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Regulatory cooperation under TTIP – a risk for democracy and national regulation?

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With contributions by:
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Abbreviations

CAC	Codex Alimentarius Commission
CEN	European Committee for Standardization
CENELEC	European Committee for Electronical Standardization
ECHA	European Chemicals Agency
ETSI	European Telecommunications Standards Institute
FAO	Food and Agriculture Organisation
FTA	Free Trade Agreement
GDP	Gross Domestic Product
GMO	Genetically Modified Organisms
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MRA	Mutual Recognition Agreement
NGO	Non-governmental Organisation
NTM	Non-tariff Measure
OECD	Organisation for Economic Cooperation and Development
OIRA	US Office of Information and Regulatory Affairs
RCC	Regulatory Cooperation Council
SCCP	Standing Committee on Cosmetic Products
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
TFEU	Treaty on the Functioning of the European Union
UNCTAD	United Nations Conference on Trade and Development
UNECE	United Nations Economic Commission for Europe
VEA	Veterinary Equivalency Agreement
WHO	World Health Organisation
WTO	World Trade Organisation

Executive Summary

One of the most central topics of the ongoing negotiations on an EU/US Transatlantic Trade and Investment Partnership (TTIP) is the removal of so called non-tariff measures (NTMs) through regulatory cooperation. Efficiency gains and GDP growth are expected from greater regulatory convergence among both legal orders.

Position papers of the EU on a cross-cutting chapter on regulatory cooperation in TTIP suggest, among other, a permanent cooperation mechanism (e.g. a Regulatory Cooperation Council), provisions on sharing information on planned regulation and the possibility for the other party to comment on it at an early stage, cooperation in collecting data and evidence underlying regulatory action and exchange of such information, as well as strengthening the assessment of impacts of planned regulation on international trade and investment on the basis of common or similar criteria and methods.

Critics have voiced concerns about regulatory cooperation in TTIP being a vehicle for a race to the bottom in levels of protection or leading to delays in regulatory action. In addition, there have been allegations that institutions could be created through TTIP mandated to take decisions that would bypass parliamentary decision-making within the EU and its Member States, or would at least give trade and investment interests an undue weight in debates about regulatory action. The fact that it is at present unclear how precisely rules and mechanisms for regulatory cooperation in TTIP would look like and what sectors and issues regulatory harmonization is to extend to has fuelled such criticism.

This study assesses some of the claims and concerns visible in the current public debate on regulatory cooperation in TTIP as well as potential effects of the EU Commission's proposals on regulatory cooperation in TTIP. The study does not investigate more broadly what effects harmonization has on levels of environmental and consumer protection and whether enhanced regulatory cooperation in TTIP is desirable. The study presents different mechanisms for regulatory cooperation already in place: multilateral mechanisms that TTIP can – and in case of WTO law has to – build on, mechanisms already used between the US and EU, models contained in EU and US free trade agreements with third countries and finally the Australia/New Zealand cooperation, representing a particularly high degree of harmonization, and the US-Canada Regulatory Cooperation Council (RCC). The study also provides a brief overview of regulatory decision-making processes within the EU and the US, including stakeholder involvement and impact assessments.

On this basis, a first central conclusion from the study is that the **high expectations relating to what progress TTIP could bring on regulatory convergence between the two legal orders appear to be overblown**. It is questionable to what extent EU and US regulation can be made more consistent through TTIP or any mechanisms for regulatory cooperation created through the agreement. In many areas, EU and US regulation diverge significantly, which is at least partially a result of diverging preferences on the regulation of health risks or environmental ambition. Where regulatory differences result from such diverging policy choices, it is neither likely nor desirable that they are removed; the reasons that have prevented a closer alignment of both legal orders in the past would not all of a sudden disappear through TTIP.

Regulatory cooperation between the US and EU does not require a comprehensive TTIP agreement, and could also be implemented without it. Whether or not regulatory cooperation is successful does not primarily depend on the legal form in which it takes place; factors making such cooperation effective identified in the literature are the proximity of regulatory set ups and preferences in the countries involved, high level political commitment, mechanisms for taking account international regulatory cooperation in domestic regulatory proposals, the existence of appropriate consultation mechanisms, trust-building among regulators, functioning mechanisms for information exchange and ensuring compliance, sharing of cost and benefits, evaluation mechanisms and enough flexibility to adapt to changing conditions.

The second central conclusion is that there appears to be **no significant risk that TTIP would create institutions mandated to take decisions that could bypass or weaken national/EU legislative procedures**. The legal

orders involved have constitutional rules on which matters need to be regulated by formal legislation and which can be delegated to e.g. decision-making by the Commission at the EU side or a regulatory agency at the US side. TTIP and any structure for regulatory cooperation created under it will have to build on these rules, and is highly unlikely to modify them. Only in cases where executive bodies are afforded much leeway for independent decision-making when implementing legislation, there appears to be a risk that they could use that power strategically to implement decisions on harmonization (for example taken in an RCC), without a parliamentary decision on that specific matter. A systematic assessment to which extent such situations occur in areas subject to negotiations under TTIP was outside the scope of this study. However, with regard to the EU, the examples of cosmetics and chemicals regulation discussed in this study show that the scope for autonomous decision-making by the Commission is very limited. Representatives of Member States (even though not the Parliament or civil society representatives) are involved in the adoption of major implementing acts. Moreover, requirements that implementing acts need to comply with are often quite specific. These examples indicate that the scope for autonomous decision-making of EU executive representatives in a future RCC would be rather limited. However, in practice Member States rarely oppose a Commission proposal in committees, giving the Commission significant power in implementing EU legislation in practice. The extent to which Member States use their power in the committees would influence how much autonomous decision-making space the EU executive representatives would have in implementing decisions of a future RCC in practice. Where political decisions are concerned, legislative decision-making, involving the Council and the Parliament is required – and this would not be changed through TTIP.

Generally, the delegation of regulatory and/or implementing power to executive actors is not new within the US or the EU, with its extensive system of comitology. Nonetheless, such delegation generally raises issues in terms of the democratic legitimacy of decision-making, which also extend to any executive regulatory cooperation under TTIP. These problems are exacerbated if executive decision-making is influenced more strongly by business interests than, for example, by environmental and consumer groups. Past experiences with standard-setting at the international level show that this is not an unlikely scenario for a body established under TTIP with the aim of regulatory cooperation. Civil society organizations often simply lack the capacities to follow decision-making in multiple international fora.

Implementing proposals to take into account the trade impacts of a future measure in impact assessments would not need specific procedures within the EU. At least for legislative acts, the assessment of trade impacts could be integrated in the existing system of impact assessments. However, it may be questioned why one specific concern – the trade interests of US companies – should be given specific weight in each of these assessments, while the EU's impact assessment guidelines already require the assessment of economic effects more broadly, in addition to social and environmental effects. What also gives reason for concern is the EU Commission's idea that TTIP should contain an obligation to communicate plans on future regulation to the respective other side at a stage where there is no formal or routine involvement of stakeholders in the domestic regulatory process: the stage before a legislative draft is adopted and published. Giving trade partners access to EU decision-making at a stage where the public and other stakeholders are not involved would unduly privilege the interests of trade partners and their economic interests as compared to domestic consumer or environmental interests.

Thus, and this a third central conclusion of the study, the different proposals on regulatory cooperation lead to a risk that the balance of interests and actors that dominate EU internal policy-making may be modified to the benefit of trade and economic interests and to the detriment of other policy goals, such as environmental or consumer protection, i.e. a discursive shift in favor of economic and trade interests. Policy-making means striking a balance among various actors with different interests, values and ideas. Which interests prevail in the end is, among others, a function of how strongly certain interests are represented in the policy discourse. The establishment of an RCC, early comments from trade partners on legislative proposals as well as the systematic consideration of trade interests in impact assessments may lead to a situation where trade interests become more visible in the EU policy process and actors within that process more openly advocate in favor of such interests. This leads to a risk that the policy decisions taken in the end also favor trade over other interests, such as environmental or consumer interests. However, at present it can only be speculated to what extent such risks will materialize, with the outcome of the negotiations open.

Introduction[1]

The ongoing negotiations on a Transatlantic Trade and Investment Partnership (TTIP) between the EU and the US cover a wide range of issues, including the lowering of tariffs, protection of investors and liberalization of services. One of the most central – if not *the* central topic – is, however, the removal of so called non-tariff measures (NTMs)[2] through regulatory cooperation. A non-tariff measure can be defined as a policy measure other than a customs tariff that can have an effect on international trade in goods, changing quantities traded, or prices or both.[3] Import-related NTMs can take a wide array of forms. For example, a recent UNCTAD study distinguishes 15 different types of import-related NTMs, including technical and health-related standards, pre-shipment inspections, but also subsidies, distribution restrictions or rules on procurement.[4]

In principle, many types of NTMs can be removed through a trade agreement. Parties can agree to make their legal orders more similar to each other, i.e. to work towards regulatory harmonization through regulatory cooperation. Where legal orders are more similar, trade is facilitated, because business only needs to comply with one set of legal rules. Economically, NTMs are generally at least as significant as tariffs. It is estimated that for TTIP "as much as 80% of the total potential gains come from cutting costs imposed by bureaucracy and regulations, as well as from liberalizing trade in services and public procurement".[5] Another study concludes that if 50% of existing NTMs were harmonized between the US and EU, the EU GDP would be 0.7% higher in 2018 compared to a scenario were no action is taken, and the US GDP 0.3%.[6] However, the underlying studies are not uncontroversial[7] as trade gains are difficult to predict accurately. Proponents of using TTIP as a vehicle for improved EU-US regulatory cooperation argue that beyond the immediate economic benefits for EU-US trade, regulatory approaches agreed between the US and EU could evolve over time into multilateral or even global "gold standards".

Generally, the economic benefits from harmonization will depend, among others, on how different the two legal orders are; politically, harmonization may be easier where two legal orders are already rather similar. Numerous attempts have been made to compare US and EU approaches to (risk) regulation across different policy fields and over time.[8] The related studies have produced differing results. One eminent scholar contends that the US in general had more stringent regulation and a more cautionary approach towards risk regulation until around 1990, while since then the EU has been leading.[9] By contrast, another major comparative study concludes that the picture is more mixed, with the EU being more precautionary concerning some risks, and the US concerning others.[10]

However, there seems to be consensus that there is no pattern whereby EU regulation is always and in each policy area more stringent than US regulation; yet there are significant regulatory differences in many areas. These differences have resulted in several major trade conflicts between the EU and the US in the recent past, e.g. import beef produced with the help of growth hormones or the import of genetically modified organisms (GMOs) into the EU. These differences in approaches have made regulatory cooperation quite central to the TTIP negotiations.

1 We thank Nils Meyer-Ohlendorf (Ecologic Institute) for helpful comments on an earlier version of this study. This study has benefitted enormously from discussions during the conference "Tausche mehr Exporte gegen weniger Verbraucherschutz – Zur Ausgestaltung des transatlantischen Freihandelsabkommens" at the Evangelische Akademie Loccum, 2-4 May 2014, Germany, . We therefore wish to thank the conference participants and in particular the conference organizer, Marcus Schaper. A draft of this study was presented as part of an expert discussion organized by the Heinrich Böll Foundation in Berlin on 17 June 2014. The authors wish to thank the participants for helpful comments and questions.

2 An alternative term often used is non-tariff barrier to trade (NTB). However, "barrier" is less neutral than "measure", as it has a negative connotation of an obstacle that needs to be removed. However, what is seen as a "barrier" from a trade perspective may be a legitimate regulation needed for attaining certain public policy goals.

3 UNCTAD, *Classification of Non-Tariff Measures*, 1.

4 UNCTAD, *Classification of Non-Tariff Measures.*

5 Francois *et al.*, *Reducing Transatlantic Barriers to Trade and Investment – an Economic Assessment, vii.*

6 Berden *et al.*, Non-Tariff Measures in EU-US Trade and Investment – an Economic Analysis, xiv.

7 See for example the presentation by Stephan, "TTIP – Das Märchen vom Wachstums- und Beschäftigungsmotor" criticising the different impact assessments on TTIP from a methodological point of view. The German title of the presentation can be translated as "A fairy tale: TTIP as an engine of growth and employment."

8 For an overview of the literature see Renn and E. Donald Elliott, "Chemicals."

9 Vogel, *The Politics of Precaution*, 1ff.

10 Renn and E. Donald Elliott, "Chemicals," 28.

Box 1: Definition used in the study

When talking about how several countries can cooperate to make their legal orders more similar, many terms are used. This study is based on the following definitions:

Regulation is defined as the imposition of enforceable rules by government, including in the form of formal laws, but also other legally bindings rules and decisions.

Standard is used in the sense of the definition of the International Organization for Standardization (ISO): "A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose."[11] A standard can be set by public authorities, but also by private standardization bodies.

For **regulatory cooperation** the OECD definition is used whereby "international regulatory cooperation is defined as any agreement or organizational arrangement, formal or informal, between countries (at the bilateral, regional or multilateral level) to promote some form of cooperation in the design, monitoring, enforcement, or ex-post management of regulation, with a view to support the converging and consistency of rules across borders."[12]

The term **harmonization** refers to a process whereby laws or standards in different countries are made more similar to each other. A situation where regulation is identical or similar in different countries can be described as **regulatory coherence, convergence, consistency** or **compatibility**.

