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Chapter 11. EU–US horizontal regulatory cooperation:

Mutual recognition of impact assessment?

Anne Meuwese

Introduction

Regulators – in the sense of ‘those involved in the setting, monitoring and enforcement of regulatory standards’ – are increasingly crossing borders; so much so that they have been called ‘the new diplomats’.ⁱ They meet with their foreign peers to solve issues that used to fall within the exclusive domain of domestic policy-making (Raustiala, 2002; Petersmann, 2000).

Transnational dialogues about regulatory standards deal with a range of issues, such as food safety and financial market regulation (for instance, the Informal Financial Markets Regulatory Dialogue).ⁱⁱ

Zooming in on regulatory governance we find that increasing cooperation is not the only transformation it has undergone. A more strategic approach to regulation has resulted from the recognition that it has a major impact on economic and social well-being. Already more common outside the regulatory arena, performance-based regulatory management systems are being set up around the globe. We can also witness a tendency among regulators to think more reflexively more about regulation and draft “horizontal” policies (that is, those that are not sector-specific) to help them regulate “better”. At least for those dealing with the subject in Europe, this second transformation is often captured by the label “better regulation”, after the general regulatory policy that the European Commission put into place in 2002. Aside from a simplification programme and a plan to reduce administrative burdens by 25 per cent by 2012, the introduction of impact assessmentⁱⁱⁱ as a systematic tool for EU policy-making was a major component of this horizontal policy. In the US the transformation towards ever more “regulation of regulation” had already been underway for longer: for many decades the broad

regulatory powers delegated to federal agencies have been accompanied by heavy procedural protection, both judicial (review) and non-judicial (hearings and regulatory impact analysis) in nature.

This chapter investigates the intersection of these two trends. An explosion of better regulation policies has occurred in many countries and as a consequence we have a new kind of regulator: the “better regulator”, dealing with the most general level of regulatory policy. Networks of better regulators have emerged, both within Europe and at the global level (Jacobsson, 2006, pp. 205–54), with the Organization for Economic Cooperation and Development and certain think tanks such as the German Bertelsmann Foundation often playing a facilitating role. Horizontal regulatory cooperation is most developed between the EU and US as exemplified by the EU–US “horizontal dialogue” on crosscutting issues of regulatory cooperation. The direct partners here are the European Commission’s Secretariat-General and the US Office of Management and Budget (OMB).

The main question addressed in this chapter is the extent to which this dialogue has indeed led to the emergence of shared norms for domestic standard-setting or for substantive regulatory cooperation.^{iv} The chapter argues that the recent attempts to achieve convergence on how to carry out (regulatory) impact assessment are illuminating as to the state of the transatlantic divide in regulatory approaches. After some general observations on the concepts of regulatory cooperation and horizontal regulatory policy, the development of horizontal regulatory cooperation over the past decade is outlined, ending with how (regulatory) impact assessment came to be the most recent focus of this transatlantic dialogue. The chapter then goes on to consider EU–US cooperation on impact assessment and concludes with some recommendations.

Regulatory cooperation and horizontal regulatory policy

Regulatory cooperation

As a mechanism for solving regulatory problems of a cross-border nature, regulatory cooperation is increasingly preferred to the traditional route of concluding a multilateral treaty. There is also a strong link between regulatory standards and trade disputes (Bermann, 1996, p. 957), whereby domestic regulation can be an obstacle to trade or governments can deliberately make use of regulation as a strategic weapon in international competition (Majone, 2000, p. 129). If a country is assertive in promoting its regulatory standards – for instance through regulatory dialogues – and succeeds in persuading others to adopt them, it lends a competitive edge to domestic industry (cf the much discussed “California effect”). How trade, regulatory cooperation and risk management interact is nicely illustrated by Alemanno in his chapter on the dispute over genetically modified organisms in this volume.^v The twofold function of regulatory cooperation – a direct rule-making strategy and a way to ease trade disputes^{vi} – has thrown the concept into the limelight in recent years.

