtain very similar data through interviews if they display a high level of trustworthiness and expertise. Moreover, the triangulation of Commission statements with assessments that societal actor representatives shared in interviews and statements contained in policy documents helped to verify if interview partners were 'speaking the truth'. The triangulation revealed a strong overlap of Commission statements with assessments of other actors overseeing regulatory cooperation, notably member state representatives and societal actors. At the same time, the difficulty to understand a complex process such as strategy formation by means of indicator-based research makes it difficult to design a quantitative research project for this issue that would improve the reliability of the data used for the conclusions.

While this book can arguably not avoid certain limitations on the reliability of the data collected, the chosen approach enhances the validity of the findings. Expert interviews with the actors responsible for the formation of the regulatory cooperation strategies allow obtaining a deep insight into the factors which shape the considerations and decisions of the responsible actors. Moreover, the possibility to clarify the sequence of issues and decisions makes it possible to describe a causal mechanism which leads to the formation of a strategy. At the same time, the confrontation of interview partners with potential rival explanations for the development of a specific strategy allows disentangling the relevance of different potential explanatory factors for the strategy. Here, the triangulation of the interviews of Commission officials with interviews conducted with societal actors and member state representatives has confirmed that I have been able to carry out interviews with the relevant stakeholders on the EU side for each sector examined.

The findings can be potentially generalised along four dimensions: the expansion of regulatory cooperation with the US in other sectors, the EU's choice of regulatory cooperation strategies with other countries than the US, the choice of regulatory cooperation strategies for multilateral regulatory cooperation and the relevance of regulatory compatibilities for other large jurisdictions beyond the EU.

Explaining the strategy choice in other sectors of transatlantic regulatory cooperation

The explanatory power of the Inter-relational Institutionalism framework for the Commission's choice of regulatory cooperation strategy should be even higher for sectors in which politicisation is low and intra-industry trade is high. The case selection sought to maximise the likelihood that the Commission would not choose to engage in regulatory cooperation because the intensity of societal contestation and politicisation was high. At the same time, it focused on sectors in which the level of intra-industry trade is high. If the intensity of politicisation is lower than in the cases analysed, Commission officials should have even larger domestic discretion in their choice of strategy.

A probe into the Commission's strategy choices for transatlantic regulatory cooperation in the pharmaceuticals and automotive sectors, two sectors in which the level of intra-industry trade between the EU and US is very high, suggests that the Inter-relational Institutionalism can also account for the Commission's choices in these sectors. In the pharmaceuticals sector, Inter-relational Institutionalism suggests that the incompatibility of the regulatory principles for the authorisation of pharmaceuticals, i.e. the adoption of the 'precautionary principle' in the EU and the rigorous reliance on scientific risk assessment in the US, makes policy cooperation inconceivable. The compatible distribution of regulatory authority, i.e. the centralisation of authority over rules with the European Medicals Agency (EMA) in the EU and the Food and Drug Administration (FDA), should allow the Commission to pursue an 'alignment of implementation procedures'. Implementation procedures in the EU are such that the EMA develops EU-wide procedures on 'Good Manufacturing Practices' (GMP) inspections and coordinates and harmonises GMP activities at the EU level. Within the context of the TTIP, the textual proposals of the Commission show that it has indeed pursued an 'alignment of implementation procedures' in the pharmaceuticals sector. More specifically, it has pursued a recognition of each other's 'Good Manufacturing Practices' inspections of pharmaceutical production facilities (Commission, 2014j). A brief look at the 'maximum' strategy selected in transatlantic regulatory cooperation in the pharmaceutical sectors thus appears to confirm the prediction of the Inter-relational Institutionalism.

In the automotive sector, in turn, regulatory principles of EU and US regulators are - at least argued to be – very similar in the regulation of automotive safety (Interview 5). This similarity makes it likely that EU and US also follow compatible regulatory principles. Moreover, authority to adopt automotive safety regulations lies with the Commission in the EU and the NHTSA in the US and is thus centralised and compatible across both jurisdictions. In line with the prediction of Inter-relational Institutionalism that compatibilities of regulatory authority structures and principle enable the Commission to pursue 'regulatory alignment', the Commission has pursued a harmonisation and mutual recognition of specific automotive safety regulations in the TTIP negotiations (Commission, 2013c).

No theoretical limitation has been made that should make the Inter-relational Institutionalism only applicable to regulatory cooperation in goods sectors. On the contrary, there is strong reason to assume that it equally applies to services sectors. On the one hand, services sectors are also increasingly characterised by high levels of intra-industry trade. On the other, certain services sectors, notably the telecommunications and the financial sector are subject to extensive regulation shaping the design and provision of services, including and even increasingly at the EU level. The Inter-relational Institutionalism framework should thus also apply to these sectors. Any probes that can be suggested here fall short of a rigorous scientific analysis, though. The applicability of Inter-relational Institutionalism to additional sectors of high intra-industry trade should be the object of future research.

Institutional conditions should also constrain the choice of regulatory cooperation strategies in sectors characterised by low intra-industry trade or in which regulations do not regulate product characteristics, but production processes[267]. Yet, limitations to the Inter-relational Institutionalist framework may arise related to the support of societal actors for regulatory cooperation and the initiation of regulatory cooperation by actors within the Commission. This should be the case for sectors such as textiles which are not characterised by high intra-industry trade at least between the EU and the US. In these cases, industry associations are likely to mobilise resources to maintain the divergence of regulations and implementation procedures to protect their position in the EU market[268]. Rather than offering guidance on which issues Commission officials could seek regulatory cooperation, firms and industry associations can be expected to lobby against regulatory cooperation. On the other hand, the low level of intra-industry trade implies that the autonomy of the Commission in regulating the safety and health protection for domestic products is not challenged by rule overlap and potential competitive pressures on domestic industries. If intra-industry trade is low, the legitimacy gains to the Commission emanating from regulatory cooperation are too small if only few firms subsequently benefit from trade liberalisation. Regulatory cooperation is thus unlikely to be a salient issue to Commissioners in sectors with low levels of intra-industry and may neither offer substantial autonomy or legitimacy gains. Limitations to the explanatory power of Inter-relational Institutionalism thus arise because societal actors do not support regulatory cooperation and lobby against its pursuit rather than offering technical guidance to Commission officials. Moreover, the explanatory power of the constraints imposed on the strategy choice by institutional conditions may be difficult to verify empirically because Commissioners may not initiate regulatory cooperation in these sectors due to the low legitimacy and autonomy gains they can expect.

[267] For the distinction between product and production process regulations see Scharpf (1997). Scharpf argued that harmonisation of product regulations in the construction of the Single Market was more likely than a harmonisation of production process regulations.

[268] Moreover, Eckhardt (2016) argues that industry organisation and the capacity to mobilise resources for lobbying is a crucial factor explaining bureaucratic action. Focussing the analysis of this book on sectors with high organisational capacity therefore potentially risks over-estimating the influence of societal mobilisation on the pursuit of and strategy choice on regulatory cooperation.

Likewise, institutional conditions and regulatory compatibilities can be expected to constrain the choice of regulatory cooperation strategy in the case of production process regulations and non-product regulations. Production process and non-product regulations include regulations related e.g. to competition policy, labour rights and climate policy. Damro's (2006) case study of cooperation between EU and US competition regulators implies that cooperation was enabled by the centralisation of authority in the hands of central-level regulators in both the EU and the US. Besides, case studies on the promotion of labour rights in TTIP (Orbie et al., 2015) acknowledge that Washington's lack of competence on issues covered by the ILO conventions makes the Commission reluctant to pursue the ratification of ILO conventions in TTIP. Limitations with regard to the explanatory power of the inter-relational institutionalist framework exist, however, for production process and non-product regulations as far as the initiation of regulatory cooperation and the support of societal actors is concerned. Since production process and non-product regulations do not (or only indirectly) lead to trade liberalisation, DG Trade is unlikely to demand (or prioritise) regulatory cooperation on these issues. Besides, firms and business associations are unlikely to mobilise resources to externalise EU competition, labour rights and climate policy regulations. On the contrary, conflicting regulatory requirements across jurisdictions on these issues allow firms to engage in regulatory arbitrage and maintain other production processes in other countries. While NGOs can be expected to support regulatory cooperation on these issues, their described scepticism towards regulatory cooperation (e.g. Peterson & Young, 2014: 84) is unlikely to induce them to offer Commission officials technical guidance on issues for regulatory cooperation. In the latter case, regulatory cooperation should only be initiated within institutional constraints if the responsible Commissioner demands the pursuit of regulatory cooperation and uses 'permeability' to encourage lobbying activities of NGOs.

In sum, the Inter-relational Institutionalism can also be applied to other sectors, both goods and services, if these are characterised by high levels of intra-industry trade. Limitations to the generalisability of the framework may exist related to sectors with low intra-industry trade and production process or non-product regulations such as competition, labour and climate. These limitations, however, refer to the initiation of regulatory cooperation rather than the depth and dimension of regulatory cooperation. If regulatory cooperation occurs, strategies should equally depend on regulatory compatibilities between the initiating jurisdiction and its interlocutor.

Explaining the strategy choice for regulatory cooperation between the EU and other countries

The Inter-relational Institutionalist framework can in principle also be applied to explain the Commission's choice of regulatory cooperation strategies in dialogues and negotiations with other countries than the US. Based on existing literature, regulatory cooperation, however, relies on sufficient

regulatory capacity of both cooperation partners (Newman & Posner, 2015). Indeed, the EU does not only pursue regulatory cooperation with the US, but also with other large economies, notably Canada, Japan and South Korea (see chapter 5.1)[269].

Anecdotal evidence from the EU's discussions with Canada in the context of the CETA negotiations imply that both the compatibility of regulatory authority structures and regulatory principles affected and constrained the depth and dimension of regulatory cooperation. In the automotive sector, the centralisation of regulatory authority in the EU and the US and the overall adoption of risk assessment methods established within the United Nations Economic Commission for Europe (UNECE) meant that both regulatory principles and regulatory authority structures were compatible for auto safety regulations. Correspondingly, the Commission pursued mutual recognition and thus a strategy of 'regulatory alignment' for certain auto safety regulations. In food safety, the pursuit of the 'scientific risk assessment principle' by the Canadian government and its incompatibility with the EU's precautionary principle has likely pushed the Commission to pursue 'equivalence' on a number of food safety issues and follow the Veterinary Equivalence Agreement. At the same time, Ottawa's lack of authority for many financial services regulations implied that the Commission did not pursue policy cooperation with Canada in this sector (Commission, 2015). Furthermore, from studies that compare EU regulations with those of South Korea and Japan (e.g. Berends, 2011; Naiki, 2010) it can be inferred that both the compatibility of regulatory authority structures and regulatory principles constrain the Commission's choice of regulatory cooperation with these countries. At least in regulatory interactions with a few other countries, such as Canada, Japan and South Korea, the Inter-relational Institutionalism should therefore apply.

Nonetheless, limitations to the generalisability of the framework for the analysis of the EU's regulatory cooperation with other countries than the US must be acknowledged. As argued in chapter 5.1., the US is an 'extreme' case for regulatory cooperation due to the complexity of both the EU and US regulatory frameworks, the similarity in market size and the high levels of intra-industry trade and mutual market penetration. Moreover, the US also enjoys a certain degree of 'soft power' (Nye, 2004) which likely contributes to the motivation of Commissioners to pursue regulatory cooperation with the EU for autonomy and legitimacy gains of the Commission. As the degree of 'soft power' is likely lower for the other countries with which the Commission is pursuing regulatory cooperation at the time of writing, the motivation of Commissioners to push regulatory cooperation can be expected to smaller. Moreover, transnational ties of EU societal actors and mutual market penetration are smaller with those countries than with the US, reducing incentives for societal actors, notably business associations, to mobilise members and prioritise the provision of technical suggestions to Commission officials for the pursuit of

[269] The Commission has not yet initiated bilateral regulatory cooperation with Russia and China, arguably due to the relatively lower 'regulatory capacity' of both countries at the time of writing. One interview partner noted, though, that the EU may also begin regulatory cooperation with these countries once their regulatory systems mature (Interview 5).

regulatory cooperation. Even where past trade negotiations have established institutional frameworks for regulatory cooperation[270], they may not lead the Commission to pursue the same strategies as in regulatory cooperation. This is a consequence of the presumably lower interest of Commissioners (or high-level bureaucrats) and the lower interest of societal actors, notably firms, in regulatory cooperation as an instrument for trade liberalisation. As a result, Commission officials in many cases choose to pursue only 'information exchange' with regulators from e.g. Canada, South Korea and Japan. Where Commissioners or high-level bureaucrats put forward regulatory cooperation and societal actors offer technical guidance on specific issues for cooperation, officials' choice of regulatory cooperation strategy beyond 'information exchange' should, however, follow the consideration of regulatory compatibilities.

At this point, a potential further limitation to the applicability of the Inter-relational Institutionalist framework shall not be omitted. The larger the asymmetry in market size between the EU and a third country, arguably the more likely it becomes that the EU uses the relative power resulting from its regulatory capacity and market size to demand that the third country reforms its regulatory institutions and adjusts its regulatory framework to that of the EU in exchange for market access. The latter falls into the logic of externalisation described by the 'Market Power Europe' approach (Damro, 2015a, Damro, 2015b; 2012). Admittedly, the Inter-relational Institutionalism offers limited explanatory power for the behaviour of the Commission towards countries in the immediate geographical proximity of the EU, such as countries in the European Neighbourhood Policy. Future research may inquire if it is possible to establish a (more precise) scope condition for the externalisation of policies according to the 'Market Power Europe' conceptual framework and regulatory cooperation according to Inter-relational Institutionalism.

Explaining the strategy choice of the Commission in international regulatory cooperation

Inter-relational Institutionalism also offers insights into the Commission's choice of regulatory cooperation strategies in international regulatory cooperation. The compatibility between regulatory principles of the EU and those of other large countries in international organisations influences and constrains the depth of regulatory cooperation that the EU can pursue. To illustrate this point, the incompatibility of the 'precautionary principle' with the 'scientific risk assessment' principle adopted e.g. by the US, Canada and Australia for instance may be linked to the absence of an ambition of the Commission to externalise its food safety policies to the Codex Alimentarius Commission (Young, 2014). Moreover, the incompatibility of regulatory authority structures in other countries, notably a lack

[270] Both the EU-Korea Free Trade Agreement and the EU-Canada Free Trade Agreement (CETA) have established such frameworks. The EU also pursues the establishment of a future regulatory cooperation framework in the negotiations with Japan which were ongoing at the time of writing.

of centralisation of authority, has contributed to constrain the ability of the EU to enforce multilateral agreements on regulatory cooperation, e.g. on labour rights in the EU (Schwellnus, 2014) or on greenhouse gas emission reductions in climate policy. In this sense, the consideration of the compatibility of regulatory institutions for the strategy that the EU is able to pursue internationally is also generalisable to international regulatory cooperation.

Moreover, the explanation of Inter-relational Institutionalism that regulatory cooperation is initiated by power dynamics within the Commission can be expected to be also generalisable to international regulatory cooperation. The demands of Commissioners and top-level bureaucrats to externalise EU policies and implementation procedures through multilateral forums and international organisations likely also contributes to explain the decision of the EU to seek international regulatory cooperation. For instance, Damro's (2005) account of the ambition of DG Competition to promote international regulatory cooperation on competition policy through the International Competition Network implies support for an emphasis on bureaucratic dynamics to explain regulatory cooperation decisions of the Commission. An analysis of this claim requires testing in future research, though.

Yet, the generalisability of Inter-relational Institutionalism to international regulatory cooperation is limited due to important differences between bilateral and international regulatory cooperation. First, in contrast to bilateral regulatory cooperation, the EU (often, but not always represented by the Commission) does not only pursue harmonisation, mutual recognition, equivalence or the mutual recognition of conformity assessment procedures in international regulatory cooperation, but also pursues strategies of policy import and policy promotion (Falkner & Müller, 2013). While in bilateral regulatory cooperation domestic regulatory capacity is a precondition for regulatory cooperation, in international regulatory cooperation the Commission may also promote regulatory decisions to enhance its domestic regulatory capacity. Kudrna and Müller (2016) argue that the Commission promoted a regulatory decision in the Basel Committee on capital equity requirements at the international level to overcome domestic resistance by member states. The rules adopted in the Basel Committee did not reflect the domestic rules of any other jurisdiction, but were a compromise and creation of participating 'countries'. The Commission's subsequent policy import of the rules did not unilaterally disadvantage EU firms and prevent adjustment costs for non-EU firms, but impose regulatory burdens on EU and non-EU financial institutions alike.

Second, the pursuit of policy promotion and the simultaneous interaction with multiple countries in international organisations and multilateral forums means that the EU also strategically uses incompatibilities of regulatory authority structures. If decisions of other jurisdictions are not recognised as equivalent, but 'new' decisions are formed, the EU can use its relatively higher regulatory capacity and higher regulatory centralisation as an instrument of power against jurisdictions with no centralisation of regulatory authority. Büthe and Mattli (2011) offer an argument that a lower degree of centralisation and hierarchisation of authority reduce the ability of jurisdictions to pass on information

efficiently and thus shape decisions in hierarchical international forums. At the same time, the EU is arguably less 'concerned' about a lack of authority centralisation in other jurisdictions when decisions within international forums are taken. As the EU does not recognise the decisions and rules of other jurisdictions as equivalent to its own ones, but agrees on 'new' rules, incompatibilities in regulatory authority structures do not undermine the autonomy of the Commission to the same extent as in bilateral regulatory cooperation. Besides, decisions on international rules tend to give domestic governments considerable discretion in implementing international rules anyway. While this book has argued that incompatible regulatory authority structures prevent the Commission from engaging regulatory cooperation with another jurisdiction, differences in regulatory authority centralisation do not obstruct international regulatory cooperation. In line with the New Interdependence Approach literature they may rather constitute a power advantage in favour of the jurisdiction with the higher degree of centralisation, given that most international organisations and multilateral forums have a hierarchical decision-making structure.

Third, although EU regulatory principles may be incompatible with the principles of some other member jurisdictions of international organisations, the regulatory state in many states, notably emerging and less developed countries, is little developed. This means that the EU will use the low development as an opportunity structure to spread its domestic regulatory principles often in competition to conflicting and incompatible regulatory principles of other jurisdictions with high regulatory capacity. The competition with the US about the establishment of an international regulatory principle on food safety, i.e. the conflict between the EU's 'precautionary principle' and the US 'scientific risk assessment' principle exemplifies this point. In this constellation, the EU will seek to form a coalition with other states which share the EU's regulatory principle to externalise its domestic policies and procedures to the international level (Newman & Posner, 2015: 891) that the Commission seeks to externalise its policies through 'coalition-building' under high preference differentials. Unlike in bilateral regulatory cooperation, however, the incompatibility of regulatory principles does not prevent the Commission (or the EU represented through member states) from seeking international regulatory cooperation.

Explaining strategy formation and choice for third-country regulators

Even if the EU may be the 'most likely' candidate to engage in bilateral regulatory cooperation, a few other jurisdictions also show the features that are credited by the international regulatory cooperation literature as power resources. Examples include notably the US and to a lesser extent also Japan and Canada. There is little reason to assume that the structural, institutional constraints on the choice of a bilateral regulatory cooperation strategy that have should not equally apply to other jurisdictions. On the contrary, this study has derived both constraints through a deductive theoretical exercise without

consideration of institutional specificities of the EU. The transferability of the 'bureaucratic pressure' argument to US, Japanese or Canadian regulators may, however, be limited. On the one hand, the embeddedness of regulators in one body with external relations actors is a specific feature of the EU. This limits the pressure that non-technical bureaucrats can exert on technical officials in other third countries. In the US, regulatory agencies are largely independent from government departments (Pérez & Dudley, 2016), restricting the influence that e.g. the USTR can have on regulatory agencies such as the FDA or EPA. On the other hand, the institutional separation of regulatory officials from external relations actors in third countries also implies that they mostly do not share the externalisation perspective of Commission officials (Shaffer, 2016; Interview 5). The transferability of the Inter-relational Institutionalism to third-country regulators could be the object of future research.

Lastly and beyond considerations on case study research, limitations should be discussed that relate to the operationalisation of the variables, in particular the independent variable "regulatory compatibilities"[271]. Here, a dichotomous operationalisation has been selected to keep analytical complexity manageable. In real politics, however, the distribution of compatibilities may not always be as clearly structured as this book suggests. As for example regulatory policies are combinations of numerous sets of ideas that themselves are derived from overarching principles, regulatory policies from two different jurisdiction in practice are likely to be partly compatible. More precisely, their compatibility is likely to vary on a range from full compatibility to low compatibility. Different degrees of compatibility can for instance result from the fact that two jurisdictions may share regulatory principles on a fundamental level, but disagree on the deduction of specific behavioural rules and ideas that they individually derive from these principles. Two jurisdictions may thus agree that environmental regulation should be based on the polluter-pays principle. However, they may still disagree who the typical polluter is in a setting and thus design regulation in a way that imposes different behavioural constraints and costs on specific actors. Furthermore, complexity results from the fact that regulators do not always clearly know if two sets of regulatory policies are compatible or not. Depending on a researcher's epistemological stance, they may not even be able to do so. In practice therefore, regulators may adhere to a notion of partial compatibility and – in line with arguments by the experimentalist governance literature - start regulatory cooperation with a strategy that does not immediately aim at the 'maximum' strategy enabled by regulatory compatibilities. Future research could examine the question whether a more differentiated operationalisation of regulatory compatibilities can offer additional analytical merit. It may thus potentially also contribute to account for the variation of strategies that have been summarised as one outcome on the dependent variable. Here, it shall be reiterated that the objective of this book has been complexity reduction to achieve analytical benefit which has made certain simplifications inevitable.

[271] Bureaucratic pressure and societal mobilisation have been operationalised in agreement with existing research. Constraints of this operationalisation with regard to displaying nuances in either internal bureaucratic politics and interest group politics are thus no different from existing studies.

7.3. Contributions

This book has started off with the argument that neither actor-centred institutionalism nor the New Interdependence Approach can individually explain the strategies of actors, especially government and sub-state actors, in actively shaping patterns of global governance in an environment of interdependence. It has argued that this theoretical gap becomes particularly apparent in the shortcomings of either approach to account for the strategy choices of government and regulatory officials in bilateral regulatory cooperation, an increasingly important empirical phenomenon. Following from this argument, this book has deduced an integrative framework to explore how these previously distinct approaches, i.e. the dominant approach in policy and governance research and the emerging research framework to study cross-jurisdictional patterns of institutional change, can be combined. This sub-section outlines the contribution of the Inter-relational Institutionalism to wider international relations (IR) theory (chapter 7.3.1.). Moreover, it resumes the debate outlined in the introduction about the costs and benefits of bilateral regulatory cooperation. Although this book has not explicitly examined the influence of bilateral regulatory cooperation on the level of consumer protection, democratic accountability and administrative efficiency, the examination of the constraints on the choice of a strategy offers corroborating evidence on the implications of bilateral regulatory cooperation for these issues. They will be discussed in chapter 7.3.2.

7.3.1. Constraints of domestic regulatory institutions on international cooperation

The Inter-relational Institutionalism contributes to a large body of Liberal Institutionalist (LI) literature explaining the emergence of international cooperation (Katzenstein, 2009; Keohane, 2009; Lake, 2009; Keohane & Martin, 2001; Moravcsik, 1993; Putnam, 1988). The framework deduced in this book complements and refines this literature. Moreover, it refines the content of existing analytical instruments in LI research, including notably the two-level game framework. This sub-section first outlines the refinement that the combination of the New Interdependence Approach and actor-centred institutionalism make to the LI literature related to the understanding of domestic constraints on international cooperation. Second, it specifies the refinement that the incorporation of the principal-agent logic offers to the understanding of the causal mechanism that explains to the engagement in international cooperation within the 'domestic politics' game.

First, the combination of actor-centred institutionalism and the New Interdependence Approach refines the domestic constraints that actors face in shaping international cooperation in the context of interdependence. The Inter-relational Institutionalism does not call into question the domestic constraints arising from the need to ensure domestic ratification of treaty agreements (Lütz, 2011; Lake, 2009). Neither does it question the role of legislatures in constraining the discretion of executives and

the influence of societal actors and contestation on the constraints that legislatures execute on executives (Newman, 2011; Lake, 2009). It also does not challenge the relevance of the power resources that enable regulators from a jurisdiction to engage in cooperation, notably a large internal market and strong regulatory capacity (Damro, 2015b; Damro, 2012). Yet, on the one hand, the incorporation of the New Interdependence Approach into actor-centred institutionalism defines the motivation of actors to engage in international cooperation and coalition-building across jurisdictional boundaries. The New Interdependence Approach shows that under interdependence, not only government negotiators as a domestic-international interface promote international cooperation. Instead, it proposes that interdependence and rule overlap across jurisdictions create incentives for government actors and 'sub-state actors', i.e. regulatory actors, to use interdependence as an opportunity structure to pursue their preferences. The constellation of societal interests in favour of cooperation is thus not per se a domestic constraint on the emergence of international cooperation. Government and regulatory actors use rule overlap as an opportunity to extend their influence, autonomy and legitimacy. The emergence of interdependence thus endogenously alters the domestic societal contestation constraint on the emergence of international cooperation. This book has therefore confirmed that the New Interdependence Approach is a promising theoretical innovation to existing Liberal Institutionalist theory in order to understand the emergence of cooperation in an environment of interdependence.

On the other hand, the combination of the New Interdependence Approach and actor-centred institutionalism helps clarify the domestic constraints that government and regulatory actors face during the engagement in international cooperation. Referring to the metaphor of the two-level game, the Inter-relational Institutionalism shares the assumption of Open Economy Politics that actors are constrained at the international level (level I) by the need to reach an agreement with foreign actors. To reach an agreement, domestic actors do not pursue strategies that entail significant legislative or institutional change in the foreign jurisdiction as this would raise the risk of a non-agreement. Moreover, it shares the assumption of previous literature working with the two-level game metaphors that actors engage in international cooperation to reduce the likelihood of political intervention, but are cautious to protect their discretionary autonomy at the domestic level (Damro, 2006). The Inter-relational Institutionalism, however, refines the domestic constraints that government and regulatory actors face in the pursuit of international cooperation. This refinement follows from the integration of rational-choice and constructivist elements into one integrative framework.

The Inter-relational Institutionalism reconciles and integrates two streams of literature that have until the time of writing been rival explanatory approaches for international cooperation and regulatory convergence. It shows that power and competence distributions and regulatory approaches and cultures cannot be studied in isolation or as rival explanations. On the contrary, in international cooperation within the discretionary authority of regulators, domestic politics constraints are the potential of additional veto players to claim political intervention rights and the intervention of legislatures in case

of a violation of institutionalised regulatory approaches. Put differently, it argues that one constraint is the compatibility of domestic institutions of power-sharing, i.e. domestic 'regulatory authority structures' which delineate the discretionary authority of regulators, with foreign institutions of power-sharing. This constraint constitutes the rational-choice element of the framework. Regulators do not enable potential veto players at level II through international cooperation if their negotiation patterns at level I do not face more veto players than they themselves do. The recognition of decisions and procedures by regulators at level I that involve veto players from a different level of government or private actors encourages potential veto players at level II to demand an expansion of their intervention rights. To protect their autonomy and discretion, regulators are therefore constrained by the compatibility of their own authority at level II with the authority of their cooperation partner at level I.

Besides, the Inter-relational Institutionalism argues that an equal domestic constraint is the compatibility of domestic regulatory approaches with foreign regulatory approaches. This constraint reflects the incorporation of constructivist elements. Regulators do not offer incentives to legislatures for political intervention in their discretionary authority if they do not recognise or accept decisions and procedures that establish regulatory approaches that conflict with the approaches given to them by their legislatures. Legislatures do not intervene into the discretion given to regulators if these do not significantly 'shirk' and undermine the regulatory objectives and approaches institutionalised through legislation. Regulators expect, however, that legislatures will politically intervene if they accept or recognise decisions and procedures at level II that establish conflicting regulatory objectives. To protect their autonomy and discretion at level II, regulators are therefore also constrained by the compatibility of their regulatory principles at level II with the regulatory principles of their cooperation partner at level I.

In a wider perspective, the incorporation of actor-centred institutionalism into the New Interdependence Approach for the deduction of the Inter-relational Institutionalism contributes to a broader trend to combine rational-choice and constructivist explanations in institutionalist approaches (e.g. Siles-Brügge, 2014, Woll, 2008). The integration of constructivist elements offers a refinement, not a rejection of dominant rational-choice frameworks. Following institutionalised ideas does not only play an essential role in times of crisis (Blyth, 2002), but is constantly conducive for actors in approximating rational behaviour under uncertainty.

Second, the Inter-relational Institutionalism contributes a micro-foundation to the engagement in international cooperation under the constraints of domestic regulatory institutions. This micro-foundation clarifies the causal mechanism which links preferences of regulators, the institutional constraints under which they act and the mobilisation of societal actors to the choices of regulatory cooperation strategies, i.e. the 'type' of international cooperation that regulators seek. To deduce this micro-foundation that specifies the causal mechanism for the formation of a regulatory cooperation strategy, the Inter-relational Institutionalism borrows a variant of the principal-agent logic. This variant specifies delegation, autonomy and control mechanisms among different bureaucratic actors within the

agent: technical officials, non-technical officials, politically appointed bureaucratic leaders. Their preferences differ due to different institutional roles and ideational influences. The relative influence of different 'agents' on the preference of the regulator as an aggregate body 'agent' depend on their access and use of access to collective internal decision-making.