(Mutual) recognition describes a situation where countries mutually accept their decisions as valid in their own legal order, even though the underlying rules are different. Mutual recognition can, in principle, relate to a variety of decisions and procedures, e.g. conformity assessments that are carried out to verify whether a product fulfills certain legal requirements or – such as within the EU's internal market[13] – marketing approval decisions (see also Box 1: Mutual recognition and levels of protection - a clarification below). It is also possible that only one country unilaterally takes a decision on recognition of another country's decisions. Often a determination that the other jurisdiction's decision or underlying legal framework is **equivalent** to the domestic legal one is a step in the decision-making process on (mutual) recognition.[14]

A **conformity assessment** is a process whereby it is verified whether a product complies with the relevant legislation.

While bringing potential gains in efficiency and thus economic benefits, regulatory harmonization is contested. Laws, technical requirements, or administrative procedures serve important policy objectives, and they are – at least in democracies – the results of democratic decision-making. Protecting the environment or consumers, notably from product-related risks or negative impacts during production, is one important example. Therefore, the prospect of changes to such standards often leads to concerns that regulation would be harmonized at the lowest common denominator or that existing levels of protection would be undermined.[15]

Moreover, approaches to (risk) regulation vary widely between countries, reflecting not only divergent perceptions

11 ISO, Standards, http://www.iso.org/iso/home/standards.htm
12 OECD, International Regulatory Co-operation: Addressing Global Challenges, http://www.oecd.org/gov/regulatory-policy/irc.htm
13 On the principle of mutual recognition within the EU's internal market, see EU Commission, DG Enterprise and Industry, Mutual Recognition, http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/index_en.htm
14 For a discussion of the terms "recognition" and "equivalence" see Trachtman, "Embedding Mutual Recognition at the WTO," 782ff.
15 This is why Trachtman, "Embedding Mutual Recognition at the WTO" argues that mutual recognition should only be pursued to the extent that states can legitimately agree on an appropriate level of regulatory protection.

of risks and cultural preferences, but also entrenched regulatory cultures – all of these may be hard to change through a trade agreement. Much of the impact of harmonization depends on what precisely is harmonized and how.

There are an ever-increasing number of mechanisms and fora for regulatory cooperation – in the words of the OECD, these approaches are "formal and informal, broad and specific".[16] Some of these approaches have been used quite frequently in practice, including between the US and EU, others are very rare, such as the creation of a joint agency of two countries.

The present paper provides factual background to the debate on regulatory cooperation within TTIP, and in particular the envisioned horizontal chapter on this issue. The focus is on mechanisms for international regulatory cooperation and their potential impact on national level regulatory decision-making by US/EU institutions. The paper is not a statement on whether regulatory harmonization between the EU and the US is desirable in substance, or, more broadly, on the merits of the TTIP project. It does not compare EU and US regulatory approaches in any specific area, either.

The paper is structured as follows. **Chapter 1** summarizes the debates on regulatory cooperation in TTIP so far. **Chapter 2** provides an overview of existing models for achieving regulatory harmonization. The overview looks at mechanisms at the multilateral level with US and EU involvement, at mechanisms used between the US and EU already, at provisions contained in EU and US trade agreements with third countries, and finally at some particularly far-reaching examples of regulatory cooperation. **Chapter 3** contains a brief overview of regulatory processes within the US and EU in order to clarify which affairs are normally decided in a (parliamentary) legislation and which are delegated to executive entities (e.g. agencies or a ministry) that are normally the main actors in international regulatory cooperation. **Chapter 4** offers conclusions and recommendations.

16 OECD, *International Regulatory Co-Operation*, 20.

1 Regulatory cooperation in the TTIP negotiations – state of affairs

TTIP negotiation documents are not public. It is therefore difficult to know to what extent negotiations on regulatory cooperation have already made progress. However, some of the relevant preparatory documents provide insights into what the negotiations on regulatory cooperation in TTIP may be all about.

The **High Level Working Group** that prepared the ground for the TTIP negotiations recommended in its final report that the two parties negotiate the following with regard to regulatory cooperation[17]:

- an "SPS-plus" chapter, building on, but going beyond the Agreement on Sanitary and Phytosanitary Measures of the World Trade Organization (WTO),[18] including establishing a mechanism for improved dialogue and cooperation;

- a "TBT-plus" chapter, building on, but going beyond the WTO Agreement on Technical Barriers to Trade,[19] including establishing a mechanism for dialogue and cooperation;

- cross-cutting disciplines on regulatory coherence and transparency;

- provisions or steps aimed at promoting regulatory compatibility in specific, mutually agreed goods and services sectors;

- a framework for future regulatory cooperation, including an institutional mechanism.

Thus, regulatory harmonization and cooperation in TTIP extend to SPS measures and technical standards and specific sectors, but are also a cross-cutting, general topic. What kind of SPS-plus and TBT-plus obligations the parties aim at is not yet clear. Examples of SPS-plus obligations in other bilateral trade agreements are mechanisms aimed at prevention of food-related risks (e.g. a registration of food producers as a pre-condition for exports) and more far-reaching and precise obligations concerning information-sharing and notification than contained in the SPS Agreement.[20] Some TBT-plus provisions in existing trade agreements are described in section 2.3. However, the current study focuses on the more general, cross-cutting and institutional aspects only.

The **EU Commission**, who is leading the negotiations on the EU side, spelled out its position on these cross-cutting aspects in some detail in a 2013 initial position paper.[21] The Commission suggests a "horizontal" chapter in TTIP that would apply to "regulation defined in a broad sense, i.e. covering all measures of general application, including both legislation and implementing acts, regardless of the level at which they are adopted and of the body which adopts them". According to the position paper the chapter should include the following elements:

- a statement on **principles**, in particular an explicit recognition of the sovereign right of either party to regulate in pursuit of its public policy objectives as well as an explicit statement that TTIP should not be used as a means of lowering the levels of protection chosen by either party. The EU also wishes to include a preference for multilateral approaches and wants to mention certain tools, notably consultations and impact assessments;

- a statement of **objectives**, with the long-term goal to "eliminate, reduce or prevent unnecessary 'behind the border' obstacles to trade and investment";

17 See High Level Working Group on Jobs and Growth, *Final Report.*
18 In short, the SPS Agreement deals with certain measures aimed at protecting animal, human, or plant life and health against diseases, pest, contaminants and certain other risks. For more details on the SPS Agreement see below, section 2.3.
19 The TBT Agreement contains disciplines on technical standards, for more details see below 2.1.1.
20 See for an overview of SPS-plus provisions in recent bilateral agreements Lin, "SPS-plus and Bilateral Treaty Network: A 'global' Solution to the Global Food-Safety Problem?," 714.
21 EU Commission, DG Trade, *EU – US Transatlantic Trade and Investment Partnership: Trade Cross-Cutting Disciplines and Institutional Provisions – Initial Position Paper.* This position paper is more specific than the Commission's negotiating mandate and is thus quoted here.

- an effective **cooperation mechanism**, including sharing information on planned regulation and the possibility for the other party to comment on that;

- cooperation in collecting **data and evidence** underlying regulatory action and exchange of such information;

- strengthening the **assessment of impacts** of regulation on international trade and investment on the basis of common or similar criteria and methods and by way of closer collaboration;

- a mandate for regulatory cooperation towards increased compatibility/convergence in **specific sectors**, including after the conclusion of the agreement, and accompanying provisions, such as on monitoring of progress made towards regulatory convergence;

- an **institutional mechanism** including a consultation procedure for discussing emerging regulatory issues, a procedure to amend the envisioned sectoral provisions, and a **regulatory cooperation council or committee**, charged with "overseeing the implementation of the regulatory provisions of the TTIP and make recommendations to the body with decision-making power". This regulatory body could be charged with assessing proposals for enhancing regulatory compatibility, among others.

A leaked position paper attributed to the EU,[22] but whose precise origin and status are unclear, spells out some of these proposals in greater detail. It elaborates on the types of legislative acts to be covered, the information to be provided to the respective other side with regard to planned regulation and timing of such information, coordinated US/EU action in international bodies, regulatory dialogues, mechanisms for stakeholder involvement, and the inclusion of impacts on international trade in impact assessments. With regard to when the information is to be provided to the respective other side, the paper states that on the EU side, the exchange on legislative initiatives with the US side should take place before the adoption of the Commission proposal for a legislative act. The institutional mechanism for regulatory cooperation is called **"Regulatory Cooperation Council (RCC)"**, to be composed of senior level representatives from regulators/competent authorities and trade representatives, as well as the Commission's Secretariat General and the US Office for Information and Regulatory Affairs (OIRA). The RCC is to prepare an annual program of priorities for regulatory cooperation and to analyze submissions from stakeholders on areas for regulatory cooperation. Compared to the published position paper by the Commission, there is a less strong emphasis on the "right to regulate" of both parties.

Proposals for greater regulatory convergence have generally been endorsed by business communities, hoping for removal of barriers to transatlantic trade and investment. Some have made rather concrete proposals on how rules on regulatory cooperation in TTIP should look like.[23] Some of these proposals go further than what is contained in official EU or US statements so far, e.g. the proposal to create a transatlantic scientific advisory body involved in regulatory cooperation.[24]

By contrast, critics have voiced concerns about regulatory cooperation in TTIP being a vehicle for a race to the bottom in levels of protection or leading to delays in regulatory action.[25] In addition, there have been allegations that institutions and processes could be created through TTIP that are mandated to take decisions that would bypass parliamentary decision-making within the EU and its Member States, or would at least give trade and investment interests an undue weight in debates about regulatory action.[26] The fact that it is, at present, unclear how precisely rules and mechanisms for regulatory cooperation would look like and what sectors and issues regulatory harmonization is to extend to has fuelled such criticism. Notably, it is not yet clear how a body for regulatory cooperation would interact with legislators.

22 The paper is available at Corporate Europe Observatory, Regulation – None of our Business?, http://corporateeurope.org/trade/2013/12/regulation-none-our-business

23 See for example the leaked American Chemistry Council (ACC) – European Chemical Industry Council (CEFIC) Joint proposal enhancing U.S. – EU chemical regulatory cooperation under TTIP, http://ciel.org/Publications/CH_Pro.pdf; Presentation by BDI/ BUSINESSEUROPE// Representative of German Industry and Trade (RGIT): Regulatory Cooperation in TTIP – Priorities for German and European Industry, Stakeholder Meeting, TTIP Negotiations, 21 May 2014, http://www.bdi.eu/images_content/GlobalisierungMaerkteUndHandel/5__Verhandlungsrunde_Stakeholder_Forum_Regulatory_Cooperation_Wendenburg_ENG.pdf

24 See the ACC – CEFIC paper cited in the previous footnote.

25 See for example the letter by 170 NGOs to the EU and US chief negotiators of May 2014, http://ciel.org/Publications/TTIP_REGCO_12May2014.pdf

26 See for example Center for International Environmental Law (CIEL), Proposed Plans for US/EU Trade Deal Would Weaken Health, Consumer, Worker, Environmental Protections, 12 May 2014, http://ciel.org/Trade_Sustainable_Dev/TTIP_Responses_12May2014.html

An issue not often discussed is the impact that an increased harmonization of the US and EU legal orders would have on third countries. An agreement between two actors as economically powerful as US and EU may mean that other countries will be more or less forced to adopt these standards as well[27] – without, however, having a say in their development.

The debate on harmonization in the context of TTIP mirrors more general debates on the topic.[28] Proponents of greater harmonization point to the economic benefits of harmonization; opponents argue that different regulations may be the optimal policy response in different settings and that it is good if there is competition among regulators on the best models for regulation. They also point out that the adoption of different risk-related rules in different places can reduce overall risks, because if one risk-reduction strategy fails, the other may work.[29] Moreover, opponents of harmonization are concerned over a race to the bottom in levels of protection e.g. the environment, consumers or workers; however, it is empirically contested whether harmonization automatically means agreeing on the lowest common denominator. The EU arguably presents a case where harmonization did not involve a race to the bottom; yet, it is also special due to its supranational character.

2 Existing mechanisms for achieving regulatory coherence

How greater regulatory coherence can be achieved is not a new question in international trade politics or international politics in general. In practice, a wide array of mechanisms for regulatory cooperation exists. Given how diverse these mechanisms are, some kind of classification is helpful; however, a 2013 OECD study observes that there is no agreed classification of instruments for international regulatory cooperation.[30]

Different criteria appear useful in this regard:

- The degree to which mechanisms are **formalized** and results are binding, notably by being incorporated in international or national law.[31]

- The level of **ambition or comprehensiveness** the mechanisms represent: For example, creating a joint agency between two countries (such as done by Australia and New Zealand, see below section 2.4.1) represents quite a high level of ambition. By contrast, a commitment to hold occasional meetings between standard-setting bodies for informal information exchange represents a low level of ambition. A similar perspective is classifying mechanisms by the degree to which they limit the regulatory freedom of countries.[32]

- The **subject matter** of regulatory harmonization: for example, efforts at regulatory harmonization could extend to documentary requirements, classification and labeling of dangerous substances, substantive legal requirements that need to be fulfilled for product marketing approval, pre-legislation risk or impact assessments, product safety testing, conformity assessments, or inspection modalities.

- The **actors** involved: a distinction can be made between cooperation among public bodies and private standard-setting organizations. Concerning state cooperation, there are again different ways in which regulatory cooperation can take place: between parliaments, between agencies entrusted with regulatory tasks, or between enforcement

27 Lester and Barbee, "The Challenge of Cooperation," 866 formulate a similar expectation, but see it as development to be welcomed.
28 For a brief overview of the debate see Ahearn, *Transatlantic Regulatory Cooperation: Background and Analysis*, 4ff.
29 Arcuri, "Law and Economics of the SPS Agreement: A Critical Perspective," 181.
30 OECD, *International Regulatory Co-Operation*, 22.
31 The OECD study itself uses the criteria of formality and comprehensiveness for classification and distinguishes 11 different mechanisms. From the most to the least formal/comprehensive these are: integration/harmonisation through supra-national/joint institutions, specific negotiated agreements, regulatory partnerships, inter-governmental organisations, regional agreements with regulatory provisions, mutual recognition agreements, transgovernmental networks, formal requirements to consider regulatory cooperation when developing regulation, recognition of international standards, soft law instruments, and dialogue/informal information exchange ibid., 22ff.
32 For such an approach see Ahearn, *Transatlantic Regulatory Cooperation: Background and Analysis*, 10ff.

bodies. However, in practice, regulatory cooperation is in most cases the domain of the executive, i.e. representatives from agencies, ministries etc.[33]

- Moreover, a distinction can be made between **bilateral, regional and multilateral mechanisms**.

