2. THIS TIME IT'S DIFFERENT: TURBO-CHARGING REGULATORY COOPERATION

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1. Introduction

When in June 2013 Presidents Barroso, Obama and Van Rompuy formally called for the launch of negotiations toward a "comprehensive and ambitious" Transatlantic Trade and Investment Partnership (TTIP) between the United States and the European Union, the regulatory part of the agreement was widely heralded as being the most novel and the most important for generating economic growth.

Two years and nine rounds of negotiation later, TTIP's regulatory component is one of the more contentious parts of the agreement. This is attributable both to persistent differences in emphasis between the negotiators and to concerns that regulatory cooperation could lead to a lowering – or, for that matter, an unjustified raising – of consumer, worker, prudential and environmental standards.[1]

In contrast, the authors believe that regulatory cooperation between the United States and the European Union is primarily about enhancing the ability of EU and US regulators to protect their citizens; positive economic gains are a secondary, if important, result. This chapter starts by presenting a framework to understanding regulatory cooperation in general, and briefly discusses developments in US and EU regulatory cooperation since 1995, before presenting, in sections 3 and 4, how TTIP can 'turbo-charge' this by enshrining good regulatory principles and practices, and by introducing new tools to deepen the

[1] Note that 'standards' here refer to regulatory *objectives* (e.g. about health, safety, etc.), which the debate has sometimes informally called 'level of protection'.

relationship between transatlantic regulators. Sections 5 and 6 compare this proposal with regulatory provisions in previous US and EU trade agreements, as well as with those the EU Commission has recommended for TTIP.

The central thesis throughout this chapter is that regulatory cooperation between the United States and the European Union should be about helping regulators become more efficient and effective in achieving their goals, and not primarily about removing or reducing 'non-tariff barriers to trade'.[2] While TTIP can help ensure that regulators are better informed about the consequences of their decisions for the transatlantic partner, it must also recognise that changes to regulation must go through our respective domestic decision-making procedures, that the regulators are, and will remain, under political oversight, and that they must retain their autonomy to make decisions appropriate to their jurisdictions, even if those decisions create divergences. This understanding addresses public concerns about transatlantic regulatory cooperation even as, we believe, TTIP will motivate the regulators to do more of it, with all the benefits that this might bring.

2. Regulatory cooperation: What it is and what the EU and US have achieved so far

2.1 Introducing international regulatory cooperation

As a bilateral agreement between two governments that will provide for some regulatory cooperation, TTIP represents merely one form of international regulatory cooperation (IRC), and must be understood in that context.

Governments have engaged in various forms of regulatory cooperation for decades, in everything from informal memoranda of understanding to full international treaties. International regulatory cooperation is pursued bilaterally (e.g. Regulatory Cooperation Councils between the US and Mexico and the US and Canada), multilaterally (the OECD MAD programme on the acceptance of

[2] This chapter focuses on the regulatory cooperation as a general matter, rather than on such regulatory issues that are traditionally covered in trade agreements -- sanitary and phyto-sanitary standards, technical barriers to trade such as standards and conformity assessment, etc., although these will of course also be incorporated in TTIP. For SPS and agri-food in TTIP, see Josling & Tangermann (2014); for the TBT chapter in TTIP, see Pelkmans (2015b).

chemical data), in global quasi-hierarchies that provide regulatory 'models' and strong incentives for voluntary implementation (e.g. financial regulation in the G-20 and the Financial Stability Board) and internationally (as treaties such as the Montreal Ozone Protocol, and in such international organizations as APEC, OECD, WTO (especially the SPS and TBT agreements), UNECE (on selected ICT standards, like Bluetooth, and car regulation), and ICAO (on safety in aviation and on minimum environmental requirements). International regulatory cooperation also happens in private international organisations such as ISO (on technical standards) and ILAC (on laboratory accreditation with recognition of conformity assessment results based on strict ILAC/ISO standards). International organisations for regulators have also emerged, such as the International Medical Devices Regulatory Forum, which focuses on global standards as well as a harmonised format of product-registration submissions, and, in medicines, the PIC/S (on common rules for inspections[3]) and the International Conference on Harmonisation (ICH) of technical aspects of marketing approval of medicines, which has issued some 50 guidelines.

This selective list shows that international regulatory cooperation has grown in importance and variety, at different levels and with a range of instruments. The OECD (2013) has done an extensive stock-taking of these various forms of IRC, and has mapped eleven distinct forms.

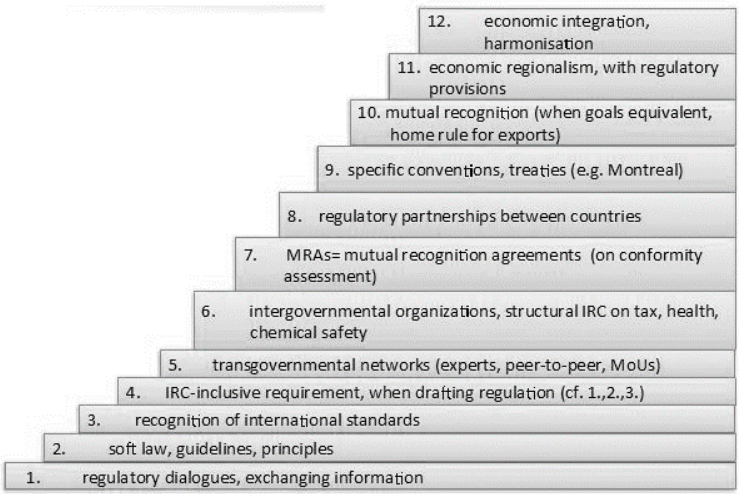
A convenient summary of the OECD mapping is depicted in Figure 2.1, which distinguishes not 11 but 12 mechanisms and presents international regulatory cooperation as a 'ladder' of increasing ambition, from non-binding and very loose mechanisms at the bottom to stringent, binding, and demanding ones at the top.

The bottom four rungs of the ladder show 'soft' - that is non-binding – IRCs, which can degenerate into a 'talk-shop' if left on their own. With respect to Step 2, principles of 'good regulatory practice' have been developed in the OECD 2012 Recommendations on Regulatory Policy and Governance (and accepted by both the US and the EU). Recognition of international standards (Step 3) is in the WTO TBT Agreement, but this obligation is not 'hard' or easily enforceable given the long-standing discord between the US and the EU about the definition of an international standard. The EU is of the view that 'international standards' are written and promulgated by established international bodies (like ISO and IEC) while the US believes the

[3] See www.picscheme.org

Agreement has a much broader application. The economic meaning of Step 3 can be rendered much more powerful if done in conjunction with Step 4, which requires the explicit consideration of international effects when drafting a domestic regulation which might affect trade. Depending on the stringency of the agreed obligations, and without undermining each party's autonomous 'right to regulate,' Step 4 can go quite far.

Figure 2.1 The ladder of international regulatory cooperation



Note: IRC = International Regulatory Cooperation.
Source: Authors' own configuration based on OECD (2013).

Trans-governmental networks of experts and regulators (Step 5) have become important too, both in EU/US relations and embedded in broader country participation. The International Competition Network, for example, goes beyond the EU and US but has been strongly influenced by the two parties. This is also true in the Bank for International Settlement's Basel Committee on banking supervision, which has a wider membership but remains dominated by the EU and the US. Regulators in medicines and medical devices have also developed multilateral or global forums, based in part on initial US-EU bilateral cooperation. This suggests that Step 5 may work bilaterally sometimes, but with global markets and global value chains), the bilateral context could become a stumbling block or be seen as insufficient.

The same may well apply to Step 6 on international organisations. In general, EU-US cooperation is essential to regulatory cooperation in these multilateral forums because work in large international organisations is frequently shallow and soft, hampered by the resistance of some members and/or a divergence in underlying policy objectives. And where IRC in such organisations is successful, it can take years, if not decades, of prudent approximation. A good example of long-winding but eventually successful IRC is the binding OECD MAD agreement on mutual acceptance of chemical safety test data, which took decades.

In Step 7, mutual recognition of conformity assessment, the EU and the US took the lead in the early 1990s, but several other countries caught up on the basis of the EU-US model, the experiences and lessons of which are summarized in Box 2.1 below. Mutual Recognition Agreement (MRAs) on conformity assessment do not affect or put in question any aspect of either party's regulatory regime. Even so, MRAs on conformity assessment are more demanding in that they are also treaties, hence 'hard' law. Equivalence agreements are another option mentioned in the WTO TBT Agreement and the 1998 US-EU Veterinary Equivalence Agreement has been partially successful (see Josling & Tangermann, 2014, for an assessment).

Step 8 (regulatory partnerships) is ill-defined. The partnerships may amount to an ambition greater than MRAs (hence, Step 8 on the IRC ladder) but that is far from certain. Thus, Canada–US regulatory cooperation (with a Council to that effect) is not binding and characterised more by the ambitions and methods of Steps 4 and 5. Such voluntarism may still yield results, though, especially as cooperating regulators build trust in each other and confidence in the partners' rules and enforcement ability. For regulatory partnerships to be as strong and effective as Step 8 would suggest, one would need to specify in much greater detail what regulatory principles, opportunities, disciplines, and cooperative obligations the parties subscribe to in a treaty or other legally-binding agreement. .

The other steps in the IRC ladder go even farther. Step 9 is about narrow treaties that bind countries in a specific area or sector. A leading and successful example is the Montreal Convention on protecting the ozone layer by forbidding or restricting F-gases. Other similar conventions are less successful because they have been drafted in far more circumspect language and with exceptions, carve-outs and other exclusions, or, like UNFCCC, form no more than a general framework for very long-term cooperation (here, on mitigating climate change).

Step 10 on mutual recognition more broadly is even more ambitious. At this level, mutual recognition agreements can stipulate that when the objectives and enforcement of safety, health, environment, investor/saver and consumer protection (SHEIC) risk regulation are 'equivalent', home rules of the exporting countries are regarded as sufficient guarantee for allowing market access into the importing country.[4] Thus, here, the equivalence does not refer to a case-by-case examination of product types by the importing country, in the framework of an 'equivalence agreement' (Step 7), but refers to policy *objectives*. This goes much further and has fairly radical implications.