The incorporation of this variant of the principal-agent approach which considers intra-agent dynamics offers an alternative specification of the causal mechanism that explains the formation of a strategy at level I. Open Economy Politics and the New Interdependence Approach mostly rely on an aggregation of societal preferences as the micro-foundation to explain the behaviour of actors in international cooperation at the domestic-international interface. The specification of the causal mechanism of this book allows an explanation of the behaviour of government and regulatory actors even in cases in which they are insulated from societal contestation, societal mobilisation is muted or contested. The Inter-relational Institutionalism can explain the pursuit of international cooperation by state and sub-state actors, including regulators, within their discretionary authority as an opportunity structure to realise their preferences. The micro-foundation based on the bureaucratic pressure argument elaborated within the Inter-relational Institutionalism thus complements the existing micro-foundation proposed by Open Economy and the New Interdependence Approach for cases in which societal contestation cannot entirely explain the behaviour of government and sub-state actors such as regulators in international cooperation.

The development of this alternative, complementary micro-foundation for the formation of a regulatory cooperation strategy for instances in which societal mobilisation is muted, contested or reactive does not presume that regulators and state actors can act in isolation from societal actors. With regard to the EU, the Commission widely consults with societal actors to specify its strategies. Societal actors influence the adoption of prior legislation that subsequently establishes regulatory principles constraining the regulator's choice among cooperation strategies (see e.g. Klüver 2012). Besides, they provide technical expertise and guidance on issues on which the regulator can focus its cooperation efforts. The mobilisation or non-mobilisation of business associations, firms and NGOs therefore rather shapes the focus on specific issues, including the failure of a regulator to identify issues within the constraints of regulatory compatibilities. At the same time, societal actors contribute to articulate differences and similarities in regulatory approaches, and to a lesser extent, authority structures.

It shall be emphasised that the contribution of this book is without prejudice to the 'passive' externalisation of EU regulations and rules through processes of diffusion, 'trading-up' by third countries and regulatory convergence (see chapter 3.1.2). Even if the EU as – arguably – the most prominent actor in bilateral regulatory cooperation does not actively seek to transfer its rules and procedures through discussions with regulators from third countries by means of the strategies laid down in this book, the large size of the Single Market, the regulatory capacity of the Commission and the stringency of EU regulations offer incentives for third countries to adopt or emulate EU legislation and

regulation. Diffusion may indirectly be promoted notably through the pursuit of information exchange with third-country regulators and the explanation of EU regulations.

To sum up, the theoretical contribution of the Inter-relational Institutionalism deduced and elaborated in this book is twofold: First, it refines the domestic constraints on actors at the domestic-international interface in international cooperation. The integration of actor-centred institutionalism and the New Interdependence Approach allows re-specifying the domestic constraints which affect state and sub-state actors beyond the immediate mobilisation of societal actors by adopting a focus on structural constraints. As a side-effect of this refinement of the domestic constraints with a view to structural, institutional constraints, this book has combined and reconciled previously separated literatures. Second, this book specifies an alternative, complementary theoretical micro-foundation for the engagement of state and sub-state actors in international cooperation beyond the existing micro-foundation offered by the Open Economy Politics and New Interdependence Approach literatures. This theoretical micro-foundation and the specification of a corresponding causal mechanism takes into account a certain degree of autonomy for state and sub-state actors in international cooperation and considers their own preference for using interdependence as an opportunity structure. It relies on an incorporation of the variant of the principal-agent approach that emphasises variation in intra-agency dynamics as an explanatory factor.

7.3.2. Benefits and costs of bilateral regulatory cooperation

In the introduction, this book has given an overview of the benefits that advocates of regulatory cooperation frequently underline. These benefits have been summarised as a) the protection and strengthening of standards for consumer safety, public health and environmental protection, b) the facilitation and liberalisation of trade flows, and c) the reduction of the workload for regulators and thus the promotion of regulatory efficiency in the face of budget cuts and austerity measures.

This section investigates the real-world implications of the empirical confirmation of the predictions formulated by the Inter-relational Institutionalism. First, as a side-result of the empirical analyses, it examines the implications for the relevance of (bilateral) regulatory cooperation in promoting greater regulatory resource efficiency while promoting and strengthening standards for consumer safety, public health and environmental protection. Second, it briefly sheds light on the implications of bilateral regulatory cooperation for the democratic accountability of regulators. Third, it draws conclusions how different actors in the EU (and in other jurisdictions) can adjust their behaviour to make regulatory cooperation a promising endeavour that can promote the achievement of regulatory objectives and at the same time promote greater resource efficiency. These conclusions will particularly focus on societal actors and the politically appointed leaders of regulators, actors that have been identified as essential in this book.

This book has admittedly not explicitly tested if bilateral regulatory cooperation leads to downward pressure on consumer safety, public health and environmental protection, the principal concerns expressed by critics and opponents of regulatory cooperation. Likewise, it has not measured the potential of regulatory cooperation to promote greater resource efficiency. Still, the confirmation of the predictions formulated by the Inter-relational Institutionalism allow drawing some conclusions with regard to the relevance of (bilateral) regulatory cooperation for downward pressure on safety, health and environmental standards as well as regulatory efficiency.

The constraints exerted by regulatory compatibilities on the regulator's choice of a regulatory cooperation strategy means that downward pressure on the stringency of regulation and the level of protection they ensure to the safety of consumers, public health or the environment is highly unlikely. In two out of the four cooperation strategies distinguished by this book, i.e. 'regulatory alignment' and the 'alignment of implementation procedures', regulators choose the strategy because they adhere to a regulatory principle that is compatible with the regulatory principle(s) shaping the regulations the responsible regulators in the third country. This implies that they share a similar definition of a regulatory problem and conceivable approaches to solving this regulatory problem even if the eventual solution subsequently differs. Under 'equivalence', regulators demand or verify that the level of protection guaranteed by status quo regulations is not undermined. Under the pursuit of 'information exchange', the substance of domestic regulations and implementation procedures is not affected.

The conclusions drawn in the last paragraph cannot exclude that the scientific assessment used to determine the level of consumer, health or environmental protection ensured by domestic regulations inadequately assesses the level of protection delivered by status quo. Scientific enquiries to measure the level of protection ensured by domestic and foreign regulations may be designed along the approaches and problem understandings underlying either domestic or foreign regulations or may be contingent on contextual factors specific to either jurisdiction[272]. Moreover, the 'appropriate' level of protection for consumers, health or the environment is often difficult to ascertain as status quo regulations may also be subject to over-regulation. Lowering e.g. the permitted maximum residue levels for a given substance in fruits or vegetables may not entail effects for the protection of public health or the environment if available scientific evidence suggests that the substance is not detrimental to either human health or the environment at the new maximum level either[273].

As 'regulatory alignment' is unlikely to be frequently chosen by regulators in bilateral regulatory cooperation for the reasons discussed in this book and the other strategies leave the substance of regulations unchanged, regulatory cooperation in practice is unlikely to have a large impact on the level of protection for consumers, health or the environment. This means that regulatory cooperation is unlikely to directly raise standards[274]. Crucially, however, it can be rather safely concluded that the constraints which regulatory compatibilities impose on the choice of a regulatory cooperation strategy make sure that regulators do not accidentally lower regulatory stringency or the level of protection ensured domestically as a direct result of bilateral regulatory cooperation[275].

Implications of bilateral regulatory cooperation can be assumed to be larger for administrative efficiency. Again, it must be acknowledged that the determination of administrative efficiency increases resulting from bilateral regulatory cooperation has not been the object of this book. There is good reason to assume that the sharing of regulatory tasks between domestic and foreign regulators reduces the workload for each regulator individually. Interviewees consulted for this book largely confirmed this assumption. Yet, no quantitative assessment is possible how coordination through bilateral regulatory

[272] One interview partner (Interview 5) explained that the level of protection ensured by car safety regulations in the EU and the US is difficult to compare based on traffic accident data. Roads in the US tend to be wider than the EU, leading to a lower density of traffic compared to traffic density in the EU. Lower traffic rates in the US may thus equally reflect different (and potentially preferable road designs in the US) just as higher safety standards entailed by US car safety regulations. Analytically, the two effects are, however, difficult to disentangle given available accident statistics.

[273] For a further reflection of these considerations see also (Vogel, 2012: 25).

[274] For the increase in standards across jurisdictions, diffusion processes and 'cross-national layering' as described by the New Interdependence Approach is likely to be much more important than bilateral regulatory cooperation. However, bilateral regulatory cooperation may support and reinforce diffusion processes through the institutionalisation and strengthening of information exchange and socialisation between domestic and foreign regulators.

[275] This paragraph has only discussed the direct effects of bilateral regulatory cooperation. It cannot draw solid conclusions on indirect implications of bilateral regulatory cooperation for regulatory stringency and the level of protection. Indirect effects can occur e.g. as the decisions of regulators are shaped and influenced by their exchanges with foreign regulators. While there is little reason to assume that regulator preferences should change as a result of information exchanges, a solid conclusion on this question requires further scientific investigation.

cooperation reduces the workload for regulators. The empirical analyses conducted for this book do not allow drawing inferences for the balance between time invested into the coordination and time savings due to the distribution and sharing of regulatory tasks, i.e. the assessment of priority chemicals, between domestic and foreign regulators. Yet, even if the empirical analyses collected for this book do not include definite evidence to which extent bilateral regulatory cooperation enhances administrative efficiency, they offer corroborating evidence why bilateral regulatory cooperation is very likely to increase administrative efficiency. First, the constraints imposed by regulatory compatibilities on the choice of a regulatory cooperation strategy ensures that regulators concentrate regulatory cooperation onto issues and questions where they share similar problem definitions and competences with foreign regulators. This reduces the likelihood that regulators engage in regulatory cooperation that is unlikely to deliver any outcomes, but only consumes time resources that regulators could better invest into domestic regulatory projects and processes. Second, the gains in legitimacy that regulators expect and obtain from societal actors that benefit from the decisions under bilateral regulatory cooperation mean that these societal actors should reduce lobbying efforts in seeking to change status quo regulations or implementation procedures. This entails that regulators need to spend less time in defending their regulatory decisions and processes to domestic and foreign societal actors. Moreover, as the legitimacy of decisions and processes increases, societal actors are less likely to engage in shirking to circumvent the requirements and objectives of regulations. Regulators may therefore need to invest less resources into enforcement and market surveillance to ensure that societal actors comply with their regulations and implementation procedures.

Given the relevance of the support of societal actors for the engagement in and pursuit of bilateral regulatory cooperation, bilateral regulatory cooperation is unlikely to negatively affect the democratic accountability of regulators. The empirical chapters have demonstrated that the Commission has continuously consulted with societal actors to identify issues for regulatory cooperation. If at all, the engagement and pursuit of regulatory cooperation enhances the accountability of regulators as regulators reach out to societal actors to identify issues for their agenda-setting activities.

This argument is notwithstanding to the broader concerns of a lack of democratic accountability of regulators, including in domestic regulatory policy-making. Although in the EU the Commission is very open to all types of societal actors and is required to justify its decisions to them (Kohler-Koch & Eising, 2011), it maintains discretion in setting the agenda and pursuing priorities in line with its own preferences. Moreover, the literature on EU interest groups discusses if the openness of the Commission towards societal actors disproportionately benefits business actors at the expense of NGOs and civil society organisations. As regulatory policy-making is highly technical, openness may offer higher benefits to those actors able to provide technical resources, i.e. business associations and firms (Klüver, 2012; Bouwen, 2004).Yet, this argument applies to regulatory policy-making in general and is not specific regulatory cooperation. Regulatory cooperation may strengthen the access of business actors to

regulatory policy-making. It may, however, also create new opportunities for NGOs to contribute to regulatory policy-making, in particular as consultations of the regulator, i.e. the Commission in the EU, become institutionalised even on issues previously not subject to formal consultations. At the time of writing, the effects of regulatory cooperation on the democratic accountability of regulators are still difficult to measure given the lack of empirical data. Yet, it can be safely assumed that regulatory cooperation does not lower the democratic accountability of regulators relative to purely domestic regulatory policy-making, even if it may substantially enhance it.

The findings of this book thus entail some implications for actors in the real world to make the engagement in bilateral regulatory cooperation promising and effective. These implications particularly address societal actors and political leaders of regulators:

Societal actors should understand bilateral regulatory cooperation as an opportunity to protect, if not in certain cases raise regulatory standards while facilitating trade[276]. They should therefore offer regulators technical knowledge and expertise that the latter need to pursue regulatory cooperation successfully. This applies in particular to business associations and firms with transnational activities. These firms are an important source of technical information for regulators because they have high technical knowledge of foreign regulations due to their need to comply with foreign regulations if they want to be active transnationally. Yet, firms and business associations should understand that the depth and dimension of regulatory cooperation they can expect is constrained by the compatibilities of regulatory institutions. Their demands for 'regulatory alignment' will therefore be inactive where domestic and foreign regulatory institutions are incompatible. On the contrary, lobbying demands for 'regulatory alignment' may be counter-productive to effective regulatory cooperation if they mobile opposition by NGOs and thus require regulators to invest their (limited) resources into defending the pursuit of regulatory cooperation. Instead, firms and business associations should appreciate the value of regulatory cooperation strategies which are less deep and far-reaching than 'regulatory alignment' and maintain their support to regulators for the pursuit of these strategies.

Bilateral, like international, regulatory cooperation is a complicated process and requires empirical assessments of regulators as well as persuasion efforts in order to be successful. Firms and business associations should not drop their support if their most preferred outcome cannot be reached due to 'structural' constraints, i.e. regulatory incompatibilities. At the same time, they should not drop their support for ambitious regulatory cooperation efforts, i.e. those aiming at 'regulatory alignment' or 'equivalence', where these are 'structurally' feasible in exchange for short-term benefits from lower-hanging fruits that are easier to achieve. This remains in particular a challenge for business associations

[276] As bilateral regulatory cooperation is restricted to jurisdictions with sufficient regulatory capacity (Damro, 2012; Bach & Newman, 2007), it is more likely to occur between developed economies. This means that trade liberalisation will liberalise intra-industry trade. Intra-industry trade liberalisation does not produce the negative effects on labour standards and workers' wages commonly associated with inter-industry trade liberalisation (e.g. Rodrik, 2005).

that need to convince firm representatives internally to raise regulatory cooperation objectives and provide technical input to regulators in lobbying papers and face-to-face exchanges with regulators[277]. Unless business associations and firms provide technical knowledge and support to regulatory cooperation initiatives, regulators may struggle to find regulatory cooperation an activity that enhances their legitimacy vis-à-vis societal actors.

Important real-world implications also exist for political leaders, in particular the political and administrative leadership of regulators. These should express their support for bilateral regulatory cooperation and adopt regulatory cooperation as a priority. In the EU, this corresponds to the Commissioners and Directors General of the Directorates-General of the Commission. Yet, these implications can also be extended to other political leaders, i.e. legislatures or executive leaders. These include the heads of state or government in the European Council or the Commission President in the EU. Political support of these actors is not only important because technical regulatory officials may see regulatory cooperation as a distraction and additional burden on top of their regulatory responsibilities (Pollack, 2005). It is also essential as high-level support reduces uncertainty among technical officials. Besides, high-level political support increases the likelihood that foreign regulatory officials will respond to cooperation offers of domestic regulators. Even if technical Commission officials in the EU share the perception of benefits from regulatory cooperation which are emphasised by advocates of regulatory cooperation, they may be unwilling to engage in efforts if foreign regulatory officials are unresponsive to their strategies and activities. High-level political support entails that political leaders, i.e. Commissioners and Directors General, address regulatory cooperation in their exchanges with their foreign counterparts and thus work towards the emergence demands of foreign political leaders towards foreign regulators to engage in regulatory cooperation. This constrains the discretion of foreign regulatory officials to reject offers for regulatory cooperation. As a consequence, technical officials can expect effective responses of foreign officials to their cooperation strategies and may be more willing to mobilise resources in favour of the pursuit of regulatory cooperation. Political support for regulatory cooperation also in the EU is particularly important as perceived similarities between the EU and other third countries, notably the US, sink and regulatory officials may be inclined to adopt a more inward focus.

In sum, this section has discussed the empirical implications of the findings of this book. It has argued that the constraints imposed by regulatory compatibilities on regulators' choice of a regulatory cooperation strategy makes it highly unlikely that bilateral regulatory cooperation lowers the level of protection for consumer safety, public health and the environment, but rather improves it. Moreover, it has offered corroborating evidence from regulators' consideration of regulatory cooperation as an opportunity structure why regulatory cooperation likely enhances administrative efficiency. It has

[277] Interviewees who requested to remain anonymous emphasised that obtaining firm support for regulatory cooperation has been a great challenge for business associations in the TTIP negotiations.

concluded that even if regulatory cooperation may not enhance the democratic accountability of regulators, the crucial role played by societal actors in agenda-setting and legitimacy ensures that the democratic accountability of regulators is not undermined by regulatory cooperation. Lastly, it has proposed implications especially for societal actors and the political leadership of regulators in order to make bilateral regulatory cooperation effective and promising.

7.4. Summary

The engagement in bilateral regulatory cooperation plays an increasingly important role especially for the EU as a result of its ambition to export its standards on consumer safety, health and environmental protection while liberalising trade. The academic literature on regulatory cooperation focuses primarily on the strategies and constraints of the EU in multilateral regulatory cooperation in international organisations. Policy-oriented literature on regulatory cooperation also addresses challenges and obstacles for the EU in bilateral regulatory cooperation. However, comprehensive and systematic analyses on the constraints that the EU reflects in the formulation of strategies for bilateral regulatory cooperation are largely lacking. This book has addressed this gap in the literature and as its main contribution has investigated the constraints that the Commission faces and considers in the formation and choice of a bilateral regulatory cooperation strategy. It addressed the main research question 'What constrains the choice and formation of a bilateral regulatory cooperation strategy?' This book is thus the first study in the political science literature that systematically examines and tests factors that determine the choice of a regulator with high regulatory capacity such as the Commission among different bilateral regulatory cooperation strategies.

Following the assumption of the New Interdependence Approach that interdependence creates incentives for regulators to cooperate internationally to prevent policy erosion under rule overlap, this book has combined the two currently dominant approaches in governance and interdependence research, the New Interdependence Approach and actor-centred institutionalism. This choice reflects the notion that a combination of both approaches should overcome the limitations with regard to the puzzle addressed by this book that each approach encounters taken individually. From this combination of two approaches, this book has deduced a new integrative analytical framework, the Inter-relational Institutionalism. This Inter-relational Institutionalism puts forward that the formation and choice of a regulator with high regulatory capacity among different bilateral regulatory cooperation strategies is constrained by the presence of bureaucratic pressure, the compatibility of domestic and foreign regulatory institutions and the mobilisation of societal actors.

To test the Inter-relational Institutionalism, this book analysed the Commission's choice of regulatory cooperation strategies with the United States in four industry sectoral regimes for three different

transatlantic cooperation initiatives between 1995 and 2016. The analysis of the formation of the Commission's cooperation strategies in the chemicals, engineering, food safety and ICT sectoral regimes during the NTA, the TEC and the TTIP negotiations showed how the involvement of Commissioners and the DG Trade initiated the formation of cooperation strategies. It also showed that the choice among different regulatory cooperation strategies is constrained by the structural, institutional factors which have been captured by the concept of 'regulatory compatibilities'.

The analysis showed that in the absence of bureaucratic pressure, technical Commission officials have preferred to concentrate their limited resources on domestic regulation and only exchange information with US regulators on an ad-hoc basis. Yet, when Commissioners, top-level officials and non-technical DGs raise bureaucratic pressure to initiate cooperation, the discretion of technical officials to concentrate resources only on EU regulation fell. While individual Commissioners and DG Trade have tended to see regulatory cooperation as an opportunity structure to enhance EU policies and procedures and create additional benefits for societal actors, technical officials have also looked at regulatory cooperation as a distraction of limited resources from domestic regulatory priorities. The willingness of technical officials to engage in bilateral regulatory cooperation with the US has also been obstructed by low success prospects as US regulators have often not shared the EU's enthusiasm for regulatory cooperation. Yet, with the emergence of demands to evaluate opportunities for regulatory cooperation they followed the priority set by Commissioners and non-technical DGs and have formed strategies for transatlantic regulatory cooperation beyond information exchange.

It has been demonstrated that the extent of regulatory cooperation, conceptualised as the 'depth' and 'dimension' of cooperation by this book, that a regulator with high regulatory capacity envisages with another large jurisdiction is shaped by two regulatory institutional constraints. These constraints are the compatibility of domestic and foreign regulatory authority structures and the compatibility of domestic and foreign regulatory principles. While the Commission welcomes the opportunity to expand its influence internationally, it has been wary about giving rise to additional domestic veto players that might undermine its status quo discretion. Besides, although Commission officials have been keen on exporting its regulatory principles and approaches, they have been cautious to recognise policy solutions that might be seen by legislators and societal actors as undermining regulatory approaches enshrined in EU legislation. The study concluded that these institutional constraints play a greater role in constraining the Commission's choice than the cooperation in international organisation, previous socialisation between EU and US regulators and the extent of societal contestation.

The study has also re-conceptualised the role played by societal actors, i.e. firms, business associations and NGOs, in regulatory cooperation. In contrast to many contributions to the Open Economy Politics literature that see societal contestation mainly as a constraint on the autonomy of government and state actors and explain strategies of the latter with an aggregation of societal preferences, this study has shown that societal actors also support the engagement in regulatory cooperation. They provide technical

expertise and give legitimacy to the pursuit of regulatory cooperation. At the same time, strategies chosen by regulators do not only reflect an aggregation of societal preferences. Societal preferences fail to affect the strategy choice where their demands exceed the constraints set by regulatory compatibilities.

The integration of actor-centred institutionalism and the New Interdependence Approach re-specifies the domestic constraints affecting state and sub-state actors in international cooperation by focussing on structural constraints. These structural constraints emanate both from the distribution of competences in a jurisdiction as well as the ideas on regulatory objectives and approaches that have become institutionalised in legislation. Second, it specifies an alternative, complementary theoretical micro-foundation for the engagement of state and sub-state actors in international cooperation. It takes into account a certain degree of autonomy for state and sub-state actors in international cooperation and considers their own preference for using interdependence as an opportunity structure. Certain points of criticism towards regulatory cooperation can be soothed. The constraints imposed by regulatory compatibilities on regulators' choice of a strategy make it highly unlikely that bilateral regulatory cooperation lowers the level of protection for consumer safety, public health and the environment. Instead, the results imply why bilateral regulatory cooperation may enhance administrative efficiency without undermining the democratic accountability of legislators and regulators.

With regard to the EU, the findings of this study generally support bureaucratic politics explanations of the Commission's behaviour. Irrespective of the level of societal contestation and the potential position of member states in the Council and the European Parliament, the study confirmed that preferences and priorities do not only differ across Commission DGs, but implied that they also differ between technical officials and politically appointed Commissioners. Taking into consideration the nature and use of inter-service consultations, these differences in preferences and positions are likely to concern decision-making in the Commission more broadly. As regulatory bureaucracies become established and functionally internally differentiated, discussions between bureaucratic divisions approximate and resemble the discussions within legislatures and among societal actors.

Future research on the formation of regulatory cooperation strategies could further address these issues and expand the empirical scope of this book. It would be worthwhile to investigate if the institutionalisation of bilateral regulatory cooperation of the EU with other third countries, including Japan and Canada, furthers opens up technical officials to bilateral regulatory cooperation and leads them to pursue strategies of 'regulatory alignment' and 'equivalence' even in the absence of bureaucratic pressure. Future investigations could also verify the constraints identified by this book that shape the choice of cooperation strategies. Research projects could also address the question why some societal actors fail to form stable transnational coalitions although their high degree of economic internationalisation would suggest an alignment of preferences and priorities. Lastly, future research could aim at addressing the unexamined link between strategy formation and strategy success: Does

increasing understanding of regulatory compatibilities between the EU and a third country, e.g. the US, lead the Commission to propose issues for cooperation which also attract the interest of third-country regulators?

Regulatory cooperation between jurisdictions with mature regulatory systems entails the confrontation and comparison of highly differentiated institutional structures of authority allocation and problem-solving approaches that developed divergently in path-dependent ways over an extended time. 'Regulatory alignment' across numerous policy fields between these differentiated institutional structures is thus neither realistic nor often desirable. The elimination of 'unnecessarily' divergent decisions within the constraints of regulatory compatibilities is arguably more effectively addressed through repeated efforts between regulators to exchange information on envisaged legislative projects and to develop a mutual understanding of the institutional structures and problem-solving approaches. Especially firms and business associations should recognise the potential of structured, institutionalised information exchange between regulators and support it correspondingly. This could pave the way for more effective and promising regulatory cooperation, both international and bilateral, in the future.

With the continuation of interdependence despite the recently proclaimed 'populist backlash' against globalisation with the election of US President Trump, bilateral regulatory cooperation will remain an important issue for the EU. This applies not only to third countries whose attractiveness as a cooperation partner for the EU has risen since 2016, i.e. Canada and Japan, but also and especially with the US. The high levels of economic and continued political interdependence between the EU and the US make addressing regulatory divergences and their implications for policy erosion and/or trade impediment hard for the Commission to ignore. The prospect of budget cuts not only for regulatory agencies in the US under the Trump Administration, but also likely budget cuts for the Commission after the missing contributions of the UK to the EU budget after Brexit raise the relevance of regulatory burden-sharing between mature regulatory systems such as the EU and the US.

There is not (yet) a general 'best practice' to make bilateral regulatory cooperation more effective. The reliance on scientific comparisons of regulatory requirements and estimation of their comparability in the level of consumer, health and environmental protection they achieve heralded by some scholars (Messerlin, 2014) has failed to improve regulators' mutual understanding of the reasons underlying distinct authority allocations and regulatory principles in other jurisdictions. At the same time, the connection of regulatory cooperation with trade negotiations in the context of TTIP has arguably contributed to creating an impression among some regulators that regulatory cooperation is mainly about making trade easier, not making regulations and implementation procedures better. While continued information exchange between regulators may contribute to avoid some 'unnecessarily divergent' or duplicative requirements, the defence of regulatory principles by established societal actors, the autonomy of legislators to adopt divergent decisions and the path-dependent development of institutional structures make many regulatory incompatibilities there to stay. Moreover, despite

continued socialisation and exchanges among EU and US regulators, political considerations and the employment of 'tit-for-tat' strategies remain inextricably linked to the conduct of regulatory cooperation. At the end of the day, regulatory cooperation is not only a technically complex exercise, it is utterly political.

8. Bibliography

Abbott, K., & Snidal, D. (2009). The Governance Triangle: Regulatory Standards Institutions and the Shadow of the State. In W. Mattli & N. Woods (Eds.), *The politics of global regulation*. Princeton, NJ: Princeton University Press: 44–88.

Abbott, K. W., Snidal, D., Genschel, P., & Zangl, B. (2015). *International organizations as orchestrators*. Cambridge: Cambridge University Press.

Abdelal, R., & Meunier, S. (2010). Managed globalization: Doctrine, practice and promise. *Journal of European Public Policy*, *17*(3), 350–367.

Adriaensen, J. (2016). *National Administrations in EU Trade Policy: Maintaining the Capacity to Control*. *European Administrative Governance*. Basingstoke: Palgrave Macmillan.

Aggarwal, V. K., & Fogarty, E. A. (2004). *EU trade strategies: Between regionalism and globalism*. Basingstoke: Palgrave Macmillan.

Ahearn, R. J. (2008). Transatlantic Regulatory Cooperation. Background and Analysis. CRS Report for Congress, RL347171.

Alemanno, A. (2011). How to Get out of the Transatlantic Regulatory Deadlock over GMOs? Time for Regulatory Cooperation. In D. Vogel & J. Swinnen (Eds.), *Transatlantic Regulatory Cooperation. The Shifting Roles of the EU, the US and California*. Cheltenham: Edward Elgar Publishing: 246–267.

Alesina, A., Angeloni, I., & Schuknecht, L. (2005). What does the European Union do? *Public Choice*, *123*(3-4), 275–319.

Alons, G. (2014). Farmers versus ideas: Explaining the continuity in French agricultural trade policy during the GATT Uruguay Round. *Journal of European Public Policy*, *21*(2), 286–302.

Alter, K. J. (1998). Who are the "masters of the treaty"? European governments and the European Court of Justice. *International organization*, *52*(1), 121–147.

Alter, K. J. (2014). *The new terrain of international law: Courts, politics, rights*. Princeton, NJ: Princeton University Press.

Alter, K. J., & Meunier, S. (2006). Nested and overlapping regimes in the transatlantic banana trade dispute. *Journal of European Public Policy*, *13*(3), 362–382.

Alter, K. J., & Meunier, S. (2009). The Politics of International Regime Complexity. *Perspectives on politics*, *7*(1), 13–24.

American National Standards Institute. (2003). *Report from the Informal Working Group on ANSI/European Cooperation*. Washington, D.C. Retrieved from https://share.ansi.org/Shared%20Documents/Standards%20Activities/Background%20Papers/Supporting%20Documents/Report%20from%20the%20Informal%20Working%20Group%20(G6)%20on%20ANSI-European%20Cooperation.pdf

Andrews, D. M., Pollack, M. A., Shaffer, G. C., & Wallace, H. (Eds.). (2005). The Future of Transatlantic Economic Relations: Continuity Amid Discord. Fiesole: Robert Schuman Centre for Advanced Studies at the European University Institute.

Ansell, C., & Vogel, D. (2006). *The Contested Governance of European Food Safety: What's the Beef: The Contested Governance of European Food Safety Regulation.* Cambridge, MA: MIT Press.

Arcuri, A. (2016). The TBT Agreement and private standards. In T. Epps & M. J. Trebilcock (Eds.), *Research Handbook on the WTO and Technical Barriers to Trade*. Cheltenham: Edward Elgar Publishing: 485–524.