- Finally, one could also classify mechanisms by their **effectiveness** in bringing about regulatory convergence, even though such effectiveness is difficult to measure. According to the quoted OECD study, which is arguably the most comprehensive attempt at analyzing existing mechanisms for regulatory cooperation, the success factors making such cooperation effective are the proximity of regulatory set ups and preferences in the countries involved, high level political commitment, mechanisms for taking into account the international regulatory cooperation in domestic regulatory proposals, the existence of appropriate consultation mechanisms, trust-building among regulators, functioning mechanisms for information exchange and ensuring compliance, sharing of costs and benefits, evaluation mechanisms and enough flexibility to adapt to changing conditions.[34]

Some of the above dimensions are obviously linked. For example, a mechanism representing a high level of ambition can be expected to have a rather high degree of formality, too, and be anchored in binding legislation at the national level. For instance, the EU legal order represents a very high degree of harmonization between Member States – which was brought about by formal laws that Member States are bound by and the creation of joint institutions. On the other hand, not every mechanism that is legally binding is very effective while mechanisms that are not, may achieve a great deal.

In the following, we present different mechanisms already in existence. They are presented by actors involved, but to the extent feasible we will also look at the other criteria identified above. Among the many mechanisms in existence, we have chosen existing multilateral mechanisms that TTIP can – and in the case of WTO law has to – build on (section 2.1), mechanisms already used between the US and EU (section 2.2), models contained in EU and US free trade agreements with third countries (section 2.3) and finally the Australia/New Zealand cooperation, representing a particularly high degree of harmonization, and the US-Canada Regulatory Council which seems to be a blueprint for debates about a Regulatory Cooperation Council in TTIP (section 2.4).

2.1 Multilateral mechanisms

In this chapter, we will look at multilateral mechanisms for regulatory cooperation and harmonization. More precisely, different fora will be presented. First, relevant mechanisms of the World Trade Organization (WTO) are described. The underlying rules are not only referenced in TTIP negotiation documents, but the WTO also provides experience with regulatory cooperation that is of relevance to the TTIP negotiations. Second, we will also look at two international standardization organizations, the private International Organization for Standardization (ISO) and the FAO/WHO Codex Alimentarius Commission (CAC). These standardization bodies are linked to the WTO: WTO law refers in several instances to such international standards as "benchmark" for national regulation.

2.1.1 World Trade Organization

Under the WTO's roof, several international agreements as well as institutional mechanisms are gathered. In the following, we will look at those that are of most relevance to regulatory cooperation.

SPS and TBT Agreements

The WTO Agreements on Technical Barriers to Trade (TBT) and on Sanitary and Phytosanitary measures (SPS) both impose restrictions on WTO Members' product-related regulation. The SPS covers certain health-related measures; the TBT is more general in scope. Both agreements contain substantive obligations for WTO Members. For example, the SPS Agreement requires that measures be based on scientific risk assessments.

In the present context, however, the focus is on the provisions in both agreements addressing regulatory cooperation as a means to reduce trade barriers. The agreements contain the following mechanisms for regulatory cooperation:

33 With regard to US-EU regulatory cooperation so far see for example Ahearn, *Transatlantic Regulatory Cooperation: Background and Analysis*.
34 OECD, *International Regulatory Co-Operation*, 100ff.

Information exchange/transparency: the TBT Agreement requires parties to provide information to other WTO Members on planned technical regulations,[35] if these are not based on international standards, to allow time for comments and to take these comments into account.[36] Detailed transparency provisions are also established for the setting of standards[37] and for conformity assessment procedures.[38] Parties are also obliged to establish "enquiry points", where information is made available on such aspects as relevant measures and standardizing bodies. The SPS Agreement requires Parties to notify changes in their measures.[39] In addition, Annex B of the agreement sets out the specific provisions for information exchange and transparency: Parties need to publish new regulations promptly; establish enquiry points; notify other Parties of proposed regulations, allow reasonable time for commenting and take comments into account.

Recognition of equivalence of measures: Article 4 SPS commits Parties to "accept the sanitary or phytosanitary measures of other Members as equivalent…if the exporting Member objectively demonstrates…that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection". Furthermore, Parties are obliged, "upon request" to enter into consultation on agreements recognizing the equivalence of SPS measures. The SPS Committee, overseeing the function of the agreement, has taken a decision on the implementation of Article 4, specifying the roles of importing and exporting Parties.[40] The TBT Agreement commits Parties "to give positive consideration to accepting as equivalent technical regulations of other Members …provided they are satisfied that these regulations adequately fulfill the objectives of their own regulations".[41] The TBT Agreement is thus less specific on the requirements that need to be fulfilled for the recognition of equivalence. Both the TBT and the SPS Committee have carried out extensive work on clarifying the rules on equivalence in the respective agreements; however, the underlying obligations are formulated in a weak manner.

Mutual recognition of conformity assessment procedures: the TBT obliges Parties to adopt and join international systems for conformity assessment, wherever practicable.[42] It also commits Parties to "ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted … provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures."[43] For this purpose, Parties are also encouraged to negotiate mutual recognition agreements.[44] The SPS agreement does not refer to "conformity assessments" but sets out provisions on control, inspection and approval procedures.[45] However, no provisions on mutual recognition or on the conclusion of mutual recognition agreements exist in this context.

Harmonization: both agreements put particular emphasis on harmonization of regulatory rules, mainly through the use of international standards. The TBT Agreement requires Parties to use international standards, where available. Only if the standard "would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued" may Parties decide to deviate from these standards.[46] The SPS Agreement also obliges Parties to base their regulatory measures on international standards. Parties may introduce SPS measures that result in a higher level of protection than would be achieved by international standards, provided they comply with the other obligations of the SPS Agreement, notably the requirement to base measures on a scientific risk assessment.[47] Parties are also obliged to participate in international standardizing bodies, respective international organizations such as International Organization of Standardization ISO, the Codex Alimentarius Commission, the International Office of Epizootics, and organizations operating within the framework of the International Plant Protection Convention.[48] Altogether, the SPS and TBT approaches may be described

35 Under the TBT Agreement a „technical regulation" is a binding instrument, while a „standard" is voluntary in nature.
36 Art. 2.9 TBT.
37 Code of Good Practice, Art. 4 TBT.
38 Art. 5 TBT.
39 Art. 7 SPS.
40 Decision on the implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures, http://www.wto.org/english/tratop_e/sps_e/equivalence2001_e.htm
41 Art. 2.7 TBT.
42 Art. 9 TBT.
43 Art. 6.1 TBT.
44 Art. 6.3 TBT.
45 Art. 11, Annex C SPS.
46 Art. 2.4 TBT.
47 See Art. 3 SPS.
48 Art. 2.6 TBT, Art. 3.4 SPS.

as "soft positive harmonization"[49]: while WTO Members are not obliged to follow international standards, these standards are used to assess whether a WTO Member's measures are in conformity with these agreements and thereby incentivize Members to use these standards in regulation. Thus, it has been observed that the relevant international standards have become quasi-binding through the SPS and TBT Agreements.[50]

Institutional mechanisms under the TBT and the SPS Agreement: the functioning of each of the agreements is overseen by a committee. The committees serve as fora for mutual exchange, the discussion of WTO Members' SPS and TBT measures and the implementation of the agreements, as well as the development of guidance for this purpose, among other functions.

As the above overview shows, the rules contained in the TBT and SPS Agreements, while legally binding, impose obligations of varying strength. Notably, the provisions on mutual recognition are formulated in a rather weak way. The picture on the practical effects of these mechanisms is mixed, even where the agreements contain strictly formulated obligations. For example, WTO Members have widely diverging practices concerning the notification of their SPS and TBT measures to the WTO, as required by the TBT and SPS Agreements: the EU notifies relevant legislative drafts to the TBT Committee, once adopted by the College of Commissioners; by contrast, the US does not notify draft legislation.[51] However, the (draft) bills in the US are much more numerous than draft legislation is in the EU. The mutual recognition provisions of the SPS Agreement have been subject to extensive debates within the WTO, but have had few practical effects. WTO Members have concluded few comprehensive mutual recognition agreements.[52]

Institutional mechanisms in the WTO: Trade Policy Review Mechanism and dispute settlement

A cross-cutting mechanism for regulatory cooperation and harmonization in the WTO also deserves mention: the **Trade Policy Review Mechanism**. Conducting Trade Policy Reviews is one of the principal functions of the WTO and an important mechanism to increase transparency of trade policy. Countries' trade policies are regularly reviewed under this mechanism, depending on their share in global trade, every two to six years. The trade policy reviews are undertaken by the Trade Policy Review Body where all WTO Members are represented. The review is based on a report from the respective government and a report from the WTO Secretariat. WTO Members can ask questions and make statements to the Member under review. The final reports contain sub-chapters on technical requirements and standards and on sanitary and phytosanitary standards. The Trade Policy Review Mechanism is thus an informal mechanism allowing Members to gather information about each other's trade policy, but also a forum where disagreement over NTMs can be voiced.

2.1.2 International Organization for Standardization

In the following, two international standardization organizations are briefly presented: the International Organization for Standards (ISO) and the Codex Alimentarius Commission (CAC). They are presented here because they produce international standards that are also of relevance in WTO law, and are thus particularly important international standardization organizations. However, they are by far not the only standardization organizations at the international or regional level.

ISO creates standards for almost all facets of technology and business.[53] It is a private, not-for-profit organization. Its membership is composed of national standardization bodies – one per country – that represent their countries. There are nearly 120 full members, with more than 40 other countries acting as observers in one way or the other.[54] The EU's standardizing bodies are not members of ISO, but Member States' bodies are. The development of new standards is request-driven, i.e. usually industry makes a request to the national standardization organization which then brings the request to ISO.[55] Most of the work of developing technical standards is undertaken in technical committees,

49 Herwig, "Transnational Governance Regimes for Foods Derived from Biotechnology and Their Legitimacy," 200.
50 For the ISO, see Wirth, "The ISO: Private Voluntary Standards as Swords and Shields," 156.
51 Parker and Alemanno, *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems*, 3.
52 Echols, "Equivalence and Risk Regulation under the World Trade Organization's SPS Agreement," 80ff.
53 Standards, http://www.iso.org/iso/home/standards.htm
54 For a description of the different membership categories in ISO as well as the actual members, see ISO Members, http://www.iso.org/iso/home/about/iso_members.htm
55 How does ISO develop standards?, http://www.iso.org/iso/home/standards_development.htm

composed of members of industry, NGOs, government and other stakeholder representatives. These members are chosen by ISO members. Consumers also have the opportunity to take part in the decision-making process through the NGO Consumers International, which is represented in ISO's technical committees, or national members can have consumer representatives within technical committees.[56] However, in general, ISO's work is described as industry-oriented.[57] Adoption of standards is through the following procedures: a draft standard is adopted based on consensus within the competent technical committee, and after comments and repeated rounds of voting by ISO members. A standard is approved if two-thirds of the full members support it, and if no more than a quarter of all votes cast are negative.[58] ISO standards are not binding on the ISO members. However, through the link that WTO law established with these standards, WTO members have advantages from using these standards as a basis for regulation.