One huge misunderstanding about mutual recognition is that it might lead to less or less ambitious regulation, once the rules of the exporting country are determined 'sufficient'. This misunderstanding is based on the famous quote from the 1979 Cassis-de-Dijon case,[5] but that quote assumes equivalence of objectives first. In this sense, mutual recognition is about overcoming different technical specifications that reach an equivalent regulatory objective – the latter refers to the market failure that matters and is addressed by that objective; the instruments or technical details are not decisive and should not be (in other words, they may differ).

Steps 11 and 12 are not expected to apply to TTIP as a rule. One should consider Step 11 as far more stringent, perhaps even somewhat centralising, than Step 8 (regulatory partnerships). For instance, the Australia-New Zealand 'Trans-Tasman' Mutual Recognition Agreement builds on mutual recognition but this is occasionally combined with common rules and, in food, with a common enforcement agency. Step 12 proposes harmonisation as a regular element of economic regionalism. TTIP is not meant to assume such ambitions and it is almost certainly not even desirable as a rule. But there are isolated instances of harmonisation between the US and the

[4] Extensive analyses of mutual recognition can be found in Pelkmans (2007) and (2012) based on the EU; the practice of MR in Trans-Tasman MRA is analysed in Pelkmans & Correia de Brito (2015a, Annex C).

[5] EU member states must allow 'a product lawfully produced and marketed in another member state into their own market'. Case C-120/78. As formulated, this is the pure origin principle. However, one must read this in conjunction with the logic of the derogations for member states, which are 'justified' if certain regulatory objectives will not be fulfilled. However, the mutual recognition logic consists of establishing whether the objectives of another member state are equivalent (even when not identical) in providing regulatory protection; if so, the origin principle prevails and imports cannot be blocked.

EU which, perhaps surprisingly, have emerged from international organisations (Step 6) and/or specific agreements. One example is far-reaching harmonisation of maritime safety rules in the IMO. As a result, the EU and the US have concluded a separate MRA in 2004 on 49 types of maritime equipment, which works well.

The OECD (2013) study and Figure 2.1 underscore that negotiators and regulators have to think in terms of many different forms for international regulatory cooperation. The spectrum comprises many options, and each option has stringent and less stringent variants. And although one might be correct in suspecting that 'soft' steps near the bottom of the ladder tend to be less effective, this is not always the case. For instance, regulators are loath to bind themselves in treaties and hence might opt for the lower steps in their cooperation. But as shown in medicines and medical devices, the voluntary follow-up in national regulatory regimes of what has been agreed in such sectorial regulatory forums has been active, and many countries adopt such guidelines or allow acceptance of single-form submissions. Regulatory cooperation in TTIP can benefit from these insights as well.

An important conclusion of the sophisticated mapping in the OECD international regulatory cooperation study is that despite "…the growing trend in regulatory cooperation, IRC is not based on a clear understanding of benefits, costs and success factors of the various IRC options" (OECD, 2013, p. 75). This warning must be kept in mind for regulatory cooperation as we look briefly at the history of US-EU regulatory cooperation, and lay out how it could be developed in TTIP. It should be clear in any event that TTIP can be based on, or linked to, many such international initiatives or regimes, or, indeed, it might assume a longer-run process of enhancing the ambitions of such IRC by setting more ambitious TTIP objectives as a leading example.

2.2 Recent US-EU regulatory cooperation: A bird's eye view

While US regulators have been working with their counterparts in major EU member states for many years, cooperation with EU-level counterparts began with the Joint Statement on Regulatory Cooperation at the end of 1997,[6] followed a year later by the

[6] "Regulatory Cooperation: Facilitating Trade while Promoting Consumer Protection," Joint Statement released in conjunction with the US-EU Summit in

'Agreement on Mutual Recognition Between the European Community and the United States of America.'[7]

As described in Box 2.1 below, these first agreements were generally limited in scope, applying mainly to recognition of certain laboratories being able to test whether locally-produced products in six sectors (in the 1998 MRA) met the regulatory requirements of the other party.

Box 2.1 The 1998 US-EU MRAs and lessons drawn

As one of their first full forays into bilateral regulatory cooperation, the US and EU concluded a Mutual Recognition Agreement (MRA) on conformity assessment in 1998. The MRA has a general set of principles, rules, and procedures in a 'chapeau' or 'umbrella,' with six distinct annexes in the sectors: telecoms equipment, electromagnetic compatibility (EMC) of equipment and appliances, electrical safety of goods (including machinery), pharmaceutical Good Manufacturing Practices (GMP), medical devices, and recreational craft. Consistent with the practices in Step 7 above, this MRA had the limited objective of allowing designated Conformity Assessment Bodies from each party to certify that products in these sectors met the regulatory requirements of the other party. As such, it reflected a conscious choice not to engage in any regulatory change but to focus solely on reducing transaction costs for market access. The economic gains from such limited MRAs tend to be relatively small, unless the costs of conformity assessment amount to a considerable surcharge on the export price. After carefully reviewing the experience with the MRA, Pelkmans & Correia de Brito (2015b) find:

1. Despite great initial efforts, only three of the six sector MRAs are operational: telecoms equipment, electro-magnetic compatibility, and recreational craft. In terms of trade values, the three MRAs that work cover only one-fifth of the bilateral trade originally foreseen under all six sectoral MRAs. In the other three – pharmaceuticals, medical devices, and electrical equipment – the initial trade policy focus was probably unsuitable for what was seen by US regulators as a loss of control of properly serving their regulatory objectives. Regulators should therefore play a major role in designing regulatory cooperation, even in the case of MRAs, whilst trade policy may generate collateral benefits but cannot be decisive.

Washington, D.C., 5 December 1997 (www.eurunion.org/partner/summit/Summit9712/regulst.htm).

[7] See http://trade.ec.europa.eu/doclib/docs/2003/october/tradoc_111718.pdf.

2. MRAs are easier in markets which are less heavily regulated, but ironically, in these cases they are also less needed because alternatives to MRAs (in particular, suppliers' declarations of conformity, or SDoCs) can serve as a low-cost and swift solution. When SDoCs are not permitted, alternatives such as subcontracting may nevertheless be used by market players. Thus, in particular, large US and EU exporters with a steady customer base (or as part of a value chain) in the EU and US have a great interest in durable relationships with trusted CABs. The practical working of the MRA will then be significant only for new entrants or occasional exporters or in cases of overload. New entrants may well be SMEs, so for them and possibly the emergence of 'new' competition, the MRA would still fulfil a useful function.

3. MRAs in heavily regulated markets require a considerable degree of convergence in desired levels of protection as well as a gradual build-up of trust and confidence between the regulators. This did not work at first for medicines and medical devices. There are also indications that at the time, in these two sectors, the EU internal market rules and supervision still left something to be desired. Simultaneously, at world level, cautious attempts were initiated to come to greater harmonisation for pharmaceuticals and medical devices [8] in some respects, such as similar data and shorter time-to-market, in which the EU and the US played a leading role. These alternative IRC tracks have meanwhile become quite successful, thereby more or less obviating the 1998 MRA provisions.

4. In electrical goods safety, the third sector that failed (the MRA was suspended by the EU in 2003), the EU attempted in 2008 to convince OSHA (the US regulator for occupational health and safety) to accept SDoCs from EU producers. SDoCs are a form of self-certification customary in the EU 'New Approach' to reducing regulatory barriers. After a two-year investigation, OSHA concluded that the empirical evidence about equivalent or better-risk reduction in the EU was insufficient. This experience underscores that regulators will only enter into agreements with their counterparts where hard evidence exists that both the rules and the enforcement of those rules demonstrate that the counterpart's approach delivers similar regulatory outcomes.

Source: Pelkmans & Correia de Brito (2015b).

[8] The Global Harmonisation Task Force for medical devices, active since the mid-1990s, and the International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human use (ICH), founded in 1989. For more detail, see Pelkmans & Correia de Brito (2015b).

These efforts were heavily backed by industry, and in particular the Transatlantic Business Dialogue (TABD), which the US and EU had helped create with the 1995 'New Transatlantic Agenda', in part to encourage more direct business engagement and advice in transatlantic trade matters. (Transatlantic Dialogues for consumers, labour, and the environment were established a few years later.) At this time TABD was also strongly encouraging great regulatory cooperation in automotive safety. This failed when the US regulator (the National Highway Transport Safety Agency, NHTSA) undertook extensive studies about certain specific auto safety features (e.g., on standards for side door crash resistance) which demonstrated that EU vehicles were less safe than their American counterparts. This experience again underscores some of the lessons learned in the earlier MRAs – that regulators cannot and will not lower safety standards just to promote trade, and that they depend on hard evidence, rather than political good will.

Despite setbacks, more substantive cooperation began to take off with the first US-EU 'Regulatory Cooperation Roadmap' in 2002, which was successively expanded from six sectors to sixteen over the next three years. An important component to this was a consensus in 2002 on good regulatory practices, which helped strengthen the cooperation and which also helped spur greater dialogue between the US Office of Information and Regulatory Affairs (OIRA) and the Commission's Secretariat General, which also oversees better regulation in the EU. This experience eventually helped in the establishment of the US-EU High Level Regulatory Cooperation Forum (HLRCF) in 2005 to further promote best practices in such cooperation.

By 2007, when the Transatlantic Economic Council (TEC) was founded, transatlantic regulatory cooperation was booming. For example, at that time the US Food and Drug Administration (FDA) informally estimated that its officers were having over 1,000 substantive contacts a year with their European counterparts in DG SANCO, the European Medicines Agency (EMEA), and the European Food Safety Authority (EFSA).

Annex 1 provides a detailed summary list of all the US-EU regulatory cooperation initiatives we have been able to identify since the first agreement on regulatory principles in 1997. This growing cooperation has had a number of significant results, both broadly as with the 2008 report comparing US and EU approaches to import safe

products,[9] and in individual sectors, from the November 2007 FDA/EMEA decision to accept a single application for orphan drugs,[10] to the 2008 US Securities and Exchange Commission's (SEC) decision to accept the EU's international accounting standards as equivalent for US capital markets purposes.[11] One of the most ambitious examples was the conclusion in 2009 of the US-EU Bilateral Aviation Safety Agreement,[12] under which the FAA and the European Aviation Safety Agency (EASA) agreed to accept one another's air-worthiness certifications for Boeing and Airbus airplanes, even though an aeroplane is arguably the most regulated product on the market and even amidst an intense WTO trade dispute on the supports both sides give to their respective companies. In 2012, the two governments concluded other agreements, including mutual recognition of their respective approaches to organic produce[13] and to container and air cargo supply chain security systems,[14] as well as joint work in such areas as electric vehicle safety and design requirements.