Article 29 Data Protection Working Party. (2016). *Working Document 01/2016 on the justification of interferences with the fundamental rights to privacy and data protection through surveillance*

measures when transferring personal data: (European Essential Guarantees) (No. 16/EN WP 237). Retrieved from: http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2016/wp237_en.pdf

Atlantic Council. (2016). *Building a transatlantic digital marketplace: Twenty Steps Toward 2020* (Report of the Atlantic Council Task Force on Advancing a Transatlantic Digital Agenda). Retrieved from http://www.atlanticcouncil.org/publications/reports/building-a-transatlantic-digital-marketplace-twenty-steps-toward-2020

Baccini, L., & Dür, A. (2012). The New Regionalism and Policy Interdependence. *British Journal of Political Science*, *42*: 57–79.

Bach, D., & Newman, A. L. (2007). The European regulatory state and global public policy: micro-institutions, macro-influence. *Journal of European Public Policy*, *14*(6), 827–846.

Bach, D., & Newman, A. L. (2010). Governing lipitor and lipstick: Capacity, sequencing, and power in international pharmaceutical and cosmetics regulation. *Review of International Political Economy*, *17*(4), 665–695.

Bach, T., Francesco, F. de, Maggetti, M., & Ruffing, E. (2016). Transnational Bureaucratic Politics: An Institutional Rivalry Perspective on EU Network Governance. *Public Administration*, *94*(1), 9–24.

Barker, D. (2014). *Trade Matters: Transatlantic Trade and Investment Partnership (TTIP) - Impacts on Food and Farming*. Retrieved from https://www.centerforfoodsafety.org/reports/3152/trade-matters-transatlantic-trade-and-investment-partnership-ttip--impacts-on-food-and-farming

Bayne, N., & Woolcock, S. (Eds.). (2003). *The new economic diplomacy: Decision-making and negotiation in international economic relations*. *The G8 and global governance series*. Aldershot: Ashgate.

Bayne, N., & Woolcock, S. (Eds.). (2013, cop. 2013). *The new economic diplomacy: Decision-making and negotiation in international economic relations* (3rd ed., revised and updated.). Farnham, Burlington: Ashgate.

Beach, D., & Pedersen, R. B. (2013). *Process-tracing methods: Foundations and guidelines*. Ann Arbor: University of Michigan Press.

Bendiek, A. (2014). Tests of Partnership: Transatlantic Cooperation in Cyber Security, Internet Governance, and Data Protection. Retrieved from https://www.swp-berlin.org/fileadmin/contents/products/research_papers/2014_RP05_bdk.pdf

Bendiek, A., & Schmieg, E. (2016). EU-Außenhandel und Datenschutz: Wie lässt sich beides besser vereinbaren? Retrieved from https://www.swp-berlin.org/fileadmin/contents/products/aktuell/2016A10_bdk_scm.pdf

Bennett, A. (1997). *Lost in the Translation: Big (N) Misinterpretations of Case Study Research: Paper presented at 38th Annual Convention of the International Studies Association, 18-22 March.* Toronto.

Bennett, A., & Elman, C. (2007). Case Study Methods in the International Relations Subfield. *Comparative Political Studies*, *40*(2), 170–195.

Berger, S. (2000). Globalization and Politics. *Annual Revue of Political Science*, *3*(1), 43–62.

Bertelsmann Stiftung. (2013). *Transatlantic Trade and Investment Partnership (TTIP): Who Benefits from a Free Trade Deal? Part 1: Macroeconomic Effects*. Retrieved from http://www.bfna.org/sites/default/files/TTIP-GED%20study%2017June%202013.pdf

Beuc. (2016). *The Incompatible Chemistry between the EU and the US: BEUC Position on Chemicals in TTIP* (No. BEUC-X-2016-007). Retrieved from Beuc website: http://www.beuc.eu/publications/beuc-x-2016-007_beuc_ttip_and_chemicals_position_paper.pdf

Beuc, & European Digital Rights. (2016). Subject: Concerns regarding US demands in TTIP and TiSA to fully prohibit data localisation policies for financial services. Retrieved from https://edri.org/files/letter_comissioner_malmstrom_ftas_dp_20160610.pdf

Beyers, J. (2005). Multiple Embeddedness and Socialization in Europe: The Case of Council Officials. *International organization*, *59*(4), 199.

Beyers, J., & Kerremans, B. (2007). Critical resource dependencies and the Europeanization of domestic interest groups. *Journal of European Public Policy*, *14*(3), 460–481.

Biedenkopf, K. (2015). EU Chemicals Regulation: Extending Its Experimentalist REACH. In J. Zeitlin (Ed.), *Extending experimentalist governance? The European Union and transnational regulation*. Oxford: Oxford University Press: 107–136.

Bièvre, D. de. (2002). The WTO and Domestic Coalitions: The Effects of Negotiations and Enforcement in the European Union (PhD thesis). European University Institute, Fiesole.

Bièvre, D. de, Poletti, A., & Thomann, L. (2014). To enforce or not to enforce? Judicialization, venue shopping, and global regulatory harmonization. *Regulation & Governance*, *8*(3), 269–286.

Binder, S. A., Rhodes, R. A. W., & Rockham, B. A. (Eds.). (2008). *The Oxford handbook of political institutions*. Oxford: Oxford University Press.

Blyth, M. (2002). *Great Transformations: Economic Ideas and Institutional Change in the Twentieth Century*. Cambridge: Cambridge University Press.

Bode, T. (2015). *Die Freihandelslüge: Warum TTIP nur den Konzernen nützt - und uns allen schadet*. Munich: DVA.

Börzel, T., & Risse, T. (2012). From Europeanisation to diffusion: Introduction. *West European Politics*, *35*(1), 1–19.

Börzel, T. A. (2005). Mind the gap! European integration between level and scope. *Journal of European Public Policy*, *12*(2), 217–236.

Börzel, T. A., & Risse, T. (2003). Conceptualizing the Domestic Impact of Europe. In K. Featherstone & C. M. Radaelli (Eds.), *The politics of Europeanisation*. Oxford: Oxford University Press: 59–80.

Bouwen, P. (2004). Exchanging access goods for access: A comparative study of business lobbying in the European Union institutions. *European Journal of Political Research*, *43*(3), 337–369.

Bradford, A. (2012). The Brussels effect. *Northwestern University Law Review*, *107*(1), 1–68.

Braithwaite, J. (2008). *Regulatory capitalism: How it works, ideas for making it work better*. Cheltenham: Edward Elgar Publishing.

Braithwaite, J., & Drahos, P. (2000). *Global business regulation*. Cambridge: Cambridge University Press.

Braun, D., & Gilardi, F. (2006). Taking 'Galton's Problem' Seriously: Towards a Theory of Policy Diffusion. *Journal of Theoretical Politics*, *18*(3), 298–322.

Breitmeier, H., Young, O. R., & Zürn, M. (2006). *Analyzing international environmental regimes: From case study to database*. *Global environmental accord*. Cambridge MA: MIT University Press.

Bremer, E. S. (2012). Incorporation by Reference in an Open-Government Age. *Harvard Journal of Law & Public Policy*, *36*.

Bretherton, C., & Vogler, J. (2006). *The European Union as a Global Actor*. London: Routledge.

Bretherton, C., & Vogler, J. (2013). A global actor past its peak? *International Relations*, *27*(3), 375–390.

Brito, A. C. de, & Pelkmans, J. (2012). Pre-empting Technical Barriers in the Single Market. Retrieved from https://www.ceps.eu/publications/pre-empting-technical-barriers-single-market

Brüggemann, M. (2005). How the EU constructs the European public sphere: Seven strategies of information policy. *Javnost - The Public*, *12*(2), 57–73.

Bund für Umwelt und Naturschutz Deutschland (BUND). (2015). *TTIP und die Chemikalienpolitik in der EU: Mögliche Auswirkungen auf bestehende und künftige Regulierungen*. Berlin. Retrieved from: https://www.bund.net/fileadmin/user_upload_bund/publikationen/ttip_und_ceta/ttip_und_ceta_chemiepolitik_eu.pdf

Bundesverband der Deutschen Industrie (BDI). (2015). Zehn Forderungen für eine gute transatlantische Regulierungskooperation. Retrieved from https://bdi.eu/media/presse/publikationen/globalisierung-maerkte-und-handel/Zehn_Forderungen_Regulierung.pdf

Bundesvereinigung der Deutschen Ernährungsindustrie. (2014). *Stellungnahme für die 15. Sitzung des Ausschusses für Ernährung und Landwirtschaft: „Geplantes Freihandels- und Investitionsabkommen zwischen der EU und den USA"*. Retrieved from https://www.bundestag.de/blob/285534/cf88ae95303ad70f1c066aa610b96377/stellungnahme_bve-data.pdf

Búrca, G. de, Keohane, R. O., & Sabel, C. (2014). Global Experimentalist Governance. *British Journal of Political Science*, *44*(3), 477–486.

Burnham, W. (2011). *Introduction to the law and legal system of the United States* (5th edition). St. Paul, MN: Thomson/West.

Business Roundtable, Transatlantic Business Dialogue, & European Round Table of Industrialists. (2012). *Forging a Transatlantic Partnership for the 21st Century: Joint Statement by Business Roundtable and the Transatlantic Business Dialogue*. Retrieved from http://businessroundtable.org/sites/default/files/legacy/uploads/general/TABD-BRT-ERT%20Public%20Comments.pdf

Busuioc, E. M., Groenleer, M., & Trondal, J. (2012). *The agency phenomenon in the European Union: Emergence, institutionalisation and everyday decision-making*. *European Policy Research Unit series*. Manchester: Manchester University Press.

Büthe, T., & Mattli, W. (2011). *The New Global Rulers: The Privatization of Regulation in the World Economy*. Princeton, NJ: Princeton University Press.

Campbell, J. L. (2004). *Institutional change and globalization.* Princeton, NJ: Princeton University Press.

Campbell, J. L. (2010). Institutional reproduction and change. In G. Morgan (Ed.), *The Oxford handbook of comparative institutional analysis* (1st ed.). Oxford: Oxford Univiversity Press.

Carlsnaes, W., Risse-Kappen, T., & Simmons, B. A. (Eds.). (2012). *Handbook of international relations* ([2nd ed.]). London: SAGE.

Cefic, & ACC. (2012). *ACC-Cefic Joint Proposal: Enhancing U.S.-E.U. Chemical Regulatory Cooperation under TTIP* (Position Paper). Retrieved from http://ciel.org/Publications/CH_Pro.pdf

Cefic, & ACC. (2014). *Cefic response to Commission's request for further details on joint ACC-Cefic proposals for enhanced cooperation on chemicals under TTIP* (Response Letter). Retrieved from http://www.cefic.org/Documents/RESOURCES/Cefic-Response-Cefic-Letter-to/[TTIP]%20Cefic%20response%20to%20Commission%20ACC-Cefic%20proposal%20on%20TTIP%207%20March%202014%20(web%20and%20click-in).pdf

CELCAA. (2014). *CELCAA position on the TTIP*. Retrieved from http://www.coceral.com/data/1374582090CELCAA%20position%20on%20the%20TTIP.pdf

CEN, & CENELEC. (2013). Position Paper on EU-US Transatlantic Trade and Investment Partnership (TTIP) – Technical Barriers to Trade. Retrieved from https://www.cencenelec.eu/news/policy_opinions/PolicyOpinions/PositionPaperTTIP.pdf

CEN, & CENELEC (2014a). *Challenges & benefits of regulatory cooperation for the EU & US industry and consumers: TTIP & standardization matters*. Retrieved from http://www.europarl.europa.eu/document/activities/cont/201403/20140318ATT81226/20140318ATT81226EN.pdf

CEN, & CENELEC. (2014b). *The risks of mutual recognition of voluntary industry standards within the context of a future EU-US trade agreement (TTIP) and alternative approaches*. Brussels.

Center for International Environmental Law. (2014). *Toxic Partnership Revealed*. Retrieved from http://ciel.org/Publications/TTIP_Leaked_29Sep2014.pdf

Center for International Environmental Law (CIEL). (2015). Lowest common denominator: How the proposed EU-US trade deal threatens to lower standards of protection from toxic pesticides. Retrieved from http://www.s2bnetwork.org/wp-content/uploads/2015/09/LCD_TTIP_Jan20151.pdf

Cerny, P. G. (2010). *Rethinking world politics: A theory of transnational neopluralism*. Oxford: Oxford University Press.

Chaban, N., Elgström, O., & Holland, M. (2006). The European Union As Others See It. *European Foreign Affairs Review*, *11*(2), 245–262.

Chase, P., David-Wilp, S., & Ridout, T. (2016). Transatlantic Digital Economy and Data Protection: State-of-Play and Future Implications for the EU's External Policies. Retrieved from http://www.europarl.europa.eu/RegData/etudes/STUD/2016/535006/EXPO_STU(2016)535006_EN.pdf

Chase, P., & Pelkmans, J. (2015). This time it's different: Turbo-charging regulatory cooperation. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers: 17–60.

Checkel, J. (2001). Why Comply? Social Learning and European Identity Change. *International organization*, *55*(3), 553–588.

Checkel, J. (2005). International Institutions and Socialization in Europe: Introduction and Framework. *International organization*, *59*(4), 801–826.

Checkel, J. (2006). Tracing Causal Mechanisms. *International Studies Review*, *8*(2), 362–370.

Checkel, J. (1997). International Norms and Domestic Politics: Bridging the Rationalist—Constructivist Divide. *European Journal of International Relations*, *3*(4), 473–495.

Checkel, J. (1999). Norms, Institutions, and National Identity in Contemporary Europe. *International Studies Quarterly*, *43*(1), 84–114.

Chemical Watch. (2014a). EU could consult us in most stages of chemicals legislation. 1 October. Retrieved from http://chemicalwatch.com/20745/ttip-negotiations-progress-on-chemicals-cosmetics-and-textiles?q=Pilot

Chemical Watch. (2014b). TTIP negotiations progress on chemicals, cosmetics and textiles. 30 July. Retrieved from http://chemicalwatch.com/20745/ttip-negotiations-progress-on-chemicals-cosmetics-and-textiles?q=Pilot

Christiansen, T. (2011). Tensions of European governance: Politicized bureaucracy and multiple accountability in the European Commission. *Journal of European Public Policy*, *4*(1), 73–90.

ClientEarth, & Center for International Environmental Law (CIEL). (2014). Toward a Toxic Partnership: A critique of the EU position on chemicals under the Trans-Atlantic Trade and Investment Partnership (TTIP) Agreement with the US. Retrieved from http://www.ciel.org/wp-content/uploads/2014/10/ToxicPartnership_Jun2014.pdf

Cline, J. (2014). U.S. takes the gold in doling out privacy fines. Retrieved from https://www.computerworld.com/article/2487796/data-privacy/jay-cline--u-s--takes-the-gold-in-doling-out-privacy-fines.html

Codex. (2016). *Understanding the Codex Alimentarius*. Retrieved from http://www.fao.org/3/a-i5667e.pdf

Copa Cogeca. (2013). Copa-Cogeca reaction to EU/Canada Trade Deal: Progress made but rise in beef and pigmeat Canadian imports still threatens market balance. CDP(13)8128:1. Retrieved from www.copa-cogeca.be/Download.ashx?ID=1121576&fmt=pdf

Copa Cogeca. (2015). Copa and Cogeca urge EU chief negotiators to make progress on eliminating red tape and non-tariff barriers to trade in transatlantic trade (TTIP) talks when meet next week, warning little headway here. Retrieved from www.copa-cogeca.be/download.ashx?id=1423806&fmt=pdf

Copa Cogeca, & FooddrinkEurope. (2013). *Annex Key Non-Tariff Measures*. BILAT(13)4719:8. Retrieved from http://www.fooddrinkeurope.eu/uploads/statements_documents/technical_annex.pdf

Corporate Europe Observatory. (2014). Agribusiness is the biggest lobbyist on the EU-US trade deal, new research reveals. Retrieved from https://corporateeurope.org/pressreleases/2014/07/agribusiness-biggest-lobbyist-eu-us-trade-deal-new-research-reveals

Corporate Europe Observatory. (2016). TTIP Regulatory Cooperation: Threat to Democracy. Retrieved from https://corporateeurope.org/international-trade/2016/03/ttip-regulatory-cooperation-threat-democracy

Corporate Europe Observatory. (2017). 'Regulatory cooperation': Big business' wishes come true in TTIP and CETA. 1 February. Retrieved from https://corporateeurope.org/international-trade/2017/02/regulatory-cooperation-big-business-wishes-come-true-ttip-and-ceta

Costa, O., & Jørgensen, K. E. (2012). *The influence of international institutions on the EU: When multilateralism hits Brussels*. Basingstoke: Palgrave Macmillan.

Council of the European Union. (2005). 2005/834/EC: Council Decision of 8 November 2005 on the equivalence of checks on practices for the maintenance of varieties carried out in certain third countries and amending Decision 2003/17/EC. Retrieved from http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005D0834

Cowles, M. G. (2001). The transatlantic business dialogue and domestic business-government relations. In M. G. Cowles, J. A. Caporaso, & T. Risse-Kappen (Eds.), *Transforming Europe: Europeanisation and Domestic Change*. Ithaca, NY: Cornell University Press: 159–179.

Cowles, M. G., Caporaso, J. A., & Risse-Kappen, T. (Eds.). (2001). *Transforming Europe: Europeanisation and Domestic Change*. Ithaca, NY: Cornell University Press.

da Conceição-Heldt, E. (2011). Variation in EU member states' preferences and the Commission's discretion in the Doha Round. *Journal of European Public Policy*, *18*(3), 403–419.

da Conceição-Heldt, E., & Meunier, S. (2014). Speaking with a single voice: Internal cohesiveness and external effectiveness of the EU in global governance. *Journal of European Public Policy*, *21*(7), 961–979.

Dąbrowska-Kłosińska, P. (2014). *'The EU and Transnational Regulation of GMO Risks*. Warsaw, *36*. Retrieved from http://cris.unu.edu/sites/cris.unu.edu/files/WP%2036_GREEN_Dabrowska-klosinska.pdf

Dąbrowska-Kłosińska, P. (2015). The EU and Transnational Regulation of Genetically Modified Organisms: From Bargaining Impasse to Experimentalist Cooperation? In J. Zeitlin (Ed.), *Extending experimentalist governance? The European Union and transnational regulation*. Oxford: Oxford University Press: 81–106.

Dai, X. (2005). Why Comply? The Domestic Constituency Mechanism. *International Organization*, *59*(02), 459.

Dai, X. (2007). *International institutions and national policies*. Cambridge: Cambridge University Press.

Damro, C. (2005). Discretionary Cooperation and the Regulation of Internationalising Business Activity: Paper prepared for the Third ECPR General Conference Budapest, Hungary. 8-11 September 2005.

Damro, C. (2006). Transatlantic Competition Policy: Domestic and International Sources of EU-US Cooperation. *European Journal of International Relations*, *12*(2), 171–196.

Damro, C. (2007). EU Delegation and Agency in International Trade Negotiations: A Cautionary Comparison. *Journal of Common Market Studies*, *45*(4), 883–903.

Damro, C. (2012). Market power Europe. *Journal of European Public Policy*, *19*(5), 682–699.

Damro, C. (2015a). Market Power Europe and new EU trade policies. In J. Wouters (Ed.), *Leuven global governance. Global governance through trade: EU policies and approaches*. Cheltenham: Edward Elgar Publishing: 19–42.

Damro, C. (2015b). Market power Europe: Exploring a dynamic conceptual framework. *Journal of European Public Policy*, *22*(9), 1336–1354.

Daugbjerg, C., & Roederer-Rynning, C. (2013). The EU's Common Agricultural Policy: a case of defensive policy import. In G. Falkner (Ed.), *Routledge series on global order studies. EU policies in a global perspective: Shaping or taking international regimes?* London: Routledge: 38–57.

Dehousse, R. (1997). Regulation by networks in the European Community: The role of European agencies. *Journal of European Public Policy*, *4*(2), 246–261.

Delimatsis, P. (2014). *Relevant International Standards' and 'Recognized Standardization Bodies' under the TBT Agreement*. TILEC Discussion Paper No. 2014-031.

Della Porta, D., & Tarrow, S. (2005). *Transnational Protest and Global Activism*. Lanham MD: Rowman & Littlefield Publishers.

Delreux, T. (2012). The rotating Presidency and the EU's external representation in environmental affairs: The case of climate change and biodiversity negotiations. *Journal of Contemporary European Research*, *8*(2), 210–227.

Demortain, D. (2012). Enabling global principle-based regulation: The case of risk analysis in the Codex Alimentarius. *Regulation & Governance*, *6*(2), 207–224.

Deutsche Gesetzliche Unfallversicherung (DGUV). (2014). Comments by the statutory accident insurance institutions in Germany on a Transatlantic Trade and Investment Partnership (TTIP) between the European Union and the USA. Retrieved from http://www.dguv.de/medien/inhalt/mediencenter/pm/pressearchiv/2014/q2/ttip_position_german_social_accident_insurance_institutions_en.pdf

Deutscher Bauernverband. (2014). *Stellungnahme Deutscher Bauernverband e.V. zur öffentlichen Anhörung "Geplantes Freihandels- und Investitionsabkommen zwischen der EU und den USA (Transatlantic Trade and Investment Partnership - TTIP)": Öffentliche Anhörung des Ausschusses für Ernährung und Landwirtschaft des Deutschen Bundestages am 30. Juni 2014*. Retrieved from https://www.bundestag.de/blob/285528/06f3f2e05961988245dc531f817d19e7/stellungnahme_dbv-data.pdf

Deutsches Institut für Normierung. (2013). *Beitrag des DIN zur Zusammenarbeit zwischen den USA und Europa in der Normung und Standardisierung als Unterstützung der Verhandlungen zur Transatlantic Trade & Investment Partnership (TTIP)*. Berlin.

Dialer, D., & Richter, M. (Eds.). (2018, forthcoming). *Lobbying in the European Union: Successful Strategies and Techniques*. London: Springer.

Digitaleurope. (2012). *Digitaleurope Position on the EU-US Regulatory Cooperation* (Position Paper). Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/december/tradoc_154085.pdf

Digitaleurope. (2013). *Digitaleurope Position on the EU-US Regulatory Cooperation: Version 2*. Retrieved from http://www.digitaleurope.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=672&language=en-US&PortalId=0&TabId=353

Digitaleurope. (2014a). *Ten Leading Principles to foster EU Digital Trade* (Position Paper). Retrieved from www.digitaleurope.org/Document-Download/Command/Core_Download/EntryId/998

Digitaleurope. (2014b). *Trilateral Dialogue JEITA-ITI-DE Forced Localization Measures: Presentation*. Retrieved from http://www.digitaleurope.org/DesktopModules/Bring2 mind/DMX/Download.aspx?Command=Core_Download&entryID=837&language=en-US&PortalId=0&TabId=353

Dijkstra, H. (2009). Commission versus Council Secretariat: An Analysis of Bureaucratic Rivalry in European Foreign Policy. *European Foreign Affairs Review*, *14*(3), 431–450.

DiMaggio, P. J., & Powell, W. W. (1983). The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields. *American Sociological Review*, *48*(2), 147–160.

Djelic, M.-L., & Quack, S. (2010). *Transnational Communities: Shaping Global Economic Governance*. Cambridge: Cambridge University Press. Retrieved from https://www.cambridge.org/core/books/transnational-communities/2194FA5FF12C4DD4841264DE61522C45

Djelic, M.-L., & Sahlin-Andersson, K. (2006). *Transnational governance: Institutional dynamics of regulation*. Cambridge: Cambridge University Press.

Dobbin, F., Simmons, B., & Garrett, G. (2007). The Global Diffusion of Public Policies: Social Construction, Coercion, Competition, or Learning? *Annual Review of Sociology*, *33*(1), 449–472.

Dolowitz, D., & Marsh, D. (1996). Who Learns What from Whom: A Review of the Policy Transfer Literature. *Political Studies*, *44*(2), 343–357.

Dolowitz, D. P., & Marsh, D. (2000). Learning from Abroad: The Role of Policy Transfer in Contemporary Policy-Making. *Governance*, *13*(1), 5–23.

Dreyer, M., & Renn, O. (2009). *Food safety governance: Integrating science, precaution and public involvement*. *Risk, Governance and Society*. Wiesbaden: Springer.

Drezner, D. W. (2001). Globalization and Policy Convergence. *International Studies Review*, *3*(1), 53–78.

Drezner, D. W. (2005). Globalization, harmonization, and competition: The different pathways to policy convergence. *Journal of European Public Policy*, *12*(5), 841–859.

Drezner, D. W. (2007). *All politics is global: Explaining international regulatory regimes*. Princeton, NJ: Princeton University Press.

Drezner, D. W. (2009). The Power and Peril of International Regime Complexity. *Perspectives on Politics*, *7*(01), 65–70.

Duchêne, F. (1973). The European Community and the Uncertainties of Interdependence. In M. Kohnstamn (Ed.), *Nation writ large? Foreign-policy problems before the European Community*. Basingstoke: Palgrave Macmillan: 1–21.

Dunleavy, P. (1991). *Democracy, bureaucracy and public choice: Economic explanations in political science*. London: Routledge.

Dür, A. (2007). Discriminating among rival explanations: Some tools for small-n researchers. In T. Gschwend & F. Schimmelfennig (Eds.), *Research design in political science: How to practice what they preach.* Basingstoke: Palgrave Macmillan: 183–202.

Dür, A. (2008). Bringing Economic Interests Back into the Study of EU Trade Policy-Making. *British Journal of Politics and International Relations, 10*, 27–45.

Dür, A. (2010). *Protection for Exporters: Power and Discrimination in Transatlantic Trade Relations, 1930–2010*. Ithaca, NY: Cornell University Press.

Dür, A., & Bièvre, D. de. (2007). Inclusion without Influence? NGOs in European Trade Policy. *Journal of Public Policy*, *27*(1), 79–101.

Dür, A., & Elsig, M. (2011). Principals, agents, and the European Union's foreign economic policies. *Journal of European Public Policy*, *18*(3), 323–338.

Dür, A., & Mateo, G. (2014). The Europeanization of interest groups: Group type, resources and policy area. *European Union Politics*, *15*(4), 572–594.

Dür, A., & Zimmermann, H. (2007). Introduction: The EU in international trade negotiations. *Journal of Common Market Studies*, *45*(4), 771–787.

Eberle, D., & Lauter, D. (2011). Varieties of private self-regulation in European capitalism: Corporate governance codes in the UK and Germany. *Socio-Economic Review*, *9*(2), 315–338.

Eberlein, B., & Grande, E. (2006). Beyond delegation: Transnational regulatory regimes and the EU regulatory state. *Journal of European Public Policy*, *12*(1), 89–112.

Eberlein, B., & Kerwer, D. (2004). New Governance in the European Union: A Theoretical Perspective. *Journal of Common Market Studies*, *42*(1), 121–142.

Eberlein, B., & Newman, A. L. (2008). Escaping the International Governance Dilemma? Incorporated Transgovernmental Networks in the European Union. *Governance*, *21*(1), 25–52.

Eckhardt, J., & Poletti, A. (2016). The Politics of Global Value Chains: Import-dependent Firms and EU-Asia Trade Agreements. *Journal of European Public Policy*, *23*(10), 1543–1562.

Eckstein, H. H. (1975). Case study and theory in political science. In F. I. Greenstein & N. W. Wolsby (Eds.), *Handbook of Political Science.* Reading, MA: Addison-Wesley.

Ecorys. (2009). *Non-Tariff Measures in EU-US Trade and Investment – An Economic Analysis*. Ecorys report prepared for the European Commission. Retrieved from http://trade.ec.europa.eu /doclib/docs/2009/december/tradoc_145613.pdf

Ecorys. (2016). *Trade Sustainability Impact Assessment (Trade SIA) in support of negotiations of a comprehensive trade and investment agreement between the European Union and the United States of America*. Ecorys report prepared for the European Commission under the Framework Contract TRADE/2013/E1/E03. Retrieved from http://trade.ec.europa.eu/doclib/docs/2017/april/ tradoc_155464.pdf

ECOS - European Environmental Citizens for Standardisation. (2016). Mutual recognition of standards in TTIP: Another threat to citizens' welfare and the environment? Retrieved from http://ecostandard.org/wp-content/uploads/ECOS-2016-POS-002-TTIP.pdf

Egan, M. (2001). *Constructing a European market: Standards, regulation, and governance*. Oxford: Oxford University Press.

Egan, M. (2005). *Creating a transatlantic marketplace: Government policies and business strategies*. *European Policy Research Unit series*. Manchester: Manchester University Press.

Egan, M., & Pelkmans, J. (2015). TTIP's Hard Core: Technical barriers to trade and standards. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers: 61–96.

Egeberg, M. (2006). *Multilevel union administration: The transformation of executive politics in Europe*. Basingstoke: Palgrave Macmillan.

Egeberg, M., & Trondal, J. (2009). Political Leadership and Bureaucratic Autonomy: Effects of Agencification. *Governance*, *22*(4), 673–688.

Eising, R., & Jabko, N. (2001). Moving Targets: National Interests and Electricity Liberalization in the European Union. *Comparative Political Studies*, *34*(7), 742–767.

Eliasson, L. J. (2014). Problems, progress and prognosis in trade and investment negotiations: The transatlantic free trade and investment partnership. *Journal of Transatlantic Studies*, *12*(2), 119–139.

Elkins, Z. (2010). Diffusion and the Constitutionalization of Europe. *Comparative Political Studies*, *43*(8-9), 969–999.

Elliott, E. D., & Pelkmans, J. (2015). Greater TTIP Ambition in Chemicals: Why and how. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership* (423-278). London: Rowman & Littlefield Publishers.

Elsig, M. (2007). The EU's Choice of Regulatory Venues for Trade Negotiations: A Tale of Agency Power? *Journal of Common Market Studies*, *45*(4), 927–948.