The **CAC** develops standards and other guidance documents for foods, with a view to improving food safety. The CAC standards database currently shows almost 340 standards.[59] The CAC is part of the Joint FAO/WHO Food Standards Programme to the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). It is composed of members of WHO and/or FAO, including regional integration organizations such as the EU. Currently there are more than 180 members.[60] The CAC admits both international organizations and NGOs as observers; among the latter are numerous business associations.[61] Observers have the right to speak at meetings. Governmental delegates may decide whether to include members of business or civil society into the delegation to the biannual Commission meetings.[62] Standards are developed in committees, composed of Commission members or members selected by the Commission.[63] The initiative for new standards lies with the Commission itself, individual members or committees. Decision-making on standards involves a multi-step process during which all interested members can comment on a new draft standard developed by a committee, before the Commission adopts its.[64] Decision-making on new standards is consensus-oriented, even though it is possible to take a decision by simple majority.[65] CAC decision-making has been criticized for a variety of reasons, including the heavy involvement of industry representatives (as compared to consumer groups) and developing countries' lack of capacity to participate meaningfully in deliberations.[66] This criticism is partially linked to the fact that while Codex standards are formally non-binding on members, they have gained in importance since the establishment of the WTO. As in the case of ISO standards, WTO members have strong incentives to use these standards as a basis for regulation.[67]

2.2 Regulatory cooperation between the US and EU

While regulatory differences between the US and EU have often been emphasized in the TTIP discussion, the idea of regulatory cooperation between the US and EU is not new. Both are part of multilateral mechanisms for regulatory cooperation. They have engaged in various efforts on regulatory cooperation over the years,[68] including e.g. Guidelines for Regulatory Cooperation and Transparency which were agreed on in 2002.[69] As part of these efforts, both sides have also agreed on a series of bilateral agreements, which have, however, been effective to varying degrees. In the following, we will briefly present these agreements which relate to different sectors and contain different mechanisms for regulatory cooperation. A few obstacles that have been identified concerning more effective regulatory cooperation are the independence of regulatory

56 Who develops ISO standards? http://www.iso.org/iso/home/standards_development/who-develops-iso-standards.htm
57 Wirth, "The ISO: Private Voluntary Standards as Swords and Shields," 147.
58 ISO Deliverables, http://www.iso.org/iso/home/standards_development/deliverables-all.htm
59 See http://www.codexalimentarius.org/standards/list-of-standards/en/?provide=standards&orderField=fullReference&sort=asc
60 Codex Members and Observers, http://www.codexalimentarius.org/members-observers/en/
61 Codex Observers, http://www.codexalimentarius.org/members-observers/observers/en/
62 Herwig, "Transnational Governance Regimes for Foods Derived from Biotechnology and Their Legitimacy," 205.
63 Codex Alimentarius Commission, *Codex Alimentarius Commission Procedural Manual*, 21st Edition.
64 For the details see ibid., 27ff.
65 Herwig, "Transnational Governance Regimes for Foods Derived from Biotechnology and Their Legitimacy," 205; Livermore, "Authority and Legitimacy in Global Governance," 787f observes that in more recent times, decisions by voting have become more frequent.
66 Livermore, "Authority and Legitimacy in Global Governance," 777ff.
67 Ibid., 776.
68 Some past initiatives are described by Lester and Barbee, "The Challenge of Cooperation," 850; Ahearn, *Transatlantic Regulatory Cooperation: Background and Analysis*, 13ff.
69 For an overview past EU-US regulatory cooperation, see Ahearn, *Transatlantic Regulatory Cooperation: Background and Analysis*, 13ff.

agencies involved, a lack of resources for transatlantic regulatory collaboration, and the complexity of the matter.[70]

2.2.1 The Mutual Recognition Agreements (MRAs) between the US and EU

In 1998, the EU and US concluded a mutual recognition agreement, containing sectoral annexes on telecommunication equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical goods manufacturing practice, and medical devices.[71] Mutual recognition in all of these agreements relates to conformity assessments. The basic mechanism is that each Party designates conformity assessment bodies. A conformity assessment body verifies whether products destined for export to the other Party conform to the latter's applicable regulation. If so, the conformity assessment body issues a certificate to this end, which is – after a transitional period of mutual trust-building built into the agreement – accepted by the importing party. A Party wishing to designate a conformity assessment body proposes so to the other Party. The other Party may accept or reject the proposal within a given time; in case of rejection, there is a procedure for resolving the controversy. The MRA appears to have largely been a failure. Only two of the annexes – on recreational craft and telecommunication equipment – have fully entered into force.[72] The other annexes did not become operational, because the agreement contained provisions, according to which they would only enter into force once a representative number of conformity assessment bodies had been designated. However, this number was not reached in all cases, which has been attributed US reluctance to accept European certifiers as equivalent to the US ones.[73]

In some other areas, the development of legislation in the EU has made the envisioned procedures largely superfluous; where no third party conformity assessment and certification is required for importing a product into the EU, there is no need for the procedures agreed with the US. The only annex to the MRA that the EU Commission describes as working "satisfactorily" is the one on telecommunications.[74]

2.2.2 US-EU Veterinary Equivalency Agreement

The 1999 Veterinary Equivalency Agreement (VEA) between the United States and the European Union was signed after six years of negotiations.[75] Its objective is to facilitate trade in animals and animal products by establishing a mechanism for the recognition of equivalence of sanitary measures and to improve communication and cooperation on sanitary measures.[76] The equivalency agreement allows differences in veterinary inspection requirements between the EU and US and ensures that each side can establish its own level of public health protection.

The agreement lays down the steps the parties have to take in a consultative process to determine whether a sanitary measure maintained by the exporting party achieves the importing party's chosen level of sanitary protection. The first step is the identification of the sanitary measure for which recognition of equivalence is sought; this is followed by an explanation by the importing party of the objective of the measure and the risks that it is to address. The exporting party then has to demonstrate that its sanitary measure achieves the importing party's level of sanitary protection, which is then verified by the importing party. The final decision rests solely with the importing party in accordance with its administrative and legislative framework.[77] When making the decision, the importing party is to use a system of equivalency rankings, which considers a measure fully equivalent or only equivalent under certain conditions.

The responsible regulatory authorities are specified in Annex II of the agreement. For the EU, the Veterinary equivalency agreements are handled through the EU's Health and Consumer Protectorate Directorate General (DG SANCO). The responsibility for monitoring the sanitary equivalence of the traded products is according to whether the product is exported or imported. For EU exports to the US, the responsibilities lie with the member states involved in the

70 Ibid., 17.
71 The text of the agreement is online at http://gsi.nist.gov/global/docs/mra/US-EU_MRA_Final_Version_1998.pdf
72 See http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/mutual-recognition-agreement/index_en.htm
73 Ahearn, Transatlantic Regulatory Cooperation: Background and Analysis, 16.
74 All information taken from EU Commission, Trade Issues... Technical Barriers to Trade: Mutual Recognition Agreements and Agreements on Conformity Assessment and Acceptance of Industrial Products, MRA Newsletter No 8.
75 Published in the EU Official Journal, L 118/3, 21 April 1998.
76 Art. 1 VEA.
77 Art. 7 VEA.

export. For imports, member states need to ensure compliance with applicable EU law.[78] The demarcation of responsibilities is quite different in the US, where it is dependent upon which regulatory agency has jurisdiction over the traded product. The US structure involves numerous agencies which are responsible for both domestically produced and imported animal products, depending on the type of commodity being traded: the US department of agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS), the Department of the Interior (DOI), the Fish and Wildlife Service (FWS), the Food and Drug Administration (FDA), the Food Safety Inspection Service (FSIS), and the Department of Commerce (DOC), the National Marine Fisheries Service (NMFS), or the Agricultural Marketing Service (AMS).[79]

After the implementation of the agreement, trade between the US and EU increased more strongly than with other trade partners, while it remained steady for US exports to the world. This suggests that the agreement fostered US-EU bilateral trade.[80] However, as a study by the US administration shows, the US more often recognizes EU standards as equivalent than vice versa. The US recognized 28 times the highest level of (full) equivalency for EU goods; the EU only did so 3 times for products originating in the US. The second highest level of equivalency, where the importing party accepts the exporting party's sanitary standards but with special conditions, is chosen 36 times by the US, but only 8 times by the EU.[81]

2.2.3 Recognition of equivalency of organic products

Article 33 of Council Regulation No 834/2007 on organic production and labeling of organic products regulates under which conditions products from third countries may be placed on the EU market as organic, because the production methods are regarded as equivalent to those set forth in the Regulation. Accordingly, the product has to be produced in accordance with rules equivalent to those laid down in the regulation for operators within the EU, the operator has to be subject to control measures of equivalent effectiveness at all stages of production, preparation and distribution in the third country and the product has to be accompanied by a corresponding certificate.[82] The assessment of equivalency shall take into account Codex Alimentarius guidelines CAC/GL 32.[83]

A list of third countries whose products are recognized as equivalent by the Commission is provided in Annex III of Commission Regulation No 1235/2008. The Commission Regulation contains rules for implementing the basic (Council) Regulation, in line with the mandate in the basic Regulation. The Commission regulation also lays down the procedure for requesting inclusion in the list of third countries:[84] The first step is a request from a third country to be included. The request shall be completed by a technical dossier, providing all the information needed for the Commission to ensure that the conditions set out in the regulation are met for products intended for import to the EU. The Commission then examines the rules of production and the control measures of the concerned third country, where necessary by sending experts for on-the-spot checks to the country concerned. The recognized countries have to send an annual report to the Commission regarding the implementation and the enforcement of the control measures established.

The Commission decides on the inclusion of countries into the list with the assistance of the Standing Committee on Organic Farming. This committee is comprised of representatives of all Member States and is chaired by a representative of the Commission.[85] The Commission submits a proposal to the Committee for a decision and the Committee issues an opinion by qualified majority.[86] If the committee opinion is positive, the Commission

78 McNulty, *Trade Policy Monitoring The US – EU Veterinary Equivalency Agreement: Content and Comparison,* 4.
79 Ibid.
80 Holo, Trade Policy Monitoring The US – EU Veterinary Equivalency Agreement: Content and Comparison, 2.
81 Ibid., 7 the figures appear to relate to the period 1999-2009.
82 Art. 33, para. 1 Council Regulation (EC) No 834/2007.
83 Art. 33, para. 2 Council Regulation (EC) No 834/2007.
84 Art. 8 Commission Regulation (EC) No 1235/2008.
85 Art. 37 Council Regulation (EC) No 834/2007; referring to Art. 5 Council Decision 1999/468/EC.
86 The procedure results from the following norms: According to Art. 37 (2) of Council Regulation No 834/2007 and Commission Regulation No 1235/2008, the decision is to follow the so called "regulatory procedure with scrutiny" as set out in Art. 5 and 7 of Decision 1999/468/EC (the so called "Comitology Decision"). However, Decision 1999/468/EC has been replaced by Regulation No 182/2011 of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing power. According to Art. 13 (1) (c) of the latter Regulation, in cases where the "regulatory procedure with scrutiny" of the old Comitology Decision had to be used, the "Examination Procedure" described in Art. 5 of the new Regulation is now applied. This is thus the procedure to use for inclusion of a country in the list of recognised countries.

adopts a regulation including the country into the list. If the Committee's opinion is negative or there is no opinion, the Commission may not adopt the proposed act, but can submit the matter to the Appeal Committee. If the opinion of the Appeal Committee is negative, the act cannot be adopted.

The first list of recognized countries included Argentina, Australia, Costa Rica, India, Israel, New Zealand and Switzerland.[87] In 2012, the US was included in this list, after on-the-spot checks had been carried out within the US.[88] The inclusion of the US into the list of third countries was a result of the EU-US Organic Equivalency Cooperation Arrangement, concluded in 2012. Under the Arrangement, the EU commits to recognizing the USDA National Organic Program (NOP) as equivalent to the EU Organic Program (under applicable EU regulations) and will allow US organic products to be marketed as "organic" in the EU using the EU organic logo, and vice versa, under the following two conditions:

1) Tetracycline and streptomycin were not used to control fire blight in apples and pears (for US exports to the EU); and
2) Antibiotics were not administered to animals (for EU exports to the US).

In addition to these restrictions, all products traded must be accompanied by an organic export certificate.[89]

A concern raised by the Commission regarding the bilateral equivalence system is that it is reaching its limits in terms of administrative burden and resources. The management of the list of equivalent third countries is impaired by the lack of resources for dealing with requests for inclusion in the list. Hence, out of the 25 applications for inclusion received by the Commission between 2000 and 2008, only 8 could be examined.[90]

2.3 Tools for regulatory cooperation in selected EU and US free trade agreements

Free trade agreements (FTAs) often contain a specific chapter on Technical Barriers to Trade (TBT) that provides for at least some tools for regulatory cooperation, building on, but often also going beyond the WTO TBT Agreement. The following section summarizes the uptake of regulatory cooperation tools in FTAs of the EU and US with third countries, based on the examples of the EU – Peru/Colombia FTA, EU-South Korea FTA, the US-Australia FTA, and the North American Free Trade Agreement (NAFTA) between the US, Canada and Mexico. The EU FTAs are relatively recent while the US-Australia agreement – like TTIP – is between two OECD countries. Finally, NAFTA constitutes a major attempt at closer regional cooperation. An overview table is contained in the Annex to this study.

The focus is on provisions that go beyond the rules in the TBT Agreement.

Information exchange procedures/ transparency measures: all FTAs listed above contain provisions on information exchange and transparency. While the US-Australia FTA mainly reaffirms the provisions on notification and consultation on proposed technical regulations or conformity assessment procedures, the EU FTAs contain a broader set of provisions. These concern the exchange of experience and underlying data, especially if the other Party is considering introducing similar measures.

Recognition of conformity assessment procedures: some FTAs encourage Parties to possibly converge or make compatible their respective conformity assessment procedures, but especially in the EU FTAs, the language of the provision is rather careful. In contrast, the US FTAs commit Parties to "accredit, approve, license, or otherwise recognize conformity assessment bodies in the territory of the other Party", and to provide reasons if the Party refuses to do so.

87 Art. 18 Commission Regulation (EC) No 1235/2008.
88 See Implementing Commission Implementing Regulation (EU) No 126/2012 of 14 February 2012 amending Regulation (EC) No 889/2008 as regards documentary evidence and amending Regulation (EC) No 1235/2008 as regards the arrangements for imports of organic products from the United States of America.
89 GAIN Report (2012): The EU-U.S. Organic Equivalence Cooperation Arrangement.
90 Sanders, *Evaluation of the EU Legislation on Organic Farming*, 175.

Recognition of results of conformity assessment procedures: when harmonization of standards and technical regulations is not possible, Parties can agree on accepting the other Party's approval procedures as equivalent to their own. Normally, specific sectoral mutual recognition agreements (MRAs) are adopted for this purpose. As exemplified by the US-EU MRAs, under such an agreement the body of the exporting country checks the conformity of the product with the rules of the importing country and the importing country accepts the results. In contrast to a situation where regulation is harmonized, under an MRA, products would still need to comply with two different regulatory systems: that of the importing and exporting country. Both the EU and the US have signed a number of MRAs with other countries, mostly relating to specific sectors.

Recognition of equivalence of technical regulation: when harmonization of relevant standards is not possible, Parties can agree on accepting the other Party's standards as equivalent to their own. This approach is based on the assumption that regulatory objectives can be achieved through different means that are equally effective. As an example, the sectoral annex to the EU-South Korea FTA on automotives contains a provision that commits Korea to recognize UN-ECE and EU standards as equivalent to Korean standards.