While the breadth and depth of US-EU regulatory cooperation has been growing, it tends to be technical, and thus known only to those directly engaged in the sectors concerned. Because of this, many outside these areas tend to be sceptical – and at times outright critical – of the cooperation. This may underscore the need for a more basic understanding of what regulatory cooperation is and should be about between the United States and the European Union.

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[9] See "Toward Enhanced Cooperation between the European Union and United States of America on the Safety of (Imported) Products" (http://ec.europa.eu/enterprise/policies/international/files/tec_safety_en.pdf).

[10] See EMEA press release, "The European Union and FDA Working Together to Create a Single Application for Orphan Designation for Medicines", 26 November 2007 (www.emea.europa.eu/docs/en_GB/document_library/Press_release/2009/11/WC500011002.pdf).

[11] See www.sec.gov/rules/final/2007/33-8879.pdf

[12] See www.faa.gov/aircraft/repair/media/Safety_Agreement_Between_US_and_EC.pdf

[13] See www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097063

[14] See www.cbp.gov/newsroom/national-media-release/2013-02-08-050000/eu-us-fully-implement-mutual-recognition-decision

3. Basic principles and motivation for TTIP regulatory cooperation

The primary role of governments in modern societies is to protect their citizens – from foreign aggression and domestic crime, of course, but also from abusive labour practices, unhealthy environments, and unsafe products and services.

This last function is the most relevant aspect when it comes to trade across borders. But here it needs to be emphasised that the job of regulators is to pre-empt or prevent any market exchange which has unacceptable adverse effects on consumers or workers, or the environment. Regulators want to prevent unsafe products and services from getting into the domestic market whether those products or services are produced at home or abroad.[15]

The level of safety that a regulator demands is primarily a function of the political system and income levels in a society.

- **Politically**, in countries with little or no input from citizens, the desired levels of safety will reflect the preferences of government officials; in an autocratic dictatorship, the preference of the ruler. In democratic societies, however, with a transparent and rules-based approach to governance, the level of safety demanded in regulation will in general reflect the risk preferences of the voters as expressed in elections. In this sense, democracy is not just a 'value', but has a very real operational significance with respect to regulation.
- **Economically**, increasing levels of protection costs money, and governments need to balance these costs with the benefits in terms of safety that regulation can bring. In a democratic society where the levels of protection will reflect the polity at large, the degree of safety demanded will therefore tend to be a function of income – the higher the level of income, the less important the additional costs of risk mitigation and the higher the level of protection demanded. This is a wholly domestic affair – democratic governments will regulate to the risk preference

[15] Governments may of course also regulate international trade to minimise the economic risks of competition from foreign firms, otherwise known as protectionism. That aspect of risk mitigation is not considered here, as both the US and the EU nominally eschew it.

demanded by their voters even in the absence of imports from another jurisdiction.

This somewhat theoretical discussion is directly relevant to the issue of regulatory cooperation in TTIP. As democratic societies with comparable levels of income and wealth and transparent and politically accountable[16] regulatory systems, the United States and the European Union have in general identified the same sorts of goods and services as posing risks to their citizens (and voters), and strive for the same level of safety in those areas—that is, their regulatory objectives and outcomes are generally similar.

This general observation is based on both impressions and empirical studies. Impressionistically, over 25 million people travel each way between the United States and Europe each year, staying in hotels, eating local foods, renting cars, buying products, and otherwise engaging in daily activities; they do not seem to perceive any difference in the level of safety provided. More academically, a 2010 study published by Resources for the Future (RFF), based on 20 case studies and 3,000 observations of risk-reducing regulatory decisions in the US and EU, found that overall risk stringency is about the same, with the differences largely due to non-safety related issues.[17]

It is precisely this political and economic foundation that permits, and indeed encourages, a truly ambitious level of regulatory cooperation in TTIP. US and EU legislators and regulators have traditionally determined the level of safety they desire based on domestic costs and benefits. The US and EU economies are so tightly integrated, however, that these inward-looking approaches are insufficient, missing both the costs and the benefits of the transatlantic implications of these domestic choices. The EU and the US have the largest trading relationship in the world, with over $1 trillion in two-way trade in goods and services each year. Further, US firms have invested over $2.3 trillion in the EU, while EU firms have invested some $1.7 trillion in the US. These investments together generate nearly $5

[16] In the United States, Congress actively oversees the activities of US regulatory agencies. In the European Union, the Council, representing the elected governments of the 28 member states, 'co-decides' the level of safety in regulation with the directly elected European Parliament, while member state governments and parliaments will be the 'first responders' to failures in market surveillance and enforcement. For an authoritative and detailed exposition of the US and EU regulatory system, see Parker & Alemanno (2014).

[17] See Wiener et al. (2010).

trillion in sales each year. Nearly half of all trade is intra-industry and intra-firm. When legislators and regulators on either side make decisions without considering this integration, even if they are separately trying to achieve the same level of safety, they may do so in ways that require products and services to be designed and produced differently to be sold in each market.

This raises costs to producers, at times to the point where they cannot profitably supply a product or service to the other side of the Atlantic. This is particularly so for smaller firms, many of which only know that the regulatory requirements and standards are different, and don't have the ability to research or re-tool to meet them. But it also affects large firms – the cost of crashing over a hundred custom-made models to meet different safety, testing, and certification requirements in automobiles, for instance, run to hundreds of millions of euros. This makes it almost impossible for smaller French and Italian car manufacturers to sell into the US market. The same can happen for medicines, especially for rare illnesses. And this, of course, raises costs to consumers, who may be wholly denied products and services that they wanted or needed.

One of the most politically interesting examples was the pressure put on the FDA in the 1980s and 1990s to fast-track approval of HIV medicines that had been working effectively in Europe for years. And both societies as a whole lose the gains in productivity that would come from more companies competing in their markets, and the advantages of synergy and global competitiveness that firms working on both sides of the Atlantic could have if they did not face these 'unnecessary' regulatory divergences: 'unnecessary' in the sense that the intended levels of safety are similar (see also Box 2.2).

The disadvantages of insufficient consideration of the transatlantic costs and benefits of greater regulatory compatibility between the United States and the European Union are, however, only one part of problem. Potentially more important is the adverse impact on the regulators themselves, and their ability to achieve their goal of keeping their citizens safe. Regulators devote their resources to ensure that rules are being observed for the products and services being sold in their market. The enormous volumes of transatlantic trade require a correspondingly large amount of resources to police. At the same time, globalisation has also greatly increased trade with many other partners. With ever-increasing volumes of imports from other - potentially more risky - jurisdictions, sophisticated and ever-lengthening supply chains, and ever-decreasing budgets, the regulators are in danger of being

stretched too thinly to do their job. If, however, they have evidence demonstrating that their transatlantic counterparts are able to enforce levels of protection similar to their own, they can develop a partnership with that counterpart regulator, allowing them to focus their enforcement resources on higher-risk problems. Indeed, it was precisely this broader gain from international regulatory cooperation that motivated President Obama to issue Executive Order 13609,[18] encouraging US regulators to be more active in this area, especially with places like the EU, which share US regulatory values.

Box 2.2 Potential economic gains from regulatory cooperation in TTIP

In the sense of our discussion above, many of the gains from regulatory cooperation cannot be easily measured. However, a number of empirical economic simulation studies on TTIP have been published in 2013 and 2014; two – Francois et al. (2013) for the Commission Impact Assessment, and Fontagne et al. (2013) - explicitly study TTIP regulatory cooperation in detail. These two studies, both of which are based on a broader ECORYS study from 2009, attempt to estimate the costs of regulatory differences as a percentage of export invoice costs (the so-called 'tariff equivalent' of technical barriers to trade, or TBTs). The studies estimate these TBT tariff equivalents between the US and the EU to range from 15-72%, depending on the sector. Such percentages are a large multiple of US and EU nominal tariffs on industrial goods and many agricultural products. Francois et al. estimate that no less than 56% of TTIP's economic gains arise from an assumed 50% cost reduction of TBTs (their ambitious scenario). Even with the difficulty of properly estimating the benefits of TBT reduction (see Pelkmans et al., 2014) as well as the limitations of even the best econometric models, the reduction of TBT costs through regulatory cooperation is obviously important to the overall economic gains of TTIP.

The ability for enhanced transatlantic regulatory cooperation to increase the efficiency and therefore the effectiveness of US and EU regulators is one of the most misunderstood benefits of TTIP, even by some of the regulators themselves. Given their political accountability at home, whether to Congress, the European Parliament or the EU member states, their ability to cooperate with a foreign counterpart is directly proportional to the level of trust and confidence that they have

[18] See www.whitehouse.gov/sites/default/files/omb/inforeg/eo_13609/eo13609_05012012.pdf

in that counterpart. And that comes only with time and experience. In this sense, the US and the EU are now better positioned for an ambitious approach to regulatory cooperation in TTIP, as the US and EU regulatory systems have improved, and as regulatory cooperation has grown over the past 15 years.

4. Turbo-charging regulatory cooperation in TTIP[19]

The most important question now is how TTIP can build upon the experiences US and EU regulators have had over the past 15 years in collaborating with one another, given the broader political, economic, consumer, and regulatory benefits of greater transatlantic regulatory cooperation.

4.1 General considerations

As discussed above, the single most important consideration is understanding that regulatory cooperation can only work if the regulators on both sides have the full trust and confidence of one another, that the levels of protection are similar, and that the enforcement of those regulatory requirements is effective. While TTIP aims to enhance regulatory collaboration and compatibility, regulators in the end must make decisions that reflect the political will of their electorate.