Regulatory convergence can occur both within and outside institutionalized contexts.^{vii} First, there is “parametric adjustment”, an umbrella term for forms of unilateral harmonization and policy imitation. This is not necessarily limited to nation-states: it is also possible for private companies to adopt public standards from overseas. For example, the American company HP is adopting the standards of several EU directives and regulations, such as the REACH Regulation ((EC) No. 1907/2006) on the registration, evaluation, authorization and restriction of chemicals) and the Restriction of Hazardous Substances (RoHS) Directive (2002/95/EC), which restricts the use of certain heavy metals. The second mode is information exchange, such as that provided for in the European Community directive on the exchange of information related to the assessment of taxes. Third, we encounter delegation to non-governmental bodies, such as the Codex Alimentarius Commission or the International Organization for Standardization, which issues the well-known ISO standards that define technical requirements. The norms issued by these bodies are usually non-binding, with the disadvantage of lacking the teeth of legal sanctions but with the advantage that technological

developments can be followed up more quickly. Moving on to more formal modes of regulatory convergence, we find joint enforcement and dispute resolution. Mutual recognition – the recognition of the foreign norms of one legal system by another and vice versa, without incorporating the norms into their own systems – is another example. In the EU context the mutual recognition of regulated products in and from non-EU jurisdictions, provided they have a comparable level of technical development and have a compatible approach to conformity assessment (European Commission, 2009), is achieved through the conclusion of Mutual Recognition Agreements on the basis of Art. 207 TFEU (formerly Art. 133 TEC).

Harmonization – ensuring norms are compatible if not similar – is possibly the most far-reaching mode. Finally, we find a mode that can operate in varying degrees of formality: transnational or transgovernmental regulatory networks. Examples are the Basel Committee on Banking Supervision, the International Association of Insurance Supervisors and the informal international networks in the field of competition law. As illustrated above, many of these modes of regulatory convergence have turned into operational mechanisms that are undertaken to increase regulatory cooperation.

Diverging or converging on horizontal regulatory issues?

The term “horizontal” refers to the general analytical basis of regulation. What tests for regulatory proposals does a legal system have in place? With the exception of a few countries like the US, where the conditions for regulation itself are regulated in many cases, this is often remarkably unclear. The EU has a few broadly defined, regulatory *objectives* in the Treaty, delineating its competences vis-à-vis the member states, but it decided to make the methodology for assessing different policy options and the *tests* used for comparing them more explicit in its horizontal, better regulation policy of 2002. It put forward impact assessment – not to be confused with environmental impact assessment^{viii} – as an analytical framework for the preparation and deliberation of EU legislation. The core of the impact assessment is to assess the environmental, social and economic impacts of proposed regulatory interventions on various

societal groups. It is not just a document, but rather a highly structured process of policy formulation and (crucially) coordination among different parts of the Commission services. This process, however, is explicitly subordinate to political decision-making and it is capable of being so because the impact assessment framework does not prescribe a *decision criterion*. This marks an important difference with the American system of regulatory impact analysis (RIA), which tends to impose a decision criterion, as fits with the general aim of using RIA to control delegated standard-setting procedures.

Institutional differences account for most of the divergences in ‘regulatory philosophies’ across the Atlantic (Löfstedt and Vogel, 2001), such as contention over the precautionary principle, which has been repeatedly asserted (Löfstedt, 2004) and with equal frequency been played down (Wiener, 2006). Some have detected a wave of convergence in US and EU regulatory approaches (Wiener, 2003; Löfstedt and Vogel, 2001). Impact assessment provides a useful lens for capturing the remaining differences. Although impact assessment is increasingly regarded as a global standard (Jacobs, 2006), it is commonly acknowledged that the US system of RIA and the EU’s impact assessment differ in scope, objectives, stringency, enforceability and methodology. A point of convergence for the US and EU impact assessment systems is actually that both comprise “integrated” assessments of economic, social and environmental impacts. If anything, the EU system is the narrower one, with its recent focus on cutting administrative burdens as opposed to investing in a better assessment of regulatory costs (a much wider category than administrative burdens) and benefits. Paradoxically, the focus on reducing administrative burdens could enhance a strong precautionary style of regulating in Europe because cheap norms in terms of measurable burdens are often vague norms, which in turn tend to be more precautionary (Wiener, 2006).