Elsig, M. (2013). The EU as an effective trade power? Strategic choice of judicial candidates in the context of the World Trade Organization. *International Relations*, *27*(3), 325–340.

Elsig, M., & Dupont, C. (2012). European Union Meets South Korea: Bureaucratic Interests, Exporter Discrimination and the Negotiations of Trade Agreements, *Journal of Common Market Studies*, *50*(3), 492–507.

Enderlein, H., Wälti, S., & Zürn, M. (2010). *Handbook on multi-level governance*. Cheltenham: Edward Elgar Publishing.

Environmental Protection Agency (EPA). (2017). How EPA Evaluates the Safety of Existing Chemicals. Retrieved from https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals

Epps, T., & Trebilcock, M. J. (Eds.). (2016). *Research Handbook on the WTO and Technical Barriers to Trade*. Cheltenham: Edward Elgar Publishing.

Epstein, P. J. (1997). Beyond policy community: French agriculture and the GATT. *Journal of European Public Policy*, *4*(3), 355–372.

eucolait. (2013). *Eucolait position on the TTIP* (Position Paper). Retrieved from http://www.eesc.europa.eu/sites/default/files/resources/docs/eucolait-position-on-the-ttip-2013_09_11.pdf

eucolait. (2016). *Dairy market access and regulatory issues in TTIP*. Retrieved from http://www.eucolait.eu/userfiles/files/Position%20papers/Eucolait%20statement%20TTIP%20and%20NTBs%20%202015_02_02.pdf

European Chemicals Agency. (2010). *Statement of Intent between the European Chemicals Agency and the US EPA Related to Chemical Management Activities*. Retrieved from https://echa.europa.eu/documents/10162/13558/soi_us_echa_usepa_en.pdf/c371c7e4-2cf4-4ec5-9caa-d0fd2d7080a1

European Chemicals Agency. (2011). Substance Evaluation. Retrieved from https://echa.europa.eu/documents/10162/13628/fs_substance_evaluation_en.pdf/631aa24f-2bc4-4736-9c9f-46655e29ee9a

European Chemicals Agency. (2016). *2016-17 Rolling Work Plan for the Statement of Intent between the European Chemicals Agency (ECHA) and the US Environmental Protection Agency (EPA)*. Retrieved from https://echa.europa.eu/documents/10162/13558/echa_rolling_work_plan_usa_en.pdf/7812978d-64c4-4181-a666-979a44ef16b1

European Commission. (1995). *The New Transatlantic Agenda*. Retrieved from: http://www.europa.eu.int/comm/external_relations/us/new_transatlantic_agenda/text/htm.

European Commission. (1996). *The Global Challenge of International Trade: A Market Access Strategy for the European Union*. COM(96) 53 final. Retrieved from http://trade.ec.europa.eu/doclib/docs/2003/june/tradoc_113175.pdf

European Commission. (1997a). EU/US Discussions on Veterinary Equivalence Agreement. Retrieved from http://europa.eu/rapid/press-release_MEMO-97-37_en.htm

European Commission. (1997b). *External Access to European Markets: The Single Market Review* (Subseries IV No. 4). Retrieved from http://ec.europa.eu/internal_market/economic-reports/docs/studies/stud13_en.pdf

European Commission. (1998). Transatlantic Economic Partnership. Retrieved from http://eeas.europa.eu/archives/docs/us/docs/trans_econ_partner_11_98_en.pdf

European Commission. (1999). Agreement on mutual recognition between the European Community and the United States of America - Joint Declaration. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:21999A0204%2801%29

European Commission. (2000a). *Communication from the Commission on the Precautionary Principle*. Retrieved from <http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf

European Commission. (2000b). *Report on United States Barriers to Trade and Investment 2000*. Brussels: European Commission.

European Commission. (2000c). *The Transatlantic Economic Partnership: Overview and Assessment*. Brussels: European Commission.

European Commission. (2001a). *Implementing policy for external trade in the fields of standards and conformity assessment: a tool box of instruments*. Brussels: European Commission.

European Commission. (2001b). *Report of the Transatlantic Economic Partnership Steering Group: EU-U.S. Summit, Göteborg, 14 June 2001*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2003/october/tradoc_111706.pdf

European Commission. (2001c). *Report on United States Barriers to Trade and Investment 2001*. Retrieved from: http://trade.ec.europa.eu/doclib/docs/2006/february/tradoc_111719.pdf

European Commission. (2002). *Report on United States Barriers to Trade and Investment 2002*. Brussels: European Commission.

European Commission. (2003a). *EU Annual Report on US Trade Barriers stresses need for enhanced co-operation*. Retrieved from http://trade-info.cec.eu.int/doclib/html/115383.htm

European Commission. (2003b). *EU-U.S. relations: Renew Commitment to Trans-Atlantic Business Dialogue*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2004/january/tradoc_115515.pdf

European Commission. (2003c). General Guidelines for the Cooperation between CEN, Cenelec and ETSI and the European Commission and the European Free Trade Association. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52003XC0416%2803%29

European Commission. (2003d). *Report on United States Barriers to Trade and Investment 2003*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2006/february/tradoc_115383.pdf

European Commission. (2003e). *The Positive Economic Agenda: European Union Factsheet*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2006/june/tradoc_114066.pdf

European Commission. (2004a). *Report on United States Barriers to Trade and Investment 2004*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2006/february/tradoc_121929.pdf

European Commission. (2004b). *Strengthening the EU-US Economic Partnership: Request for comments and proposals of the services of the European Commission*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2004/september/tradoc_119170.pdf

European Commission. (2005a). *A stronger EU-US partnership and a more open market for the 21st century: Communication*. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:r14105

European Commission. (2005b). *Roadmap for U.S. - EU Regulatory Cooperation*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2006/march/tradoc_127674.pdf

European Commission. (2005c). *The European Union and the United States Initiative to Enhance Transatlantic Economic Integration and Growth*. Retrieved from http://www.europarl.europa.eu/cmsdata/41557/att_20100427ATT73625-1958936763896641007.pdf

European Commission. (2006a). *2006 EU-US Summit Progress Report on the Economic Initiative: 21 June 2006, Vienna*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2006/june/tradoc_129054.pdf

European Commission. (2006b). *Global Europe: A Stronger Partnership to Deliver Market Access for European Exporters*. COM(2006)567. Retrieved from http://eur-lex.europa.eu/legal-content/en/TXT/?uri=celex:52006DC0567

European Commission. (2006c). *Joint Report on the Roadmap for EU-US Regulatory Cooperation*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2006/july/tradoc_129222.pdf

European Commission. (2007a). *2007 EU-U.S. Summit Economic Progress Report*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2007/may/tradoc_134656.pdf

European Commission. (2007b). *Framework for advancing Transatlantic Economic Integration between the European Union and the United States of America*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2007/may/tradoc_134654.pdf

European Commission. (2007c). *Joint Report on the Roadmap for US-EU Regulatory Cooperation*. Retrieved from https://obamawhitehouse.archives.gov/sites/default/files/omb/oira/irc/joint_report_on_the_roadmap_for_us-eu_regulatory_cooperation_april_2007.pdf

European Commission. (2007d). *The external dimension of the Single Market review*. SEC(2007)1519. Retrieved from http://ec.europa.eu/citizens_agenda/docs/sec_2007_1519_en.pdf

European Commission. (2007e). *United States Barriers to Trade and Investment Report for 2006*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2007/february/tradoc_133290.pdf

European Commission. (2008). *United States Barriers to Trade and Investment Report for 2007*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2008/april/tradoc_138559.pdf

European Commission. (2009). *United States Barriers to Trade and Investment Report for 2008*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2009/july/tradoc_144160.pdf

European Commission. (2010). *Memorandum of Understanding between the United States Department of Health and Human Services and the European Commission Cooperation surrounding Health Related Infomation and communication Technologies*. Retrieved from https://www.state.gov/p/eur/rls/or/153422.htm

European Commission. (2011a). *Building Bridges Between the U.S. and EU Standards Systems*. Retrieved from https://obamawhitehouse.archives.gov/sites/default/files/omb/oira/irc/us-eu-standards-bridges.pdf

European Commission. (2011b). *The EU-Korea Free Trade Agreement in Practice*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2011/october/tradoc_148303.pdf

European Commission. (2012). *Risk management and trade: Risk assessment procedures in SPS issues - the EU versus the USA approach Seminar*. Stockholm.

European Commission. (2013a). *Sanitary and phytosanitary issues: Initial EU position paper: EU-US Transatlantic Trade and Investment Partnership*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151625.pdf

European Commission. (2013b). *Technical barriers to trade: EU-US Transatlantic Trade and Investment Partnership Initial EU position paper*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151627.pdf

European Commission. (2013c). The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues: EU position on motor vehicles. Retrieved from http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152467.pdf

European Commission. (2013d). *Transatlantic eHealth/health IT Cooperation Roadmap.* Brussels: European Commission.

European Commission. (2013e). *Transatlantic Trade and Investment Partnership: The Economic Analysis Explained,* Retrieved from http://trade.ec.europa.eu/doclib/html/151787.htm

European Commission. (2013f). *Transatlantic Trade and Investment Partnership: The Regulatory Part*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151605.pdf

European Commission. (2014a). Chemicals - How to put ideas for cooperation under TTIP into practice: Non-Discussion Paper. Retrieved from http://trade.ec.europa.eu/doclib/docs/2014/november/tradoc_152913.pdf

European Commission. (2014b). *EU position on chemicals: The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues*. Retrieved from European Commission website: http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152468.pdf

European Commission. (2014c). *EU position paper on TTIP regulatory issues - Engineering industries*. Retrieved from: http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153022.pdf

European Commission. (2014d). European Commission position for Internet Governance Forum (IGF) 2014. Retrieved from http://europa.eu/rapid/press-release_MEMO-14-513_en.htm

European Commission. (2014e). *Factsheet on Information and communication technology (ICT) in TTIP: Working together to enforce standards and protect consumers.*

European Commission. (2014f). *Outline for provisions on chemicals*. Retrieved from: http://trade.ec.europa.eu/doclib/docs/2014/november/tradoc_152912.pdf

European Commission. (2014g). Report of the Seventh Round of Negotiations: 7th round, 29 September 2014. Retrieved from http://trade.ec.europa.eu/doclib/docs/2014/october/tradoc_152859.pdf

European Commission. (2014h). *Sanitary and phytosanitary measures (SPS): EU Textual Proposal for the Transatlantic Trade and Investment Partnership*. Retrieved from: http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153026.pdf

European Commission. (2014i). *Stellungnahme Europäische Kommission (Ulrich Weigl) für die 15. Sitzung des Ausschusses für Ernährung und Landwirtschaft: „Geplantes Freihandels- und Investitionsabkommen zwischen der EU und den USA (Transatlantic Trade and Investment Partnership - TTIP).* Retrieved from https://www.bundestag.de/blob/285532/ead902c58b5e98571559fb8234e8bd6b/stellungnahme_europaeische_kommission-data.pdf

European Commission. (2014j). The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues: EU position on pharmaceutical products. Retrieved from http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152471.pdf

European Commission. (2014k). *Transatlantic Taskforce on Antimicrobial Resistance: Progress report: Recommendations for future collaboration between the US and EU.* Brussels: European Commission

European Commission. (2014l). Transatlantic Trade & Investment Partnership (TTIP) Advisory Group: Member information. Retrieved from http://trade.ec.europa.eu/doclib/docs/2014/january/tradoc_152102.pdf

European Commission. (2014m). Transatlantic Trade & Investment Partnership Advisory Group: Meeting report, 23 April 2014. Exchange of views on chemicals. Retrieved from http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152503.pdf

European Commission. (2014n). TTIP Stakeholder Presentations Event: 4 February 2014. Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153079.pdf

European Commission. (2015a). Communication from the Commission: A Digital Single Market Strategy: COM(2015) 192 final. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52015DC0192

European Commission. (2015b). Report of the 10th Round of Negotiations: Brussels, 13–17 July 2015. Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/july/tradoc_153667.pdf

European Commission. (2015c). Report of the 11th Round of Negotiations: Miami, 19–23 October 2015. Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153935.pdf

European Commission. (2015d). Report of the 8th Round of Negotiations: 2-6 February 2015. Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153175.pdf

European Commission. (2015e). Report of the 9th Round of Negotiations: New York, 20-24 April 2015. Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/may/tradoc_153437.pdf

European Commission. (2015f). *Textual Proposal Technical Barriers to Trade: Transatlantic Trade and Investment Partnership*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153025.pdf

European Commission. (2015g). *Chemicals in TTIP – What is under discussion? What will it mean for REACH? REACH Information and Experience Exchange Forum (RIEF IV)*. Retrieved from http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Workshops/RIEF-IV-16-6-2015/09%20REACH%20and%20TTIP%20-%20Klaus%20Berend.pdf

European Commission. (2015h). *Textual Proposal Trade in Services, Investment and E-Commerce: Transatlantic Trade and Investment Partnership*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/july/tradoc_153669.pdf

European Commission. (2015i). *EU proposal to include an article on Anti-Microbial Resistance within the SPS Chapter of TTIP*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2015/november/tradoc_153936.pdf

European Commission. (2016a). Advancing the Internet of Things in Europe: SWD(2016)110/2. Retrieved from https://ec.europa.eu/digital-single-market/en/news/staff-working-document-advancing-internet-things-europe

European Commission. (2016b). Communication on Online Platforms and the Digital Single Market Opportunities and Challenges for Europe: COM(2016)288. Retrieved from https://ec.europa.eu/digital-single-market/en/news/communication-online-platforms-and-digital-single-market-opportunities-and-challenges-europe

European Commission. (2016c). EU and US strengthen their collaboration on eHealth IT. Retrieved from https://ec.europa.eu/digital-single-market/en/news/eu-and-us-strengthen-their-collaboration-ehealth-it

European Commission. (2016d). *EU Proposal for an Annex on Engineering: EU-US TTIP Negotiations*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2016/july/tradoc_154804.pdf

European Commission. (2016e). EU Proposal for Annex/Chapter on Chemicals. Retrieved from http://trade.ec.europa.eu/doclib/docs/2016/july/tradoc_154795.pdf

European Commission. (2016f). Report of the 12th Round of Negotiations: Brussels, 22-26 February 2016. Retrieved from http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154391.pdf

European Commission. (2016g). Report of the 13th Round of Negotiations: New York, 25-29 April 2016. Retrieved from http://trade.ec.europa.eu/doclib/docs/2016/may/tradoc_154581.pdf

European Commission. (2016h). Report of the 14th Round of Negotiations. Retrieved from http://trade.ec.europa.eu/doclib/docs/2016/august/tradoc_154837.pdf

European Commission. (2016i). Report of the 15th Round of Negotiations: October 2016. Retrieved from http://trade.ec.europa.eu/doclib/docs/2016/october/tradoc_155027.pdf

European Commission. (2016j). The 'Blue Guide' on the implementation of EU products rules. Brussels: European Commission.

European Commission. (2016k). *Transatlantic eHealth/Health IT Cooperation Roadmap*. Retrieved from http://ec.europa.eu/information_society/newsroom/image/document/2016-30/eu_us_roadmap_16674.pdf

European Commission. (2016l). *TTIP-Tactical State of Play of the TTIP Negotiations: Note*. Retrieved from https://wikileaks.org/ttip/Tactical-State-of-Play/Tactical-State-of-Play.pdf

European Commission. (2016m). TTIP Stakeholder Presentations Event. Retrieved from http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc_154316.pdf

European Commission. (2016n). EU-US agricultural trade and TTIP impact: TTIP – US Ambassador's note to EU Perm Reps. Retrieved from http://www.politico.eu/wp-content/uploads/2016/05/2016-06-27-TTIP-agriculture-US-Amb-Gardner-letter-to-MSs-FINAL2.pdf

European Commission. (2017a). Mutual Recognition Agreements. Retrieved from https://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements_en

European Commission. (2017b). Sanitary and Phytosanitary Agreements. Retrieved from https://ec.europa.eu/food/safety/international_affairs/trade/agreements_en

European Commission. (2017c). Sectors. Retrieved from https://ec.europa.eu/growth/sectors_en

European Commission, & United States Trade Department. (2002). Guidelines on Regulatory Cooperation and Transparency. Retrieved from https://ustr.gov/archive/assets/World_Regions/Europe_Middle_East/Transatlantic_Dialogue/asset_upload_file350_5680.pdf

European Commission, & United States Trade Department. (2016). *Sanitary and Phytosanitary Measures: Consolidated Proposals*. Retrieved from https://trade-leaks.org/ttip/sanitary-and-phytosanitary-measures/

European Council. (1998). *Transatlantic Economic Partnership 1998*. Retrieved from http://eeas.europa.eu/archives/docs/us/docs/trans_econ_partner_11_98_en.pdf

European Digital Rights. (2015). TTIP and Digital Rights: the Booklet. Retrieved from https://edri.org/ttip-and-digital-rights-the-booklet/

European Food Safety Authority. (2007). *Memorandum of Understanding between the European Food Safety Authority and the US Food and Drug Administration*. Retrieved from https://www.efsa.europa.eu/en/press/news/070702

European Food Safety Authority. (2014). *Multi-annual programme on International Scientific Cooperation 2014–2016*. Luxembourg: Publications Office of the European Union.

European Parliament. (2015). Negotiations for the Transatlantic Trade and Investment Partnership (TTIP): European Parliament resolution of 8 July 2015 containing the European Parliament's recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership (TTIP). 2014/2228(INI). Retrieved from http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0252+0+DOC+PDF+V0//EN

European Parliament & Council. (2008). Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0765

European Parliament & Council. (2012). Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance.

European Parliamentary Research Service. (2015). Consumer protection in the EU: A policy overview. Retrieved from http://www.europarl.europa.eu/RegData/etudes/IDAN/2015/565904/EPRS_IDA(2015)565904_EN.pdf

European-American Business Council. (2011a). *EABC + AHIMA Recommended Actions Following the EU-US eHealth MOU*. Retrieved from http://www.transatlanticbusiness.org/wp-content/uploads/2014/05/EABC-+-AHIMA-EU-US-eHealth-Actions-2011-2012-June-27.pdf

European-American Business Council. (2011b). *US-EU eAccessibility Standardization*. Retrieved from http://www.transatlanticbusiness.org/wp-content/uploads/2014/05/EABC-eAccessibility-TEC-Policy-Paper-2011-2011-October-17-Noon.pdf

Eurostat. (2017). International trade in goods. Retrieved from http://ec.europa.eu/eurostat/web/international-trade-in-goods/data/database

Evans, P. B. (2003). Is trade policy democratic? And should it be? In N. Bayne & S. Woolcock (Eds.), *The G8 and global governance series. The new economic diplomacy: Decision-making and negotiation in international economic relations*. Aldershot: Ashgate: 147–159.

Evans, P. B., Jacobson, H. K., & Putnam, R. D. (1993). *Double-edged diplomacy: International bargaining and domestic politics*. Berkeley, CA: University of California Press.

Evenett, S. J., & Stern, R. M. (Eds.). (2011). *Systemic implications of transatlantic regulatory cooperation and competition*. Hackensack, NJ: World Scientific.

Falke, A. (2005). EU–USA Trade Relations in the Doha Development Round: Market Access Versus a Post-modern Trade Policy Agenda. *European Foreign Affairs Review*, *10*(1), 1–20.

Falkner, G. (Ed.). (2013). *EU policies in a global perspective: Shaping or taking international regimes? Routledge series on global order studies*. London: Routledge.

Falkner, G., Hartlapp, M., & Treib, O. (2007). Worlds of compliance: Why leading approaches to European Union implementation are only sometimes-true theories? *European Journal of Political Research*, *46*(3), 395–416.

Falkner, G., & Müller, P. (2013). *EU Policies in a Global Perspective: Shaping Or Taking International Regimes?* London: Routledge.

Farrell, H., & Finnemore, M. (2009). Ontology, methodology, and causation in the American school of international political economy. *Review of International Political Economy*, *16*(1), 58–71.

Farrell, H., & Newman, A. (2015). The new politics of interdependence: cross-national layering in Trans-Atlantic regulatory disputes. *Comparative Political Studies*, *48*(4), 497–526.

Farrell, H., & Newman, A. (2016). The new interdependence approach: theoretical development and empirical demonstration. *Review of International Political Economy*, *23*(5), 713–736.

Farrell, H., & Newman, A. L. (2010). Making global markets: Historical institutionalism in international political economy. *Review of International Political Economy*, *17*(4), 609–638.

Farrell, H., & Newman, A. L. (2014). Domestic institutions beyond the nation-state: Charting the new interdependence approach. *World Politics*, *66*(2), 331–363.

Featherstone, K., & Radaelli, C. M. (Eds.). (2003). *The politics of Europeanisation*. Oxford: Oxford University Press.

Federal Communications Commission (FCC). (2015). Post-Market Surveillance Requirements for TCBs. Retrieved from https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=20540&switch=P

Federal Trade Commission (FTC). (2011). Does the EU Need a System of Private Competition Remedies to Supplement Public Law Enforcement? Remarks of J. Thomas Rosch* Commissioner, Federal Trade Commission. Retrieved from https://www.ftc.gov/sites/default/files/documents/public_statements/does-eu-need-system-private-competition-remedies-supplement-public-law-enforcement/110923privatecomp.pdf

Filipec, O. (2014). U.S. chemical policy under review: How much Europeanisation. *Eastern Journal of European Studies*, *5*(2), 159–180.

Finnemore, M. (1996). *National interests in international society*. Ithaca, NY: Cornell University Press.

Finnemore, M., & Sikkink, K. (2001). Taking stock: The Constructivist Research Program in International Relations and Comparative Politics. *Annual Revue of Political Science*, *4*, 391–416.

Finnemore, M., & Sikkink, K. (1998). International Norm Dynamics and Political Change. *International organization*, *52*(4), 887–917.

Fioretos, K.-O. (Ed.). (2017). *International politics and institutions in time*. Oxford: Oxford University Press.

Fioretos, O. (2011). Historical Institutionalism in International Relations. *International organization*, *65*(2), 367–399.

Fliess, B. (2010). *The Use of International Standards in Technical Regulation* (OECD Trade Policy Papers). Paris.

Follesdal, A., & Hix, S. (2006). Why There is a Democratic Deficit in the EU: A Response to Majone and Moravcsik. *Journal of Common Market Studies*, *44*(3), 533–562.

Fontagné, L., Gourdon, J., & Jean, S. (2013). Transatlantic Trade: Whither Partnership, Which Economic Consequences? Retrieved from http://www.cepii.fr/pdf_pub/pb/2013/pb2013-01.pdf

Fontanella-Khan, J. (2013). Data protection ruled out of EU-US trade talks. *Financial Times*.

Franchino, F. (2000). Control of the Commission's Executive Functions: Uncertainty, Conflict and Decision Rules. *European Union Politics*, *1*(1), 63–92.

Francois, J., Manchin, M., & Norberg, H. (2012). *Reducing Transatlantic Barriers to Trade and Investment: An Economic Assessment*. Prepared under implementing Framework Contract TRADE10/A2/A16. Retrieved from http://trade.ec.europa.eu/doclib/html/150737.htm

Frennhoff Larsén, M. (2007). Trade Negotiations between the EU and South Africa: A Three-Level Game. *Journal of Common Market Studies*, *45*(4), 857–881.

freshfel. (2015). Freshfel statement on TTIP negotiations. Retrieved from https://www.eesc.europa.eu/resources/docs/20150629---freshfel-statement-on-ttip-negotiations.pdf

Freund, C., & Oliver, S. (2015). Gains from Convergence in US and EU Auto Regulations under TTIP. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers: 505–536.

Frieden, J. (1991). Invested interests: The politics of national economic policies in a world of global finance. *International organization*, *45*(4), 425–451.

Frieden, J. (1999). Actors and Preferences in International Relations. In D. A. Lake & R. Powell (Eds.), *Strategic Choice and International Relations*. Princeton, NJ: Princeton University Press: 39–76.

Frieden, J. (2006). *Global capitalism: Its fall and rise in the twentieth century*. London: Norton.

Friends of the Earth. (2016). Dangerous Liaisons: The New Trade Trio. Retrieved from http://www.foei.org/wp-content/uploads/2016/11/foe-trade-bookletWEB.pdf

Gardner, A. (1997). *A New Era in US-EU Relations? The Clinton Administration and the New Transatlantic Economic Agenda*. Aldershot: Ashgate.

Garrett, G., & Lange, P. (1991). Political responses to interdependence: What's “left” for the left? *International organization*, *45*(4), 539–564.

Garrett, G., & Lange, P. (1995). Internationalization, institutions, and political change. *International Organization*, *49*(04), 627.

Garrett, G., & Weingast, B. (1993). Ideas, Interests, and Institutions: Constructing the European Community"s Internal Market. In J. L. Goldstein & R. O. Keohane (Eds.), *Cornell studies in political economy. Ideas and foreign policy: Beliefs, institutions, and political change*. Ithaca, NY: Cornell University Press: 179–206.

Gehring, T., Oberthür, S., & Mühleck, M. (2013). European Union Actorness in International Institutions: Why the EU is Recognized as an Actor in Some International Institutions, but Not in Others. *Journal of Common Market Studies*, *51*(5), 849–865.

George, A. L., & Bennett, A. (2005). *Case studies and theory development in the social sciences*. Cambridge MA: MIT Press.

George, A. L., & McKeown, T. J. (1985). Case Studies and Theories of Organizational Decision Making. In R. A. Smith & R. F. Coulam (Eds.), *Advances in Information Processing in Organizations: Research on Public Organizations*. London: JAI Press: 21–58.

Gerring, J. (2001). *Social science methodology: A criterial framework*. Cambridge: Cambridge University Press.

Gerring, J. (2004). What Is a Case Study and What Is It Good for? *American Political Science Review*, *98*(2), 341–354.

Gerstetter, C. (2013). *Legal implications of the EU-US trade and investment partnership (TTIP) for the Acquis Communautaire and the ENVI relevant sectors that could be addressed during negotiations* (Study No. 09). Brussels.

Gilardi, F. (2012). Transnational diffusion: Norms, ideas, and policies. In W. Carlsnaes, T. Risse-Kappen, & B. A. Simmons (Eds.), *Handbook of international relations* (2nd ed.). London: SAGE: 453–477.

Gilpin, R. (2001). *Global Political Economy: Understanding the International Economic Order*. Princeton, NJ: Princeton University Press.

Goldstein, J. (1988). Ideas, institutions, and American trade policy. *International Organization*, *42*(01), 179.

Goldstein, J. (1996). International law and domestic institutions: reconciling North American "unfair" trade laws. *International organization*, *50*(4), 541–564.

Goldstein, J. L., & Keohane, R. O. (Eds.). (1993). *Ideas and foreign policy: Beliefs, institutions, and political change*. *Cornell studies in political economy*. Ithaca, NY: Cornell University Press.

Goldthorpe, J. H. (2000). *On sociology: Numbers, narratives, and the integration of research and theory*. Oxford: Oxford University Press.

Götz, M. (2018, forthcoming). Representation of SME interests in the TTIP negotiations: A German case study. In D. Dialer & M. Richter (Eds.), *Lobbying in the European Union: Successful Strategies and Techniques.* Wiesbaden: Springer.

Gourevitch, P. (1978). The second image reversed: The international sources of domestic politics. *International organization*, *32*(4), 881–912.

Gourevitch, P. (1986). *Politics in hard times: Comparative responses to international economic crises*. *Cornell studies in political economy*. Ithaca, NY: Cornell University Press.

Graziano, P., Jacquot, S., & Palier, B. (2011). *The EU and the domestic politics of welfare state reforms*. *Work and welfare in Europe*. Basingstoke: Palgrave Macmillan.

Greenpeace. (2015). Freihandelsabkommen TTIP: Gift für den Menschen. Retrieved from https://www.greenpeace.de/sites/www.greenpeace.de/files/publications/ttip-kosmetika_10_2015.pdf

Greenpeace. (2016). Regulatory Cooperation under CETA: Implications for Environmental Policies. Retrieved from https://www.greenpeace.de/sites/www.greenpeace.de/files/publications/20161104_greenpeace_studie_regulatorycooperationunderceta.pdf

Greenstein, F. I., & Wolsby, N. W. (Eds.). (1975). *Handbook of Political Science*. Reading, MA: Addison-Wesley.

Groenleer, M. (2014). Managing financial regulation: The Regulator's toolkit, the role of private actors, and internationalisation. *Public Administration*, *92*(3), 769–775.

Grossman, E. (2004). Bringing politics back in: Rethinking the role of economic interest groups in European integration. *Journal of European Public Policy*, *11*(4), 637–654.

Grossman, G., & Helpman, E. (1994). Protection For Sale. *American Economic Review*, *84*(4), 833–850.

Grueff, J., & Tangermann, S. (2013). *Achieving a Successful Outcome for Agriculture in the EU–U.S. Transatlantic Trade and Investment Partnership Agreement* (Discussion Paper). Washington, D.C. Retrieved from International Food & Agricultural Trade Policy Council website: http://www.agritrade.org/Publications/documents/FINAL_US_EU_FTA_fordistribution.pdf

Grugel, J. (2007). Democratization and Ideational Diffusion: Europe, Mercosur and Social Citizenship. *Journal of Common Market Studies*, *45*(1), 43–68.

Gschwend, T., & Schimmelfennig, F. (Eds.). (2007). *Research design in political science: How to practice what they preach*. Basingstoke: Palgrave Macmillan.

Haas, P. M. (1992). Epistemic communities and international policy coordination. *International organization*, *46*(1), 1.

Hall, P. A. (1993). Policy Paradigms, Social Learning, and the State: The Case of Economic Policymaking in Britain. *Comparative Politics*, *25*(3), 275–296.

Hall, P. A. (2005). Preference formation as a political process: The case of the monetary union in Europe. In I. Katznelson & B. R. Weingast (Eds.), *Preferences and Situations: Points of Intersection Between Historical and Rational Choice Institutionalism.* New York: Russell Sage Foundation.