A second critical consideration is a clear delimitation of the scope of regulatory cooperation under TTIP. Regulatory cooperation in TTIP should focus on laws and regulations that directly apply to goods and services traded between the two parties. Laws and regulations that go to wholly domestic matters, such as those on working hours, wage levels, air pollution standards, etc., should be outside the scope of any general disciplines on regulatory cooperation, even though those measures may have an indirect effect on trade

A third consideration which also affects the scope is that the obligations on regulatory cooperation in TTIP should apply to the EU Commission and the US Executive branch and independent agencies, not the respective legislatures (Congress in the United States, the

[19] The comments in this section are jointly drafted but reflect the first author's experiences in transatlantic regulatory cooperation as well as his work in the US Chamber; see, for instance, www.uschamber.com/sites/default/files/regulatory_coherence_regulatory_cooperation_-chamber_ttip_paper_-_final_3-02.pdf, February 2015.

Council and European Parliament in the EU). This third consideration is elaborated upon below.

With these three considerations in mind, the regulatory part of TTIP (here, not counting SPS and TBTs, see before) should have three essential components:

- agreement on principles and best practices in domestic regulation (sometimes referred to as 'regulatory coherence'),
- general (or 'horizontal') provisions governing regulatory cooperation and
- sectoral annexes reflecting agreements that have been, and will be, agreed between counterpart US and EU regulators, both during and after the TTIP treaty negotiations.

This structure, and in particular the use of sectoral annexes, is essential to the acceptance and functioning of transatlantic regulatory cooperation in the context of the TTIP negotiations. It is essential, firstly because it recognises pragmatically that trust and confidence between counterpart sectoral regulators is the core of regulatory cooperation; secondly because it guarantees, for citizens and politicians alike, that the regulators themselves (rather than trade negotiators) are in charge of the details of the cooperation for which they are politically accountable; and thirdly because it allows the regulatory part of TTIP to be a 'living' agreement, with the inclusion of additional regulator-to-regulator agreements even after the TTIP is concluded, as additional experience, trust, and confidence are gained between the counterpart agencies.

The remainder of this section will focus on the regulatory coherence and cooperation aspects of TTIP, as well as the sectoral annexes, since these are the most novel aspects of the regulatory part of the agreement.

4.2 Regulatory coherence

The opening section of a TTIP regulatory chapter must lay out the principles and practices that are the foundation on which the trust and confidence of regulators are to be built – a common understanding of what constitutes a strong, democratically accountable regulatory system. This should not be difficult to draft: the US and EU have twice

issued joint statements on this (2002[20] and 2011[21]), focusing in particular on the need for transparency, stakeholder participation, and accountability in rule-making, as well as the need for quality impact assessments, evidence-based decision-making and the like, as described in Box 2.3 below.

Box 2.3 US-EU consensus on regulatory principles and practices

The US and the EU have been developing a consensus on regulatory principles and practices since the late 1990s. In fact, its origin may be traced back to the 1995 recommendation of the OECD Council on Improving the Quality of Government Regulation. In addition to the 1997 US-EU guidelines on regulatory cooperation, the three main expressions of this consensus include the joint statements of 2002 and 2011 noted earlier and, more recently, the 2012 recommendation of the OECD Council on Regulatory Policy and Governance.[22] The 2011 'Common Understanding' demonstrates that the two partners have already developed regulatory principles that are very similar, if not the same. The Understanding reaffirms their shared commitment to good regulation, and is based on EU and US documents that already guide domestic regulatory policy. When regulation is to be developed, it should be evidence-based (with impact assessment or equivalents), include an analysis of relevant alternatives, evaluate the effectiveness of existing regulation, and apply approaches that minimise the burden while aiming for simplicity. The regulatory process should be transparent and should solicit, evaluate, and respond to input from all stakeholders.

Further, the 2011 Common Understanding says explicitly that "regulatory measures should aim to avoid unnecessarily divergent or duplicative requirements between the US and the EU, when appropriate". Moreover, the US and the EU "should also explore a process to exchange regulatory information of the Unified Agenda and Work Programme, respectively, … and have a fixed agenda item at the High Level Regulatory Cooperation Forum" with a view to seeing whether the two parties can work together on areas both are considering. The Understanding also encourages new regulatory

[20] See www.whitehouse.gov/sites/default/files/omb/oira/irc/2002-guidelines-on-reg-coop-and-transparency.pdf, April 2002

[21] See www.whitehouse.gov/sites/default/files/omb/oira/irc/common-understanding-on-regulatory-principles-and-best-practices.pdf, 8 June 2011.

[22] See www.oecd.org/gov/regulatory-policy/49990817.pdf. Note that between the US and the EU, the starting point is still the 2011 Common Understanding.

cooperation measures, and obliges both to flag upcoming regulatory proposals likely to have international trade and investment effects, and/or publishing an Annual Notice to solicit public comments.

The 2002 guidelines are more detailed but otherwise very similar. They begin with seven steps which "will help minimise and resolve trade frictions and facilitate trade." None of these seven steps are surprising or controversial, and are presumably often, if not always, in the domestic public interest, too. Among other things, they include the commitment to "pursue… harmoni[s]ed, equivalent or compatible solutions…. and to minimize… or eliminate unnecessary divergence in regulations" through dialogue at all phases of the regulation development process. Transparency is strongly emphasised, as is the need for adequate time to provide meaningful comments, and their reasonable consideration, on draft proposals. These should be performance-oriented and cost effective, and hence have fewer adverse effects. These and other suggestions are by now well accepted throughout the OECD.

The issue being addressed in the TTIP negotiations now is how precisely the two sides think these principles and practices should be implemented, and indeed how to go beyond the 2011 Common Understanding. The United States, which has emphasised the importance of the concepts of transparency, participation, and accountability, argues in particular that the Commission should publish draft legislation and regulation ('implementing measures' and 'delegated acts' under the EU's 'comitology' procedures) on the internet for comment from all stakeholders, and that it should then summarise and respond to the substantive comments and evidence provided through that process when it finalises the proposal.

These ideas are less straightforward than they seem in the EU context. When it comes to legislative proposals, publication of a draft for comment prior to adoption of a proposal by the College of Commissioners is a sensitive issue for the Commission, as it is seen as undermining one of the central powers of the Commission under the EU treaties – the right to initiate legislation. The Commission is concerned that the member states in the Council and Members of the European Parliament would be among the most active participants in the public consultations about the drafts, which would essentially eliminate its right to initiate legislation. It therefore balks at making such a radical constitutional change in the context of a trade negotiation.

But it should be stressed that the idea of providing an opportunity to comment on draft legislation is not just a request of the US government, but one made by many European stakeholders as well, both in the business sector, in civil society, and by a 2009 broad Task Force of an EU think-tank.[23] As such, changes that might come about here can and should happen independently of TTIP, and be consistent with the Commission's own efforts to improve its domestic regulatory processes. And indeed, First Vice-President Timmermans and the Secretariat General of the Commission are now considering responses to the June 2014 request for comments on guidelines on the use of stakeholder input in the legislative and regulatory process.[24]

There are a number of ways input on legislative proposals could be handled without endangering the right of initiative. Publishing a draft after the initial inter-services consultation might be one approach; at this point, the serious politics (and thus the sensitivities) in the Commission have not yet begun. An alternative might be to stay with the current system and publish legislative proposals after adoption by the College - after all, these are proposals that must go through the legislative process in the Council and European Parliament. The Commission could accept comments on the proposals for, say, 60 days; these comments would be published on the Commission website, and the Commission's analysis and response to them could then be made available to the Council and Parliament upon formal presentation of

[23] See, e.g., the many responses to the request of the Commission's Secretariat General on 1 July 2014 for comments on draft guidelines concerning impact assessments and stakeholder consultation, which can be found respectively at http://ec.europa.eu/smart-regulation/impact/consultation_2014/contributions/index_en.htm and http://ec.europa.eu/smart-regulation/impact/planned_ia/consultation_2014/contributions/index_en.htm. For the Task Force report, see a CEPS book on reforms of EU regulation and policy-making (Renda, 2009, p. xii and pp. 36-37, as 'idea no. 13').

[24] As this chapter was being prepared for publication, the Commission adopted "Better Regulation for Better Results – An EU Agenda" (COM(2015) 215 of 19 May 2015, which includes an open eight-week comment period on Commission legislative proposals after the College adopts them; comments will be provided to the European Parliament and Council. The Commission will also introduce a four-week comment period on delegated acts and implementing measures.

the proposals to those institutions (see footnote 24 acknowledging this idea).

In the case of such regulatory measures as delegated acts and implementing measures, where the Commission has considerably more authority over the proposal, the idea of publishing drafts for notice and comment should be far less controversial, as acknowledged in the new Better Regulation package of the Commission. However, these two types of technical implementation refer to a massive quantity of acts/measures, many of which are actually of little importance, so there may well be a practical issue of overload.[25]

The EU too has demands of the United States when it comes to regulatory coherence. The legislative process in the United States appears more chaotic to Europeans than that in the EU, with literally thousands of bills being offered each Congress. Many of these are never acted on, yet can form the basis for amendments of a significant nature that (in the Senate at least) can often come to the floor for a vote with little or no notice, never mind an opportunity to comment. (That said, US legislation tends to be much more general in nature than it does in the EU, so that the effects on traded products and services are more likely to come later in the process, when legislation is implemented during the regulatory phase.)

Under the US Constitution, the executive branch has no control over the legislative process, just as the EU Commission has no control over the Council or the European Parliament. Nor will any of those political bodies surrender in a trade agreement their autonomy to legislate. This is why the third key consideration noted in section 3 above is necessary, and one of the first things both sides need to do in TTIP is to recognise that they can only demand some semblance of coherence between the Executive and the Commission, acknowledging that the political and legislative process outside those two bodies is necessarily a bit messy on both sides.[26]

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[25] In COM (2015) 215 (ibid., p. 50), the Commission writes that delegated acts can be commented on by stakeholders, but does not refer to, say, a selection of them. This is not the case for the other category where only 'important implementing acts' which are 'subject to Committee opinion' will be made public for comments.