An evaluation of the quality of European impact assessments concluded that they have become more informative since moving out of the pilot phase, but claimed that quite a few impact assessments are still missing important pieces of economic information, such as the

monetization of benefits (Cecot et al., 2008, p. 420). The study also found that the quality of EU impact assessments on measures that are estimated to cost more than \$100 million is similar to that of regulatory impact analyses in the US. It points out that the range of initiatives scrutinized in Europe is much broader and asks whether it is not time for the US to expand the scope of RIA to include laws, policies and minor regulations. Yet in the EU one of the main topics of discussion in this context has been whether the scope should be narrowed because the current regime is sometimes perceived to be suffering from its own success, producing such a large stream of impact assessments that they are becoming difficult to manage.

A brief history of EU–US horizontal regulatory cooperation

The Transatlantic Declaration of 22 November 1990 contained what could be called an implicit reference to transatlantic regulatory cooperation (Bermann, 1996). It states that the European Community and the US ‘will inform and consult each other on important matters of common interest, both political and economic, with a view to bringing their positions as close as possible, without prejudice to their respective independence’.^{ix} In 1994 the “Sub-Cabinet Group” issued a declaration endorsing bilateral regulatory cooperation between the US and the European Community (Vogel, 1997, p. 10). This was the first explicit encouragement for regulatory officials to consult their transatlantic peers and to consider using international standards instead of creating new domestic ones. In the following May, the Sub-Cabinet Group formalized its endorsement in a text on transatlantic regulatory cooperation, urging regulators to explore ways of cooperating in their regulatory and enforcement activities, ‘while still allowing [them to] meet their legitimate health, safety, consumer protection, and environmental objectives, and other broadly shared policy goals’ (Bermann, 1996). More high-level political support followed in a joint declaration that was part of the New Transatlantic Agenda at the EU–US summit on 3 December 1995 in Madrid: ‘We will strengthen regulatory cooperation, in particular by encouraging regulatory agencies to give a high priority to cooperation with their respective transatlantic counterparts, so as to address technical and non-tariff barriers to trade resulting

from divergent regulatory processes' (EU Delegation to the US, New Transatlantic Agenda, 3 December 1995, EU–US Summit, Madrid,

http://eurunion.org/eu/index.php?option=com_content&task=view&id=2602).

Regulatory cooperation was put to the service of creating a “new transatlantic marketplace” and the call for strengthened cooperation was repeated in a Joint Statement on Regulatory Cooperation in December 1997. At the EU–US London summit of May 1998, the EU and US launched the Transatlantic Economic Partnership and enhanced regulatory cooperation was made one of its cornerstones.

Regulatory cooperation was and is mainly envisaged as happening among agencies, although agencies are relatively rare in the EU context and almost always lack regulatory powers, in the sense of standard-setting powers. Instead, US agencies will often find directorates-general of the European Commission at the dialogue table, raising the issue of ‘institutional mismatch’ (Macey, 2000; Bermann, 1996). The question of whether US agencies and European Commission divisions bring comparable political authority to the dialogue (Bermann, 1996, p. 980) is newly relevant in the current horizontal version of the transatlantic regulatory dialogue, in which the OMB is talking to the Secretariat-General of the European Commission.

The *Guidelines on Regulatory Cooperation and Transparency* (hereafter “Guidelines”) were drafted and negotiated on the basis of the action plan of the Transatlantic Economic Partnership. The Guidelines were first published in 2002 and politically endorsed at the EU–US summit later that year. The topics addressed in the Guidelines are regular government-to-government consultation, exchange of data and information, and an early warning system for anticipated regulatory action. Although the term “impact assessment” is not mentioned – which is understandable given that in 2002 the European Commission had not even started its pilot project on impact assessment – the Guidelines certainly push in the direction of cooperating through impact assessments: ‘[R]egulators should . . . [u]pon request by their counterparts

concerning a specific proposal, supplement the annual work programs, to the extent possible, with information regarding regulatory approaches under consideration, including potential benefits, costs and other impacts for all parties, domestic and non-domestic, where assessed and available.^x