Recognition of fully harmonized technical regulation: harmonization is the most effective tool for avoiding technical barriers to trade, but is often unlikely to be realized and not always desirable given underlying differences in policy environments and levels in protection. The EU internal market area is the best example for a full harmonization. Another possibility is to make use of internationally-agreed standards and regulations. The FTAs listed above (and the WTP TBT/SBS agreements) require Parties to base their technical regulation on these standards where possible, and to cooperate in relevant fora for developing international standards. As countries adapt their regulatory systems to these standards, regulations across countries are increasingly harmonized. However, there are many sectors for which no such international standards exist, and it requires lengthy negotiations to agree on these.

The FTAs exhibit different degrees of **institutionalization** of the TBT chapters and the above tools or provisions. Both the examined EU FTAs establish a specific committee or coordination mechanism which monitors the implementation of the TBT provisions and facilitates further cooperation on TBT matters in the form of working groups or dialogues. The NAFTA established a Committee on Standards-Related Measures and additional subcommittees on specific topic areas have been established, namely for Land Transportation Standards, Telecommunications Standards, Automotive Standards, and for Labeling of Textile and Apparel Goods.

2.4 Others

In this section, we will look at two mechanisms for regulatory cooperation that are of particular interest to the TTIP discussion: the Australia-New Zealand regulatory cooperation (section 2.4.1) and the US-Canada Regulatory Cooperation Council which could serve as a point of reference for negotiations on a similar institution in US/EU relations (section 2.4.2).

2.4.1 Australia – New Zealand Cooperation

A particularly close form of regulatory cooperation can be found between Australia and New Zealand. The two countries have strong historical, political and cultural ties, which support a high degree of economic, operational and legal cooperation and coordination and even the establishment of shared institutions. The Australian New Zealand Closer Economic Relations Trade Agreement (ANZCERTA, also short CER), concluded in 1983, has been the key framework advancing the bilateral economic relationship and has led to free trade in goods and nearly all services in 1990. The WTO describes the agreement as the world's most comprehensive and effective free trade agreement.[91] The following figure shows, by way of an overview, different institutions and decision-making procedures established through the agreement. A notable feature is the creation of joint agencies.

91 Australia and New Zealand School of Government (2007): Arrangements for facilitating trans-Tasman government institutional co-operation. http://www.finance.gov.au/sites/default/files/TTpaper.pdf

Australia New Zealand Closer Economic Relationship Trade Agreement (CER)

Food Standards Australia New Zealand Act (1991)

Food Standards Australia New Zealand (FSANZ):

The FSANZ is a bi-national government agency which develops and administers the Code.

In NZ: responsible for standards relating to labeling, composition and contaminants.

In Australia: it has a much wider scope. As well as labeling and composition, it also develops food standards for food safety, maximum residue limits, primary production and processing as well as a range of other functions, including the coordination of recall systems and assessing policies about imported food.

(http://www.foodstandards.gov.au)

Australia New Zealand Food Standards Code:

The Code is a law that applies in Australia and NZ and provides a common set of food composition and labeling rules.

It lists requirements for foods such as additives, food safety, labeling and GM foods. The enforcement and interpretation of the Code is the responsibility of state and territory departments and food agencies within Australia and New Zealand.

(http://www.foodstandards.gov.au)

Australia New Zealand Therapeutic Products Agency (ANZTPA)

Australia and New Zealand signed a Treaty in 2003, setting out the two countries' desire to establish a joint agency for the regulation of therapeutic products. The primary objective of the parties was to safeguard public health and safety. The Treaty also aims to reduce barriers to trans-Tasman trade and enhance Australia's and NZ's profile and influence internationally over the development of international regulatory standards and harmonization initiatives. In 2011, both countries began to share resources, expertise and information. The ANZTPA is expected to be operational in 2016.

(http://www.anztpa.org/)

Trans-Tasman Mutual Recognition Arrangement (TTMRA), 1998:

Under the TTMRA, with a few exceptions:

- a good that may be legally sold in Australia may be sold in New Zealand, and vice versa. This is regardless of differences in standards or other sale-related regulatory requirements between Australia and New Zealand; and

- a person registered to practice an occupation in Australia is entitled to practice an equivalent occupation in New Zealand, and vice versa, without the need for further testing or examination.

The TTMRA incorporates a Temporary Exemption mechanism giving participating jurisdictions the right to ban unilaterally, for 12 months, the sale of goods in their jurisdiction for health, safety or environmental reasons.

(http://www.coag.gov.au/the_trans-tasman_mutual_recognition_arrangement)

The differences between the NZ and Australian systems for regulating therapeutic products made a special exemption to the TTMRA necessary. The options identified for resolving the special exemption were mutual recognition, permanent exemption and harmonization of regulatory systems. The latter was agreed to be the best option.

2.4.2 US-Canada Regulatory Cooperation Council

In the TTIP negotiations, reference is made to a Regulatory Cooperation Council. This terminology may have been inspired by the US-Canada Regulatory Cooperation Council (in the following RCC). It is thus worth taking a look at this institution. The origins of the US-CAN RCC are, interestingly, not from an international trade agreement.[92] The Council was created in 2011 by the US President and the Canadian Prime Minister; it is aimed at better alignment in regulation, enhancing mutual recognition of regulatory practices and establishing new effective regulations in specific sectors. The RCC is composed[93] of high-level representatives of regulatory oversight bodies as well as senior representatives from the international trade departments, but other regulatory agencies are also involved.[94] The Council's first steps were to give itself terms of reference[95] and to develop, after stakeholder consultations, a Joint Action Plan on Regulatory Cooperation, identifying key targets for regulatory cooperation.[96]

The terms of reference state that "each country maintains its own sovereign regulations – reliance on the other country's system to inform one's own decision making, and closer alignment of existing Federal regulatory systems, consistent with our respective domestic laws, are to be the focus".[97]

The non-binding[98] RCC Joint Action Plan addresses four key sectors, which encompass 29 specific initiatives: agriculture and food, transportation, health and personal care products and workplace chemicals, and environment.[99] The initiatives are advanced through 13 bilateral working groups, which have been responsible for the development of detailed work plans for the initiatives and for the engagement of stakeholders in the course of their implementation.[100]

Stakeholders were involved in both the initial identification of key elements in the Action Plan and the development of the detailed work plans. The public consultations process provided input on priority areas and initiatives.[101] According to the Canadian government, the RCC received during the consultation period feedback from private citizens, think tanks, corporations, and a wide range of industry and business associations representing several sectors of the Canadian economy.[102]

Several areas of progress are identified in the RCC News of May 2014[103] :

- Concerning agriculture and food, both countries harmonized the terminology for wholesale cuts of meat. The common understanding of terms is supposed to benefit industry through reducing the costs of maintaining separate inventories.

- Regarding transportation, the Canadian and US administrations are developing a Memorandum of Cooperation to facilitate the exchange of information on rail-related regulatory development and safety research, and signed a cooperation guideline for aligning their Unmanned Aircraft Systems regulatory programs.

- Concerning health care and personal care products, in January 2014 Canada implemented the Common Electronic Submissions Gateway, making it possible for companies to send drug authorization data to Health Canada online using a special dedicated channel of the United States Food and Drug Administration's (USFDA) existing system. This is supposed to make it faster, easier and cheaper for companies to submit information to regulators.

- In March 2014, the Government of Canada endorsed the "RCC nanotechnology policy principles for decision-making concerning regulation and oversight of nanotechnology and nanomaterials" confirming that Canada and the United States will use a consistent policy approach to guide the regulatory oversight of nanomaterials.

92 Lester and Barbee, "The Challenge of Cooperation," 860.
93 The OIRA in the US and the Regulatory Affairs Sector of the Treasury Board Secretariat in Canada.
94 Heynen, *International Regulatory Co-Operation*, 12ff.
95 Terms of Reference for the United States-Canada Regulatory Cooperation Council, http://actionplan.gc.ca/page/rcc-ccr/terms-reference-united-states-canada-regulatory-cooperation-council
96 The Plan is available online at http://actionplan.gc.ca/en/page/rcc-ccr/joint-action-plan-canada-united-states-regulatory
97 "Terms of Reference for the United States – Canada Regulation Cooperation Council."
98 Heynen, "The Canada – U.S. Regulatory Cooperation Council," 16.
99 *United States – Canada Regulatory Cooperation Council: Joint Action Plan.*
100 Heynen, "The Canada – U.S. Regulatory Cooperation Council," 13.
101 United States – *Canada Regulatory Cooperation Council: Joint Action Plan, 3.*
102 Government of Canada, *Regulatory Cooperation. What Canadians Told Us: A Report on Consultations on Regulatory Cooperation between Canada and the United States.*
103 Ibid.

Regarding environmental issues, Canada intends to amend the reporting requirements under its greenhouse gas emission regulations for light-duty vehicles to address areas of incompatibility with those in the US and to reduce administrative burden. Efforts in the rail sector have so far focused on the joint development of options for reducing GHG emissions from locomotives, possibly including the development of voluntary GHG emissions reduction targets.[104]

The approach of the US-CAN RCC has been described as a "technical and pragmatic way that seeks modest solutions to specific regulatory divergence problems".[105] The involvement of a broad range of stakeholders in informing the work of the RCC has been identified as a particular feature of the US-CAN RCC and a factor behind progress already made towards greater alignment of the two legal orders in some areas.[106] However, some other factors identified by the OECD[107] as being conducive to successful international regulatory cooperation are clearly also present, e.g. high-level political support and relative proximity of the regulatory systems.

Box 2: Mutual recognition and levels of protection - a clarification

"Mutual recognition" is one of the buzzwords in the debate on regulatory cooperation under TTIP. However, it is not always clear that mutual recognition can extend to many different aspects of regulation, with varying potential consequences for environmental or health protection. A few examples help illustrate this:

A practically relevant form of mutual recognition relates to **conformity assessments**. As the example of the US-EU MRAs shows, such recognition does not involve any change to existing substantive rules on e.g. product safety or environmental requirements. Rather, one country accepts the conformity assessments by selected bodies in the other countries. To put it simply: if a US body states that a product complies with EU legislation, the EU accepts that statement. This type of mutual recognition would only lead to a lowering in levels of e.g. consumer protection, if the bodies carrying out conformity assessments in one country performed significantly worse than in the other. However, usually measures are taken to prevent such bad performance. For example, the countries involved often carry out spot-check in the respective other country in order to ensure that conformity assessments are done thoroughly. Mutual recognition of conformity assessments does not lead to substantive harmonization of rules – it merely makes life easier for exporters as they can have their products checked within their own country.

Mutual recognition can also relate to **marketing authorizations**. This is the model applied within the EU: if a product is authorized for marketing within one EU Member State, all other Member States in principle accept that decision. By consequence, the product can be marketed in all other Member States, too.[108] This form of mutual recognition pre-supposes that one state accepts the other's regulatory framework as guaranteeing an equivalent level of safety, consumer or environmental protection. It is no coincidence that it is mainly countries with very close economic and political relationships that mutually recognize marketing authorizations. Where regulatory frameworks are of very different ambition or scope, mutual recognition of marketing authorizations under these frameworks would lead to changes in levels of protection. A related aspect is the mutual recognition of methods for **safety testing or risk assessments** that typically precede approval decisions for products.

Mutual recognition could also extend to certain **sub-aspects of the regulatory framework itself**, e.g. to accepting another country's decision on the safety of a certain substance or the equivalency of a certain technical standard. An example is the

104 *Canada – United States Regulatory Cooperation Council Joint Action Plan. Progress Report to Leaders, 17.*
105 Lester and Barbee, "The Challenge of Cooperation," 861.
106 Ibid., 862; Heynen, *International Regulatory Co-Operation,* 12.
107 For the success factors see above, introduction to section 2.
108 On mutual recognition within the EU see Schmidt, "Mutual Recognition as a New Mode of Governance"; there are, of course, exceptions to the principle of mutual recognition within the EU.

classification of certain substances as safe and hence permitted for the manufacturing of chemicals (see below box on EU cosmetics regulation). This type of mutual recognition appears to be infrequent in practice so far. The reason is probably that such recognition would entail changes in levels of protection, unless the respective regulatory frameworks are already quite similar in scope and ambition.

An interesting aspect of the debate about mutual recognition is how such decisions relate to **production processes and methods**. For example, the EU requires biofuels to fulfill certain sustainability criteria if the use of biofuels is to be counted towards the climate-related targets of the EU. These criteria relate, for example, to which land was used in the production of biofuels. The underlying EU directive contains a provision according to which the EU shall seek to conclude agreements with third countries containing provisions on sustainability criteria that correspond to those of the EU. Where such agreements have been concluded, the Commission may decide that those agreements demonstrate that biofuels produced from raw materials cultivated in those countries comply with the EU's sustainability criteria.[109] Here, as the sustainability impact of a product is mainly related to the way it was produced, mutual recognition relates to the production process. The above example of recognition of organic products is another example.

Moreover, frequent forms of mutual recognition relate to recognition of certain documents, (e.g. court judgments), or professional qualifications in another jurisdiction. However, none of this is very relevant for TTIP.

In sum, some types of mutual recognition are highly unlikely to lead to changes in levels of protection, while others are very likely to do so. Therefore, it is very important to be clear on what the subject of mutual recognition is.