[26] But legislation could still be TTIP-relevant, if the administrations on both sides can take on commitments and attempt to convince Congress and EP/Council to incorporate them. Also, the legal dichotomy between legislation

Even so, the Europeans could ask the US executive branch to take steps to make the US legislative process less confusing for its largest trading partner. Proposed bills are only serious if they are brought to the relevant Congressional committee for a hearing and mark-up. At this stage, the Executive branch is almost always requested to testify. If it is, and if the proposal would affect a product or service traded between the US and EU, TTIP could oblige the Administration to alert the EU of the hearing, and provide a copy of the Administration's testimony as a courtesy. In addition, if and when legislation is to be voted on, the Executive branch often issues a statement of the administration's position. This too could be provided to the EU if the bill affects a product or service that the EU exports to the US. In both instances, the Office of Management and Budget (OMB) is responsible for coordinating the Administration's agreed position on the legislation, and should be the point of contact for these efforts to enhance transparency.[27]

In contrast, by law under the Administrative Procedures Act, the US regulatory process is already generally open for participation by any stakeholder, including those in Europe. Proposed rules are published well in advance; all comments must be received and published, and must be responded to by the regulatory agency in adopting its final rule. Violations of these procedures can – and frequently are – brought before administrative court, which can – and frequently does – require the agency to undertake additional evaluation before a rule is implemented. The system is not perfect[28] (no system is), but it is generally open, transparent, and accountable.

In addition, for the US side to truly provide coherence, it must recognize that TTIP must also cover the activities of US 'independent' regulatory agencies. These agencies, generally known as Commissions (Federal Communications Commission, etc.), are outside the Executive branch and answer to both Congress and the President. Although such Commissions do not and legally cannot come under OMB, and so will

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and administration is not always followed in practice. Thus, recent Acts like the Jobs Act, the Affordable Care Act, and a recent one on cybersecurity were drafted by the administration and (mostly) taken over by Congress.

[27] In fact, this procedural courtesy is already often practiced with respect to the European Commission, and the OMB already de facto coordinates.

[28] See, e.g. statement of Michelle Sager, Director, Strategic Issues, Government Accountability Office, to the US Senate Committee on Homeland Security and Governmental Affairs, 11 March 2014 (www.gao.gov/assets/670/661540.pdf).

need to be treated differently in some respects, the legislation that implements TTIP can provide Congressional assent to bring them into the scope of transatlantic regulatory cooperation. This is particularly important in the context of financial services regulation.

The EU too must assure institutional coherence by fully including its autonomous agencies (the European Chemicals Agency, the European Food Safety Authority, the European Banking Authority and the like) in TTIP, for while these are, strictly, not rule-making bodies (but often risk assessors), they are instrumental and increasingly influential in the rule-making process and/or as supervisors. Legally, the EU might not follow our advice to include these agencies fully, as they are not independent regulators, but we advocate the strongest possible involvement, without affecting ultimate regulatory responsibility.

4.3 Regulatory cooperation

While the regulatory coherence part of TTIP should help improve both sides' understanding of and trust and confidence in the domestic rule-making procedures of the other side, the regulatory cooperation part should establish obligations that apply generally to all regulatory agencies on both sides to ensure that their decisions are informed about the impact of proposals on the transatlantic partner. And, as noted above, it should also include annexes that reflect regulator-to-regulator agreements in specific product and service areas.

Again, it's important to re-emphasise here the three considerations spelled out in section 3 above: the need to explicitly affirm regulator autonomy, primarily through the use of the annexes; the focus on regulations that directly affect products and services that are or could be traded between the United States and the EU; and the application of these regulatory cooperation commitments to the Executive branch and independent agencies in the United States, and the Commission and relevant autonomous agencies or advisory bodies in the EU.

Within this scope, the horizontal regulatory cooperation provisions of TTIP should:

- establish the explicit goal of making US and EU regulatory regimes increasingly compatible,
- provide the necessary tools to regulators to achieve this goal and
- create an institutional framework to oversee and guide this process.

The goal should be simple, and unbounded by time. It provides a direction to the ongoing regulatory cooperation process, but should not mandate that that goal must be achieved in all instances (it won't). Further, it cannot be subject to a timetable, in the recognition that building trust and confidence between counterpart regulators takes time, and indeed can be quickly lost. TTIP will set the trajectory for greater and deeper collaboration, but it will not reach an end-point, for among other things, laws and regulations in our society are and should be dynamic (in contrast, for instance, with the static tariff levels that are a normal subject of trade talks).

The 'tools' that should apply to all sectors falling within the specified scope should both inform the individual sectorial agreements and the regulatory processes of each side. Among other things, they should explicitly provide regulators on either side the legal authority to enter into agreements with their transatlantic counterpart, consistent with their existing legislative authority and on the understanding that such agreements will be subject to political oversight on either side. It should also affirm that all regulator-to-regulator agreements under TTIP can be suspended immediately, should something happen that leads a regulator on one side to lose confidence in the other, and that the agreements can be unilaterally terminated within a specified period of time, should the trust and confidence not be restored following consultation.

But more specifically, the general disciplines should ensure that regulators on both sides of the Atlantic are better informed about the costs and benefits of their domestic regulation as it affects the other party, and the trade in goods and services between them. This applies to both proposed new regulation, and to existing regulatory provisions affecting products and services. In both cases the objective is to inform decisions, not to determine them. While better informed of the transatlantic consequences, the regulator will in the end make the choice appropriate for its jurisdiction.

For new regulations that will a) have a significant cost of compliance to the economy and b) affect a product or service in which there is a significant amount[29] of transatlantic trade, TTIP should

[29] What is meant by a 'significant' amount of trade could be defined in the agreement, for example, if a regulation would affect a product or service where there is $100 million or more of trade. This level could even be sliding (from, say $500 million to $50 million) over a period of time to allow regulators to

mandate that regulators include a regulatory compatibility assessment (RCA) in the impact assessment process they would normally undertake in any event. While the details and methodology of this would need to be spelled out in more detail, the RCA would, in any case: a) require the regulator to contact its transatlantic counterpart, b) ascertain whether the product or service is regulated on the other side of the ocean, c) determine whether the counterpart had a similar or different definition of the problem the regulation is meant to address, d) assess whether the proposed approach is compatible with that of the counterpart and e) evaluate the costs and benefits of adopting a non-compatible approach. As this impact assessment is to be made available for public comment, all stakeholders would be able to see and provide new evidence related to the RCA. Again, a non-compatible approach that would affect trade between the two parties could be adopted, but the decision would be informed by an evaluation of the consequences for transatlantic trade.

For existing regulations, TTIP could establish a regulatory equivalence assessment (REA) process. Under this process, interested parties could send a petition to the relevant regulator stating that the levels of safety, or the required tests or manufacturing processes, for a specified product or service (or groups of products or services) achieve the same regulatory outcomes on both sides of the Atlantic. The petition should be accompanied by evidence supporting the contention of equivalence. The regulator receiving the petition would share it with his or her counterpart, and both would publish the petition and the evidence provided for public notice and comment. The two would then review the responses, and hold hearings on them. They would then write a joint or separate report in response to the petition, including what, if any, follow-on steps they would propose. Again, there would be no requirement that any specific result comes from this.

The RCA and REA procedures would be applicable to all regulated sectors, including, for instance, financial services. But, as noted above, they would not jeopardise a regulator's autonomy, only ensure better informed regulatory decisions. If agreements for enhanced regulatory cooperation emerge from the process, those agreements (after going through the appropriate domestic approval process) could then be reflected in the relevant TTIP sectoral annex.

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grow accustomed to the process. Indeed, it might be worthwhile to have different values of 'significance' for different sectors.

Arguably, regulators on both sides are already meant to consider the trade implications of their proposed regulations, and additional transparency, participation and accountability would help provide information about these impacts. Further, regulators on both sides probably already could receive and consider petitions asserting equivalence. But enshrining these procedures as obligations under TTIP would ensure that they are followed, and that there is increased consultation between the regulatory agencies. It would also give grounds for one party to complain if it had reason to believe that a regulatory agency on the other side did not undertake the required consultation steps.

The regulatory cooperation section should also establish an institutional mechanism to oversee the regulatory cooperation process. This could be the existing US-EU High Level Regulatory Cooperation Forum (HLRCF)[30] established in 2005, although it would make sense in the context of the increased requirements in TTIP to enhance it. In the Executive Order on international regulatory cooperation, mentioned above, President Obama recommended the establishment of regulatory cooperation councils (RCCs) with certain partners. The US currently has RCCs with Canada[31] and Mexico.[32] These RCCs meet once or twice a year, bringing together select regulatory agencies to develop work plans for regulatory cooperation, report on progress to date, discuss best practices and other such steps. They have no law-making capability as regulatory agencies on both sides must go through their domestic decision-making procedures to change any rules. This would be true as well for whatever oversight body TTIP creates. In addition to helping set the regulatory cooperation agenda and ensuring public reports, the oversight body would review experience, identify best practices among regulators, help resolve misunderstandings, expand and update the RCA and REA methodologies, and the like.

In contrast to the HLRCF, which is fairly ad hoc in its participation, TTIP should identify the bodies which should participate. Ideally it would be co-chaired by the two bodies which oversee the regulatory activities of the two governments, the Office of Information and Regulatory Affairs (OIRA) of the US Office of Management and Budget (OMB), and the European Commission

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[30] See www.whitehouse.gov/omb/oira_irc_europe.

[31] See www.whitehouse.gov/omb/oira_irc_north_america#canada. See also OECD (2013b) for a report on how it works in actual practice.

[32] See www.whitehouse.gov/omb/oira_irc_north_america#mexico.

Secretariat General. All relevant agencies, including those dealing with risk assessment or regulation directly, should participate.

The RCC name, while legally significant in the US context, has slightly different political connotations in the EU, where 'Councils' are ministerial-level bodies that make law. This may be one reason why some in Europe distrust the idea. Another name should be chosen for the oversight body in TTIP to avoid this misperception. Indeed, the EU first draft on Regulatory Cooperation in TTIP speaks of a 'body'.

4.4 The sectoral annexes

Structurally, one of the most important components of the regulatory cooperation part of TTIP is a set of sectorial annexes, for it is this structure which most clearly demonstrates that regulators are in the lead on regulatory cooperation, not trade negotiators. It is the former who are responsible for implementing the laws governing the level of safety of the products and services they regulate, and which are thus politically accountable to the relevant political oversight committees of Congress, the European Parliament and Council, and the national governments and parliaments. And it is this structure which clearly demonstrates to the legislative bodies, and to the public, that the desired levels of safety cannot be arbitrarily reduced (or increased) because of TTIP.