Regulators are also encouraged to facilitate comment by ‘[p]roviding a public explanation of the reasoning underlying the regulation. The elements of this explanation would ideally include the need for the regulation, its aims, its anticipated impacts (quantified where possible), its economic and technical feasibility, and alternative regulatory options.’^{xi}

The impact of these Guidelines is, as is often the case with such things, hard to pin down. On the one hand, little effort has been made to implement them and their primary function seems to be a symbolic one, namely to ‘enshrine a political commitment to dialogue between EU and US regulators’.^{xii} On the other hand, these Guidelines worried the French government enough to contest the legality of the Guidelines before the European Court of Justice (ECJ). A decade earlier, France had already challenged the extension of horizontal regulatory cooperation, phrasing legitimacy concerns as competence problems. In this landmark case from 1994, the French government contested the legality of the US–European Community competition law agreement.^{xiii} The ECJ held that the Commission does not have the competence to *obligate* itself to a particular form of cooperation with foreign authorities, including consultation on the preparation of draft proposals or even the sharing of data *without observing the treaty-making procedures laid down in the EC Treaty*.^{xiv}

The second, lesser known case concerning the Guidelines on regulatory cooperation and transparency was decided by the ECJ in 2004 in favour of the Commission.^{xv} The provisions that the French government considered problematic were those on jointly defined general principles for effective regulatory cooperation, joint review of mutually agreed issues and the idea that the EU and US can identify ways to improve access to each other’s regulatory procedures while preserving the independence of their regulatory authorities.^{xvi} France claimed

that this step in transatlantic regulatory cooperation was illegal for similar reasons as those applied in the 1994 competition agreement case, as the Guidelines amounted to a binding international agreement. '[D]espite the measure of care taken in choosing the language used in the Guidelines'^{xvii}, they are complete and operational in nature and set out very precisely the objectives pursued, the field of application and the measures to be taken. The French government also claimed that the Guidelines infringed the Treaty by restricting the exercise of the Commission's exclusive right of initiative and thereby the whole of the Community's legislative process. Nevertheless, the ECJ first of all established that the Guidelines do not have legally binding effect, pinning this on the 'intentions of the parties'^{xviii}. The ECJ also said that it follows from the conclusion on the lack of binding effect that 'the Guidelines cannot impose obligations on the Commission in carrying out its role of initiating legislation'^{xix}. While acknowledging that the Commission had taken upon itself an obligation to take the Guidelines into account, the ECJ – rather formalistically – ruled that the Guidelines provided mere possibilities, such as engaging in prior consultation and gathering all necessary information before submitting appropriate proposals.^{xx}

In this phase of institutionalization of the transatlantic horizontal dialogue, the emphasis was on formalizing networks. Transatlantic stakeholder dialogues were already in place, notably the Transatlantic Business Dialogue and the Transatlantic Consumer Dialogue. In particular the former, representing a transatlantic coalition of big businesses on both sides of the Atlantic, developed into an 'effective framework for enhanced cooperation between the transatlantic business community and the governments of the European Union and the United States' (Ahearn, 2008, p. 17).

A more formal dialogue on horizontal regulatory issues was still lacking, in spite of the Guidelines. As part of the 2005 initiative to enhance transatlantic economic integration and growth, a High-Level Regulatory Cooperation Forum was set up by the 2005 EU–US summit to encourage EU and US senior regulators to exchange views, share experiences and learn from

each other.^{xxi} This Forum is essentially a more institutionalized dialogue on good regulatory practices between the European Commission and the US Office of Information and Regulatory Affairs, part of the OMB.^{xxii} The Forum meets twice a year and its deliberations provide input to the Transatlantic Economic Council, which reports on the achievements of the sector-specific and horizontal dialogues. The Forum has acquired more of a profile lately, as also testified by the fact that member states have asked for greater participation in the Forum's events.^{xxiii} A more informal OMB–European Commission dialogue on methodological issues takes place alongside the Forum's activities, with contacts among officials reportedly on the rise (Allio, 2008). In this dialogue good regulatory practices are being discussed, with a focus on transparency provisions, public consultation and the respective impact-assessment methodologies (see the dedicated section below).^{xxiv} One of the main functions of the Forum is to lend senior-level support and visibility to the concrete activities of the informal dialogue.