Hall, P. A. (2008). Systematic Process Analysis: When and how to use it. *European Political Science*, *7*(3), 304–317.

Hall, P. A. (2010). Historical institutionalism in rationalist and sociological perspective. In J. Mahoney & K. A. Thelen (Eds.), *Explaining institutional change: Ambiguity, agency, and power.* Cambridge: Cambridge University Press.

Hall, P. A., & Taylor, R. C. R. (2016). Political Science and the Three New Institutionalisms. *Political Studies*, *44*(5), 936–957.

Hamilton, D. S., & Pelkmans, J. (2015). Rule-makers or rule-takers? An introduction to TTIP. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers: 1–16.

Hamilton, D. S., & Quinlan, J. P. (Eds.). (2005). *Deep integration, how transatlantic markets are leading globalization*. Retrieved from https://www.ceps.eu/publications/deep-integration-how-transatlantic-markets-are-leading-globalization

Hamilton, D. S., & Quinlan, J. P. (Eds.). (2007). *Sleeping Giant: Awakening the Transatlantic Services Economy*. Washington D.C.: Brookings Institution Press.

Hanegraaff, M., Braun, C., Bièvre, D. de, & Beyers, J. (2015). The Domestic and Global Origins of Transnational Advocacy: Explaining. Lobbying Presence During WTO Ministerial Conferences. *Comparative Political Studies*, *48*(12), 1591–1621.

Hartlapp, M., Metz, J., & Rauh, C. (2010). *The agenda set by the EU Commission: the result of balanced or biased aggregation of positions?* London. *LSE 'Europe in Question' Discussion Paper Series*.

Hartzog, W., & Solove, D. J. (2014). The Scope and Potential of FTC Data Protection. *George Washington Law Review*. (2230).

Häusermann, S. (2010). Solidarity with whom? Why organised labour is losing ground in Continental pension politics. *European Journal of Political Research*, *49*(2), 223–256.

Hawkins, D., & Jacoby, W. (2006). How Agents Matter. In D. Hawkins, D. A. Lake, D. A. Nielson, & M. J. Tierney (Eds.), *Delegation and Agency in International Organizations*. Cambridge: Cambridge University Press: 199–228.

Hawkins, D., Lake, D. A., Nielson, D. A., & Tierney, M. J. (Eds.). (2006). *Delegation and Agency in International Organizations*. Cambridge: Cambridge University Press.

Heims, E. M. (2016). Regulatory co-ordination in the EU: A cross-sector comparison. *Journal of European Public Policy*, *24*(8), 1116–1134.

Héritier, A., & Lehmkuhl, D. (2008). Introduction: the shadow of hierarchy and new modes of governance. *Journal of Public Policy*, *28*(1), 1–17.

Heyvaert, V. (2009). Globalizing Regulation: Reaching Beyond the Borders of Chemical Safety. *Journal of Law and Society*, *36*(1), 110–128.

High Level Working Group on Jobs and Growth. (2013). *Final Report*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf

Hill, C. (1990). European Foreign Policy: Power Bloc, Civilian Model - or Flop? In R. Rummel (Ed.), *The evolution of an international actor: Western Europe's new assertiveness*. Boulder: Westview Press: 31–55.

Hiscox, M. J. (2002). *International trade and political conflict: Commerce, coalitions, and mobility*. Princeton, NJ: Princeton University Press.

Hocking, B., & McGuire, S. (2002). Government-Business Strategies in EU-US Economic Relations. *Journal of Common Market Studies*, *40*(3), 449–470.

Holmes, P., & Young, A. R. (2001). Emerging Regulatory Challenges to the EU's External Economic Relations. Retrieved from https://www.sussex.ac.uk/webteam/gateway/file.php?name=sei-working-paper-no-42.pdf&site=266

Holzinger, K., & Knill, C. (2005). Causes and Conditions of Cross-National Policy Convergence. *Journal of European Public Policy*, *12*(5), 775–796.

Holzinger, K., Knill, C., & Sommerer, T. (2008). Environmental Policy Convergence: The Impact of International Harmonization, Transnational Communication, and Regulatory Competition. *International organization*, *62*(4), 553-587.

Holzinger, K., & Sommerer, T. (2013). EU environmental policy: greening the world? In G. Falkner (Ed.), *Routledge series on global order studies. EU policies in a global perspective: Shaping or taking international regimes?* London: Routledge: 111–130.

Hooghe, L., & Marks, G. (2001). *Multi-level governance and European integration*. *Governance in Europe*. Lanham, MD: Rowman & Littlefield.

Hristova, V. (2013). Food safety: the resilient resistance of the EU. In G. Falkner (Ed.), *Routledge series on global order studies. EU policies in a global perspective: Shaping or taking international regimes?* London: Routledge: 58–75.

Hufbauer, G. C., & Jung, E. (2016). *The US-EU Privacy Shield Pact: A Work in Progress* (Policy Brief). *2016*, *12*. Retrieved from https://piie.com/publications/policy-briefs/us-eu-privacy-shield-pact-work-progress

Ikenberry, G. J. (2001). *After victory: Institutions, strategic restraint, and the rebuilding of order after major wars*. *Princeton Studies in International History and Politics*. Princeton, NJ: Princeton University Press.

Inside US Trade. (2010a). TEC meeting yields new commitments on raw materials, secure shippers. 24 December.

Inside US Trade. (2010b). U.S., EU Without Common Vision For TEC In Advance Of De Gucht Visit. 7 May.

Inside US Trade. (2010c). US, EU to unveil new areas of regulatory cooperation at TEC meeting. 26 November.

Inside US Trade. (2011a). Back to results (previous record) Document 6 of 12 (next record) Kirk, EU Health Official Discuss Beef Lactic Acid Wash, Other SPS Issues. 23 September.

Inside US Trade. (2011b). EU, U.S. to explore deeper economic ties by end of 2012, including FTA. 2 December.

Inside US Trade. (2012a). EU-U.S. officials discuss options for regulatory cooperation in HLWG. 12 October.

Inside US Trade. (2012b). Meat groups demand solution for thorny SPS problems in EU-U.S. FTA. 9 November.

Inside US Trade. (2012c). U.S. Presses for Changes on EU Regulation On Lactic Acid Beef Wash. 17 February.

Inside US Trade. (2012d). U.S.-EU Working Group Report likely delayed; Business coalition gears up. 21 December.

Inside US Trade. (2013a). Business Groups Prioritize Action On Cross-Border Data Flows In TTIP. 31 May.

Inside US Trade. (2013b). Commission's TBT Position Paper Seeks To Assuage TTIP Deregulation Fears. 29 October.

Inside US Trade. (2013c). EU Sets Most Ambitious Goals In Auto Sector Regulations In TTIP Talks. 12 July.

Inside US Trade. (2013d). MEP Calls For Common U.S.-EU Data Privacy Standards Parallel To TTIP. 28 June.

Inside US Trade. (2013e). U.S. Chemicals, Pesticides Makers Rail Against EU Endocrine Proposal. 15 November.

Inside US Trade. (2014a). De Gucht rebuts claims TTIP will freeze Chemicals regulations. 24 October.

Inside US Trade. (2014b). EU Approach To SPS 'Equivalency' In TTIP Echoes Failed Veterinary Deal. 15 August.

Inside US Trade. (2014c). EU Official Says TTIP Regulatory Proposal 'Inspired' by EU System. 21 November.

Inside US Trade. (2014d). EU Seeks To Tackle Food Safety 'Equivalency' With TTIP SPS Proposal. 18 July.

Inside US Trade. (2014e). New TTIP Pilot Programs Show Chemical Industry Ideas Gaining Traction. 8 August.

Inside US Trade. (2014f). TTIP Negotiators Point To Technical Work To Demonstrate Forward Motion. 3 October.

Inside US Trade. (2014g). U.S., EU Manufacturing Groups Slowly Build Common Ground on TTIP. 31 October.

Inside US Trade. (2014h). Vilsack Says SPS, Regulations In Forefront Of TTIP More Than 'Market Access'. 2 May.

Inside US Trade. (2015). TTIP Negotiators Create Joint Text on Regulatory Cooperation, Discuss TBT. 1 May.

Inside US Trade. (2016a). 12th TTIP round to focus on new proposals, regulatory work. 19 February.

Inside US Trade. (2016b). EU Engineering Proposal in TTIP Signals Lack of U.S. Engagement. 22 July.

Inside US Trade. (2016c). EU Readies Five Regulatory Cooperation Proposals for Next TTIP Round. 27 May.

Inside US Trade. (2016d). O'Sullivan: No Work on TTIP Digital Chapter until Privacy Shield in Place. 20 May.

Institute for Agriculture and Trade Policy. (2014). Trading away localization in TTIP: Commentary. Retrieved from https://www.iatp.org/files/2014_05_01_Localization_KHK.pdf

Institute for Agriculture and Trade Policy. (2016). *Leaked TTIP text shows U.S. negotiators push to lower food safety standards, farmer protections*. Retrieved from https://www.iatp.org/documents/leaked-ttip-text-shows-us-negotiators-push-to-lower-food-safety-standards-farmer-protectio

International Centre for Trade and Sustainable Development. (2016). *Maximizing the Opportunities of the Internet for International Trade*. Retrieved from http://www3.weforum.org/docs/E15/WEF_Digital_Trade_report_2015_1401.pdf

Jabko, N. (2006). *Playing the market: A political strategy for uniting Europe, 1985–2005*. Ithaca, NY: Cornell University Press.

Jacoby, W., & Meunier, S. (2010). Europe and the management of globalization. *Journal of European Public Policy*, *17*(3), 299–317.

Jacquot, S., & Woll, C. (2003). Usage of European integration – Europeanization from a sociological perspective. Retrieved from http://www.eiop.or.at/eiop/texte/2003-012a.htm

Jensen, M. D., Koop, C., & Tatham, M. (2014). Coping with power dispersion? Autonomy, co-ordination and control in multilevel systems. *Journal of European Public Policy*, *21*(9), 1237–1254.

Joachim, J. (2003). Framing issues and seizing opportunities: The UN, NGOs, and women's rights. *International Studies Quarterly*, *47*(2), 247–274.

Johnson, R. (2012). U.S.-EU Poultry Dispute on the Use of Pathogen Reduction Treatments (PRTs). Retrieved from https://fas.org/sgp/crs/misc/R40199.pdf

Jordana, J., & Levi-Faur, D. (2004). *The politics of regulation: Examining regulatory institutions and instruments in the age of governance*. *The CRC series on competition, regulation and development*. Cheltenham: Edward Elgar Publishing.

Jordana, J., Levi-Faur, D., & i Marín, Xavier Fernández. (2011). The global diffusion of regulatory agencies: channels of transfer and stages of diffusion. *Comparative Political Studies*, *44*(10), 1343–1369.

Jørgensen, K. E. (2006). Intersecting Multilateralisms: The European Union and Multilateral Institutions. In K. Laatikainen & K. Smith (Eds.), *The European Union at the United Nations: Intersecting Multilateralisms*. Wiesbaden: Springer: 195–211.

Jørgensen, K. E. (2009). *The European Union and international organizations*. London: Routledge.

Jørgensen, K. E., Oberthür, S., & Shahin, J. (2011). Introduction: Assessing the EU's Performance in International Institutions – Conceptual Framework and Core Findings. *Journal of European Integration*, *33*(6), 599–620.

Josling, T. E., & Tangermann, S. (2015a). Agriculture, Food and TTIP: Possibilities and pitfalls. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers: 259–296.

Josling, T. E., & Tangermann, S. (2015b). *Transatlantic food and agricultural trade policy: 50 years of conflict and convergence*. Cheltenham: Edward Elgar Publishing.

Jupille, J., & Caporaso, J. A. (1998). States, Agency, and Rules: The European Union in Global Environmental Politics. In C. Rhodes (Ed.), *The European Union in the world community*. Boulder, CO: Lynne Rienner Publishers: 213–230.

Kahler, M. (2009). *Networked politics: Agency, power, and governance*. *Cornell studies in political economy Cornell paperbacks*. Ithaca, NY: Cornell University Press.

Kahler, M., & Lake, D. A. (2003). *Governance in a global economy: Political authority in transition*. Princeton, NJ: Princeton University Press.

Kassim, H., Peterson, J., Bauer, M., Connolly, S., Dehousse, R., Hooghe, L., & Thompson, A. (2013). *The European Commission of the twenty-first century*. Oxford: Oxford University Press.

Katzenstein, P. J. (Ed.). (1978). *Between Power and Plenty: Foreign Economic Policies of Advanced Industrial States*. Madison, WI: University of Wisconsin Press.

Katzenstein, P. J. (1985). *Small states in world markets: Industrial policy in Europe*. Ithaca, NY: Cornell University Press.

Katzenstein, P. J. (2009). Mid-Atlantic: Sitting on the knife's sharp edge. *Review of International Political Economy*, *16*(1), 122–135.

Katznelson, I., & Milner, H. V. (Eds.). (2002). *Political science: State of the discipline*. New York: W.W. Norton.

Katznelson, I., & Weingast, B. R. (Eds.). (2005). *Preferences and Situations: Points of Intersection Between Historical and Rational Choice Institutionalism*. New York: Russell Sage Foundation.

Kauffmann, C., & Mayshev, N. (2015). *International Regulatory Co-operation: The Menu of Approaches: E15 Task Force on Regulatory Systems Coherence Think Piece*. Retrieved from International Centre for Trade and Sustainable Development website: http://e15initiative.org/wp-content/uploads/2015/09/E15-Regulatory-Kauffmann-and-Malyshev-final.pdf

Keck, M., & Sikkink, K. (1998). *Activists beyond borders: Transnational activist networks in international politics*. Ithaca, NY: Cornell University Press.

Kelemen, R. D. (2010). *Eurolegalism: The transformation of law and regulation in the European Union*. Cambridge, MA: Harvard University Press.

Kelemen, R. D., & Tarrant, A. D. (2011). The Political Foundations of the Eurocracy. *West European Politics*, *34*(5), 922–947.

Kelemen, R. D., & Vogel, D. (2010). Trading Places: The Role of the United States and the European Union in International Environmental Politics. *Comparative Political Studies*, *43*(4), 427–456.

Kelly, D., & Grant, W. (Eds.). (2005). *The politics of international trade in the 21st century: Actors, issues, and regional dynamics*. *International political economy series*. Basingstoke: Palgrave Macmillan.

Keohane, R. O. (1984). *After hegemony: Cooperation and discord in the world political economy*. Princeton, NJ: Princeton University Press.

Keohane, R. O. (2009). The old IPE and the new. *Review of International Political Economy*, *16*(1), 34–46.

Keohane, R. O. (2017). Observations on the Promise and Pitfalls of Historical Institutionalism in International Relations. In K.-O. Fioretos (Ed.), *International politics and institutions in time*. Oxford: Oxford University Press: 321–336.

Keohane, R. O., & Martin, L. L. (1995). The Promise of Institutionalist Theory. *International Security*, *20*(1), 39–51.

Keohane, R. O., & Nye, J. S. (1974). Transgovernmental relations and international organizations. *World Politics*, *27*(1), 39–62.

Keohane, R. O., & Nye, J. S. (1977). *Power and interdependence: World politics in transition*. Boston MA: Little Brown.

Keohane, R. O., & Nye, J. S. (1987). Power and Interdependence revisited. *International organization*, *41*(4), 725–753.

Keohane, R. O., & Victor, D. G. (2011). The regime complex for climate change. *Perspectives on politics*, *9*(1), 7–23.

Kiewiet, D. R., & McCubbins, M. D. (1991). *The logic of delegation: Congressional parties and the appropriations process*. Chicago: University of Chicago Press.

Kim, I. S. (2017). Political Cleavages within Industry: Firm-level Lobbying for Trade Liberalization. *American Political Science Review*, *111*(01), 1–20.

King, G., Keohane, R. O., & Verba, S. (1994). *Designing social inquiry: Scientific inference in qualitative research*. Princeton, NJ: Princeton University Press.

Kissack, R. (2011). The Performance of the European Union in the International Labour Organization. *Journal of European Integration*, *33*(6), 651–665.

Kissack, R. (2015). 'Man Overboard!': Was EU influence on the Maritime Labour Convention lost at sea? *Journal of European Public Policy*, *22*(9), 1295–1315.

Klein, N. (2000). *No logo: No space, no choice, no jobs*. London: Fourth Estate.

Klüver, H. (2012). *Lobbying in the European Union: Interest groups, lobbying coalitions, and policy change*. Oxford: Oxford University Press.

Knill, C. (2005). Introduction: Cross-national policy convergence: concepts, approaches and explanatory factors. *Journal of European Public Policy*, *12*(5), 764–774.

Kohler-Koch, B., & Rittberger, B. (2006). The 'Governance Turn' in EU Studies. *Journal of Common Market Studies*, *44*(1), 27–49.

Kohnstamn, M. (Ed.). (1973). *Nation writ large? Foreign-policy problems before the European Community*. Basingstoke: Palgrave Macmillan.

Kommerskollegium. (2015). *Regulatory Co-operation and Technical Barriers to Trade within Transatlantic Trade and Investment Partnership (TTIP)*. Retrieved from https://www.kommers.se/Documents/dokumentarkiv/publikationer/2015/Publ-Regulatory-Co-operation-and-Technical-Barriers-to-Trade-within-TTIP.pdf

Koremenos, B., Lipson, C., & Snidal, D. (2001). The rational design of international institutions. *International organization*, *55*(4), 761–799.

Krasner, S. D. (1976). State Power and the Structure of International Trade. *World Politics*, *28*(3), 317–347.

Krasner, S. D. (Ed.). (1983). *International regimes* (2. print). Ithaca, NY: Cornell University Press.

Krasner, S. D. (1991). Global communications and national power: Life on the Pareto frontier. *World Politics*, *43*(3), 336–366.

Krasner, S. D. (2011). Changing state structures: Outside in. *Proceedings of the National Academy of Sciences of the United States of America*, *108*, 21302–21307.

Kudrna, Z. (2013). EU financial market regulation: protecting distinct policy preferences. In G. Falkner (Ed.), *Routledge series on global order studies. EU policies in a global perspective: Shaping or taking international regimes?* London: Routledge: 186–205.

Kudrna, Z., & Müller, P. (2016). Harmonizing Internationally to Harmonize Internally: Accounting for a Global Exit from the EU's Decision Trap. *Journal of Common Market Studies*, *55*(4), 815–831.

Laatikainen, K., & Smith, K. (Eds.). (2006). *The European Union at the United Nations: Intersecting Multilateralisms*. Wiesbaden: Springer.

Laidi, Z. (2008). The Unintended Consequences of European Power. *Les Cahiers européene de Sciences Po*, *5*.

Lake, D. A. (2009). Open economy politics: A critical review. *The Review of International Organizations*, *4*(3), 219–244.

Lake, D. A., & Powell, R. (Eds.). (1999). *Strategic Choice and International Relations*. Princeton, NJ: Princeton University Press.

Lavenex, S. (2004a). EU external governance in 'wider Europe'. *Journal of European Public Policy*, *11*(4), 680–700.

Lavenex, S. (2004b). EU external governance in'wider Europe'. *Journal of European Public Policy*, *11*(4), 680–700.

Lavenex, S. (2014). The power of functionalist extension: How EU rules travel. *Journal of European Public Policy*, *21*(6), 885–903.

Lavenex, S., & Schimmelfennig, F. (2009). EU rules beyond EU borders: theorizing external governance in European politics. *Journal of European Public Policy*, *16*(6), 791–812.

Leech, B. L. (2002). Asking Questions: Techniques for Semistructured Interviews. *PS: Political Science & Politics*, *35*(04), 665–668.

Lenschow, A., & Knill, C. (2005). Compliance, Competition and Communication: Different Approaches of European Governance and their Impact on National Institutions. *Journal of Common Market Studies*, *43*(3), 583–606.

Lester, S., & Barbee, I. (2013). The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership. *Journal of International Economic Law*, *16*(4), 847–867.

Leuffen, D. (2007). Case selection and selection in small-n research. In T. Gschwend & F. Schimmelfennig (Eds.), *Research design in political science: How to practice what they preach*. Basingstoke: Palgrave Macmillan: 145–162.

Levi-Faur, D. (2005). The Global Diffusion of Regulatory Capitalism. *The ANNALS of the American Academy of Political and Social Science*, *598*(1), 12–32.

Levi-Faur, D. (2011). Regulatory networks and regulatory agencification: towards a single European regulated space. *Journal of European Public Policy*, *18*(6), 810–829.

Lewis, J. (2005). The Janus Face of Brussels: Socialization and Everyday Decision Making in the European Union. *International Organization*, *59*(04), 559.

Lewis, N. D. (2001). *Law and Governance: The Old Meets the New*. London: Cavendish Publishing.

Lieberman, R. C. (2002). Ideas, Institutions, and Political Order: Explaining Political Change. *American Political Science Review*, *96*(4), 697–712.

Long, W. J., & Quek, M. P. (2002). Personal data privacy protection in an age of globalization: The US-EU safe harbor compromise. *Journal of European Public Policy*, *9*(3), 325–344.

Lowi, T. J. (1964). American Business, Public Policy, Case-Studies, and Political Theory. *World Politics*, *16*(4), 677–715.

Lucarelli, S., & Manners, I. (Eds.). (2006). *Values and principles in European Union foreign policy*. London: Routledge.

Maggetti, M. (2012). *Regulation in practice: The de facto independence of regulatory agencies*. Colchester: ECPR.

Maggetti, M., & Gilardi, F. (2014). Network governance and the domestic adoption of soft rules. *Journal of European Public Policy*, *21*(9), 1293–1310.

Mahoney, C. (2008). *Brussels versus the Beltway: Advocacy in the United States and the European Union*. *American governance and public policy*. Washington, D.C: Georgetown University Press. Retrieved from http://www.jstor.org/stable/10.2307/j.ctt2tt58r

Mahoney, J. (2005). Qualitative Methodology and Comparative Politics. *Comparative Political Studies*, *40*(2), 122–144.

Mahoney, J., & Thelen, K. (2009). *Explaining institutional change: ambiguity, agency, and power*. Cambridge: Cambridge University Press.

Mahoney, J., & Thelen, K. (2010). A theory of gradual institutional change. In J. Mahoney & K. A. Thelen (Eds.), *Explaining institutional change: Ambiguity, agency, and power.* Cambridge: Cambridge University Press.

Mahoney, J., & Thelen, K. A. (Eds.). (2010). *Explaining institutional change: Ambiguity, agency, and power*. Cambridge: Cambridge University Press.

Maier, M. L. (2008). *The regulatory state goes global: EU participation in international food standard-setting by the Codex Alimentarius Commission*. Bonn: Federal Ministry of Food, Agriculture and Consumer Protection.

Majone, G. (1994). The rise of the regulatory state in Europe. *West European Politics*, *17*(3), 77–101.

Majone, G. (1996). *Regulating Europe*. London: Routledge.

Manger, M. S. (2009). *Investing in protection: The politics of preferential trade agreements between North and South*. Cambridge: Cambridge University Press.

Manheim, J. B., & Rich, R. C. (1995). *Empirical political analysis: Research methods in political science* (4. ed.). White Plains, NY: Longman.

Manners, I. (2002). Normative power Europe: a contradiction in terms? *Journal of Common Market Studies*, *40*(2), 235–258.

Manners, I. (2006). The European Union as a normative power: a response to Thomas Diez. *Millennium*, *35*(1), 167–180.

March, J. G., & Olsen, J. P. (1983). The New Institutionalism: Organizational Factors in Political Life. *American Political Science Review*, *78*(3), 734–749.

March, J. G., & Olsen, J. P. (2008). Elaborating the "New Institutionalism". In S. A. Binder, R. A. W. Rhodes, & B. A. Rockham (Eds.), *The Oxford handbooks of political science. The Oxford handbook of political institutions*. Oxford: Oxford University Press: 2–23.

Marks, G., Scharpf, F. W., Schmitter, P. C., & Streeck, W. (Eds.). (1996). *Governance in the European Union*. London: SAGE.

Marsh, D., & Stoker, G. (2010). *Theory and methods in political science* (3rd ed.). Basingstoke: Palgrave Macmillan.

Mattli, W., & Büthe, T. (2003). Setting International Standards: Technological Rationality or Primacy of Power? *World Politics*, *56*(1), 1–42.

Mattli, W., & Woods, N. (Eds.). (2009). *The politics of global regulation*. Princeton, NJ: Princeton University Press.

Mayntz, R., & Scharpf, F. (1995). *Gesellschaftliche Selbstregelung und politische Steuerung*. *Schriften des Max-Planck-Instituts für Gesellschaftsforschung, Köln: Bd. 23*. Frankfurt, New York: Campus.

McGuire, M., & Agranoff, R. (2011). The Limitations of Public Management Networks. *Public Administration*, *89*(2), 265–284.

McGuire, S. M., & Smith, M. (2008). *The European Union and the United States. Competition and Convergence in the Global Arena,* Basingstoke: Palgrave Macmillan.

Messerlin, P. (2015). TTIP: The services dimension. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers: 341–370.

Meunier, S. (2005). *Trading voices: the European Union in international commercial negotiations*. Princeton, NJ: Princeton University Press.

Meunier, S. (2007). Managing Globalization? The EU in International Trade Negotiations. *Journal of Common Market Studies*, *45*(4), 905–926.

Meunier, S., & Nicolaidis, K. (2006). The European Union as a Conflicted Trade Power. *Journal of European Public Policy*, *13*(6), 906–925.

Milner, H. V. (1988). *Resisting protectionism: Global industries and the politics of international trade*. Princeton, NJ: Princeton University Press.

Milner, H. V. (1997). *Interests, institutions, and information: Domestic politics and international relations*. Princeton, NJ: Princeton University Press.

Moravcsik, A. (1993). Preferences and Power in the European Community: A Liberal Intergovernmentalist Approach. *Journal of Common Market Studies*, *31*(4), 473–524.

Moravcsik, A. (1997). Taking Preferences Seriously: A Liberal Theory of International Politics. *International organization*, *51*(4), 513–553.

Morgan, G. (Ed.). (2010). *The Oxford handbook of comparative institutional analysis* (1. publ. in paperback). Oxford: Oxford University Press.

Müller, P., Kudrna, Z., & Falkner, G. (2014). EU–global interactions: policy export, import, promotion and protection. *Journal of European Public Policy*, *21*(8), 1102–1119.

Naiki, Y. (2010). Assessing Policy Reach: Japan's Chemical Policy Reform in Response to the EU's REACH Regulation. *Journal of Environmental Law*, *22*(2), 171–195.

NEMA. (2013). NEMA Comments on TTIP Priorities: Transatlantic Trade and Investment Partnership Docket USTR—2013—0019. Retrieved from https://www.nema.org/Policy/Trade/Documents/NEMA%20Comments%20on%20TTIP%20Priorities%20May%209%202013.pdf

Netzpolitik. (2014). *TTIP and TiSA: big pressure to trade away privacy*. Retrieved from https://netzpolitik.org/2014/ttip-and-tisa-big-pressure-to-trade-away-privacy/

Newland, K. (1999). Workers of the world, now what? *Foreign Policy*, 52–65.

Newman, A. L. (2008). *Protectors of privacy: Regulating personal data in the global economy*. Ithaca, NY: Cornell University Press.

Newman, A. L. (2015). European Data Privacy Regulation on a Global Stage: Export or Experimentalism? In J. Zeitlin (Ed.), *Extending experimentalist governance? The European Union and transnational regulation*. Oxford: Oxford University Press: 227–246.

Newman, A. L., & Posner, E. (2011). International interdependence and regulatory power: Authority, mobility, and markets. *European Journal of International Relations*, *17*(4), 589–610.

Newman, A. L., & Posner, E. (2015). Putting the EU in its place: Policy strategies and the global regulatory context. *Journal of European Public Policy*, *22*(9), 1316–1335.

Nicolaïdis, K. A., & Egan, M. (2001). Transnational market governance and regional policy externality: Why recognize foreign standards? *Journal of European Public Policy*, *8*(3), 454–473.

Nicolaïdis, K. A., & Schmidt, S. K. (2007). Mutual recognition ‘on trial’: The long road to services liberalization. *Journal of European Public Policy*, *14*(5), 717–734.

Nicolaïdis, K. A., & Shaffer, G. (2005). Transnational Mutual Recognition Regimes: Governance Without Global Government. *Law and Contemporary Problems*, *68*(3), 263–318.

Niemann, A. (2004). Between communicative action and strategic action: The Article 113 Committee 1 and the negotiations on the WTO Basic Telecommunications Services Agreement. *Journal of European Public Policy*, *11*(3), 379–407.

Niemann, A., & Bretherton, C. (2013). EU external policy at the crossroads: The challenge of actorness and effectiveness. *International Relations*, *27*(3), 261–275.

Nordic. (2016). *What is CE marking*. Hällefors: CE marking Nordic. Retrieved from http://www.cemarkingnordic.se/pdf/english/what_is_ce_marking.pdf

Oatley, T. (2011). The reductionist gamble: Open economy politics in the global economy. *International organization*, *65*(2), 311–341.

Oberthür, S. (2011). The European Union’s Performance in the International Climate Change Regime. *Journal of European Integration*, *33*(6), 667–682.

Oberthür, S., & Gehring, T. (2006). *Institutional interaction in global environmental governance: Synergy and conflict among international and EU policies.* Cambridge, MA: MIT Press.

Oberthür, S., & Rabitz, F. (2013). On the EU's performance and leadership in global environmental governance: The case of the Nagoya Protocol. *Journal of European Public Policy*, *21*(1), 39–57.