Indeed, in both the US and EU, changes in the level of regulatory protection would undoubtedly require legislative or at least regulatory measures. In the US, any such change would be subject to the requirements of the Administrative Procedures Act, and thus subject to legal challenge, should the public notice and comment process not be followed. Similar requirements exist on the EU side.

In this sense, TTIP can only occasionally be expected to bring about changes in underlying law; rather, it is a way to build bridges between two regulatory regimes. And bridges can only be built if the two sides are relatively close to one another. If the regulatory outcomes demanded by the two sides are far apart, then, at the very least, spans will need to be constructed to bring them closer together before anything further can be accomplished.

The annexes should be kept simple, but should encourage results in TTIP: each should have a heading reflecting the class of regulated products or services being referred to (autos, pharmaceuticals, medical devices, cosmetics, toys, apparel, banking, insurance, etc.); each should list the relevant regulatory agencies on both sides and perhaps points

of contact in them; and each should reflect agreements that have been reached between the relevant regulators. One annex, for instance, could be on large civil aircraft: the Federal Aviation Administration and the European Aviation Safety Agency would be listed as the regulators, and the 2009 Bilateral Aviation Safety Agreement, mentioned above, should be linked on it.

As this example highlights, the annexes should include existing agreements between counterpart US and EU regulators (such as on organic produce and supply chain security systems), any additional ones agreed during the TTIP negotiations, and any that may be agreed subsequent to agreement on TTIP. In other words, concrete results in regulator-to-regulator exchanges should find their way into the annexes, so that they are anchored in TTIP, now or later.

It is this last part, i.e. the ability to add new regulator-to-regulator agreements in the annexes, that makes TTIP a 'living' agreement. As described previously, over the past decade and a half, many of our regulatory agencies have reached agreements with one another; they didn't need TTIP to do this. But TTIP, with its horizontal obligations for such things as the RCA and the REA, will provide direction to that cooperation and 'turbo-charge' it, without undermining our respective regulatory processes.

And this 'living' agreement both recognises that such regulator-to-regulator agreements can only come where regulators have trust and confidence in one another, and that such trust and confidence takes time to build. TTIP as a trade agreement should not and need not be delayed as that process unfolds.

Annex 1 to this report provides an illustrative list of existing US-EU regulatory agreements in over 20 different sectors, on which these annexes should be built.

5. Comparing regulatory cooperation chapters in three FTAs

In order to get an idea of the ambition, nature, and level of intensity of bilateral regulatory cooperation between the US and of the EU so far, it might seem instructive to compare the regulatory chapters of recent bilateral trade agreements concluded by the parties. However, this is only partly true. Because no published information of any substantive detail is available about TPP (the Asia-Pacific FTA of 12 parties

including the US),[33] the only recent FTA concluded by the US is KORUS, the Korea-US FTA. The EU has concluded three recent FTAs, with Korea (KOREU in 2010), Singapore, and CETA. The latter two are still being legally scrubbed prior to signature and subsequent ratification. In the present section, some comparative remarks will be made about KOREU and SINGEU, on the one hand, and KORUS on the other. The relevant chapters in these three FTAs are all about transparency, only one aspect of regulatory coherence. What there is about regulatory cooperation is linked to sectors or may arise from general clauses for future initiatives of the ministerial-level body governing the FTA. No specific regulatory cooperation framework or chapter is included. This is different in CETA (see section 6).

KOREU[34] does not include a chapter entitled 'Regulatory Cooperation'. Instead, chapter 12 is entitled 'Transparency'. There is a possibility that this is caused by the simultaneity of the negotiations on KORUS and KOREU. It has often been suggested that KORUS served as a lead example for KOREU, and indeed the structure and substance of the two agreements are quite similar, and KORUS also has a chapter (21) called 'Transparency'. The substance of chapter 12 of KOREU goes some modest distance towards what one would expect from a chapter on horizontal regulatory cooperation, knowing that sectorial and other specific regulatory cooperation is also scattered throughout the treaty and annexes. Article 12.2 on objective and scope clarifies that: "Recognising the impact which their respective regulatory environment may have on trade between them, the Parties shall pursue an efficient and predictable regulatory environment for operators, especially small ones doing business in their territories." The chapter lays down clarifications and improved arrangements for transparency, consultations, and better administration of measures of general application. Subsequent articles re-iterate some of the OECD guidelines and recommendations referred to in Box 2.3 – most EU member states as well as Korea are members of the OECD – such as on timely publications, with the opportunity to comment and endeavours to take

[33] From Schott, Kotschwar and Muir (2013, p. 13), it appears that regulatory coherence texts focus on promoting transparency and streamlining standards, certification, and regulatory processes. In any event, the Honolulu APEC Ministerial was also the occasion for TPP to release a broad mandate, with regulatory coherence as one of the priorities. But no details are available beyond these generalities.

[34] OJEU L 127 of 14 May 2011, pp. 6-1450.

such comments into account before legislating for the measures. These are followed by provisions on mechanisms for enquiries and contact points, administrative proceedings, review and appeal, and cooperation in promoting regulatory quality. Chapter 14 of the provisional text of SINGEU[35] on transparency is almost a copy of KOREU's chapter 12. The objective, scope and structure is essentially the same, and often textually identical.

KORUS's chapter 21 is concerned with transparency. For TTIP purposes, it looks rather elementary. Compared to chapter 12 of KOREU, it lacks a broader objective on an 'efficient and predictable regulatory environment for operators,' although one surmises that drafters must have had this in mind. Article 21.1 goes into great detail about several aspects of publication of laws, regulations, procedures and administrative rulings, such as timely publication in advance of proposals, providing a reasonable opportunity for stakeholders to comment, and a host of details ensuring easy access to information (e.g. a single official journal, a comment period of 40 days, setting out the rationale, and addressing significant comments). Article 21.2 reiterates this for 'requests'. Article 21.3 insists on administering 'in a consistent, impartial and reasonable manner', complemented with, again, reasonable notice and opportunity. Somewhat similar provisions apply (Art. 21.4) to review and appeal. Presumably because of occasional informal past campaigns in Korea against certain imported goods, Art. 21.5 seeks confirmation that that is not standing policy. A detailed anti-corruption and anti-bribery provision is found in Art. 21.6. In the light of recent APEC initiatives on regulatory reform and principles, largely overlapping with those of the OECD, one suspects that Chapter 21 of KORUS is more a reflection of the past (KORUS was negotiated up to 2007) than of today.

Whereas it is often suggested that KORUS is the template of how modern FTAs are negotiated by the US, this is clearly not true for the transparency chapter, and even less so for the US and the EU together, which have moved beyond the KORUS-type provisions in their regulatory cooperation during the last few decades. Nevertheless, for purposes of transparency for business in TTIP, one might go much further still. One example: wouldn't it be a good idea to facilitate two-way business for SMEs, by creating a one-stop-shop on both sides, with easy access to regulatory requirements, both at the federal (or EU) and the sub-central (or member state) levels? Demanding surely for both

[35] See http://trade.ec.europa.eu/doclib/press/index.cfm?id=961

partners, but undoubtedly extremely helpful for SMEs, lowering the costs - and perceived costs - of entry.

6. TTIP's regulatory cooperation: What CETA and the EU TTIP proposal tell us

Regulatory cooperation is dealt with very differently in CETA. One important explanation for this difference in ambition is the existence of regulatory cooperation under the Canada-EU Framework on Regulatory Cooperation and Transparency, which dates back nearly a decade. Chapter 26 of the provisional consolidated text of CETA[36] - which is about regulatory cooperation - states (in Art. 26.2 sub 5) that the chapter replaces the earlier framework, which implies an upgrade. Given the parallel histories of regulatory cooperation between the US and the EU and Canada and the EU, and the fact that Canada and the US have enjoyed a considerable degree of market integration in NAFTA for more than two decades, it is reasonable to regard CETA as a possible benchmark for a regulatory chapter in TTIP. However, it is not sure whether the TTIP negotiators see it that way; in any event, the US position on this chapter is as yet unknown. In Table 2.1 we compare the CETA chapter with the EU draft proposal on regulatory cooperation in TTIP.[37]

Table 2.1 shows that CETA and – probably – TTIP are going to be very different from recent FTAs in terms of regulatory coherence and cooperation. Although there are differences between the two texts, and some confusing disparities in structure, the overlap in the substantial provisions about regulatory cooperation and coherence is quite large. Both also envisage a joint body with a fairly wide and flexible remit which enables future cooperation in many ways. It would also facilitate the idea and operation of a 'living agreement'. In the regulatory coherence part, the reference to the OECD 2012 recommendations (in the EU proposal) re-affirms a common set of principles and practices in an explicit and well-codified form which effectively overlaps with what CETA Articles 2 and 3 contain. In the EU TTIP text the 'regulatory exchanges' are to be led by the regulators (Art. 9.4); this is not explicit in CETA. On the other hand, one would surmise, at this stage, that the TTIP approach as proposed by the EU is more ambitious in terms of commitments and procedures than CETA, as the hard core of the CETA

[36] See http://trade.ec.europa.eu/doclib/2014/september/tradoc_1528

[37] See http://trade.ec.europa.eu/doclib/docs/2015/february/trade_153120

chapter are (19) voluntary cooperative 'activities' whereas TTIP regulatory cooperation is far more about commitments in law. Still, much will depend on the actual functioning of the chapter under each treaty. In any event, TTIP already has (tentatively) agreed on as many as nine sectorial chapters or annexes, and the EU proposal suggests that more might eventually emerge from the 'living agreement', whereas in CETA it does not look nearly as ambitious when taking the text literally.