The EU's better regulation initiative was a topic of discussion at the US–EU summit in Washington, D.C. on 20 June 2005, and was followed by several renewed calls for closer cooperation. In the same year, the US and EU agreed on a roadmap for regulatory cooperation and the European Commission issued a Communication on a stronger EU–US partnership and a more open market for the 21st century (European Commission, 2005), which suggested a 'reinforced approach' to regulatory policy cooperation. This reinforced approach was envisaged to entail 'enhanced upstream cooperation'. Concretely, according to European Commission (2005), this comprises the following elements:

[Extract]

- (a) timely exchange of the annual work programmes of the Commission and US regulators,

- (b) a “regulators’ hotline” to be used where one party requests to be consulted on new regulatory initiatives being planned by the other which have the potential to affect its important interests,
- (c) identification of sectors where cooperation has the greatest chance of delivering increased economic benefits,
- (d) consultation in international standard-setting bodies at the development stage of new standards or policy initiatives,
- (e) encouragement of proportionate assessments of the economic, social and environmental impacts beyond the borders of the respective parties,
- (f) exchange and development of best practice in terms of risk analysis regarding the protection of consumers and the environment, taking into account the precautionary principle,
- (g) additional measures to promote improved understanding of each other’s regulatory practices and more effective and consistent application of regulatory approaches and tools.

The additional measures mentioned in the final bullet point concern exchanging ‘best general regulatory practices’ such as, ‘transparency provisions and public consultation; recognition of equivalence where regulations and standards, while different, provide equivalent levels of protection and quality; [and] development of common standards, where appropriate’ (European Commission, 2005, p. 7).

Finally, a guidebook for regulators, intended to complement the *Guidelines on Regulatory Cooperation and Transparency*, appeared in June 2006, but seems to have led a dormant existence.^{xxv}

Upon concluding that the declarations and guidelines mentioned above had made little impact, the transatlantic partners again called for more explicit and structural cooperation in April 2007.^{xxvi} At the second meeting of the Transatlantic Economic Council in May 2008, the official goal of the transatlantic, horizontal regulatory dialogue was declared to be a move towards ‘a more convergent transatlantic regulatory environment’.^{xxvii} At the EU–US summit in Slovenia on 10 June 2008, political leaders stated that they expected that ‘improvements to our respective regulatory processes will benefit stakeholders and help diminish unnecessary regulatory divergences’ (Council of the European Union, 2008 EU-US Summit Declaration Brdo, Slovenia, 10 June 2008, 10562/08 (Presse 168), Brdo, 10 June 2008, http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/er/101043.pdf).

Zooming in on impact assessment

The High-Level Regulatory Cooperation Forum turned its attention to convergence in (regulatory) impact assessment, first publishing a joint discussion paper that had been prepared in the methodological dialogue for public consultation in November 2007. The report, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment* (OMB and European Commission, 2008, hereafter “Review”) was presented at the second meeting of the Transatlantic Economic Council on 13 May 2008, which concluded that the report confirmed ‘a common interest in working more closely together on these issues’ (Joint Statement of the European Commission and the United States following the second meeting of the Transatlantic Economic Council, No. 47/08, op. cit.).

Substantive horizontal norms

Requirements to assess extra-territorial impacts

The Review justifies the assessment of trade and investment impacts^{xxviii} mainly in terms of domestic benefits (OMB and European Commission, 2008, pp. 14–15). The part that deals with

the European Commission's guidelines concludes that they require that 'all impacts be assessed, regardless of where they are likely to materialise or whom they are likely to affect. More specifically, they ask that impacts on international trade and relations, and impacts on third countries or international agreements, are taken into account' (ibid., p. 4).

The Review also emphasizes the role of the Impact Assessment Board – an internal control body with relatively few powers but considerable leverage – in strengthening the analysis of international impacts: 'The Impact Assessment Board has consistently checked the submitted impact assessments for adequate reference to regulatory dialogues with third countries, including the United States, and where necessary encourages the responsible Directorates General to take issues arising from these dialogues properly into account' (ibid., p. 6).