2.5 Conclusions with regard to TTIP

The above short overview of various mechanisms shows that the discussion on regulatory cooperation in TTIP does not need to start from zero – there are many mechanisms already in place and experiences to build on. These range from mechanisms with relatively low ambition and intrusiveness into regulatory decision-making at the national level (e.g. the notification requirements in the TBT and SPS Agreements) to very ambitious and highly intrusive (such as the joint agencies created between Australia and New Zealand). The overview also shows that the mere existence of a legal obligation to undertake certain steps does not mean that regulatory cooperation is actually pursued (e.g. the example of the US – EU MRA). Finally, it also provides a first idea on how mechanisms for regulatory harmonization are implemented in national law (e.g. the EU's organic production regulation). The latter aspect will be more fully developed in the next chapter.

109 See Art. 18 (4) of Directive 2009/28/EC of 23 April 2009 on the promotion of the use of energy from renewable sources.

3 Regulatory cooperation and the national level

So far, we have looked at instruments for regulatory cooperation used at the international level. However, an aspect that has come under critical scrutiny in the context of the TTIP negotiations is the link of these instruments to national decision-making. This is the aspect that this chapter turns to. We will look at the "entry points" that the EU and the US legal orders provide for such cooperation, but also the formal requirements that such efforts and the results they produce are subject too. The objective is to analyze whether fears are justified that an entity like a US-EU Regulatory Cooperation Council has the potential to undermine national democratic decision-making. In general, international regulatory cooperation is mostly a domain of administrative entities (agencies, ministries, the EU Commission); it is therefore important to understand what autonomous decision-making space these entities have when it comes to binding regulatory decisions.

3.1 The EU regulatory process

In the EU, legally binding regulation on political matters falling within the EU's competence must generally be through a legislative act – a directive or a regulation. The Commission, the Council and the European Parliament are all involved in the legislative process. However, the Commission may be given, within a legislative act, the mandate to adopt either **delegated** or **implementing** acts.[110] Delegated and implementing acts have been described as the "rule, not the exception" in practice.[111]

Delegated acts may modify existing legislation in "non-essential" ways; implementing acts serve to create uniform conditions for implementation across Member States. While the EU treaty does not spell out what is meant by "non-essential", the EU Court of Justice has clarified that "political choices falling within the responsibility of the EU legislature cannot be delegated, in particular where conflicting interests at issue must be weighed".[112]

In cases of both implementing and delegating acts, the original legislative act must contain an authorization for the Commission to adopt a delegated or implementing act. Procedures for adopting delegated and implementing acts vary. Draft delegated acts by the Commission are subject to review by both the European Parliament and the Council; both have the power to reject the delegated act. Implementing acts are adopted through the so called comitology procedure, where committees composed of Member State representatives are involved in decision-making in one way or the other.[113]

For international regulatory cooperation this means that basic provisions and conditions need to be set out in a directive or regulation; the arrangements for the inclusion of countries into the list of countries whose conditions for production of organic production and labeling of organic products are recognized as equivalent to the EU conditions are one example for this. With such basics provisions and conditions set forth, the Commission could then be entrusted with making case-by-case decisions on individual countries, products, or standards or spelling out in greater detail certain conditions for a product to enter the EU market. Thus, if a future EU-US Regulatory Cooperation Council decided that certain regulations containing technical requirements needed and could be approximated in the two legal orders, this could only translate into a Commission implementing act, if a basic legislative framework was already in

110 See Art. 290 TFEU.

111 Parker and Alemanno, *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems,* 18.

112 CJEU, Judgment of 5 September 2012, Council of the European Parliament vs. European Council, Case C-355/10, para. 65. The case concerned implementing powers in the area of the surveillance of the external sea borders.

113 There are two different procedures with different roles for the committees, the more rare advisory procedure and the more widely used examination procedure, see: The Commission's implementing powers, http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/ai0043_en.htm. The underlying legal act is Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

place. Otherwise, normal legislative decision-making procedures would need to be initiated by the Commission.

In terms of the use of **international technical standards**, it is furthermore important to note that the EU has three standard-setting bodies of its own, the European Committee for Standardization (CEN), the European Committee for Electronical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). The OECD estimates that within the EU the majority of standards incorporated into national regulation stems from the EU standard-setting bodies. However, the EU standard-setting bodies have special agreements with their international counterparts; this means that for example 21% of CEN standards are identical to ISO standards and about 60% of CENELEC standards are identical to the ones of its international counterpart IEC.[114]

Box 3: Overview: impact assessments and consultation during regulatory processes in the US and EU[115]

Some of the proposals on regulatory cooperation within TTIP relate to early information exchange between competent bodies on regulatory initiatives as well as the possibility for mutual comments on such initiatives and related impact assessments. It is thus worth taking a brief look at the existing structures within the US and EU.

On the **US side**, a bill, i.e. draft legislation, is introduced by a Member of Congress. There is a comprehensive database on such bills at *www.congress.gov*. There is neither an impact assessment nor a formal requirement for consulting stakeholders at the stage of drafting bills; the process for compiling bill has been described as "opaque"[116] to the public – and this would also mean to trade partners. Once the bill has been introduced, committee hearing etc. are usually open to the public, which can, however, not participate actively in the congressional debate. There is no formal requirement to conduct an impact assessment on draft legislation.

When regulatory agencies develop implementing acts, a Notice of Proposed Rule-Making is published; the Notice contains an overview of the proposed rule[117] and is accompanied by a draft regulatory impact assessment. Under US administrative procedures, the opportunity for comments must be given to stakeholders; the final rule must be accompanied by statements on responses to comments and an explanation of why the rule was adopted, as compared to alternatives. A dedicated portal exists for comments: *http://www.regulations.gov*. Trade partners such as the EU are treated as any other stakeholder.

On the **EU side**, legislative action is initiated by the Commission. Documents such as Commission annual work programs provide early information on planned legislation. The legislative process has been described as typically offering significant opportunities for consultation with stakeholders on various policy options.[118] Stakeholders are not limited to those coming from the EU; for example, in a public online consultation undertaken by the Commission each individual or organization globally could produce a submission. However, draft legislation is only published at the stage where the draft is transmitted to the EP and the Council for comments; involvement of stakeholders before a draft is tabled

114 All information taken from OECD, International Regulatory Co-Operation, 40. There are slightly varying figures on this, though. According to an October 2013 press release by CEN and CENELEC to inform TTIP negotiations, 42% of European Standards (and other technical documents) published by CEN and CENELEC are identical to international standards published by ISO or the IEC (31% of CEN standards are identical to ISO standards, 69% of CENELEC standards are identical to IEC standards), see CEN and CENELEC provide clarification on standards-related aspects of issues to be addressed during EU-US trade talks, http://www.cencenelec.eu/News/Press_Releases/Pages/PR-2013-11.aspx

115 The following draws on Parker and Alemanno, *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems.*

116 Ibid., 2.

117 This is set forth in § 553 of the Administrative Procedure Act, available at http://usgovinfo.about.com/library/bills/blapa.htm. The requirement to involve the public appear in addition to stem from the Freedom of Information Act and Government in the Sunshine Act, see Ahearn, Transatlantic Regulatory Cooperation: Background and Analysis, 9.

118 Parker and Alemanno, *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems,* 2.

is rather informal and *ad hoc*. Generally, empirical research has shown that business groups have better access to the Commission than other interest groups.[119]

While the Commission may involve stakeholders in one way or the other in developing delegated or implementing acts, the process for doing so is not "particularly transparent".[120] Some transparency is provided for implementing acts through the Comitology Register,[121] containing information on committee agendas, deliberations etc.

Legislative initiatives are mostly subject to formal **impact assessments**, conducted frequently with the help of external consultants. There are, for the Commission's impact assessments,[122] impact assessment guidelines.[123] These guidelines spell out procedures and steps to be carried out, and require the assessment of social, economic and environmental impacts. Trade aspects are only mentioned as a sub-aspect of the economic impact so far. Delegated and implemented acts by the Commission are only subject to such impact assessment or consultation when they are expected to have a significant economic, environmental or social impact; however, in practice impact assessments are rare for these acts.

In sum, both regulatory systems provide opportunities for stakeholders – and that would include foreign stakeholders – to inform themselves, and at least in the case of formal legislation to voice opinions, on planned regulation. Less transparency usually exists at the stage before a draft legislative act is table, and for delegated and implementing acts by the EU Commission. Impact assessments routines exist at the EU side, but are less well-developed for legislation at the US side.

3.2 Overview: the US and international regulatory cooperation[124]

In the US, the Congress is mandated by the Constitution and the intra-state commerce clause to legislate on most issues of relevance in TTIP negotiations. However, in practice there are some domains where state governments and licensing boards have assumed responsibility (e.g. land use planning or licensing of professions), and federal legislators are expected to be reluctant to intrude into these domains.

Generally, in the US, legal order agencies have no competence to modify congressionally enacted legislation; they can only implement it. However, the Congress has been observed to routinely only state the "overall purposes and core requirements of the law at moderate-to-high-level of generality, then set forth criteria to guide the agency's implementation".[125] Thus, there are significant opportunities – and often an obligation contained in the law – for regulatory agencies to engage in rule-making.

With regard to international regulatory cooperation, there is a 2012 Executive Order on Promoting International Regulatory Cooperation.[126] This Order mandates the existing inter-agency Regulatory Working Group to discuss the US involvement in international regulatory cooperation. Regulatory agencies are also required to ensure that regulations that the agency identifies as having significant international impacts are described as such in the relevant official publication channels. In their plan for review of existing rules, regulatory agencies are also to give specific consideration, among other, to "existing significant regulations that address unnecessary differences in regulatory requirements between the United States and its major trading partners…when stakeholders provide adequate information to the agency establishing that the differences

119 Coen, "Empirical and Theoretical Studies in EU Lobbying," 335f.
120 Parker and Alemanno, *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems*, 5.
121 Online at http://ec.europa.eu/transparency/regcomitology/index.cfm
122 Impact assessments can and should also be carried out by the Council and the European Parliament for significant amendments they propose; however, so far these are less frequent.
123 Commission Impact Assessment Guidelines, http://ec.europa.eu/smart-regulation/impact/commission_guidelines/commission_guidelines_en.htm
124 The following draws on Parker and Alemanno, *Towards Effective Regulatory Cooperation under TTIP: A Comparative Overview of the EU and US Legislative and Regulatory Systems.*
125 Ibid., 41.
126 Available online at http://www.whitehouse.gov/the-press-office/2012/05/01/executive-order-promoting-international-regulatory-cooperation

are unnecessary". Moreover, "for significant regulations that the agency identifies as having significant international impacts" the agency is to, consider, "to the extent feasible, appropriate, and consistent with law, any regulatory approaches by a foreign government that the United States has agreed to consider under a regulatory cooperation council work plan". The latter reference to regulatory cooperation council work plans may be one of the rationales behind the suggestions of establishing an EU-US Regulatory Cooperation Council through TTIP.

Box 4: What could an EU-US RCC do in the area of EU chemicals and cosmetics regulation?

Certain fears are linked to an EU-US RCC, which would in all likelihood be composed of representatives of the executive (notably the Commission on the EU side and regulatory agencies on the US side). A scenario that critics of such an institution appear to have in mind is that the representatives of the executive in such a body might be interested in pursuing an agenda of their own and come with high levels of ambition with regard to the aim of regulatory harmonization. It is feared that they might be able to directly implement within the EU legal system whatever is decided in an RCC – which is in addition seen as potentially subject to heavy influence by industry interests.

In order to gain a clearer picture of what influence an EU-US RCC could have in the EU legal order in such a "worst-case scenario", it is helpful to look at concrete examples. We look at two areas that are part of the TTIP negotiations where there is strong divergence between US and EU legislation and thus marked interest in greater regulatory consistency: cosmetics and chemicals. Concerning cosmetics, EU regulation is mainly aimed at protecting consumers from health risks and animal welfare; EU chemicals regulation also has a strong environmental component.

On **cosmetics**, the EU Commission has published a position paper, outlining its ambition for the TTIP negotiations.[127] In this paper, the Commission states that the following issues could, among other, be covered in TTIP: mutual recognition of lists of allowed and prohibited cosmetic substances, collaboration in good manufacturing practices and mutual recognition of inspection results, collaboration in, and regulatory acceptance of validated alternative test methods to animal testing, harmonization of test methods (based on ISO standards) and test requirements, and an approximation of labeling requirements. Assuming that these issues would actually be the subject of the TTIP negotiations and would not be decided as part of the actual TTIP agreement, but be left for later deliberations of an US-EU RCC: To what extent could decisions on such issues be taken by an EU-US RCC and be implemented by the Commission under the current EU legislative framework, without modifying the legislative framework itself and involving the European Parliament and the Council?

According to the EU Cosmetics Regulation,[128] a pre-marketing approval for placing cosmetics on the EU market is not required. There only is an obligation to notify the Commission and submit specified information.[129] Those placing cosmetic products on the market have the obligation to ensure that the conditions set forth in the regulation, aimed at making cosmetics safe to use, are observed. Among these conditions is that "good manufacturing practice" is observed.[130] Good manufacturing practice is defined by reference to the relevant ISO Guidelines.[131]

127 EU Commission, DG Trade, *The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues: EU Position on Cosmetics.*
128 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.
129 Art. 13 Cosmetics Regulation.
130 Art. 8 Cosmetics Regulation.
131 Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices (ISO 22716:2007), see: http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/cosmetic-products/index_en.htm

The Regulation contains lists of substances authorized for use in cosmetic products as colorants (listed in Annex IV), as preservatives (Annex V), and as UV filters (listed in VI). Colorants, preservatives and UV filters not contained in the annexes may not be used in cosmetics. In addition, the Regulation also defines substances prohibited in cosmetics (Annex II) and substances subject to specific restrictions (Annex III).[132] The Commission may amend these annexes with a view to risks to human health or in order to adapt certain annexes to scientific and technical progress. For changing an annex, the following procedure applies:[133] The Commission must submit its suggested decision to the Standing Committee on Cosmetic Products (SCCP), composed of representatives of the Member States. The SCCP members may make suggestions for amending the proposed decision; the SCCP then delivers an opinion on the decision, adopted by a qualified majority. If the opinion is negative or there is no opinion from the SCCP, the decision may not be adopted by the Commission. In this case, the Commission may refer the matter to the Appeal Committee. If the latter delivers a negative opinion on the decision suggested by the Commission, the Commission may not adopt the decision. In sum, the Commission does not take a decision on amending any of the Annexes of the Cosmetics Regulation alone, but representatives of Members are also involved.