Table 2.1 Comparing regulatory cooperation in CETA and the EU TTIP proposal

CETA on	**Specifications in CETA**	**Specifications in EU TTIP proposal**
Scope (Art. 1)	Development, review, and methodological aspects of regulatory measures of the Parties; reference to WTO SPS and TBT, plus GATT and GATS ; and to six chapters in the draft treaty, including environment and labour	Art. 3: applies to regulatory acts at central level on goods and services; with 'significant impact'; and regulatory acts concerning specific or sectorial provisions (to be determined later). The type of regulatory acts at central level are precisely defined in Art. 2, a and b for resp. the EU and the US] [note, that the first EU draft will be completed with provisions on regulatory acts at sub-central level][reference to WTO elsewhere in CETA]
Principles (Art. 2)	Quite detailed. Their cooperation is to be open to other trading parties; should 'enhance the climate for competitiveness and innovation, including through pursuing regulatory compatibility, recognition of equivalence and convergence'; promote regulatory processes that ....better ... fulfil the mandates of regulatory bodies... [and] 'enhanced use of best practices'	Art. 1.3 : 'the Parties reaffirm their shared commitment to good regulatory principles and practices, as laid down in the OECD Recommendation of 22 March 2012 on Regulatory Policy and Governance'

Objectives (Art. 3)	Four very detailed objectives, i.e. contributing to SHIEC objectives (by leveraging international resources and helping risk assessment), building trust and deepening mutual understanding of regulatory governance (in seven ways, typical 'good regulatory practices' items, including transparency and predictability), facilitating bilateral trade and investment (e.g. by reducing unnecessary regulatory differences), and contributing to competitiveness and efficiency of industry (by e.g. minimizing administrative costs and reducing duplicative regulatory requirements, plus pursuing compatible regulatory approaches e.g. recognition of equivalence or the promotion of convergence)	Art.1.1 comprises four objectives: a. 'to reinforce regulatory cooperation thereby facilitating trade and investment…. to stimulate growth and jobs while pursuing a high level of protection..' in SHEIC but also working conditions, personal data, cybersecurity, cultural diversity or preserving financial stability; b. 'reduce unnecessarily burdensome, duplicative or divergent regulatory requirements…. by promoting … compatibility of… EU and US… acts' c. 'promote an effective, pro-competitive environment… transparent and predictable ' d. 'to further… international instruments … to strive towards consistent regulatory outcomes'
Regulatory cooperation activities (Art. 4)	A very wide and ambitious set of provisions on 19 (!) regulatory cooperation activities, many of those on sharing /exchange of information on a host of areas, examining opportunities to minimise unnecessary divergences, cooperation on developing international standards and guides, data collection, cooperative research agendas, conducting post-implementation reviews, reducing adverse trade effects by e.g. greater	In the draft EU proposal, many (not all) regulatory cooperation activities, as they are called in CETA, are found in different articles: Art. 5 (on early and public information on planned acts) and Art. 6 (on stakeholder consultations) are under a subsection 'transparency', whereas the first (early information) is in Art. 26.4 of CETA, that is not the case for stakeholder participation (except for a very open clause in Art. 26.8, CETA).

	convergence, mutual recognition, minimising the use of trade-distorting instruments, and the use of international standards, etc.	Provisions on impact assessment (in CETA Art. 26.4, item 6b) are in Art. 7 in the EU proposal. Some of what CETA calls 'activities' are the subject of 'regulatory exchanges' in the EU proposal (art. 9 and 10), the essential difference being a greater precision in procedures and timing. (For the CETA provision on post-implementation reviews, there is a weak counterpart in the EU draft, in Art. 7.3c) On the other hand, CETA has no explicit provision on promoting international regulatory cooperation, as in Art. 13 of the EU draft.)
Compatibility of regulations (Art. 5)	'With a view to enhancing convergence and compatibility between regulatory measures of the Parties, each Party shall, when appropriate, consider the regulatory measures or initiatives of the other Party on the same or related topics…'	Compatibility is in Art. 8.1 as well as in Art. 11, following from (in some cases) so-called 'regulatory exchanges', specifying mutual recognition of equivalence (of regulatory acts or outcomes), harmonization or simplification; goes further than CETA via a proposal for joint examination.
Role and Composition of the Regulatory Cooperation Forum (Art. 6)	'...to facilitate and promote regulatory cooperation between the Parties'; functions: i) a setting for discussion of regulatory policy issues of mutual interest, ii) assist individual regulators (identifying partners; model confidentiality agreements); iii) reviews of whether regulatory initiatives	The TTIP Regulatory Cooperation Body will have seven functions (Art. 14): i) Annual Regulatory Cooperation Programme; ii) monitoring of the implementation and reporting; iii) technical preparation of new or added sectoral provisions; iv) considering new proposals for regulatory cooperation,

	'provide potential for cooperation'; iv) encourage bilateral regulatory cooperation activities (as the 19 types in Art. 4) and review sectorial initiatives. The RCF reports to the CETA trade Council	including on compatibility; v) preparation of joint proposals of international regulatory instruments; vi) ensuring transparency; vii) open clause on relevant 'other issue'
Further cooperation of the Parties (Art. 7)	Is about monitoring forthcoming regulatory projects, as well as exchange of information on a host of issues, e.g. standardisation, market surveillance, risk assessment methods and product recalls and early warnings. Endorsement of other initiatives are encouraged too.	Not explicit but probably subsumed in Art. 14; presumably, market surveillance, risk assessment and product recalls may require more specific provisions
Consultations (Art. 8)	'In order to gain non-governmental perspectives, the Parties may jointly or separately consult' all kinds of private entities	Much more detailed and forthcoming or encouraging on consultation in Art. 15 of EU proposal
Contact points (Art. 9)	Specified for both Parties	Not (yet) specified

Of course, the EU text is still incomplete with respect to sub-central governments. Neither the CETA nor the EU text is very detailed with respect to some 'coherence' aspects discussed in our section 4 above. For example, there is not much detail on early information of planned drafts for the other party or the public at large. With respect to the horizontal aspects of cooperation, nothing even nearly as ambitious as Regulatory Compatibility Assessments for new regulations and/or Regulatory Equivalence Assessment for existing regulations is referred to in either text.

In the absence of a publicised US text proposal or a revision after nine rounds of negotiation, it would be wrong to draw any further conclusion at this stage.

7. Conclusion: Building bridges and enhancing social objectives

The purpose of the Transatlantic Trade and Investment Partnership is to build on the unique trade and investment-based US-EU economic relationship to promote growth and, most importantly, jobs on both sides of the Atlantic.

It will do this in many ways, but one of the key steps will be in tackling unnecessary differences in regulation, which create unintended obstacles to trade without any corresponding regulatory or social benefit. The US and EU can do this, as they are both democratic, high-income economies that in general seek similar levels of consumer, worker, environmental and prudential safety.

But TTIP can succeed only if it frames this process correctly. TTIP will not be, and perhaps cannot be, the most ambitious form of regulatory cooperation, as seen in some treaties focused on discrete issues. But it can, and probably will, be more than either side has done in any previous trade agreement. Done properly, regulatory coherence and cooperation under TTIP will enhance regulatory efficiency and effectiveness, increasing consumer safety even as it improves the competitiveness of US and EU firms. TTIP should help ensure that regulators on both sides of the Atlantic agree on the principles and practices that make for a robust, evidence-based and transparent regulatory system, as confidence in each other's domestic systems is a prerequisite for cooperation.

It should set the clear goal for our regulators of improving regulatory compatibility, while reaffirming their autonomy and their accountability to their political oversight bodies and their citizens. It should give them tools such as the Regulatory Compatibility Assessments and the Regulatory Equivalence Assessments, to ensure informed decision-making without trying to predetermine the outcomes. And it should recognise that regulatory cooperation can succeed only where there is trust and confidence between the regulators, and that TTIP must be patient enough and flexible enough with a living agreement, to allow for this trust and confidence to be built on sufficiently strong foundations.

For only with these foundations will TTIP be able to build a bridge between the US and the EU, one that is safe, that meets the needs and concerns of our politicians and our citizens, while at the same time fostering economic growth and job creation.

References

Francois, J., M. Manchin, H. Norberg, O. Pindyuk and P. Tomberger (2013), "Reducing Transatlantic barriers to trade and investment: An economic assessment", study for the European Commission supporting the Impact Assessment of TTIP (http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf).

Fontagne, L., J. Gourdon and S. Jean (2013), "Transatlantic trade: whither partnership, which economic consequences?", CEPII Policy Brief No. 12, CEPII, Paris, September (www.cepii.fr).

Josling, T. and S. Tangermann (2014), "Agriculture, Food and the TTIP: Possibilities and pitfalls", CEPS Special Report No. 99, CEPS, Brussels, December and chapter 9 in this volume.

Kommerscollegium [Swedish Board of Trade] (2014), "Regulatory cooperation and TBTs within TTIP", Stockholm, April (www.kommers.se).

Morrall, John III (2011), "Determining Compatible Regulatory Regimes between the US and the EU", US Chamber of Commerce, Washington, D.C. (www.uschamber.com/sites/default/files/documents/files/Determining%2520Compatible%2520Regulatory%2520Regimes.pdf).

OECD (2012), Recommendations of the Council on Regulatory Policy and Governance, Paris (www.oecd.org/gov/regulatory-policy/499908.pdf).

_____ (2013), *International Regulatory Cooperation*, Paris.

Parker, R. and A. Alemanno (2014), "Towards Effective Regulatory Cooperation under TTIP: A comparative overview of the EU and US legislative and regulatory systems", CEPS Special Report No. 88, Brussels, May (www.ceps.eu).

Pelkmans, J. (2007), "Mutual Recognition in goods, on promises and disillusions", *Journal of European Public Policy*, Vol. 14, No. 5, pp. 699-716.

_____ (2012), "Mutual recognition: economic and regulatory logic in goods and services", in T. Eger and H-B. Schaefer (eds), *Research Handbook on the Economics of EU Law*, Cheltenham: E. Elgar, pp. 113-145.

_____ (2015), EP Briefing Paper for the IMCO and INTA Committees on TBTs in TTIP; working title: "The TTIP: Challenges and opportunities for the internal market and consumer protection in the area of standards", April, forthcoming on EP website.

Pelkmans, J. and A. Correia de Brito (2015a), "Study on Mutual Recognition Agreements", OECD, Paris, forthcoming.