On the US side, the Review reiterates that the OMB Circular A-4 on Regulatory Analysis contains some guidance on this requirement established by the executive order for economically significant rules: 'The role of Federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully' (ibid., p. 12).

Yet the Review goes on to state that there is no clear guidance on *how* to assess the international trade and investment effects of US regulation, since the requirement from the executive order to include distributional effects so that decision-makers can properly consider them along with the effects on economic efficiency, 'usually focuses on domestic rather than international effects' (ibid.).

So there is some encouragement from the inclusion of trade and investment impacts in the overall assessments on both sides of the Atlantic, but the outcome of the Review is that the dialogue partners 'are considering whether our respective regulatory analysis approaches should be modified to better incorporate international trade impacts into the analysis of regulation'

(*ibid.*, p. 14). The final version of the Review contained more analysis of the OMB guidance on the trade aspects of regulatory analysis, possibly to take away the impression that there is reluctance on the part of the OMB to commit to changes in its guidelines.^{xxix}

A common methodology?

The impression has arisen that the US–EU High-Level Regulatory Cooperation Forum is working on ‘a methodological framework that ensures the comparability of regulatory reviews, with an emphasis on risk assessments, cost/benefit analysis, and trade and investment impacts’ (Ahearn, 2008, p. 18). The example above illustrates why a shared methodology is a quite different matter from a shared acknowledgement that trade and possibly other extra-territorial impacts should be assessed. “Assessing” is relatively harmless and the potentially harmful effect of interfering with trade on the ‘overall economic welfare in each nation’ (Review) is easy to acknowledge. How to take these impacts into account when reaching the final decision is the hard question here (Radaelli and Meuwese, 2010). Or in the careful wording of the Review: ‘It is important to emphasize: this discussion is not meant to convey that a regulation with such a trade impact cannot have net benefits. It merely points to a cost that should be assessed and compared with the estimated benefits of a regulation’ (OMB and European Commission, 2008, pp. 14–15).

A real common methodology includes some form of agreement on valid decision criteria, or at least a degree of comparability of criteria that is currently not achievable without running into legal or even constitutional problems. Hence it is not surprising that as for substantive principles (methodology and the policy objective of regulatory analysis) the OMB and the Secretariat-General of the European Commission “agree to disagree”, reaching the compromise that ‘even if economic efficiency is not the only or primary public policy objective, an understanding of the costs and benefits of a regulatory action is important for decision-makers and the public’ (*ibid.*, p. 14).

Still, as is clear from the stakeholder input collected in the consultation, this compromise either goes too far or not far enough for most stakeholders. The German industry association BDI also calls for explicit cost-benefit analysis, which ‘should give due weight to the burden anticipated for affected companies’^{xxx}. Furthermore, it puts forward the far-reaching and unrealistic suggestion that ‘US and EU regulatory authorities should consider a common threshold for determining when to cancel or modify regulatory plans based on the net cost generated by the cost-benefit analysis’^{xxxi}. The American Chamber of Commerce to the EU (AmCham) proposes that ‘common regulatory methodologies should be created in the long run’^{xxxii}. The note contains an accurate analysis of the differences between impact assessment systems in the EU and US:

[Extract] European impact assessments appear to be a tool for informing legislators about, and legitimizing, the Commission’s choices in formulating legislative proposals. However, in the US – even though impact assessments may be carried out in preparing for legislative measures – impact analysis is mainly understood as a means by which executive action may be disciplined and influenced.^{xxxiii}

The conclusion drawn from this analysis, however, does not seem to follow necessarily or logically: ‘Indeed, these differing impact assessment practices on both sides of the Atlantic necessitate the development of a methodological framework to help ensure the comparability of the EU and US impact assessment systems.’^{xxxiv}

The suggestion that institutional differences can be overcome by convergence on methodology is interesting but worrying. “Institutional spillover” from dialogues that claim to be restricted to “substance” and “technical areas of regulation” is exactly what the French government feared when it sought judicial recourse. The Transatlantic Consumer Dialogue

explicitly reproaches the Commission and the OMB for masking institutional engineering under the guise of exchanging good practices on methodology. In the words of the Transatlantic Consumer Dialogue, the Review attempts to converge on ‘the relative weight to be attached to the impact on trade and investment of any given regulatory proposal’ with a ‘privileged place [given] to the impact on trade and investment relative to other impacts on other factors’.^{xxxv}