Before a product is placed on the EU market, a safety assessment must be conducted by the relevant business actor.[134] The requirements for safety assessments are defined in Annex I of the Cosmetics Regulation; the Commission is given the task of adopting guidelines for carrying out the safety assessments. The adoption of these guidelines also must follow the above procedure, involving the SCCP.

Cosmetics that have been subject to animal testing may not be placed on the EU market; a derogation may be granted by the Commission after a request from a Member State under certain conditions set forth in the Regulation.[135]

The Cosmetics Regulation also contains detailed (labeling) requirements on the information to be provided on the cosmetic product when placed on the market.[136]

What implications does the Regulation have for decisions by an eventual EU-US RCC, taking into account the above proposals from the Commission in the field of cosmetics? Let us take a look first at the mutual recognition of lists of allowed and prohibited cosmetic substances. Including an individual substance, for example, an individual colorant recognized by the US side as safe, in Annex IV of the list of colorants permitted in the EU could be done through a Commission act. Decision-making would, however, also have to involve the SCCP composed of Member States' representatives. By contrast, there could not be under the current EU legislative framework an automatic recognition of all substances permitted in cosmetics and safe for human health in the US as permissible within the EU, too. For that, the Regulation itself would have to be changed, involving the Council and the European Parliament. Similarly, modifying the quite detailed labeling requirements would also require an amendment of the Regulation itself, with no scope for independent executive decision-making. Changes to accepted good manufacturing practices could, under the current EU legislative framework, be made mainly through a change in the relevant ISO standard and would thus involve a decision-making process involving many more actors than the US and EU relevant executive actors. Amendments to

132 Art. 14 Cosmetics Regulation, see also Art. 15 for a further prohibition of certain substances.

133 The procedure results from the following norms: According to Art. 31 (1) and (2) and Art. 32 (2) of the Cosmetics Regulation, the Commission was to follow in most cases of amending the Annexes, the so called "regulatory procedure with scrutiny" as set out in Art. 5 and 7 of Decision 1999/468/EC (the so called "Comitology Decision"). Only "on imperative grounds of urgency", the so-called "urgency procedure" could be used. Given that the threshold for the use of the urgency procedure is so high, it is not considered any further here. However, Decision 1999/468/EC has been replaced by Regulation No 182/2011 of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing power. According to Art. 13 (1) (c) of the latter Regulation, in cases where the "regulatory procedure with scrutiny" of the old Comitology Decision had to be used, the "Examination Procedure" described in Art. 5 of the new Regulation is now applied. This is thus the procedure to use for amendments of the Annexes of the Cosmetics Regulation described above in the main text.

134 Art. 10 Cosmetics Regulation.

135 Art. 18 Cosmetics Regulation; there are some phase-out periods.

136 Art. 19 Cosmetics Regulation.

the guidelines for safety assessments would also require involvement of the SCCP, composed of Member State representatives. In sum, it is not evident that any decisions with a significant impact on protecting the health of EU consumers against risks from cosmetics could be taken by an EU-US RCC and directly be implemented by the EU's executive branch, the Commission. Some decisions aimed at greater regulatory convergence between the US and EU would require a formal amendment of the Cosmetics Regulation and involvement of the Council and the EP. Others would not, but at least the SCCP, where EU Member States are represented, would have to be involved.

In the area of **chemicals**, the Commission has also published a position paper for the TTIP negotiations;[137] whether or not the positions expressed therein will in the end translate into an agreement with the US or not, is, of course, not predictable at this stage. However, there is currently no more reliable document on which an assessment could be based in the present context. In the position paper, the Commission states that "neither full harmonization nor mutual recognition seems feasible on the basis of the existing framework legislations in the US and EU" and that proposals for greater consistency should be within the existing legislative framework of the EU. However, the Commission sees scope for better alignment of both systems in four areas: priority-setting for assessment and assessment methodologies, classification and labeling of chemicals, cooperation on new and emerging issues (e.g. nanomaterials), and information sharing (e.g. on test data to reduce animal testing).

In the area of **chemicals regulation**, the central piece of legislation is the REACH regulation.[138] Classification and labeling of substances is governed by the so called CLP (classification, labeling, packaging) regulation.[139] Given the complexity of the EU regulation, only some central elements of REACH can be discussed here:[140]

Basically, under REACH, producers or importers must register chemicals to be put on the market in quantities exceeding a certain threshold with the European Chemicals Agency (ECHA).[141] As part of the registration, they must provide certain information on the properties of the chemicals to ECHA; a chemical safety assessment must be conducted by registrants. Certain chemicals, included in Annex XIV of the Regulation, are subject to pre-marketing authorization; criteria for including substances into the list are defined.[142] ECHA or the Commission have the following important decision-making powers under the REACH Regulation:

- adopting guidance on testing methods;[143]
- deciding on criteria for priority-setting for substances to be evaluated (in cooperation with Member States) and an Action Plan for evaluation based on these criteria;[144]
- review of submitted registration for completeness and formal compliance with REACH requirements;[145]
- the inclusion of substances into the list of substances that require pre-marketing authorization[146] and the granting of authorizations;[147] and

137 EU Commission, DG Trade, T*he Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues: EU Position on Chemicals.*
138 Regulation No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
139 Regulation No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures.
140 For a more in-depth and also comparative overview of US and EU chemicals regulation see Renn and E. Donald Elliott, "Chemicals."
141 Art. 5 REACH Regulation.
142 Art. 56ff REACH Regulation.
143 Art. 13 REACH Regulation.
144 Art. 44 REACH Regulation.
145 Art. 41, 51 REACH Regulation.
146 Art. 58 REACH Regulation.

- amending Annex XVII of the Regulation which lists substances which can only be put on the market when certain conditions are observed.[148]

The EU Commission has stated quite clearly that none the elements of the present regulatory system is to be modified through TTIP. However, in principle, decisions emanating from an US-EU RCC could influence EU decision-making, on e.g. inclusion of substances in any of the Annexes; this could also have an influence on the level of health and environmental protection against risks from chemicals. The EU internal decision-making processes on these issues are all quite similar:[149] again, reference is made in the Regulation to various comitology processes. Thus, the Commission may formulate a proposal and the relevant Committee, composed of Member States representatives, is involved in decision-making. In other decisions to be taken under REACH, ECHA itself is involved or the competent authorities of Member States are.

Thus, in both areas presented in this box, it is never the Commission alone that takes implementing decisions of major importance. In addition, criteria by which important decisions can be taken are already specified in the legislation itself. Thus, the scope for independent executive decision-making within a body such as the RCC is very limited in both cases.

This does not mean that the current system of comitology decision-making is beyond criticism. For example, one commentator refers to comitology as "story of an administration that has major virtues but which, by withdrawing into itself, confiscates power delegated by the member states and organizes things it as it wishes. It neglects the democratic control of legislators…".[150] Indeed, it is rare for Member State representatives to vote against a Commission proposal in the committees.[151] However, a criticism of comitology is not the focus of this study. The point made here is more limited: it is unlikely that regulatory cooperation in TTIP would lead to by-passing normal decision-making procedures within the EU (and Member States). TTIP will not change the fundamental decision-making structure of the EU. Thus, regulatory decision-making within the EU would involve a number of actors, mostly the Commission and committees with representatives of the EU Member States in comitology decisions, and the Council and the Parliament for more far-reaching political decisions.

3.3 Conclusions with regard to TTIP

The following conclusions focus on three major proposals from the Commission on regulatory cooperation that may influence domestic decision-making within the EU: the creation of an RCC, the opportunity for the US side to comment early on planned legislation, and integrating a consideration of trade impacts in EU impact assessments.

With regard to the creation of an RCC, there are concerns that the establishment of such an institution could favor corporate interests over environmental or consumer concerns; there also seem to be fears that whatever the representatives of the US and EU executive decide in an RCC would be implemented in the EU without appropriate involvement of the EU Parliament or Member States.

Such fears only appear to be partially justified. Fairly clear rules exist in both legal orders on what can be delegated through a formal law to agencies, the Commission or other executive entities. Whether the results produced by an US-EU RCC would need to be translated into a formal law is thus determined by these legal rules. It is hardly conceivable that such constitutional rules would be modified through TTIP. It is hence not evident how the work of an RCC, which is likely to be composed of representatives of the executive branch of government, could lead to by-passing parliamentary decision-making procedures. As evident from some of the examples above, e.g. the bilateral instruments already in place between the US and EU, it is the formal law that creates the openings and defines the conditions for other actors to engage in international regulatory cooperation (e.g. for recognizing a decision taken in another jurisdiction as equivalent).

147 Art. 60 REACH Regulation.
148 Art. 68ff REACH Regulation.
149 Slightly different procedure are in Art. 133 REACH Regulation which refers, like in the case of the Cosmetics Regulation, to different comitology procedures.
150 Guéguen, *Comitology – Hijacking European Power?*, 16.
151 Dehousse, Fernández Pasarí, and Plaz, "Regulatory Governance in the EU: Unveiling the Consensual Nature of Comitology," 4.

However, the above comes with a *caveat*: the more leeway executive bodies are afforded in legislation and in practice, the more independent decision-making space they have for acting. Theoretically, where an agency, ministry or other public body wields significant independent decision-making power, it could use that power strategically to implement decisions taken in the framework of an RCC without a parliamentary decision on that specific matter. How often such situations exist in the US and EU regulatory frameworks could not be assessed systematically in the framework of this study. With regard to the EU, the examples of cosmetics and chemicals regulation show that the scope for autonomous decision-making by the Commission is very limited; in major implementing acts, representatives of Member States (even though not the Parliament or civil society representatives) are involved. Moreover, the basic legislative acts often contain quite well-defined criteria guiding the Commission's implementing decisions. Given the huge number of existing EU committees, which all have role in EU decision-making, it appears generally unlikely that decisions with a sustained impact on levels of protection would silently and unobserved pass through the EU's regulatory system. However, practically Member States have been observed to rarely oppose a Commission proposal in a committee, giving the Commission significant power in implementing EU legislation in practice. The extent to which Member States use their power in the committees would influence how much autonomous decision-making space the EU executive representatives would have in implementing decisions of a future RCC in practice.

To what extent the decision-making of a future RCC would be subject to public scrutiny and input from civil society would, obviously, depend on the modalities agreed in TTIP or by the RCC itself. The example of the US-CAN RCC shows that broad involvement of stakeholders and the public at large can actually contribute to the success of such a body; however, from an environmental and consumer perspective it is important that civil society is appropriately represented in such a process.

Concerning requirements to provide trade partners with information on planned regulation and to give them an opportunity to comment, the above overview of regulatory processes shows that on both sides consultations, impact assessments as well as many actors are involved – hence these processes take time anyway. While a requirement to involve trade partners in decision-making is likely to create at least some additional administrative costs and may also make national decision-making more complex, it is not evident that this would slow down the regulatory process. Delays could likely be avoided through tailoring procedures appropriately. What gives more reasons for concern is the EU Commission's idea that TTIP should contain an obligation to communicate plans on future regulation to the authorities on the respective other side at a stage where there is no formal routine for involving stakeholders in the domestic regulatory process: the stage before a legislative draft is tabled. Civil society organizations often depend on access to public documents to assess policy proposals and intervene in a public debate. Giving trade partners access to EU decision-making at a stage where the public and other stakeholders are not involved, would unduly privilege the interests of trade partners and their economic interests as compared to domestic consumer or environmental interests.

Implementation of proposals to take into account the trade impacts of a future measure in impact assessments would not need specific procedures within the EU, but could be integrated into the existing system of EU impact assessments at least for legislative acts. However, it may be questioned why one specific concern – the trade interests of US companies – should be given specific weight in each of these assessments, while the EU's impact assessment guidelines already require the assessment of economic impacts in general. Within the EU system, the main effect of requirements to assess the trade impacts of planned regulation would likely be at the level of delegated or implementing acts where consultation and impact assessment are less frequent; however, much would depend on what concretely is agreed in TTIP.

Taken together, these different proposals lead to a risk that the balance of interests and actors that dominate EU internal policy-making may be modified to the benefit of trade and economic interests and to the detriment of other policy goals, such as environmental or consumer protection. Policy-making is an outcome of a balance being struck between different actors with different interests, values and ideas. Which interests prevail in the end is, among other, a function of how strongly certain interests are represented in the policy discourse. The establishment of an RCC, early comments from trade partners on legislative proposals as well as the systematic consideration of trade interests in impact assessments may lead to a situation where trade interests become more visible in the EU policy process and actors within that process more openly advocate in favor

of such interests. This leads to a risk that the policy decisions taken at the end also favor trade over other interests, such as environmental or consumer interests. However, at this stage it can only be speculated to what extent such risks would materialize in the end, with the outcome of the negotiations open at present.