Occupational Safety and Health Administration (OSHA). (2008). Nationally Recognized Testing Laboratories; Supplier's Declaration of Conformity. Retrieved from https://www.osha.gov/laws-regs/federalregister/2008-10-20

Occupational Safety and Health Administration (OSHA). (2010). Nationally Recognized Testing Laboratories; Supplier's Declaration of Conformity. Retrieved from https://www.osha.gov/laws-regs/federalregister/2010-12-17

OECD. (1980). OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data. Retrieved from http://www.oecd-ilibrary.org/science-and-technology/oecd-guidelines-on-the-protection-of-privacy-and-transborder-flows-of-personal-data_9789264196391-en

OECD. (2008a). OECD Glossary of Statistical Terms. Paris: OECD Publishing.

OECD. (2008b). OECD Policy Guidance for Digital Content. Retrieved from https://www.oecd.org/sti/ieconomy/40895797.pdf

OECD. (2010). *Trade & Innovation: Report on the Chemicals Sector* (OECD Trade Policy Working Paper). Paris: OECD Publishing, *103*.

OECD. (2013a). Chemical safety. In OECD (Ed.), *International Regulatory Co-operation: Addressing Global Challenges*. Paris: OECD Publishing: 9–26.

OECD (Ed.). (2013b). *International Regulatory Co-operation: Addressing Global Challenges*. Paris: OECD Publishing.

OECD. (2013c). OECD Privacy Guidelines. Retrieved from https://www.oecd.org/sti/ieconomy/2013-oecd-privacy-guidelines.pdf

OECD. (2014). OECD Principles for Internet Policy-Making. Retrieved from https://www.oecd.org/sti/ieconomy/oecd-principles-for-internet-policy-making.pdf

OECD. (2017). Trade in Services. Retrieved from https://data.oecd.org/trade/trade-in-services.htm

Orbie, J. (Ed.). (2008). *Europe's global role: External policies of the European Union* (Reprinted.). Farnham: Ashgate.

Orbie, J., & Tortell, L. (2009). *The European Union and the social dimension of globalization: How the EU influences the world*. London: Routledge.

Orgalime. (2011). EU manufacturers suffer from malfunctioning of the US certification market: Potential abuse of dominant position. Retrieved from http://www.orgalime.org/position/eu-manufacturers-suffer-malfunctioning-us-certification-market-potential-abuse-dominant

Orgalime. (2013). Orgalime position paper on the Negotiations of the comprehensive Transatlantic Trade and Investment Partnership. Retrieved from http://www.orgalime.org/sites/default/files/position-papers/PP_TTIP%20EU-US%20FTA_may13.pdf

Orgalime. (2014). *The Transatlantic Trade and Investment Partnership negotiations - a way forward: Position Paper*. Retrieved from http://www.orgalime.org/position/transatlantic-trade-and-investment-partnership-negotiations-way-forward

Orgalime. (2015). Orgalime comments on EU's position paper on the engineering industries and TTIP. Retrieved from http://www.orgalime.org/sites/default/files/position-papers/PP_TTIP_engineering_apr15.pdf

Orgalime. (2016). *Regulatory Cooperation in the Transatlantic Trade and Investment Partnership: Position Paper*. Retrieved from http://www.orgalime.org/position/regulatory-cooperation-transatlantic-trade-and-investment-partnership

Orgalime, & NEMA. (2014). TTIP: joint statement by EU and US industry associations Orgalime and NEMA. Retrieved from http://www.orgalime.org/sites/default/files/TTIP_Joint_position_Orgalime-NEMA_Oct14.pdf

Parker, R., & Alemanno, A. (2014). Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Regulatory Systems. Report commissioned by DG Trade. Retrieved from http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152466.pdf

Pelkmans, J. (2005). REACH: getting the chemistry right in Europe. In D. S. Hamilton & J. P. Quinlan (Eds.), *Deep integration, how transatlantic markets are leading globalization.* Brussels: Centre for European Policy Studies.

Pelkmans, J. (Ed.). (2015a). *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers.

Pelkmans, J. (2015b). *TTIP: Engineering, including Machinery: Study for the IMCO Committee*. Retrieved from http://www.europarl.europa.eu/RegData/etudes/STUD/2015/542233/IPOL_STU(2015)542233_EN.pdf

Pelkmans, J., & Brito, A. C. de. (2015). Transatlantic MRAs: Lessons for TTIP? Retrieved from https://www.ceps.eu/publications/transatlantic-mras-lessons-ttip

Pérez, D. R., & Dudley, S. (Eds.). (2016). *US-EU Regulatory Cooperation: Lessons & opportunities*. Washington, D.C: The George Washington University.

Peters, G. (1995). Bureaucracy in a divided regime: the United States. In J. Pierre (Ed.), *Bureaucracy in the modern state: An introduction to comparative public administration*. Cheltenham: Elgar: 18–38.

Peters, G. (1998). 'Managing horizontal government: the politics of co-ordination. *Public Administration*, *76*(2), 295–311.

Petersmann, E.-U., & Pollack, M. A. (Eds.). *Transatlantic Economic Disputes. The EU, the US, and the WTO*. Oxford: Oxford University Press.

Pierre, J. (Ed.). (1995). *Bureaucracy in the modern state: An introduction to comparative public administration* (Repr). Cheltenham: Elgar.

Poletti, A. (2009). *The changing politics of preference formation in international trade negotiations: the European Union in the Doha Round*. Bologna: University of Bologna.

Poli, S. (2004). The European Community and the adoption of international food standards within the Codex Alimentarius Commission. *European Law Journal*, *10*(5), 613–630.

Pollack, M. A. (1997). Delegation, agency, and agenda setting in the European Community. *International organization*, *51*(1), 99–134.

Pollack, M. A. (1998). The Engines of Integration? Supranational Autonomy and Influence in the European Union. In W. Sandholtz & A. Stone Sweet (Eds.), *European integration and supranational governance*. Oxford: Oxford University Press.

Pollack, M. A. (2002). Learning from the Americanists (Again): Theory and Method in the Study of Delegation. *West European Politics*, *25*(1), 200–219.

Pollack, M. A. (2003). *The Political Economy of the Transatlantic Partnership*. Fiesole.

Pollack, M. A. (2005). The New Transatlantic Agenda at Ten: Reflections on an Experiment in International Governance. *Journal of Common Market Studies*, *43*(5), 899–919.

Pollack, M. A., & Shaffer, G. C. (2001). *Transatlantic governance in the global economy*. *Governance in Europe*. Lanham, Md., Oxford: Rowman & Littlefield.

Pollack, M. A., & Shaffer, G. C. (2009). *When cooperation fails: The international law and politics of genetically modified foods*: Oxford University Press on Demand.

Posner, E. (2009). Making Rules for Global Finance: Transatlantic Regulatory Cooperation at the Turn of the Millennium. *International organization*, *63*(4), 665–699.

Prakash, A., & Potoski, M. (2006). Racing to the Bottom? Trade, Environmental Governance, and ISO 14001. *American Journal of Political Science*, *50*(2), 350–364.

Princen, S. (2004). Trading Up in the Transatlantic Relationship. *Journal of Public Policy*, *24*(1), 127–144.

Putnam, R. D. (1988). Diplomacy and domestic politics: the logic of two-level games. *International organization*, *42*(3), 427–460.

Putnam, T. L. (2009). Courts without Borders: Domestic Sources of U.S. Extraterritoriality in the Regulatory Sphere. *International Organization*, *63*(3), 459–490.

Quick, R. (2008). Regulatory cooperation – a subject of bilateral negotiations or even for the WTO. *Journal of World Trade*, *42*(3), 391–406.

Quick, R. (2011). Transatlantic Regulatory Cooperation on Chemicals- An Idealist's Dream? In S. J. Evenett & R. M. Stern (Eds.), *World scientific studies in international economics: Vol. 15. Systemic implications of transatlantic regulatory cooperation and competition*. Hackensack, NJ: World Scientific: 241–286.

Radaelli, C. M. (2003). The Europeanisation of European Public Policy. In K. Featherstone & C. M. Radaelli (Eds.), *The politics of Europeanisation*. Oxford: Oxford University Press: 27–56.

Radaelli, C. M. (2005). Diffusion without convergence: How political context shapes the adoption of regulatory impact assessment. *Journal of European Public Policy*, *12*(5), 924–943.

Ragin, C. C. (1997). *Constructing social research: The unity and diversity of method*. Los Angeles: SAGE Publications.

Raustiala, K. (1997). Domestic Institutions and International Regulatory Cooperation: Comparative Responses to the Convention on Biological Diversity. *World Politics*, *49*(4), 482–509.

Raustiala, K. (2002). The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law. *SSRN Electronic Journal*. Advance online publication.

Raustiala, K. (2009). *Does the constitution follow the flag? The evolution of territoriality in American law*. Oxford: Oxford University Press.

Raustiala, K., & Victor, D. G. (2004). The regime complex for plant genetic resources. *International organization*, *58*(2), 277–309.

Renda, A. (2005). Telecom Services: a Transatlantic Perspective. In D. S. Hamilton & J. P. Quinlan (Eds.), *Deep integration, how transatlantic markets are leading globalization*. Brussels: Centre for European Policy Studies: 156–192.

Renda, A. (2007). The Costs and Benefits of Transatlantic Convergence in Telecom Services. In D. S. Hamilton & J. P. Quinlan (Eds.), *"Sleeping Giant: Awakening the Transatlantic Services Economy* (146-183). Washington D.C.: Brookings Institution Press.

Renda, A., & Yoo, C. S. (2015). Telecommunications and the Internet: TTIP's digital dimension. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers: 371–422.

Renn, O., & Elliott, E. D. (2011). Chemicals. In J. B. Wiener, M. D. Rogers, J. K. Hammitt, & P. H. Sand (Eds.), *The reality of precaution: Comparing risk regulation in the United States and Europe*. London: Routledge: 223–225.

Rhodes, C. (Ed.). (1998). *The European Union in the world community*. Boulder, CO: Lynne Rienner Publishers.

Risse, T. (2000). "Let's Argue!": Communicative Action in World Politics. *International organization*, *54*(1), 1–39.

Risse-Kappen, T. (1995). *Bringing transnational relations back in: Non-state actors, domestic structures and international institutions*. Cambridge: Cambridge University Press.

Rittberger, B., & Wonka, A. (2011). Introduction: agency governance in the European Union. *Journal of European Public Policy*, *18*(6), 780–789.

Rixen, T., Viola, L. A., & Zürn, M. (2016). *Historical institutionalism and international relations: Explaining institutional development in world politics*. Oxford: Oxford University Press.

Rodrik, D. (1997). *Has globalisation gone too far?* Washington D.C.: Institute for International Economics.

Rogowski, R. (1989). *Commerce and coalitions: How trade affects domestic political alignments*. Princeton, NJ: Princeton University Press.

Rogowski, R. (1999). Institutions as Constraints on Strategic Choice. In D. A. Lake & R. Powell (Eds.), *Strategic Choice and International Relations*. Princeton, NJ: Princeton University Press: 115–136.

Ruggie, J. G. (1982). International regimes, transactions, and change: Embedded liberalism in the postwar economic order. *International organization*, *36*(02), 379.

Ruggie, J. G. (1993). Territoriality and beyond: Problematizing modernity in international relations. *International organization*, *47*(1), 139.

Rummel, R. (Ed.). (1990). *The evolution of an international actor: Western Europe's new assertiveness*. Boulder: Westview Press.

Sabel, C. F., & Zeitlin, J. (2008). Learning from Difference: The New Architecture of Experimentalist Governance in the EU. *European Law Journal*, *14*(3), 271–327.

Sabel, C. F., & Zeitlin, J. (Eds.). (2010). *Experimentalist Governance in the European Union: Towards a New Architecture*. Oxford: Oxford University Press.

Sandholtz, W., & Stone Sweet, A. (Eds.). (1998). *European integration and supranational governance*. Oxford: Oxford University Press.

Sapir, A. (2011). The Political Economy of Transatlantic Regulatory Cooperation and Competition.: A (Unofficial) View. In S. J. Evenett & R. M. Stern (Eds.), *World scientific studies in international economics: Vol. 15. Systemic implications of transatlantic regulatory cooperation and competition*. Hackensack, NJ: World Scientific: 47–62.

Saurugger, S. (2013). Constructivism and public policy approaches in the EU: From ideas to power games. *Journal of European Public Policy*, *20*(6), 888–906.

Savin, A., & Trzaskowski, J. (2014). *Research handbook on EU Internet law* ([Stan prawny: 1 June 2014]). *Research Handbooks in European Law*. Cheltenham: Edward Elgar Publishing.

Sbragia, A. (2010). The EU, the US, and Trade Policy: Competitive Interdependence in the Management of Globalization. *Journal of European Public Policy*, *17*(3), 368–382.

Scharpf, F. W. (1997). *Games Real Actors Play: Actor-centred Institutionalism in Policy Research*. Boulder, CO: Westview Press.

Scharpf, F. W. (2000). Institutions in Comparative Policy Research. *Comparative Political Studies*, *33*(6-7), 762–790.

Schimmelfennig, F. (2001). The Community Trap: Liberal Norms, Rhetorical Action, and the Eastern Enlargement of the European Union. *International organization*, *55*(1), 47–80.

Schimmelfennig, F., & Wagner, W. (2004). Preface: External governance in the European Union. *Journal of European Public Policy*, *11*(4), 657–660.

Schmidt, S. K. (2007). Mutual recognition as a new mode of governance. *Journal of European Public Policy*, *14*(5), 667–681.

Schmitter, P. C. (1996). Imagining the Future of the Euro-Polity with the Help of New Concepts. In G. Marks, F. W. Scharpf, P. C. Schmitter, & W. Streeck (Eds.), *Governance in the European Union*. London: SAGE: 121–152.

Schwartz, P. M. (2012). The EU-U.S. Privacy Collision: A Turn to Institutions and Procedures. *Harvard Law Review*, *126*, 1966–2013.

Schwarzman, M., & Wilson, M. (2011). Reshaping chemicals policy on two sides of the Atlantic: the promise of improved sustainability through international collaboration. In D. Vogel & J. Swinnen (Eds.), *Transatlantic Regulatory Cooperation. The Shifting Roles of the EU, the US and California*. Cheltenham: Edward Elgar Publishing: 102–124.

Scott, J. (2014). Extraterritoriality and Territorial Extension in EU Law. *American Journal of Comparative Law*, *62*(1), 87–125.

Seattle To Brussels Network. (2016). *TTIP and Information Communication Technology*. Retrieved from http://www.s2bnetwork.org/wp-content/uploads/2015/09/Paper_03.pdf

Seawright, J., & Gerring, J. (2008). Case Selection Techniques in Case Study Research. *Political Research Quarterly*, *61*(2), 294–308.

Selin, H., & VanDeveer, S. D. (2006). Raising Global Standards: Hazardous Substances and E-Waste Management in the European Union. *Environment*, *48*(10), 6–18.

Shaffer, G. C. (2002). Reconciling Trade and Regulatory Goals: The Prospects and Limits of New Approaches to Transatlantic Governance Through Mutual Recognition and Safe Harbor Agreements. *Columbia Journal of European Law*, *9*(1), 29–77.

Shaffer, G. C. (2012). *Transnational legal ordering and state change*. Cambridge: Cambridge University Press.

Shaffer, G. C. (2016). Alternatives for Regulatory Governance under TTIP: Building from the past. *Columbia Journal of European Law*, *22*(3), 403–419.

Shepsle, K. A. (2005). *Analyzing politics: Rationality, behavior, and institutions* (Second edition). *The new institutionalism in American politics*. New York: W.W. Norton.

Shore, C. (2011). 'European Governance' or Governmentality? The European Commission and the Future of Democratic Government. *European Law Journal*, *17*(3), 287–303.

Sidley. (2016). *Essentially equivalent: A comparison of the legal orders for privacy and data protection in the European Union and United States*. Retrieved from https://www.sidley.com/en/insights/publications/2016/01/essentially-equivalent

Siles-Brügge, G. (2011). Resisting Protectionism after the Crisis: Strategic Economic Discourse and the EU–Korea Free Trade Agreement. *New Political Economy*, *16*(5), 627–653.

Siles-Brügge, G. (2014). *Constructing European Union trade policy: A global idea of Europe*. *International Political economic series*. Basingstoke: Palgrave Macmillan.

Siles-Brügge, G., & Ville, F. d. (2015). *TTIP: The truth about the Transatlantic Trade and Investment Partnership*. Cambridge, MA: Polity.

Simmons, B. A. (2001). The International Politics of Harmonization: The Case of Capital Market Regulation. *International organization*, *55*(3), 589–620.

Simmons, B. A., Dobbin, F., & Garrett, G. (2006). Introduction: The international diffusion of liberalism. *International organization*, *60*(4), 781–810.

Simmons, B. A., & Elkins, Z. (2004). The Globalization of Liberalization: Policy Diffusion in the International Political Economy. *American Political Science Review*, *98*(01), 171–189.

Skocpol, T., & Pierson, P. (2002). Historical Institutionalism in Contemporary Political Science. In I. Katznelson & H. V. Milner (Eds.), *Political science: State of the discipline.* New York: W.W. Norton.

Slaughter, A.-M. (1997). The Real New World Order. *Foreign Affairs*, *76*(5), 183.

Slaughter, A.-M. (2004). *The New World Order*. Princeton, NJ: Princeton University Press.

Smith, M. (2009). Transatlantic Economic Relations in a Changing Global Political Economy: Achieving Togetherness but Missing the Bus? *The British Journal of Politics & International Relations*, *11*(1), 94–107.

Smith, R. A., & Coulam, R. F. (Eds.). (1985). *Advances in Information Processing in Organizations: Research on Public Organizations*. London: JAI Press.

Statista. (2017). Größte Volkswirtschaften: Länder mit dem größten BIP im Jahr 2017. Retrieved from https://de.statista.com/statistik/daten/studie/157841/umfrage/ranking-der-20-laender-mit-dem-groessten-bruttoinlandsprodukt/

Steffenson, R. (2005). *Managing EU-US relations: Actors, institutions and the new transatlantic agenda*. Manchester: Manchester University Press.

Strange, S. (1996). *The Retreat of the State: The Diffusion of Power in the World Economy*. *Cambridge Studies in International Relations: no. 49*. Cambridge: Cambridge University Press.

Streeck, W., & Thelen, K. A. (2005). *Beyond continuity: Institutional change in advanced political economies*. Oxford: Oxford University Press.

Stross, S. (2014). One goal, many paths. The promotion of Policy Coherence for Development in EU policy formulation (PhD). University of Cologne, Cologne. Retrieved from http://kups.ub.uni-koeln.de/5712/

Tansey, O. (2007). Process Tracing and Elite Interviewing: A Case for Non-probability Sampling. *PS: Political Science & Politics*, *40*(04), 765–772.

Tarrow, S. (2001). Transnational Politics: Contention and Institutions in International Politics. *Annual Revue of Political Science*, *4*(1), 1–20.

Telò, M. (2009). *The European Union and global governance*. London: Routledge.

Thatcher, M. (2011). The creation of European regulatory agencies and its limits: a comparative analysis of European delegation. *Journal of European Public Policy*, *18*(790-809).

The Greens. (2014). *TTIP Talks: What's Cooking – Perspectives on Food and Farming European Parliament Conference*. Retrieved from https://www.greens-efa.eu/en/article/ttip-talks-whats-cooking/

Thelen, K. A. (2004). *How Institutions Evolve: The Political Economy of Skills in Germany, Britain, the United States, and Japan*. Cambridge: Cambridge University Press.

Trans Atlantic Consumer Dialogue. (2001). Resolution on Unsolicited Commercial Electronic Mail. Retrieved from http://tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=98

Trans Atlantic Consumer Dialogue. (2012). Resolution on Internet of Things. Trans Atlantic Consumer Dialogue. Retrieved from http://tacd.org/wp-content/uploads/2013/09/TACD-INFOSOC-48-12-Internet-of-Things.pdf

Trans Atlantic Consumer Dialogue. (2013a). Resolution on Data Flows in the TransAtlantic Trade and Investment Partnership. Retrieved from http://test.tacd.org/wp-content/uploads/2014/01/TACD-INFOSOC-50-13-Data-Flows-in-the-Transatlantic-Trade-and-Investmemt-Partnership.pdf

Trans Atlantic Consumer Dialogue. (2013b). Resolution: The Consumer Perspective on addressing e-commerce within the Transatlantic Trade and Investment Partnership. Retrieved from http://test.tacd.org/wp-content/uploads/2013/09/TACD-INFOSOC-51-13-E-commerce-in-the-Transatlantic-Trade-and-Investment-Partnership.pdf

Trans Atlantic Consumer Dialogue. (2015). Resolution on the open and neutral Internet. Retrieved from http://tacd.org/wp-content/uploads/2015/06/TACD-INFOSOC-Resolution-on-Net-Neutrality-2015-GREEN.pdf

Trans Atlantic Consumer Dialogue. (2016a). Resolution on the EU-U.S. Privacy Shield Proposal. Retrieved from http://tacd.org/wp-content/uploads/2016/04/TACD-Resolution_Privacy-Shield_April16.pdf

Trans Atlantic Consumer Dialogue. (2016b). Resolution on the proposed chapter on Sanitary and Phytosanitary Measures in the Transatlantic Trade and Investment Partnership (TTIP) Agreement. Retrieved from http://tacd.org/wp-content/uploads/2015/01/TACD-Resolution-TTIP-SPS_-GREEN_rev0216.pdf

Trans-Atlantic Business Council. (2014). TABC Position on the Open Internet. Retrieved from http://www.transatlanticbusiness.org/wp-content/uploads/2014/05/TABC-Position-on-the-Open-Internet-FINAL.pdf

Trans-Atlantic Business Council. (2016). TABC Press Release on Final Adoption of General Data Protection Regulation. Retrieved from http://www.transatlanticbusiness.org/wp-content/uploads/2016/04/TABC-Press-Release-Final-Adoption-of-GDPR.pdf

Transatlantic Business Dialogue (TABD). (1996). Progress Report. 23 May.

Transatlantic Economic Council. (2007a). Joint statement of the Transatlantic Economic Council: November 9, 2007. Retrieved from http://trade.ec.europa.eu/doclib/docs/2007/november/tradoc_136949.pdf

Transatlantic Economic Council. (2007b). Review of Progress under the Framework for Advancing Transatlantic Economic Integration between the United States of America and the European Union. Retrieved from http://trade.ec.europa.eu/doclib/docs/2007/november/tradoc_136950.pdf

Transatlantic Economic Council. (2008). Review of Progress under the Framework for Advancing Transatlantic Economic Integration: Ares(2014)3756731. Retrieved from https://www.state.gov/p/eur/rls/or/137358.htm

Transatlantic Economic Council. (2009). Message to the EU-US Summit: Transatlantic Economic Council Joint Statement. Retrieved from http://www.europarl.europa.eu/meetdocs/2009_2014/documents/d-us/dv/d-us_tec_joint_statement27/d-us_tec_joint_statement2710.pdf

Transatlantic Economic Council. (2010a). *TEC - Sector Specific Statements*. Retrieved from https://www.state.gov/p/eur/rls/or/153297.htm

Transatlantic Economic Council. (2010b). *U.S.-EU Transatlantic Economic Council Joint Statement*. Retrieved from http://trade.ec.europa.eu/doclib/docs/2011/january/tradoc_147173.pdf

Transatlantic Economic Council. (2011a). *Report of the Transatlantic Economic Council Co-Chairs to the Summit*. Retrieved from https://2009-2017.state.gov/p/eur/rls/or/178424.htm

Transatlantic Economic Council. (2011b). *Transatlantic Economic Council: Annexes to the TEC Joint Statement*. Retrieved from https://www.state.gov/p/eur/rls/or/178419.htm

Transatlantic Policy Network. (1998). Toward Transatlantic Partnership: Cooperation Project Report.

Treib, O. (2003). *EU governance, misfit and the partisan logic of domestic adaptation: An actor-centered perspective on the transposition of EU directives*. Paper presented at the EUSA 8th International Biennial Conference, Nashville TN, 27-29 March 2003.

Trondal, J. (2010). *An emergent European executive order*. Oxford: Oxford University Press.

Tsebelis, G. (2002). *Veto Players*. Princeton, NJ: Princeton University Press.

UNCTAD. (2016). *Data protection regulations and international data flows: Implications for trade and development*. Retrieved from http://unctad.org/en/PublicationsLibrary/dtlstict2016d1_en.pdf

Union Européenne du Commerce du Bétail et de la Viande (UECBV). (2016). UECBV's European Newsletter April 2016. Retrieved from http://www.uecbv.eu/UECBV/documents/UECBV NewsletterApril20168753.pdf

United States Department of State. (2007). Economic Integration and Global Growth: BRUSSELS 00000078. Retrieved from https://wikileaks.org/plusd/cables/09BRUSSELS78_a.html

United States Department of State. (2008a). The May 13 U.S.-EU Transatlantic Economic Council: BRUSSELS 00000859. 13 May. Retrieved from https://wikileaks.org/plusd/cables/08USEU BRUSSELS859_a.html

United States Department of State. (2008b). The May 13 U.S.-EU Transatlantic Economic Council.: BRUSSELS 00000881. Retrieved from https://wikileaks.org/plusd/cables/08BRUSSELS881_a.html

United States Department of State. (2009a). The fourth meeting of the U.S.-EU Transatlantic Economic Council: BRUSSELS 00001420. Retrieved from https://wikileaks.org/plusd/cables/09BRUSSELS1420_a.html

United States Department of State. (2009b). Transatlantic Economic Council meeting 29 June: BRUSSELS 00000948. Retrieved from https://wikileaks.org/plusd/cables/09 BRUSSELS948_a.html

United States Department of State. (2015). *US Department of State 2015 Joint Press Statement for the 2015 US EU Information Society Dialogue*. Retrieved from https://2009-2017.state.gov/r/pa/prs/ps/2015/04/240680.htm

United States International Trade Commission. (2014). *Trade Barriers That U.S. Small and Medium-Sized Enterprises Perceive As Affecting Exports to the European Union* (No. 4455). Washington D.C. Retrieved from United States International Trade Commission website: https://www.usitc.gov/publications/332/pub4455.pdf

US Chamber of Commerce. (2015). *TTIP and Flawed Policies on Standards Don't Mix*. Retrieved from US Chamber of Commerce: Center for Global Regulatory Cooperation website: https://www.uschamber.com/issue-brief/ttip-and-flawed-policies-standards-don-t-mix

US Government Accountability Office. (2007). Chemical regulation, comparison of US and recently enacted EU approaches to protect against the risks of toxic chemicals. Retrieved from https://www.gao.gov/new.items/d07825.pdf

USDA Foreign Agricultural Service. (2005). Trade Policy Monitoring. The US-EU Veterinary Equivalency Agreement: Content and Comparison. Retrieved from https://apps.fas.usda.gov/gainfiles/200512/146131719.pdf

van Ballaert, B. (2017). The European Commission's use of consultation during policy formulation: The effects of policy characteristics. *European Union Politics*, *18*(3), 406–423.

van den Hoven, A. (2004). Assuming Leadership in Multilateral Economic Institutions: The EU's 'Development Round' Discourse and Strategy. *West European Politics*, *27*(2), 256–283.

van den Hoven, A. (2006). European Union Regulatory Capitalism and Multilateral Trade Negotiations. In S. Lucarelli & I. Manners (Eds.), *Routledge advances in European politics: Vol. 37. Values and principles in European Union foreign policy*. London: Routledge: 185–200.

van Schaik, L. (2013). The EU's growing pains in negotiating international food standards. *International Relations*, *27*(3), 292–307.

Verband der Chemischen Industrie (VCI). (2015a). *Transatlantisches Freihandelsabkommen TTIP: Argumente und Positionen*. Retrieved from https://www.vci.de/langfassungen/langfassungen-pdf/2015-07-28-fakten-zu-ttip.pdf

Verband der Chemischen Industrie (VCI). (2015b). *VCI zur TTIP-Resolution des Europäischen Parlaments Chancen der regulatorischen Kooperation nicht erkannt*. Retrieved from https://www.vci.de/presse/pressemitteilungen/chancen-der-regulatorischen-kooperation-nicht-erkannt-vci-zur-ttip-resolution-des-europaeischen-parlaments.jsp

Verband der TÜV (VdTÜV). (2014). *TTIP zum Erfolg führen: Zwölf VdTÜV-Anforderungen Zum TTIP*. Retrieved from https://www.vdtuev.de/dok_view?oid=516460

Verband Deutscher Maschinen- und Anlagenbau (VDMA). (2013). VDMA on Transatlantic Trade and Investment Partnership (TTIP): VDMA's TOP 10 TTIP Priorities. Retrieved from https://oesterreich.vdma.org/documents/106103/960660/VDMA_PP_%20on%20TTIP_09_2013/294b845b-6faa-4653-813a-5c13abe212bf

Verband Deutscher Maschinen- und Anlagenbau (VDMA). (2014). *Ten reasons why the Transatlantic Trade and Investment*. Retrieved from https://www.vdma.org/documents/106103/960660/TTIP%20ten%20reasons/1347a698-605d-4112-a47a-b81e0b5f006d

Verbraucherzentrale Bundesverband (vzbv). (2015). TTIP und Lebensmittel: Knackpunkte und mögliche Gefahren der TTIP-Verhandlungen. Retrieved from https://www.vzbv.de/sites/default/files/downloads/TTIP_und_Lebensmittel-Forderungen_vzbv-2015-07.pdf

Verbraucherzentrale Bundesverband (vzbv). (2016). Regulatorische Zusammenarbeit in TTIP. Retrieved from https://www.vzbv.de/sites/default/files/downloads/2017/08/29/ttip-regulatorische-zusammenarbeit-positionspapier-vzbv-2016-02-18_0.pdf

Vieweg, H.-G. (2012). An introduction to Mechanical Engineering: Study on the Competitiveness of the EU Mechanical Engineering Industry: Within the Framework Contract of Sectoral. Competitiveness Studies – ENTR/06/054.