Procedural horizontal norms

Data sharing on and for impact assessment

An issue that has been on the agenda for a few years (AmCham, 2007) is the sharing of impact assessments. The Review proposes that both sides should ‘make their proposed policies and accompanying impact assessments public’ as early as possible in the process, which would enable the other side to respond if significant international trade and investment issues are expected. The key question of course is, how early is early? AmCham argues that the release of impact assessments for comment should take place in advance of releasing proposed regulations for comment, preferably through a ‘common, publicly available EU–US website or online platform for proposals with transatlantic impacts’. The Transatlantic Business Dialogue concurs: ‘Ideally the regulatory cooperation process should be entirely visible on line from the earliest stages of impact assessment and cost benefit analysis.’^{xxxvi}

The idea behind sharing impact assessments is that data on costs and benefits of regulatory options can be valuable to others. At the same time, acquiring relevant, complete and high-quality data is one of the main problems for anyone who is doing an impact assessment. This is partly a problem of capacity, but also one of confidentiality. For shared data to be useful, in view of the scientific principle of reproducibility, *all* data have to be available, down to the micro level. But the more that the details are published, the harder it will be to convince stakeholders – still the primary data source for the European Commission’s impact assessments at least – to disclose them. This explains why the 2002 Guidelines can only be vague on this: ‘Regulators may share non-public information to the extent [that] such information may be

shared with foreign governments in accordance with applicable rules.^{xxxvii} Another reason sharing information early on can be problematic is that it can give an advantage to its recipients, both in the sense of more time to prepare comments but also in the sense of an unfair business opportunity.

Mutual access to regulatory processes

Regulatory cooperation triggers tensions between the role of stakeholders and that of governments. The US government has presented itself as a “stakeholder” (a stakeholder in a process is an actor who wins or loses from the outcome of that process) in the EU’s better regulation initiative from the beginning. Apart from the horizontal dialogue that is the object of this chapter, the US government has been commenting on policy documents, becoming involved in concrete impact assessment procedures^{xxxviii} and organizing training seminars^{xxxix} and conferences.^{xl} The timing of consultation and publication of assessments by the European Commission has long been a major concern for the US government.^{xli} Indeed on the part of the US government the 2002 Guidelines are apparently seen as a means to address the concern ‘[t]hat EU regulatory processes still are not always transparent’ (Ahearn, 2008, p. 10). Here lies the root of the French fear that an explicit call to ‘improve access to each other’s regulatory procedures’^{xlii} is part of an attempt to foster institutional change by actors who are not constitutionally mandated to initiate it.

Potential access mechanisms can be placed on a spectrum that goes from “informing” to “co-decision-making”. The idea that has been embraced in the EU–US horizontal dialogue falls somewhere between informing and “participating”. If ‘American and European officials keep each other fully informed about new regulatory initiatives and provide either formal or informal mechanisms for participation in each other’s policy deliberations’ this would ‘encourage the development of similar regulatory policies for new and currently unregulated products and processes, such as for nanotechnology’ (Vogel, 2007). Business stakeholders have also argued

that the regulatory process should allow for ‘some measure of participation by “the other side”’.^{xliii}

Experience has nonetheless shown that participation by governments alongside “regular” stakeholders can lead to confusion as to the nature of the authority exercised, especially when impact assessment is used as the means. An example of the latter is again the REACH Regulation, the adoption of which was fought by the US government through the language and framework of impact assessment. Because of the huge implications for the American chemicals industry – including that the industry would have to have its chemicals tested and registered in order to do business in Europe – the REACH proposal stirred up a major, transatlantic regulatory clash. Having raised some concerns about the implications of REACH for US businesses at an early stage without finding a listening ear, the US trade representative circulated a so-called ‘non-paper’ (meaning that no public body takes direct responsibility for it) in 2002, which argued that REACH gave rise to important concerns regarding compliance with the WTO’s “least trade-restrictive” requirement.^{xliv} According to one interest group study, the content of this paper was very close to an impact study by the American Chemistry Council (Schörling, 2004). Also the arguments against REACH that were put forward at the highest political level almost literally reiterated the industry concerns (US House of Representatives, 2004). Even the “meta-argument” that the Commission’s impact assessment was insufficient was echoed by the then US Secretary of State Colin Powell, when he urged the European Commission to complete a cost-benefit analysis of the draft legislation, with particular emphasis on the effect on small and medium enterprises and downstream users of chemical products (Meuwese, 2008, p. 193).