4 Conclusions and recommendations

This study has presented proposals on regulatory cooperation in TTIP, discussed existing mechanisms for regulatory cooperation and analyzed the interface between international regulatory cooperation and domestic decision-making, in particular within the EU. It has not investigated more broadly what effects harmonization has on levels of environmental and consumer protection and whether enhanced regulatory cooperation in TTIP is desirable. Instead, the study pursues a more modest ambition: assessing some of the claims and concerns visible in the current public debate on regulatory cooperation in TTIP as well as potential effects of the EU Commission's proposals on regulatory cooperation in TTIP. In this regard, the following conclusions and recommendations can be made:

Given the multiplicity of the mechanisms for regulatory cooperation, the effect of any agreement on regulatory cooperation will depend on what precisely is agreed and how the agreement is implemented. In order for a more informed debate on this topic in the TTIP context, it is highly desirable that negotiators make the details of their plans on regulatory cooperation in TTIP transparent as soon as possible and update the public on the evolving negotiations. Much of what is known today about the plan on regulatory cooperation in TTIP is preliminary; the EU positions discussed above are subject to negotiations. However, even in the absence of more detailed and conclusive information, the above overview of mechanisms for regulatory cooperation yields some important lessons for the TTIP context.

A first one – and this may be supporting those being critical about regulatory cooperation and harmonization in TTIP – is that regulatory cooperation between the US and EU **does not require a comprehensive TTIP agreement**. The above overview of mechanisms shows that there are many alternatives towards a comprehensive trade agreement for achieving more regulatory cooperation. For example, the US-CAN RCC, which seems to have facilitated regulatory harmonization between the two legal orders, was established outside the framework of a trade agreement. Alternative avenues for the US and EU to explore for working towards greater regulatory coherence would e.g. be acting in a more coordinated manner in multilateral standardization bodies and using the agreed standards systematically as a basis for their own regulation. Or they could conclude further sectoral mutual recognition agreements relating to conformity assessment procedures and provide them with high level political support to ensure they function better than the ones from the past. In addition, regulatory agencies involved in regulatory cooperation could be provided with the finances and staff to engage seriously such efforts. As noted in the cited OECD study, whether or not a mechanism for regulatory cooperation is agreed in a legally binding way is not a crucial success factor for international regulatory cooperation; other factors, including the domestic arrangements for international regulatory cooperation, appear to be more important.

This argument also has a **procedural dimension**: The brief overview of existing transparency and consultation mechanisms on the US and EU side has shown that it is at present possible for both parties to keep track of new planned regulation on the other sides. This definitely applies at the stage where a formal legislative or regulatory proposal is tabled, but, to an extent, also earlier. Arguably, a clarification of procedures may make it easier for regulators from both sides to understand planned regulation of the other party and at an early stage; however, if both parties see the need for more information sharing, they could, e.g. accomplish that in the multilateral framework of the WTO on a voluntary basis.

It is also questionable to what extent EU and US regulation can be made more consistent through TTIP or any

mechanisms for regulatory created through the agreement. In many areas, EU and US regulation diverge significantly, at least partially a result of diverging preferences on the regulation of health risks or environmental ambition. Where regulatory differences results from such different policy choices, it is neither likely nor desirable that they be removed;[152] the reasons that have prevented a closer alignment between both legal orders in the past would not all of a sudden disappear through TTIP.

A second set of conclusions relates to the potential impacts of regulatory cooperation under TTIP on **national decision-making processes.** The study has focused on three major proposals from the Commission on regulatory cooperation that may influence domestic decision-making within the EU: the creation of an RCC, the opportunity for the US side to comment early on planned legislation, and integration a consideration of trade impacts in EU impact assessments.

With regard to the creation of an **RCC**, there are concerns that the establishment of such an institution could favor corporate and interests over environmental or consumer concerns; there also seem to be fears that whatever the representatives of the US and EU executive decide in an RCC would be implemented in the EU, without appropriate involvement of the EU Parliament or Member States. Such fears **only appear to be partially justified.**

There appears to be **no significant risk that TTIP would create institutions mandated to take decisions that could bypass national/EU legislative procedures** or would lead to the weakening of such procedures. Nothing in the documents or statements published so far indicates that ambitious approaches, such as the creation of a bilateral agency as between the Australia and New Zealand, are envisioned – even though negotiations may produce a different outcome. Generally, such more ambitious forms of regulatory cooperation are rare in practice. For example, agreements concluded under the heading of mutual recognition often relate to the recognition of assessments of conformity with the existing domestic law of a party, rather than e.g. the mutual recognition of marketing approval decisions taken by a trade partner in line with its domestic legal framework. Many mechanisms for regulatory cooperation do not imply a change to existing levels of protection; in fact, most of the mechanisms discussed above do not. For example, mere information sharing or a requirement to provide reasons for a certain decision to trade partners may increase administrative costs, but will hardly affect substantive levels of protection. The example of the EU-US Organic Equivalency Cooperation Arrangement also shows that in certain areas mutual recognition agreements may foster trade in "green" goods.[153]

Formally, there are fairly **clear constitutional rules** in both legal orders on what can be delegated through a formal law to agencies, the Commission or other executive entities. Whether the results produced by an US-EU RCC would need to be transposed into a formal law is thus determined by these legal rules and would depend on the respective outcome of RCC deliberations. It is hardly conceivable that constitutional rules on decision-making at the EU level or on the division of competences between the EU and its Member States would be modified through TTIP. It is hence not evident how the work of such a RCC, which is likely to be composed of representatives of the executive branch of government, could lead to by-passing parliamentary decision-making procedures. As evident from some of the examples above, e.g. the bilateral instruments already in place between the US and EU, it is the formal law that creates the openings and defines the conditions for other actors to engage in international regulatory cooperation (e.g. for recognizing a decision taken in another jurisdiction as equivalent).

The **delegation of regulatory and/or implementing power to executive actors** is not new in either the US or the EU, with its extensive system of comitology. Nonetheless, such delegation generally raises issues in terms of the democratic legitimacy of decision-making, which also extend to any executive regulatory cooperation under TTIP. These problems are worsened if executive decision-making is influenced more strongly by business interests than, for example, by environmental and consumer groups. Past experiences with standard-setting at the international level show that this is not an unlikely scenario for an EU-US RCC. Civil society organizations often simply lack the capacities to follow decision-making in multiple international fora.

The more leeway executive bodies are afforded in legislation and in practice, the more independent decision-making space they have for acting. Theoretically, where an

152 See Lester and Barbee, "The Challenge of Cooperation," 849 for a similarly skeptical position.

153 Even though it is debatable whether local agricultural production is not a better option anyway from an environmental of view. However, this issue is beyond the scope of this study.

agency, ministry or other public body wields significant independent decision-making power, it could use that power strategically to implement decisions taken in the framework of an RCC without a parliamentary decision on that specific matter. A systematic assessment of how often such situations exist in the US and EU regulatory frameworks was beyond the scope of this study. However, with regard to the EU, the examples of cosmetics and chemicals regulation show that the scope for autonomous decision-making by the Commission is very limited; in major implementing acts, representatives of Member States (even though not the Parliament or civil society representatives) are involved. Moreover, the basic legislative acts often contain quite well-defined criteria guiding the Commission's implementing decisions. Given the huge number of existing EU committees, which all have role in EU decision-making, it appears generally unlikely that decisions with a sustained impact on levels of protection would silently and unobserved pass through the EU's regulatory system. However, practically Member States have been observed to rarely oppose a Commission proposal in committees, giving the Commission significant power in implementing EU legislation in practice. The extent to which Member States use their power in the committees would influence how much autonomous decision-making space the EU executive representatives would have in implementing decisions of a future RCC in practice.

To what extent the decision-making of a future RCC would be subject to public scrutiny and input from civil society would, obviously, depend on the modalities agreed in TTIP or by the RCC itself. The example of the US-CAN RCC shows that broad involvement of stakeholders and the public at large can actually be a factor in contributing to the success of such a body; however, from an environmental and consumer perspective it is important that civil society is appropriately represented in such a process.

Further, there is the idea to include a procedure in TTIP to provide trade partners with information on planned regulation and to give them an opportunity to comment before an EU draft legislative act is formally published. While this has not been researched in-depth for the present study, the above overview of regulatory processes shows that on both sides consultations, impact assessments as well as many actors are involved – hence these processes take time anyway. While a requirement to involve trade partners in decision-making is likely to create at least some additional administrative costs and may also make national decision-making more complex, it is not evident that this would slow down the regulatory process. Delays could likely be avoided through tailoring procedures appropriately. What gives more reason for concern is the EU Commission's idea that TTIP should contain an obligation to communicate plans on future regulation to the authorities on the other side at a stage where there is no formal routine for involving stakeholders in the domestic regulatory process: the stage before a legislative draft is tabled. Civil society organizations often depend on access to public documents to assess policy proposals and intervene in a public debate. Giving trade partners access to EU decision-making at a stage where the public and other stakeholders are not involved, would unduly privilege the interests of trade partners and their economic interests as compared to domestic consumer or environmental interests.

Implementing proposals to take into account the trade impacts of a future measure in impact assessments would not require specific procedures within the EU, but could be integrated into the existing system of EU impact assessments at least for legislative acts. However, it may be questioned why one specific concern – the trade interests of US companies – should be given specific weight in each of these assessments; the EU's impact assessment guidelines already require the assessment of economic impacts in general. Within the EU system, the main effect of requirements to assess the trade impacts of planned regulation would likely be at the level of delegated or implementing acts where consultation and impact assessment are less frequent; however, much would depend on what concretely is agreed in TTIP.

In sum, there appears no tangible risk that decision-making processes at the EU level or the Member State level would be undermined through TTIP regulatory cooperation or that there would be any less parliamentary oversight. **The real risk lies elsewhere.** Taken together, the different proposals on regulatory cooperation lead to a risk that the balance of interests and actors that dominate EU internal policy-making may be modified to the benefit or trade and economic interests and to the detriment of other policy goals, such as environmental or consumer protection. That is, **a discursive shift in favor of economic and trade interests could occur**. Policy-making is an outcome

of a balance being struck among different actors with different interests, values and ideas. Which interests prevail in the end is, among others, a function of how strongly certain interests are represented in the policy discourse. The establishment of an RCC, early comments from trade partners on legislative proposals as well as the systematic consideration of trade interests in impact assessments may lead to a situation where trade interests become more visible in the EU policy process and actors within that process more openly advocate in favor of such interests. This leads to a risk that the policy decisions taken at the end also favor trade over other interests, such as environmental or consumer interests. However, at present it can only be speculated to what extent such risks would materialize in the end, with the outcome of the negotiations open at present.

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Annex: Overview of tools for regulatory cooperation in the US and EU free trade agreements

	EU – Peru/ Colombia	EU-South Korea	NAFTA	US-Australia
Information exchange procedures/ transparency measures	Exchange information, experiences, data; simplify standard and technical regulations; Inform other Party and consider views of the other Party when developing new regulations (subject to specific rules)	Exchange information, experiences, data; simplify technical regulations standards and CAPs; provide info on adopted or proposed regulations; uniform and consistent application of technical regulations (EU specific) Inform other Party and consider views of the other Party when developing new regulations (subject to specific rules)	Establish inquiry point; provide technical advice, information and assistance to enhance that Party's standards-related measures; encourage cooperation of standardizing bodies; Inform other Party and consider views of the other Party when developing new regulations (subject to specific rules)	Inform other Party and consider views of the other Party when developing new regulations (subject to specific rules)
Observance of principal trade policy provisions	Fulfil transparency/ notification obligations of TBT Use international standards where possible	Fulfil transparency/ notification obligations of TBT Use international standards where possible Adhere to Code of Good Practice for Standard Setting	Fulfil transparency/ notification obligations of TBT Use of international standards where possible	Fulfil transparency/ notification obligations of TBT Use of international standards where possible
Recognition of conformity assessment procedures (CAPs)	Working towards the possibility of converging or aligning CAPs Examine the possibility of recognising CAP bodies	Exchange info on CAPs, criteria and accreditation procedures used	Make compatible CAPs to the greatest extent practicable; accredit, approve, license or otherwise recognize conformity assessment bodies in the territory of another Party on terms no less favorable than those accorded to conformity assessment bodies in its territory	Accredit, approve, license, or otherwise recognise conformity assessment bodies in the territory of the other Party on terms no less favourable than those it accords to conformity assessment bodies in its territory

	EU – Peru/ Colombia	EU-South Korea	NAFTA	US-Australia
Recognition of results of conformity assessment procedures	Ensure that results are accepted if body is recognised under a multilateral accreditation agreement Consider negotiations on agreements facilitating acceptance of CA results	Works towards facilitating acceptance of CA results	Accept the results of a conformity assessment procedure conducted in the territory of another Party, provided that it is satisfied that the procedure offers an assurance that the relevant good or service complies with the applicable technical regulation or standard adopted or maintained in the Party's territory	Exchange information on these and other similar mechanisms with a view to facilitating acceptance of conformity assessment results
Recognition of equivalence of technical regulation	Work towards the possibility of establishing equivalence of technical regulation		Treat a technical regulation adopted or maintained by other Party as equivalent to its own where that Party demonstrates that its technical regulation adequately fulfillls the importing Party's legitimate objectives	Give positive consideration to accepting as equivalent technical regulations of the other Party provided it is satisfied that these regulations adequately fulfil the objectives of its regulations
Recognition of fully harmonized technical regulation	Work towards the possibility of converging or aligning technical requirements If other party also wants to develop similar technical regulation, share information Cooperate in development of intl standards Exchange info on use of standards	Work towards the possibility of converging or aligning technical requirements Develop common understanding of application of intl SPS standards Cooperate in development of intl standards, guidelines and recommendations	Make compatible respective standards-related measure to greatest extent possible	Identify trade facilitating bilateral initiatives regarding standards, technical regulations, and conformity assessment procedures appropriate for particular issues or sectors