Vogel, D. (1995). *Trading Up: Consumer and Environmental Regulation in a Global Economy*. Cambridge MA: Harvard University Press.

Vogel, D. (1997). *Barriers or benefits? Regulation in transatlantic trade*. Washington, D.C.: Brookings Institution Press.

Vogel, D. (2012). *The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States*. Princeton, NJ: Princeton University Press.

Vogel, D., & Kagan, R. A. (2004). *Dynamics of regulatory change: How globalization affects national regulatory policies*. Berkeley: University of California Press.

Vogel, D., & Swinnen, J. (Eds.). (2011). *Transatlantic Regulatory Cooperation. The Shifting Roles of the EU, the US and California*. Cheltenham: Edward Elgar Publishing.

Weimer, M., & Vos, E. (2015). *The role of the EU in transnational regulation of food safety*: *Extending Experimentalist Governance?* In J. Zeitlin (Ed.), Extending experimentalist governance? The European Union and transnational regulation. Oxford: Oxford University Press: 51–80.

Wessels, W. (2008). *Das politische System der Europäischen Union*. Wiesbaden: VS/Verlag für Sozialwissenschaften.

Wessels, W. (2016). *The European Council*. Basingstoke: Palgrave Macmillan

Wessels, W., & Diedrichs, U. (2003). The Transatlantic Business Dialogue (TABD) - A New Model of Decision-Making between Economic and Political Actors? Unpublished Project Report.

Wiener, J. B., Rogers, M. D., Hammitt, J. K., & Sand, P. H. (Eds.). (2011). *The reality of precaution: Comparing risk regulation in the United States and Europe*. London: Routledge.

Wille, A. (2013). *The normalization of the European Commission: Politics and bureaucracy in the EU executive*. Oxford: Oxford University Press.

Wilson, J. Q. (1989). *Bureaucracy*. New York: Basic Books.

Woll, C. (2008). *Firm interests: How governments shape business lobbying on global trade*. *Cornell studies in political economy*. Ithaca, NY: Cornell University Press.

Woolcock, S., Holzer, B., & Kusmu, P. (2015). TTIP and Consumer Protection. In J. Pelkmans (Ed.), *Rule-Makers or Rule-Takers? Exploring the Transatlantic Trade and Investment Partnership*. London: Rowman & Littlefield Publishers: 207–236.

Woolcock, S. (2005). European Union trade policy: domestic institutions and systemic factors. In D. Kelly & W. Grant (Eds.), *International political economy series. The politics of international trade in the 21st century: Actors, issues, and regional dynamics*. Basingstoke: Palgrave Macmillan: 234–252.

Woolcock, S. (2010). The Treaty of Lisbon and the European Union as an actor in international trade: ECIPE Working paper, 1/2010. Retrieved from http://www.ecipe.org/app/uploads/2014/12/the-treaty-of-lisbon-and-the-european-union-as-an-actor-in-international-trade.pdf

World Organisation for Animal Health (oie). (2012). *Risk assessment in international trade The SPS agreement and the international standard setting organizations* (Seminar on Risk Assessment procedures in SPS issues: the EU versus the USA approaches). Stockholm. Retrieved from http://www.ksla.se/wp-content/uploads/2012/05/Joseph-Domenech.pdf

World Trade Organisation (WTO). (1994). Multilateral Agreements on Trade in Goods. Retrieved from https://www.wto.org/english/docs_e/legal_e/06-gatt.pdf

World Trade Organisation (WTO). (1995a). Agreement on Technical Barriers to Trade. Retrieved from https://www.wto.org/english/docs_e/legal_e/17-tbt.pdf

World Trade Organisation (WTO). (1995b). Agreement on the Application of Sanitary and Phytosanitary Measures. Retrieved from https://www.wto.org/english/docs_e/legal_e/15-sps.pdf

Wouters, J. (Ed.). (2015). *Global governance through trade: EU policies and approaches*. *Leuven global governance*. Cheltenham: Edward Elgar Publishing.

Wouters, J., Bruyninckx, H., Basu, S., & Schunz, S. (2012). *The European Union and multilateral governance: Assessing EU participation in United Nations human rights and environmental fora*. *Palgrave studies in European Union politics*. Basingstoke: Palgrave Macmillan.

Wunderlich, J.-U., & Bailey, D. J. (2011). *The European Union and global governance: A handbook*. *Routledge International Handbooks*. London: Routledge.

Young, A. R. (2003). Political Transfer and "Trading Up"? Transatlantic Trade in Genetically Modified Food and U.S. Politics. *World Politics*, *55*(04), 457–484.

Young, A. R. (2007). Trade Politics Ain't What It Used to Be: The European Union in the Doha Round. *Journal of Common Market Studies*, *45*(4), 789–811.

Young, A. R. (2009). Confounding Conventional Wisdom: Political not Principled Differences in the Transatlantic Regulatory Relationship. *British Journal of Politics and International Relations*, *11*(4), 666–689.

Young, A. R. (2011). Of executive preferences and societal constraints: The domestic politics of the transatlantic GMO dispute. *Review of International Political Economy*, *18*(4), 506–529.

Young, A. R. (2014). Europe as a global regulator? The limits of EU influence in international food safety standards. *Journal of European Public Policy*, *21*(6), 904–922.

Young, A. R. (2015a). Liberalizing trade, not exporting rules: The limits to regulatory co-ordination in the EU's 'new generation' preferential trade agreements. *Journal of European Public Policy*, *22*(9), 1253–1275.

Young, A. R. (2015b). The European Union as a global regulator? Context and comparison. *Journal of European Public Policy*, *22*(9), 1233–1252.

Young, A. R. (2016). Not your parents' trade politics: The Transatlantic Trade and Investment Partnership negotiations. *Review of International Political Economy*, *23*(3), 345–378.

Young, A. R., & Peterson, J. (2006). The EU and the new trade politics. *Journal of European Public Policy*, *13*(6), 795–814.

Young, A. R., & Peterson, J. (2014). *Parochial Global Europe: 21st Century Trade Politics*. Oxford: Oxford University Press.

Zeitlin, J. (Ed.). (2015a). *Extending experimentalist governance? The European Union and transnational regulation.* Oxford: Oxford University Press.

Zeitlin, J. (2015b). Introduction: Theoretical Framework and Research Agenda. In J. Zeitlin (Ed.), *Extending experimentalist governance? The European Union and transnational regulation*. Oxford: Oxford University Press: 1–22.

Zeitlin, J. (2015c). Conclusions: empirical findings and experimentalist pathways. In J. Zeitlin (Ed.), *Extending experimentalist governance? The European Union and transnational regulation*. Oxford: Oxford University Press: 324–354.

Zentralverband Elektrotechnik und Elektronikindustrie (ZVEI). (2015). *TTIP – Transatlantic Trade and Investment Partnership: Die deutsche Elektroindustrie: Kernthemen, Forderungen, Rote Linien und mögliche Lösungsansätze*. Frankfurt. Retrieved from https://www.zvei.org/fileadmin/user_upload/Presse_und_Medien/Publikationen/2015/september/TTIP_-_Transatlantic_Trade_and_Investment_Partnership_-_Die_deutsche_Elektroindustrie__Kernthemen__Forderungen__Rote_Linien_und_moegliche_Loesungsansaetze/ZVEI-Positionspapier-zum-TTIP-Freihandelsabkommen-September-2015.pdf

ZeroProject. (2016). Transatlantic e-Accessibility standards cooperation: Innovative Policy 2016 on Inclusive education and ICT. Retrieved from https://zeroproject.org/policy/transatlantic-e-accessibility-standards-cooperation/

Ziegler, O. (2013). *EU Regulatory Decision Making and the Role of the United States: Transatlantic Regulatory Cooperation as a Gateway for U. S. Economic Interests?* Wiesbaden: Springer. Retrieved from http://site.ebrary.com/lib/alltitles/docDetail.action?docID=10602394

Zielonka, J. (2008). Europe as a global actor: Empire by example? *International Affairs*, *84*(3), 471–484.

Zürn, M. (2015). Opening up Europe: Next steps in politicisation research. *West European Politics*, *39*(1), 164–182.

Annex

Annex 1: List of interviews

Interview 1	Commission Official, DG Grow, Brussels, 28 October 2016
Interview 2	Industry Official, Verband der Chemischen Industrie, Brussels, 20 October 2016
Interview 3	Industry Official, Cefic, Brussels, 23 August 2016
Interview 4	Commission Official, DG Trade, Brussels, 22 June 2016
Interview 5	Commission Official, DG Grow, Brussels, 23 August 2016
Interview 6	Industry Official, Orgalime / VDMA, Frankfurt, 11 January 2017
Interview 7	Commission Official, DG Sante, Brussels, 2 December 2017
Interview 8	Commission Official, DG Trade, Brussels, 15 December 2016
Interview 9	Industry Official, freshfel, Brussels, 18 January 2017
Interview 10	Industry Official, UECBV, Brussels, 2 February 2017
Interview 11	Industry Official, Deutscher Bauernverband, phone, 2 September 2017
Interview 12	Commission Official, DG Trade, Brussels, 19 January 2017
Interview 13	Commission Official, DG Connect, Brussels, 28 November 2016
Interview 14	Industry Official, Digitaleurope, Brussels, 24 August 2016
Interview 15	Industry Official, Digitaleurope, Brussels, 1 September 2016
Interview 16	Commission Official, DG Trade, Brussels, 24 August 2016
Interview 17	Ministry Official, Federal Ministry of Economics, Berlin, 6 July 2015
Interview 18	Industry Official, Bundesverband der Deutschen Industrie, Berlin, 12 August 2015
Interview 19	Industry Official, Deutscher Industrie- und Handelskammertag, Berlin, 13 May 2015
Interview 20	Ministry Official, Federal Ministry of Economics, Berlin, 14 August 2015
Interview 21	Industry Representative, VDMA, Cologne, 30 January 2015
Interview 22	Industry Representative, Die Familienunternehmer, Cologne, 3 February 2015
Interview 23	Industry Representative, DIHK, Cologne, 9 April 2015
Interview 24	Industry Official, Die Familienunternehmer, Berlin, 13 May 2015
Interview 25	Industry Official, Bundesverband der mittelständischen Wirtschaft, 7 July 2015
Interview 26	Industry Official, Verband der Automobilindustrie, Berlin, 12 May 2015

Annex 2: Samples of interview questionnaires

Commission Official, Food Safety

- How long have you followed SPS issues? Which processes have you followed in cooperation with the US? Mechanisms/Fora

Actors

- Which processes have contributed to the formation of the Commission's position?
- How were you involved in these processes?
- Why did you participate in these processes? What has been your interest? How do you assess your influence in these processes?
- Which other DGs participate in RC on food safety? What is their interest?
- Do other actors in the EU influence TRC on food issues? Member States? EP?
- What is the interest of US actors on TRC (USDA, APHIS, IFIS, FDA, EPA)? Are there differences in their interest on TRC?
- Have there been other influences?

Societal Actors

- Does the lack of agreement among US and EU agricultural groups impede TRC? Is there alignment among processed food producers? Which are the leading / most relevant groups?
- Has the interest of businesses in TRC changed over time?
- Have NGOs affected TRC? How?

Processes

- Through which bilateral fora does the EU engage with the US (ex. TATFAR)?
- How do multilateral and bilateral talks affect each other?

Topics

- Please describe the US regulatory approach on risk assessment and risk management. How do you think that it differs from the EU approach on this issue?
- Why did you take a negative position on pathogen reduction treatments? Have there been internal debates on the EU approach on this?
- What impedes further equivalence of food standards? Is US less ambitious on implementing equivalence ("knowledge acquired through experience with the other Party's competent authorities")
- Why has there been no agreement on Grade A? (since 2002)
- Does US reject facilitating MRCA in the audits paragraph?
- Why has AMR entered the TTIP negotiations rather late? Is there tension between EU and US on AMR standards in Codex?

Commission Official, Information and Communications Technology

- How long have you followed transatlantic regulatory cooperation (TRC)? Which processes have you followed?

Actors

- Which processes have contributed to the formation of the Commission's position?
- How were you involved in these processes? Who has set agenda topics for the Transatlantic Economic Council?
- Why did you participate in these processes? What has been your interest? How do you assess your influence in these processes?
- Which other DGs participate in RC on ICT? What is their interest?
- Do other actors in the EU influence TRC on ICT issues? Member States? EP?
- What is the interest of US actors on TRC (USTR, FCC)? Are there differences in their interest on TRC?
- Have there been other influences?

Societal Actors

- From your perception, do EU and US firms and business associations agree in their positions on TRC?
- Has the interest of businesses in TRC changed over time? Has this affected TRC? How?
- Have NGOs affected TRC? How?

Processes

- The Information Society Dialogue has been interrupted between 2010 and 2014. Why? Why has it been taken up again? What is the objective of this dialogue? How does it relate to the sectoral regulatory dialogues envisioned in the TTIP negotiations?
- How do multilateral and bilateral talks affect each other?

Topics

- The Transatlantic Economic Council has agreed on common standards on e-Health. How has this agreement been achieved? Why was an agreement on common standards possible in the case of e-Health?
- Discussions have been ongoing on common standards on e-Labelling since the early days of the TEC. Why have these discussions not yet led to common standards? Why has the EU decided to set its own standard on e-Labelling for medical devices in 2013? How has this decision affected the discussions on e-Labelling in TTIP?
- Could you describe the US approach on e-accessibility? How do you compare it to the EU approach?
- Why have Cloud Computing and Internet of Things not been put on the agenda of the TTIP?

Annex 3: EU exports to the US 2016 by industry sector

Industry Sector	**EU exports to the US, 2016 value in millions of Euro**
Engineering	60729,1
Pharmaceuticals	48263,6
Information and Communications Technology	37369,3
Chemicals	32658,9
Automotive	22367,6
Food	18389,8
Raw Materials	10061,4
Textiles	6601,8

Own calculation, source: Eurostat (2017)

Industry Sector	**Standard International Trade Classification (SITC) sections**
Engineering	72,73,74, 77
Pharmaceuticals	54
Information and Communications Technology	75, 76 + "Information, Telecommuncations and Computer Services" (OECD, 2017)
Chemicals	51,52,53,55,56,59
Automotive	71
Food	01-19, 22
Raw Materials	32,33,34,35
Textiles	83,84,85

Own calculation, source: Eurostat (2017)

Annex 4: EU imports of US products and exports to the US, 2006-2016

EU imports of US products in millions of euros

Sector	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Food	6308	6839	7467	5545	6996	7663	7720	9179	9831	11519	10793
Chemicals	15191	17307	17071	13910	17560	17140	17476	17659	17233	19812	19253
Pharmaceuticals	15416	14261	14511	16468	17256	19149	22035	21141	23803	31149	31678
Automotive	13793	14615	14903	15275	16694	18063	20626	21014	21533	26347	28826
Engineering	25847	25567	25419	19742	23409	24370	24924	24273	25985	30613	30396
ICT	17154	16506	13221	8831	22143	22603	24765	25264	26625	27223	28849

EU exports to US in millions of euros

Sector	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Food	11376	11222	10031	9266	10792	11954	13499	13814	14595	17314	18390
Chemicals	27566	26090	25453	23915	26716	27945	29725	27813	27215	34164	32659
Pharmaceuticals	23525	25907	24489	27304	30480	30722	32988	30055	35535	49803	48264
Automotive	14798	16216	16252	13725	15717	17880	20364	19487	21499	24430	22368
Engineering	43597	42534	40067	29688	34903	42537	48007	47772	52531	60156	60729
ICT	9633	8383	7689	6907	19777	21846	25313	26105	30493	34284	37369

Source: Own calculation (Eurostat, 2017; OECD, 2017)

Annex 5: SPS legal text comparison: EU TTIP SPS proposal and US TTIP SPS proposal

Title	EU TTIP	US TTIP	Comments
Objectives	The objectives of this chapter are to: 1.Facilitate trade between the Parties to the greatest extent possible while preserving each Party's right to protect human, animal or plant life and health in its territory and respecting each Party's regulatory systems, risk assessment, risk management and policy development processes; 2. Ensure that the Parties' sanitary and phytosanitary (SPS) measures do not create unnecessary barriers to trade; 3. Further the implementation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement); 4. Build upon and extend the scope of the Veterinary Agreement which is fully integrated in this Chapter; 5. Improve communication and cooperation on sanitary and phytosanitary measures between the Parties; 6. Improve consistency, predictability and transparency of each Party's SPS measures; 7. Provide a framework for dialogue and cooperation with a view to enhancing the protection and welfare of animals and reaching a common understanding concerning animal welfare standards.		EU: Specific mention of respect for each Party's regulatory systems, differentiation and mentioning of risk assessment, risk management and policy development More ambitious on furthering the implementation of the SPS Agreement Mention of the Veterinary Agreement More ambitious on predictability and transparency Listing of animal welfare as a specific objective US: Less ambitious on SPS implementation Introduction of consultation of competent authorities Specific mention of adoption of international standards
Scope and Coverage	This Chapter applies to all SPS measures that may, directly or indirectly, affect trade between Parties. This Chapter shall also apply to collaboration on animal welfare matters.	This Chapter, unless otherwise specified, applies to all SPS measures that may, directly or indirectly, affect trade between Parties.	EU: inclusion of animal welfare
Affirmation of the SPS Agreement (EU: Rights and Obligations)	The Parties affirm their rights and obligations under the WTO SPS Agreement. Nothing in this Chapter shall limit the rights and obligations of the Parties under the Agreement established by the World Trade Organisation and its Annexes. The Parties shall avail themselves of the necessary resources to effectively implement this Chapter.	The Parties affirm their rights and obligations with respect to each other under the WTO SPS Agreement.	EU: specific mention of implementation of the SPS Chapter
Competent Authorities	For the purpose of this Chapter, the competent authorities of each Party	Upon entry into force this Agreement, each Party shall	US:

Title	EU TTIP	US TTIP	Comments
(US: and Contact Points)	are those listed in (Annex 2). The Parties shall inform each other of any change of these competent authorities.	provide the other Party with the following information in writing: (a) with respect to each of the Parties' competent authorities that have responsibility for developing, implementing, and enforcing SPS measures that may affect trade between the Parties; a. a description of each authority, including the authority's specific responsibilities, and b. a point of contact within each authority; and (b) the name and contact information for a representative of the Party with authority to accept correspondence or inquiries from the other Party regarding matters arising under this Chapter. Each Party shall promptly transmit to the other Party any material changes to this information.	More extensive information requirements on competent authorities
Equivalence	The importing Party shall accept sanitary and phytosanitary measures of the exporting Party as equivalent to its own if the Party objectively demonstrates to the importing Party that its measures achieve the importing Party's appropriate level of protection. Equivalence may be recognised in relation to an individual measure and/or groups of measures and/or systems applicable to a sector or part of a sector. For the determination, recognition and maintenance of equivalence the Parties shall <u>follow</u> the principles set out in the available <u>guidance</u> of international standard-setting bodies recognised by the WTO SPS Agreement, as well as in the provisions of (Annex IV), where applicable. The final determination whether a sanitary measure maintained by an exporting Party achieves the importing Party's appropriate level of sanitary protection <u>rests solely with the importing Party acting in accordance with its administrative and legislative framework.</u> Where the importing Party has concluded a positive equivalence determination, the <u>importing Party shall take the necessary legislative and/or administrative measures to</u>	Each Party recognises that determining that SPS measures of the other Party achieve an equivalent level of sanitary or phytosanitary protection as its own SPS measures <u>can facilitate trade between the Parties</u>. Each Party shall permit such determinations of equivalence to be made with respect to a specific measure, on the basis of a product or category of products or on a system-wide basis. Each Party, in determining whether an SPS measure of the other Party achieves the Party's appropriate level of protection, <u>shall take into account</u> the following, where relevant: <u>a. decisions of the WTO SPS Committee</u> b. the work of the relevant international organisations; and <u>c. knowledge acquired through experience with the other Party's relevant competent authorities.</u> Each Party shall follow the process set forth in Annex X-A with respect to determinations of equivalence.	<u>EU:</u> Specific mention that determination of equivalence rests solely with importing Party (but US implies the same) More ambitious implementation requirements of recognised equivalence Equivalence based on same level of protection Equivalence linked to trade facilitation <u>US:</u> more discretion in choosing methods for determining equivalence: importing Party may use knowledge acquired through experience with the other's Party's relevant authorities more discretion in implementation of recognising equivalence no mention of specific exclusive right of importing Party to determine equivalence (but implied) Equivalence shall not only be granted on same level of protection, but same effect However, importing Party needs to justify non-recognition of equivalence

Title	EU TTIP	US TTIP	Comments
	implement it without undue delay and normally within six months. If necessary and objectively justified, the Parties may identify special conditions which, in combination with the exporting Party's measures, will achieve the importing Party's appropriate level of protection. (Annex V) sets out: (a) The areas for which the importing Party recognises that the measures of the exporting Party are equivalent to its own, and (b) The areas for which the importing Party recognises that the fulfilment of the specified special conditions, combined with the exporting Party's measures, achieve the importing Party's appropriate level of protection. The Parties may agree on simplified sanitary or phytosanitary certificates for products for which equivalence has been recognised.		
Science and Risk		In undertaking a risk assessment appropriate to the circumstances, each Party shall ensure that it takes into account: (a) relevant available scientific evidence, including quantitative or qualitative data and information; and (b) relevant guidance from the WTO SPS Committee and international standards, guidelines, and recommendations concerning the risk at issue. Prior to adopting an SPS regulation, each Party shall evaluate- in light of results of any risk assessment that it undertook or relied upon in developing SPS regulation- any alternatives to achieve the appropriate level of protection being considered by the Party or identified through timely submitted public comments, including where raised, the alternative of not adopting any regulation. Each Party shall conduct such evaluation with a view to ensuring compliance with the Party's obligation under 5.6 of the SPS Agreement. 1.Each Party shall ensure that any risk assessment that it undertakes related to developing or reviewing an	US: Weaker commitment to take into account available science into risk assessment Requirement to evaluate alternatives to individual SPS regulations to achieve the level of protection Notice and comment Requirement to discuss comments in the SPS Committee Risk assessment open for public review "under normal circumstances" Justification for regulation in light of available scientific evidence No mention of risk management TPP: more right to regulate (3(a) No formal justification requirements Notice-and-comment at the discretion of importing Party Only requires document risk analysis (not adoption of regulation) Perhaps "Science and Risk" article along TPP template?

Title	EU TTIP	US TTIP	Comments
		SPS regulation is under normal circumstances made available on the Internet for public review and comment. Each Party shall ensure that any of its competent authorities responsible for undertaking a risk assessment take into account any relevant comments the Party receives during the period afforded for interested parties to provide public comment, including where appropriate by revising the risk assessment. Each Party shall also ensure that any of its competent authorities that are responsible for undertaking the risk assessment or that may use it in connection with developing or reviewing an SPS regulation, shall, upon request, discuss with the other Party in a timely manner any matters the other Party raises in its comments related to the risk assessment, including possible alternatives to achieve the Party's level of protection. 2. At the time a Party makes a risk assessment available for public comment, it shall include the following explanations: 3. When issuing or submitting any final administrative decision for an SPS regulation, the Party shall make publicly available on the Internet an explanation of: (a) the relationship between the regulation and the scientific evidence and technical information, including any risk assessment and any other analyses or information the regulatory authority considered in the preparing the regulation, as well as how the specific requirements set out in the regulation address the risks the regulation seeks to address; (a) any alternative identified through public comments, including by a Party, as significantly less restrictive to trade; and Where a regulatory authority of a Party submits a proposal	

Title	EU TTIP	US TTIP	Comments
		for an SPS measure for approval by a committee comprising national representatives and (a) the committee rejects or modifies the proposal; or (b) the regulatory authority of a Party modifies the proposal in response to feedback, including any rejection, from the committee each member of the committee or the regulatory authority of the Party, as the case might be, shall make publicly available an explanation of the basis for rejecting or modifying the proposal, including the extent to which it is supported by relevant scientific evidence and technical information and analysis, including any risk assessment. Each Party that provisionally adopts an SPS measure pursuant to Article 5.7 of the SPS Agreement that affects trade between Parties shall, upon request, explain: (a) to the extent possible, any alternatives significantly less restrictive to trade it considered and why it considered that any such alternatives do not achieve the Party's appropriate level of protection or are not technically or economically feasible; (a) its view on any comments and information submitted by the other Party; (b) the additional information it believes (c)cunder which circumstances, and if possible when, it will review whether to maintain or modify the measure. This Article shall not apply with respect to any SPS measure that conforms to international standards, guidelines, or recommendations necessary for a more objective assessment of risk and plans for obtaining such information.	
Trans-parency	**Notification** <u>Each Party shall notify the other Party without undue delay of:</u>	1. During the time period described in paragraph 2, when a regulatory authority of a Party is developing an SPS regulation, it shall, under	Rather diametrical <u>EU:</u> Notification of changes in pest/disease status, changes

Title	EU TTIP	US TTIP	Comments
	(a) significant changes in pest/disease status, such as the presence and evolution of diseases in {Annex II Process of Recognition of Regional Conditions}; (b) changes in their respective sanitary or phytosanitary measures; (c) findings of epidemiological importance with respect to animal diseases which are not in Annex II, or which are new diseases; (d) significant food safety issues relating to products traded between the Parties; and (any significant changes to the structure and organization of their competent authorities. **Information exchange** 2. The Parties will endeavor to exchange information on other relevant issues including: (a) on request, the results of a Party's official controls and a report concerning the results of the controls carried out; (b) the results of import checks provided for in Article 13 {Import Checks and Fees} in case of rejected or non-compliant consignments of products; (c) on request, risk analyses and scientific opinions relevant to this Chapter and produced under responsibility of a Party. 3. Unless otherwise decided by the Committee referred to in Article 18 {Joint Management Committee}, when the information referred to in paragraph 1 or 2 has been made available via notification to the WTO or another relevant international standard-setting body in accordance with the relevant rules, the requirements in paragraph 1 and 2 as they apply to that information are fulfilled.	normal circumstances,4 make publicly available on the Internet: (a) the text of the regulation it is developing; (b) any risk assessment, as well as the scientific evidence and technical information and any other analyses and information the regulatory authority relied upon in support of the regulation and an explanation of how such evidence, information and analyses support the regulation; (c) an explanation of how the regulation, including its objectives, achieves those objectives, the rationale for the material features of the regulation, and any major alternatives being considered; and (d) the name and contact information of an official who may be contacted for questions regarding the regulation. 2. Each Party shall make publicly available the information described in paragraph 1: (a) after the relevant authority of the Party has developed a text for the regulation that contains sufficient detail so as to allow persons to evaluate how the regulation, if adopted, would affect their interests; and (b) before the relevant authority of the Party that is developing the measure issues or submits any final administrative decision with respect to the regulation so that this authority may take into account timely received comments and, as appropriate, revise the regulation. 3. Where a regulatory authority of a Party is developing an SPS regulation and makes publicly available the information described in paragraph 1, the Party shall ensure that any person, regardless of domicile, has an opportunity, on no less favorable terms than any person of the Party, to submit comments on the regulation,	in SPS measures, findings on animal diseases, significant Only notification of changes in measures Endeavour for Information exchange on controls and rejected import consignments US: Notice and comment for proposed regulations No notification of changes in pest/disease status and changes in SPS measures (but included in TPP) No information exchange

Title	EU TTIP	US TTIP	Comments
		including by providing written comments and other input with respect to the information described in paragraph 1, to the regulatory authority. The Party shall promptly make publicly available any comments it receives on the regulation, except to the extent necessary to protect confidential information or withhold personal identifying information or inappropriate content, in which case the Party shall ensure it makes publicly available a version that redacts such information or a summary of the comment that does not contain such information. 4. In determining the time period during which interested persons may submit comments on the regulation, each Party shall take into account the relevant decisions of the WTO SPS Committee. 5. Where a regulatory authority of a Party issues any final administrative decision for an SPS regulation, each Party shall also make publicly available: (a) the text of the regulation; (b) an explanation of the regulation, including its objectives, and how the regulation achieves those objectives, and the rationale for the material features of the regulation (to the extent different from the explanation provided in accordance with paragraph 1 (c)); (c) the regulatory authority's views on substantive issues raised in the comments; and (d) an explanation of the nature and the reason for any significant revisions to the regulation since the Party made it available for public comment. 6. Each Party shall publish, in print or electronically, all final SPS regulations in a single official journal or website. Each Party shall publish in this single official journal or website the text of	

Title	EU TTIP	US TTIP	Comments
		any SPS regulation it is developing and that it makes publicly available in accordance with paragraphs 1 and 2.	
Elimination of Redundant Controls	The Parties recognize each other's competent authorities as responsible to ensure that establishment, facilities and products eligible for exports meet the applicable sanitary or phytosanitary requirements of the importing Party. 2. The importing Party shall accept establishments or facilities that were authorized and listed by the exporting Party without re-inspection, third party certification or any other additional guarantees.		EU: Proposal of MRA
EU: Audits and Verification US: Audit and Inspections)	1.In order to maintain confidence in the effective implementation of the provisions of this Chapter, each Party has the right to carry out an audit or verification, or both, of all or part of the other Party's control system. Audits shall follow a systems based approach which relies on the examination of a sample of system procedures, documents or records and, where required, a selection of sites. 2. The nature and frequency of audits and verifications shall be determined by the importing Party taking into account the inherent risks of the product the track record of past import checks and other available information, such as audits and inspections undertaken by the competent authority of the exporting party. 3. For the purpose of paragraph 1, the importing Party shall endeavor to rely on audits and verifications undertaken by the competent authority of the exporting Party. 4. Audits and verifications shall be conducted in accordance with {Annex VII} and in line with internationally agreed guidelines5. 5. Verification procedures may include, but are not limited to: (a) an assessment of all or part of the exporting Party's total control program, including, where appropriate, reviews of the exporting Party's inspection and audit programs, and (b) on-site checks and inspections of a selection of sites within the scope of the audit.	1. Each Party shall conduct any audits of the other Party's competent authorities in accordance with Annex X-C. 2. Each Party recognizes that, in order to verify compliance with applicable SPS measures and any applicable requirements agreed upon by the Parties, a Party may inspect premises, laboratories, and other relevant facilities in the other Party's territory.**]**	EU: Accommodates US concerns on frequency and nature of audits and verifications Importing Party shall endeavour to rely on audits of exporting Party Measures taken in response to audits shall be taken in proportion to risk (mention of proportionality of action) US: No mention that importing Party shall endeavour to rely on audits of exporting Party Transparency requirements for audits Discretion in taking decisions and actions based on audits (knowledge of authorities, objective evidence)