_____ (2015b), "Transatlantic MRAs: Lessons for TTIP?", CEPS Special Report No. 101, Brussels, February (www.ceps.eu).

Pelkmans, J., A. Lejour, L. Schrefler, F. Mustilli, J. Timini et al. (2014), "The impact of TTIP: The underlying economic model and comparisons", CEPS Special Report No. 93, Brussels, October (www.ceps.eu; also published as report to the EP (www.europart.europa.eu/RegData/etudes/etudes/join/2014/528798/IPOL_JOIN_ET%282014%29528798_EN.pdf).

Renda, A. (2009), *Policy-making in the EU: Achievement, challenges and proposals for reform*, CEPS, Brussels (www.ceps.eu).

Schott, J., B. Kotschwar and J. Muir (2013), *Understanding the Trans-Pacific Partnership*, Peterson Institute of International Economics, Washington, D.C.

Wiener, J., M. Rogers, J. Hammitt, and P. Sand (2010), *The reality of precaution, comparing risk regulation in the US and Europe*, Resources for the Future Press, Washington, D.C. and London.

US-EU High Level Group (2013), Final Report of the High Level Working Group on Jobs and Growth, February (http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf).

US Chamber of Commerce (2015), "Regulatory Coherence and Cooperation in the TTIP", February, Washington, D.C. (www.uschamber.com/sites/default/files/regulatory_coherence_regulatory_cooperation_-chamber_ttip_paper_-_final_3-02.pdf).

Annex 1. 20 Years of US-EU Regulatory Cooperation

Regulators in the United States and the European Union (as opposed to individual EU member states) have been collaborating since the 1995 US-EU "New Transatlantic Agenda" declaration. While there are a number of agency-to-agency agreements, much of the early work was captured in the general reports on progress under the Regulatory Cooperation Roadmaps (starting in 2002), to the High Level Regulatory Cooperation Forum (established 2005) and ultimately the Transatlantic Economic Council (TEC), created in 2007. A review of these general reports, listed in the first section below, gives a good overview of progress in the many sectors covered.

Issue/Agencies	Description
General (All)	US-EU Joint Statement on Regulatory Cooperation (Dec. 1997) US-EU MRA Agreement (December, 1998) Guidelines for use of the MRAs, 2001 Transatlantic Economic Partnership Report (Bonn Summit, June 1999) Transatlantic Economic Partnership; Commission Overview and Assessment, October 2000 Guidelines on Regulatory Cooperation and Transparency Implementation Roadmap (April 2002) Regulatory Roadmap – 2004 Regulatory Roadmap – June 2005 Joint Report on the Roadmap, June 2006 Joint Report on the Roadmap, April 2007 HLRCF Report, April 2008 Joint Report on Impact Assessments and Trade, May 2008 HLRCF Report, October 2008 HLRCF Report, July 2009 HLRCF Report, June 2010 HLRCF Report, December 2010 Common Understanding re Regulatory Principles and Best Practices, June 2011
Standards US: National Institute of Standards and Technology (NIST)	EU and US Extend Scientific Cooperation on Measurements and Standards July 2013 (JRC news release) Building Bridges between the US and EU Standards Systems Nov 2011 Memorandum of Understanding Dec 2010

EU: DG Enterprise (GROW); Joint Research Centres	US–EU HLRCF Joint Statement on Standards in Regulation Dec 2010 Collaborative Arrangement regarding cooperation in the fields of metrology and measurement standards Feb 2008 Memorandum of Understanding regarding cooperation on scientific research and measurement standards Dec 2007
Import Product Safety US: OIRA EU: DG Enterprise	Implementation of Recommendations Report, December 2008 Safety of Imported Products, April 2008: looks at motor vehicle, food, pharmaceutical, cosmetic, toy, consumer–use electrical equipment sectors
Agriculture US: FDA, USDA, FSIS, APHIS EU: DG SANCO/SANTE, DG AGRI	National Organic Program June 2012: the US and EU created an equivalence arrangement in regards to organic standards USDA press release Competent authorities responses of the US to recommendations from DG SANCO 2011 FCA and EFSA information sharing agreement July 2007: the two agencies signed the first EU–US agreement in the area of assessing food safety risk. EFSA Statement FDA Statement EU-US Safe Food 2005-2007: A program that ran for two years in order to contribute to and communicate knowledge about food-born zoonoses Report, 2007: complete Implementation Plan under their confidentiality arrangement; experts hold joint meeting on nanotechnology in food to share perspectives on the issue
Chemicals US: EPA EU: DG ENVI, ENT; ECHA	ECHA and EPA statement of Intent Dec 2010: The document asserts the agencies intent to enhance technical cooperation and share information regarding chemical management. EPA press release US-EU Conference Draft Nanotechnology in the Workplace July 2012: Establishing standardization OSH principles for developing best practices applied to nanotechnology work settings
Pharmaceuticals	EC wavier for export of US pharmaceutical manufactures June 2013

US: FDA EU: DG ENT, EMEA	Update on the implementation of recommendations made by Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) Feb 2013 Programme to rationalize international GMP inspections Feb 2012 Enhancing GMP Inspection Cooperation between EMA and FDA Dec 2011 Report on the Pilot EMA-FDA GCP Initiative July 2011 Implementation Report on Transatlantic Administration Simplification action plan July 2011 Interactions between EMA and FDA June 2011 Report on the International API inspection Pilot May 2011 EMA-FDA pilot program for parallel assessment of Quality by design applications March 2011 Transatlantic Taskforce on Antimicrobial Resistance Report 2011 EMEA and FDA statements re non-disclosure of confidential information from partner agency (September 2010) FDA EMEA Administrative Simplification Implementation Report Oct 2009 EMEA-FDA Good Clinical Practice (GCP) Initiative Terms of engagement and procedures for participating authorities: Sep 2009 EMEA-FDA GCP Initiative July 2009 EMEA-DFA Parallel Scientific Advice July 2009 Confidentiality Commitment between the FDA and EDQM May 2009 Update on pilot project to collaborate on international GMP inspection activities Jan 2009 FDA/EMEA Joint Press Release re Cooperation on Medicines, Oct 2008 Medicines Regulation: Transatlantic Administrative Simplification Action Plan June 2008

Veterinary Medicines US: FDA, USDA EU: EC, EMEA	(See also above re medicines and reports on TATFAR) CVM / EMA Exchange of Experts 2012 FDA EDQM Confidentiality Commitment, May 2009: EMEA/Veterinary Medicines and Inspections Unit – Parallel Scientific Advice Meetings, May 2008 Implementation Procedures for Veterinary Medicinal Products Cluster, May 2008
Medical Devices US: FDA EU: DG ENTR – EMEA	October 2012 EU proposed changes to Medical Device laws and allowed US comments Statement From the International Medical Device Regulators' Forum October 2011 Exchange of Letters to facilitate information sharing re the safety, quality and efficiency of medical devices, July 2007
Cosmetics US: FDA EU: DG Enterprise and Industry (cosmetics unit), ECVAM	ICCR (International Cooperation on Cosmetic Regulation): made up of the US, EU, Japan, and Canada Meeting reports: 2012, 2011, 2010, 2009, 2008, 2007 FDA – DG Enterprise – Related to Cosmetics July 2007: Press Release
Automotive Safety US: NHTSA EU: DG ENT	Europe, USA, Japan will harmonise electric Vehicle Regulations Nov 2011 Proposal for two working groups re e-Vehicles November 2011 Global Technical Regulations 2004-2011 Memorandum of Cooperation Automobiles June 2008
Aircraft Safety US: FAA, TSA EU: DG ENT, EASA	Cooperation Agreement on Civil Aviation Safety, March 2011 Regulation of Civil Aviation Aircraft
Marine Equipment US: USCG EU: DG Energy and Transport; European Marine Safety Agency	Memorandum of Understanding regarding marine optical radiometry, March 2011 US-EC Marine Equipment MRA Joint Committee, February 2009 US-EU Mutual Recognition Agreement for Conformity Assessment for Marine Equipment, June 2001

Energy Efficiency, Eco-Design US: DOE, FERC, EPA EU: DG EVN, DG ENER, DG ENT	EU – US Energy Council Press statements following meetings of the Council o December 2012 o November 2011 o November 2010 o Website on the council is here EU US Energy Council Working Group on Technology, Research, Development and Demonstration 2009 Establishment of EU-US Energy Council, 2009 EU U.S advance Energy dialogue, March 2008 Energy Star Agreement renewed, Jan 2013 Implementing Arrangement for Environmental Research and Ecoinformatics, Feb 2007: Energy star agreement, December 2001 Working link First Energy Star Agreement – November 2001
Consumer Products, Toy Safety US: CPSC EU: DG SANCO	China–US – EU trilateral meetings o Sep 2008 Joint Press Statement o October 2010 Joint Press Statement o June 2012 Joint Press Statement Roadmap Feb 2010: Council grants mandate for the EC Nov 2009: EU US HLRCF Report on the Safety of Imported Products, Dec 2008 EU US HLRCF Report on Safety of Imported Products May 2008 Report, 2007 Guidelines for Information Exchange and on Administrative Cooperation on consumer product safety Report, 2006 Toy Safety, January 2010
Financial Regulation/Supervision US: Treasury, Federal Reserve, SEC, CFTC, NAIC, FASB, PA EU: DG Market, EBA, ESMA, EIOPA	Derivatives Agreement, July 2013 (Press release and text from CFTC) SEC and CESR Announcement Nov 2010: The SEC abolished reconciliation to GAAP for foreign companies using IFRS Nov 2007 CESR and SEC Protocol to implement work plan Sept 2007 SEC and CESR Work Plan Aug 2006

	Insurance US-EU Dialogue Project Update, April 2013 EU-US Dialogue Project Report, Dec 2012 EU-US Dialogue Project: The Way Forward, Dec 2012
Transportation Security US : DHS/CBP and TSA, FAA, FMC EU: DG JHA	CBP, EU Sign C-TPAT Mutual Recognition Decision, May 2012 (Implement this report Feb 2013) Air Cargo Agreement June 2012. TSA press release, EU press release US-EU Joint Declaration on Aviation Security, January 2010 Joint Statement, September 2008 Agreement Between the United States of America and the European Union on the Use and Transfer of Passenger Name Records to the United States Department of Homeland Security, December 2011 Agreement re: Passenger name Records, July 2007 Trusted Trader Program, May 2012

Source: Compiled by Peter Chase.