Title	EU TTIP	US TTIP	Comments
	6. For the European Union, the European Commission will carry out the verification procedures provided for in paragraph 1. The US agencies identified in {Annex I} shall facilitate the performance of these verification procedures by the Commission. 7. The US agencies identified in Annex I will carry out the verification procedures provided for in paragraph 1 for the US. The European Union shall facilitate the performance of these verification procedures by those agencies. 8. Any measures taken as a consequence of audits and verifications shall be proportionate to risks identified. If so requested, technical consultations regarding the situation shall be held in accordance with Article X.17 {Technical Consultation}. The Parties shall consider any information provided through such consultations. 9. Either Party may publish the results and conclusions of its verification procedures. 10. Each Party shall bear its own costs associated with the audit or verification.**]**		
Regulatory Approvals for Products of Modern Agricultural Technology		1. Where a Party requires a product of modern agricultural technology to be approved or authorized prior to its importation, use or sale in its territory, the Party shall allow any person to submit an application for approval at any time. 2. Where a Party requires a product of modern agricultural technology to be approved or authorized prior to its importation or sale in its territory, each Party shall make publicly available: (a) a description of the processes it applies to accept, consider, and decide applications for approval or authorization; (b) the competent authorities responsible for receiving and deciding applications for approval or authorization; (c) the timelines for completion of any steps or procedures in the approval or authorization;	US:

Title	EU TTIP	US TTIP	Comments
		(d) any documentation, information, or actions it requires from applicants as part of its approval or authorization processes; and under normal circumstances7 each Party shall promptly make publicly available any risk assessment it conducts as part of an approval or authorization process for a product of modern agricultural technology. 3. Each Party shall endeavor to meet applicable timelines for all steps in its approval or authorization processes for products of modern agricultural technology. Where a Party does not meet the timeline for a step in an approval or authorization process, upon request of the other Party, the Party shall provide a timely notification to the other Party explaining why the timeline for that step was not met and identify and update the timeline for all remaining steps in the approval or authorization process. 4. Each Party shall avoid unnecessary duplication and burdens with respect to: (a) any documentation, information, or actions required of applicants as part of its approval or authorization processes for products of modern agricultural technology; and (b) any information the Party evaluates as part of the approval or authorization processes for products of modern agricultural technology. 5. Each Party shall promptly publish any changes to its required approval or authorization processes or related requirements for products of modern agricultural technology. Except in urgent circumstances, each Party shall endeavor to provide a transition period between publication of any material changes to its approval or authorization processes or	

Title	EU TTIP	US TTIP	Comments
		related requirements for products or modern agricultural technology and their entry into force to allow interested persons to become familiar with and adapt to such changes, and endeavor to accommodate and avoid lengthening the approval or authorization process for applications that were submitted prior to publication of the changes. However, where the change reduces burdens on interested persons, entry into force should not be unnecessarily delayed. 6. Each Party shall maintain mechanisms or processes that provide an applicant seeking approval or authorization for a product of modern agricultural technology to timely obtain: (a) information on the status of its application for approval or authorization; (b) answers to questions regarding the approval or authorization processes and regulatory requirements for approval; (c) notice that the Party requires clarification or additional information from the applicant; 7. Each Party shall participate in the Global Low Level Presence Initiative to develop an approach or set of approaches to manage low-level presence in order to reduce unnecessary disruptions affecting trade. 8. The Parties hereby establish a Working Group on Trade in Products of Modern Agricultural Technologies ("Working Group") to be co-chaired by representatives of each Party's trade agency. Each Party shall designate officials from its competent authorities, including officials from authorities that conduct or evaluate risk assessments in connection with applications for approval of products of modern agricultural technology, to participate in	

Title	EU TTIP	US TTIP	Comments
		the Working Group. The Working Group shall be a forum for the Parties to: (a) discuss specific measures or issues related to modern agricultural technologies that may affect, directly or indirectly, trade between the Parties; (b) discuss and resolve specific trade concerns arising from a measure of a Party affecting products of modern agricultural technology; (c) facilitate the exchange of information, including on laws, regulations and policies of each Party, related to the trade of products of modern biotechnology; and (d) consult on issues and positions related to international cooperative and standard-setting efforts related to modern agricultural technologies. The Working Group shall provide an annual report to the Joint Committee concerning its activities as well as any progress it has made toward resolving trade concerns raised by a Party.	
Import Checks EU: and Fees			
Application of SPS Measures	Except as provided for in Article X.6 {Adaptation to regional conditions} each Party shall apply its sanitary or phytosanitary import conditions <u>to the entire territory of the other Party.</u> Where harmonized import conditions exist in one Party, these conditions shall apply to the entire territory of the exporting Party. Without prejudice to Article X.6 {Adaptation to regional conditions} each Party shall ensure that products which are in conformity with these import conditions can be placed on the market and used in its entire territory on the basis of a single authorization, approval or certificate.		<u>EU:</u> SPS measures shall be applied to entire territory of the other Party
(EU: Joint Management) Committee (US: on Sanitary and Phytosanitary Matters)	1. The Parties hereby establish a Joint Management Committee (JMC) for SPS Measures, hereafter called the Committee, compromising regulatory and trade representatives of each Party who have responsibility for SPS measures.	1. The Parties hereby establish a Committee on Sanitary and Phytosanitary Matters (the "Committee") compromising representatives of each Party. No later than {15}) days after the date of entry into force of	

Title	EU TTIP	US TTIP	Comments
	2. The functions of the Committee include: (a) To monitor the implementation of this Chapter and to consider any matter relating to this Chapter, and to examine all matters which may arise in relation to its implementation; (b) To provide direction for the identification, prioritization, management and resolution of issues; (c) To address any requests by the Parties for the modification of import checks; (d) To review the Annexes to this Agreement; (e) To provide a regular forum for exchanging information relating to each Party's regulatory system, including the scientific basis; (f) To prepare and maintain a document detailing the state of discussions between the Parties on their work on recognition of the equivalence of specific SPS measures. 3. In addition, the Committee may, *inter alia*: (a) identify opportunities for greater bilateral engagement, including enhanced relationships, which may include exchanges of officials; (b) discuss at an early stage, changes to, or proposed changes to, measures being considered; (c) facilitate improved understanding between Parties related to the implementation of the WTO SPS Agreement, promoting cooperation between Parties on SPS issues under discussion in multilateral fora, including the WTO SPS Committee and international standard-setting bodies, as appropriate; (d) identify and discuss, at an early stage, initiatives that have an SPS component and would benefit from cooperation. 4. The Committee may establish working groups consisting of expert-level representatives of the Parties, to address specific SPS issues. When additional expertise is needed, participants from nongovernmental organizations may be included, with the agreement of the parties. 5. A Party may refer any SPS issue to the Committee. The Committee	this Agreement, the Parties shall establish the Committee's terms of reference and identify through an exchange of letters the primary representative of each Party that shall serve as its co-chair on the Committee. Each Party shall ensure that its representatives on the Committee are the appropriate officials from its relevant trade agencies or ministries and competent authorities with responsibility for the development, implementation, and enforcement of SPS measures. The Committee shall meet at least once a year, unless the Parties decide otherwise. 2. The functions of the Committee shall include: (a) enhancing each Party's implementation of this Chapter and facilitating the exchange of information on each Party's progress in implementing this Chapter; (b) consulting on issues and positions related to the meetings and work of the WTO SPS Committee, the International Plant Protection Convention (hereinafter "IPPC"), World Animal Health Organization (hereinafter "OIE"), and the Codex Alimentarius Commission (hereinafter "Codex"); (c) providing a forum for discussion of and reviewing progress on addressing specific trade concerns related to the application of SPS measures and other SPS matters with a view to reaching mutually acceptable solutions; (d) referring issues to technical working groups in support of work that the Committee considers to be a priority, establishing additional technical working groups, and eliminating technical working groups other than those established pursuant to Article X.13; (e) {approving any modifications to the Annexes of this Chapter}; and	

Title	EU TTIP	US TTIP	Comments
	should consider any matter referred to it as expeditiously as possible. 6. In the event that the Committee is unable to resolve an issue expeditiously, the Committee shall, upon request of a Party, report promptly to the {TTIP Oversight Body}. {***Pending outcome of institutional chapter}***] 7. Unless the Parties otherwise agree, the Committee shall meet and establish its work program no later than six months following the entry into force of this Agreement, and its rules of procedure no later than one year after the entry into force of this Agreement. 8. Following its initial meeting, the Committee shall meet as required, normally on an annual basis. If agreed by the Parties, a meeting of the Committee may be held by videoconference or teleconference. The Committee may also address issues out of session by correspondence. 9. The Committee shall report annually on its activities and work program to the [TTIP Oversight Body. {***Pending outcome of institutional chapter}*** 10. Upon entry into force of this Agreement, each Party shall designate and inform the other Party of a Contact Point to coordinate the Committee's agenda and to facilitate communications on SPS matters.]	(f) reporting, at least annually, to the Joint Committee on its activities and progress on resolving specific trade concerns and other SPS matters, including those specific trade concerns for which a technical working group has developed an action plan. 3. A Party may request the Committee to refer a specific trade concern regarding an SPS measure or other SPS matter to a technical working group. If the Committee decides to refer the matter to a technical working group, it shall forward the request to the relevant technical working group and the requesting Party shall at that time provide the technical working group with technical information in support of its preferred approach for resolving the matter. Any decision to refer a matter to a technical working group shall take into account the resources of each Party and the need to balance the respective interest of each Party. The Committee may refer matters to a technical working group no more than once a year, except in cases of exceptional urgency.]	
Technical Working Groups			
Technical Consultation			
Emergency Measures	1. The importing Party may, on serious grounds, provisionally take emergency measures necessary for the protection of human, animal or plant health. 2. Emergency measures shall be notified to the other Party within 24 hours after the decision to implement them is taken and, on request, technical consultations regarding the situation shall beheld in accordance with Article 17 {Technical consultation}. The Parties shall consider the information provided through such consultations.		

Title	EU TTIP	US TTIP	Comments
	3. The importing Party shall: (a) consider information provided by the exporting Party when making decisions with respect to consignments that, at the time of adoption of emergency measures, are being transported between the Parties; (b) consider the most suitable and proportionate solution for consignments in transport between the Parties, in order to avoid unnecessary disruptions to trade and (c) revise or repeal, without undue delay, the emergency measures or replace them by permanent measures with a view to avoiding unnecessary trade disruption		
Animal Welfare	1. The Parties recognize that animals are sentient beings. They undertake to respect trade conditions for live animals and animal products that are aimed to protect their welfare. 2. The Parties undertake to exchange information, expertise and experiences in the field of animal welfare with the aim to align regulatory standards related to breeding, holding, handling, transportation and slaughter of farm animals. 3. The Parties will strengthen their research collaboration in the area of animal welfare to develop adequate and science-based animal welfare standards related to animal breeding and the treatment of animals on farms, during transport and at slaughter. 4. In accordance with Article X.20 {Collaboration in international fora (multilateral and bilateral)}, the Parties undertake to collaborate in international fora with the aim to promote the further development of good animal welfare practices and their implementation. 5. The Committee described in Article X.15 [Joint Management Committee] may appoint a working group to implement this provision.**]**		
Anti-Microbial Resistance			
Collaboration in International For a	The Parties will collaborate in the international standard-setting bodies (OIE, *Codex Alimentarius*, IPPC, etc.), with a view to reaching mutually satisfactory outcomes.**]**		

Title	EU TTIP	US TTIP	Comments
(US TPP: Cooperation)			
Recognition and Termination of the Veterinary Agreement	The Parties recognize the achievements that have been accomplished under the Agreement between *the European Community and the Government of the United States of America on sanitary measures to protect public and animal health in respect of trade in live animals and animal products* (the Veterinary Agreement) and confirm their intention to continue this work under the framework of this Agreement. {This Veterinary Agreement of 21 April 1998, as amended, is terminated from the date of entry into force of this Agreement.		

Annex 6: TBT legal text comparison: EU TTIP TBT proposal and Consolidated TTIP TBT text

Article	EU Initial Position TBT TTIP	Consolidated EU-US TBT TTIP Text (European Commission & USTR, 2016)	Comments
Objective and Scope (US: Scope and Coverage)	First, as far as possible, measures should aim at removal of unnecessary barriers to trade arising from differences in the content and application of technical regulations, standards and conformity assessment procedures. Second, although compatibility is important, it must be recognised that the systems of the two regions are different, both to meet the specific needs of their economies and for historical reasons, and it is not possible for one side to impose its system on the other; nor can either side be expected to treat its partner more favourably than its own side. Third, while the need for a high level of protection remains, measures should aim for methods of regulation, standardisation and conformity assessment that are not more trade-restrictive than necessary to achieve the relevant public interest objective, while taking into account the need to give preference to internationally harmonized methods. Fourth, closer co-operation between the EU and the US should not result in new hindrances to their trade with the rest of the world. Finally, it should be recognised that there are existing voluntary instruments of transatlantic co-operation in or related to TBT matters, arising from earlier sectoral or general trans-Atlantic initiatives, and that the results of such initiatives should not be compromised in any new Agreement. As stated under Section 3 above, while taking into account any divergences with regard to the above aspects, the EU considers that the aim of maintaining an overall balance of commitments in the TBT area can only be achieved if both the sub-regional (in the EU) and the sub-federal (in the US) regulations are covered.	1. The objective of this Chapter is to promote convergence in regulatory approaches by reducing or eliminating conflicting technical requirements as well as redundant and burdensome conformity assessment requirements. 2. This Chapter applies to the preparation, adoption and application of technical regulations, standards and conformity assessment procedures that may affect trade in goods between the Parties. 3. This chapter does not apply to: (a) purchasing specifications prepared by a governmental body for production or consumption requirements of governmental bodies; or (b) sanitary and phytosanitary measures as defined in Annex A of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. 4. All references in this Chapter to technical regulations, standards and conformity assessment procedures shall be construed to include any amendments thereto and any additions to the rules or the product coverage thereof.]	Similar
Incorporation of the WTO TBT Agreement	The WTO Agreement on Consideration should be given to incorporating the TBT Agreement into this agreement, in order to make its terms part of the	1. The WTO Agreement on Technical Barriers to Trade (hereinafter referred to as "the TBT Agreement") is	Similar

Article	EU Initial Position TBT TTIP	Consolidated EU-US TBT TTIP Text (European Commission & USTR, 2016)	Comments
	agreement, and to allow disputes arising out of its terms to be dealt with bilaterally.	hereby incorporated into and made part of this Agreement. 2. References to "this Agreement" in the TBT Agreement, as incorporated into this Agreement are to be read, as appropriate, as references to this Agreement (the TTIP). 3. The term "Members" in the TBT Agreement, as incorporated into this Agreement, shall have the same meaning in this Agreement as it has in the TBT Agreement. 4. Terms referred to in this Agreement, shall have the same meaning in this Agreement as they have in the TBT Agreement.	
Technical Regulations	Clearly, there is a gain from removing unnecessary duplicative compliance costs in the transatlantic market. There is also a potential gain to be had through measures such as improvements in information transfer and regulatory co-operation, and where possible through measures towards convergence – or at least, compatibility - of the parties' regulations themselves. Where neither side has regulations in place, the making of common – or at any rate coherent – technical regulations may be considered by the Parties. Wherever appropriate, consistent with Article 2.8 of the TBT Agreement, consideration should be given to basing such common / coherent regulations on product requirements in terms of performance rather than detailed design prescriptions. The EU's positive experience of the "New Approach" as a method of regulating based on setting "essential requirements" for health and safety without prescribing specific technical solutions, which themselves are laid down in supporting voluntary standards, shows that this is, for large industrial product sectors, a very efficient, flexible and innovation-friendly regulatory technique. Wherever possible, global harmonization of technical requirements should be pursued in the framework of international agreements / organisations in which both the EU and the US participate. This would then allow	1. The Parties undertake to co-operate as far as possible to ensure that their technical regulations are compatible with one another. 2. If a Party expresses an interest in developing a technical regulation of equivalent scope to one existing in or being prepared by the other Party, that other Party shall on request provide to the interested Party, to the extent practicable, relevant data upon which it has relied in the preparation of the technical regulation, and on request discuss the possibility of developing harmonized or compatible technical regulations. The Parties recognize that it may be necessary to clarify and agree on the scope of a specific request, and that confidential information may be withheld. A Party planning to introduce a technical regulation shall, on request of the other Party, discuss the possibility of the elaboration of compatible technical regulations, or the enhancement of the compatibility of existing technical regulations by the Parties. 3. The Parties undertake to co-operate towards global harmonization of technical requirements in the framework of existing or planned international agreements or organizations in which the US and the EU or its Member States participate.	(No mention of performance requirements, New Approach, standards should be left voluntary) Persuasion: Efforts towards convergence and compatibility Enhanced information exchange Global harmonisation

Article	EU Initial Position TBT TTIP	Consolidated EU-US TBT TTIP Text (European Commission & USTR, 2016)	Comments
	both sides to recognise each other's technical regulations as equivalent. Such standards ought in principle to be left voluntary, in order to allow sufficient flexibility for industry to choose the technical solution that best fits its needs, thus also stimulating innovation. Ideally, mandatory legislation should only set general requirements (e.g. health, safety, and the protection of the environment) and then leave flexibility to the market as to how compliance should be assured.	4. Each Party shall endeavor to ensure that products originating in the other Party that are subject to technical regulation can be marketed or used across all the territory of each Party on the basis of a single authorization, approval or certificate of conformity.	
Transparency	There is an interest in providing for improved transparency through a dialogue of regulators with regard to notification of draft legislation and replies to written comments received from the other party. In this context, notification of all draft technical regulations and conformity assessment procedures (including proposed new legislation), regardless of the initiator of the proposal in compliance with Articles 2.9 and 5.6 of the TBT Agreement, as well as the possibility to receive feedback and discuss the written comments made to the notifying party in compliance with Articles 2.9.4 and 5.6.4 of the TBT Agreement shall be ensured. Of particular importance will be the possibility to receive written replies to comments and the ability of regulators to communicate with each other during the comments procedures. The possibility to provide for an advanced information exchange between regulators, before the TBT notifications are carried out, may also be examined in this chapter or the context of cross-cutting disciplines.	1. In line with Articles 2.9.2, 5.6.2 and 3.2 of the TBT Agreement, the Parties agree: (I) to notify all relevant draft technical regulations and conformity assessment procedures to the WTO, regardless of the kind or form of the legal act, the level of government (central or local), or the authority adopting them, (ii) to make the draft text publicly available; (iii) in principle, to allow a period of no less than 60 calendar days following notification for the other Party to provide comments in writing to the proposal. 2. (a) Each Party shall, upon request of the other Party, provide information regarding the objectives of, legal basis and rationale for, a technical regulation or conformity assessment procedure, that the Party has adopted or is proposing to adopt. (b) Where a Party has received comments on proposed technical regulations or conformity assessment procedures from the other Party, it shall (i) upon request of the other Party, discuss written comments made by the other Party on such proposed technical regulations or conformity assessment procedures, with the participation of its competent regulatory authority, at a time when	(No mention of transparency in participation, reflecting that US is already very open) Bargaining: Introduction of notification system similar to that of national draft laws in non-harmonised areas of goods regulation, in which regulations and standards are notified, and may be subject to a "standstill measure" if the EU wishes to pursue regulatory action. Notification of draft technical regulations and CAPs, possibility to receive feedback and discuss written comments Possibility to receive written replies, ability of regulators to communicate with each other

Article	EU Initial Position TBT TTIP	Consolidated EU-US TBT TTIP Text (European Commission & USTR, 2016)	Comments
		they can be taken into account; and (ii) provide written replies to such comments to the other Party no later than the date of publication of the final technical regulation or conformity assessment procedure. 3. (a) From the date of entry into force of this Agreement, each Party shall make publicly available all new technical regulations, adopted either at central level or by entities at a lower level than Federal (US) or Union (EU). (b) Within [..] years of the date of entry into force of this Agreement, each Party shall make publicly available a complete registry of all its applicable technical regulations, new or existing, adopted either at a central level or by entities at a lower level than Federal (US) or Union (EU). (c) Within [..] years of the date of entry into force of this Agreement, each Party shall make publicly available a complete registry of the titles and references of standards that have been selected for reference in, or use in connection with, technical regulations. (d) The Parties agree to make the information referred to in (a), (b) and (c) of this paragraph accessible to the public through a single information point and to keep it up to date. 4. Where a Party detains at a port of entry a good imported from the territory of the other Party on the grounds that the good has failed to comply with a technical regulation, it shall without undue delay notify the importer of the reasons for the detention of the good, and provide an opportunity for the importer to appeal against the decision to detain the good.	
Conformity Assessment Procedures	While we should not abandon hopes to achieve greater compatibility of our conformity assessment regimes in those areas over time, we should pragmatically acknowledge that prospects for	1. The Parties undertake to co-operate with a view to reducing unnecessary burdens arising from differences in their respective conformity assessment requirements.	(Only in negotiating text: Movement towards, avoid dominant position, avoid specific CABs)

Article	EU Initial Position TBT TTIP	Consolidated EU-US TBT TTIP Text (European Commission & USTR, 2016)	Comments
	substantial convergence will generally be less promising than in new areas linked to innovative technologies or emerging risks. However, as both the US and EU regularly re-evaluate the regulations applicable to different industrial sectors over time, some re-evaluation might be possible on a common basis when it is prompted by the same reasons. A future commitment might be explored by which regulators on both sides, when introducing new rules, agree in principle (as set out in the TBT agreement) to apply common criteria with a view to identifying the least trade restrictive means of conformity assessment, commensurate with the relevant risks. In areas where registration / authorisation procedures and similar requirements apply in both Parties, approaches could be devised to make such procedures as compatible as possible and identify opportunities for administrative simplification that would alleviate burdens for manufacturers and facilitate their business under both systems. In situations where there is a valid case for mutual recognition (e.g., where the Parties both require third party conformity assessment), experience has shown that the application of mutual recognition is much more successful when based on similar requirements, usually based themselves on an international standard and/or an international agreement / scheme; furthermore, it is preferable from a trade-facilitation perspective if the agreement / scheme is not closed or applied bilaterally only, but open to several partners who apply the international standard and wish to be part of the agreement / scheme. It is therefore not proposed to consider extending the 1998 MRA in its present form to new areas. In the other areas that it nominally covers as well in any additional specific, mutually agreed sectors, other approaches to facilitate conformity assessment may be considered at a sectoral level.	2. To that end, the Parties undertake to review within [*timeline to be discussed*] their conformity assessment procedures in order to move progressively towards the least burdensome possible procedures, commensurate with the risk that the underlying technical regulations are intended to address. Priority areas for consideration shall include electrical safety, electro-magnetic compatibility, machinery and telecommunications. 3. [*Placeholder for referencing specific outcomes on conformity assessment resulting from the negotiations in individual sectors*] 4. Where Parties require third party conformity assessment of products as a condition of compliance with technical regulations applicable on their respective territories, the Parties undertake to give consideration to mechanisms to facilitate the mutual acceptance of the results of conformity assessment conducted by conformity assessment bodies (CABs) located on the territory of the exporting Party. 5. (a) The Parties shall take measures sufficient to avoid actual or potential conflicts of interest between conformity assessment bodies and standardization bodies, notably by establishing a clear separation of functions between them in cases where a standard referenced in technical regulations or otherwise allowed to be used to achieve compliance with technical regulations is set by an entity that also operates in the conformity assessment market. (b) The Parties shall ensure that standards referenced in technical regulations do not contain technical requirements that limit the choice of CABs or that refer to specifics CABs. 6. The Parties agree that, where a class of products is subject to conformity assessment procedures, and	(only in position paper: mention of agreeing on common criteria for the choice of conformity assessment procedures, mention of international standards as a basis for third-party conformity assessment in negotiating text, accreditation of CABs based on international standards) Persuasion: Gradual movement towards SDoC in limited sectors Mechanisms to facilitate mutual acceptance of conformity assessment Compatibility of registration and authorisation procedures Bargaining: Conflict of interest of SDOs No duplicative testing of components Avoid referencing of specific CABs in technical regulations

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	Arrangements for cooperation and mutual recognition between accreditation bodies exist through organisations such as the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF); there may be some merit in encouraging greater use of these agreements to facilitate the mutual recognition of accreditation certificates and, as a result, of accredited conformity assessment results.	where components or parts of such products are also subject to conformity assessment procedures (and thus constitute products in their own right), CABs approved by the regulator to assess products that include such components or parts shall be obliged by the regulator not to require as a condition of assessing the product as a whole, that such components or parts be re-assessed by the CABs themselves, independently of the final product. 7. The Parties shall take appropriate steps to prevent the establishment or abuse of dominant positions by any CAB in the market of its territory for the assessment of a specific product or class of risks. 8. In those areas where registration or authorization procedures or similar requirements apply in both Parties, the Parties undertake to co-operate with a view to making such procedures and related requirements as compatible as possible and to identify opportunities for administrative simplification that would alleviate burdens for economic operators and facilitate bilateral trade in the products concerned.	
Standardisation / Standards	Further consideration should be given to improving links between the systems, while allowing each to maintain its distinctive character. In a joint document adopted in November 2011, entitled "Building bridges between the US and EU standards systems", the EU and the US agreed on specific actions to improve each side's processes for the use of voluntary standards in regulation. Mechanisms should be created to promote cooperation and coherence in this area, in view of minimizing unnecessary regulatory divergences and better aligning the respective regulatory approaches. Improved cooperation between US and EU standardisation bodies should be sought, including the development of joint programmes of work, and the use – or potential	1. The Parties shall promote closer cooperation between the standardization bodies located within their respective territories with a view to facilitating, *inter alia*: (a) the exchange of information about their respective *activities*, (b) the harmonization of standards based on mutual interest and reciprocity, according to modalities to be agreed directly by the standardization bodies concerned, (c) the development of common standards, and (d) the identification of suitable areas for such co-operation, in particular in new technologies. 2. The Parties shall use their best endeavors to ensure that standardization bodies located within their respective territories (i) provide information in	(Only in position paper: implementation of the "building bridges" document) (Only in negotiating text: encourage SDOs to provide early notification of planned standardisation work criteria for selection of standards consider relevant international standards if referencing standards Updating of referenced standards) Persuasion: Closer cooperation between SDOs, development of joint work programmes

Article	EU Initial Position TBT TTIP	Consolidated EU-US TBT TTIP Text (European Commission & USTR, 2016)	Comments
	use – of the resulting common standards in connection with legislation. The results of bilateral cooperation should be also used to further global harmonization through the development of international standards. There may be areas in which the development of common or technically equivalent standards could be considered. A mechanism by which the EU and US standards systems could – by common agreement – work on common standards, for transposition in both economies, might be developed (maybe in the form of a common web-based standardisation platform). Clearly the preference would be for such common standards to be developed by international standardisation organisations and such a bilateral approach could not apply in the general case, but the possibility should be considered in some areas of mutual interest. Consideration could be given to systematic co-operation in the context of such bodies, possibly with exchange of technical data, common actions within such bodies, and commitment to transposing the results.	advance on their planned standardization activities that concern the development of new, or the review of existing, standards intended to support public policies, including the scope and purpose of the planned standards, and the prospective timetable procedures for their adoption, and (ii) publish drafts for public comment before finalizing or adopting such standards. 3. If a Party intends to select an existing or planned voluntary standard for reference in technical regulations, such selection shall be subject to objective, clear and transparent criteria, which shall be published before the selection is made. Standards for reference in technical regulations applicable on all or part of the territory of the Parties shall be selected following consideration of relevant international standards and other standards developed through an open and transparent process, including standards developed by standardization bodies located within the territory of the other Party. 4. The Parties undertake to keep references to standards in support of technical regulations up to date with the latest version of the standard and the latest review of the technical regulation. 5. The Parties shall endeavor to ensure that, in using standards to achieve compliance with the requirements of technical regulations or parts thereof, suppliers are free to use standards other than those chosen by domestic regulators for reference in such technical regulations, without prior authorization from the regulator, provided that such suppliers can demonstrate (e.g., through adequate technical documentation) that the applied alternative solution complies with the requirements of the technical regulation, or parts thereof.	use of other standards than referenced ones for compliance Bargaining: encourage SDOs to provide early notification of planned standardisation work criteria for selection of standards consider relevant international standards if referencing standards Updating of referenced standards

Article	EU Initial Position TBT TTIP	Consolidated EU-US TBT TTIP Text (European Commission & USTR, 2016)	Comments
Cooperation		The Parties shall strengthen their co-operation in the areas of technical regulations, standards, metrology, conformity assessment procedures, accreditation, market surveillance and monitoring and enforcement activities in order to facilitate the conduct of trade between the Parties, as laid down in Chapter […] (*Regulatory Cooperation*). This may include promoting and encouraging cooperation between their respective public or private organizations responsible for standardization, metrology, conformity assessment, accreditation, market surveillance and conformity assessment bodies to participate in cooperation arrangements that promote the acceptance of conformity assessment results.	