Avoiding a situation like this by regulating ‘transatlantic access to legislative procedures’ through horizontal regulatory policy would not necessarily lead to a better outcome. A kind of joint ‘pre-assessment’ to screen for trade impacts could easily lead to preliminary negotiations,^{xlv} putting too much political pressure on the early stages of the policy-making

process and possibly trespassing on the legal limits set by the ECJ. A more fundamental reason this issue would be difficult to regulate is that foreign authorities participating in legislative procedures face a dilemma that is inherent in regulatory cooperation. On the one hand it could be considered illegitimate that they are not accountable to their domestic constituencies (Slaughter, 2000, p. 522), while on the other regulators need to trust their foreign peers not to arrive at the dialogue table with the exclusive aim of representing their domestic stakeholders and voters.

Policy implications and concluding remarks

Regulation is more and more conceived as a policy area in its own right (Radaelli, 2007, p. 195), as an object of strategic management and as an activity that can be regulated too. This chapter has analysed the recent attempts to achieve convergence on norms for standard-setting and regulatory impact assessment in particular through the enhanced dialogue between the European Commission and the OMB.

We have seen that most transatlantic learning to date has taken place in the realm of procedures (European Policy Centre, 2005). The EU institutions have now internalized the practice of consulting stakeholders much more than before and the EU's minimum standards on consultation have been integrated in the impact assessment framework. On the US side, actors are starting to realize that there is no reason impact assessment cannot be used in primary legislative processes – although it does require a different kind of assessment. Also, the development of a common vocabulary and frame of reference is an important achievement. We can characterize the learning in the EU–US horizontal dialogue as the exchange and promotion of potentially far-reaching horizontal norms, with actors underlining their non-binding nature. The 'soft law' status of norms floated in the dialogue can contribute to normative commitments on the part of individual actors, however, who are more motivated by the desire to be innovative than by legal constraints.

This chapter has identified two different faces of the OMB–European Commission horizontal dialogue:

- 1) the learning face – how regulation itself is regulated on the two sides of the Atlantic and which best practices can be used to improve the quality of regulation in each jurisdiction; and
- 2) the facilitative face – how sector-specific regulatory cooperation can run more smoothly and be put to the service of reducing trade obstacles.

The analysis has shown that the emphasis has come to be more on the former. In particular, the focus on impact assessment can be interpreted as a move away from the goal of convergence. Still, an important assumption in the horizontal dialogue is the claim that sector-specific regulatory convergence can be aided by convergence on the general way in which regulators approach standard setting.^{xlvi}

It is important for policy-makers to outline the limits of the horizontal dialogue and yet be more ambitious in other respects. One important policy implication for transatlantic regulatory cooperation and learning is that the two faces of the horizontal dialogue should be retained as separate rationales. Currently the conflict takes place in the sector-specific dialogues; the horizontal dialogue is meant to appease, to counter the “negotiation mode” of sector-specific dialogues and to gloss over fundamental differences by presenting regulatory policy as a nice set of best practices that can be transplanted. The reasoning that “better regulation” is more trade-friendly regulation and therefore regulatory learning will automatically reinforce regulatory cooperation is too simplistic. Too much emphasis on “exporting best practices” ignores the question of the comparability of the constitutional and legal systems of the US and EU at the risk of achieving nothing but the illusion of convergence and raising unrealistic expectations among stakeholders. Concrete shared norms for standard-setting, certainly substantive ones, are a bridge too far for EU–US regulatory cooperation, because of a lack of (discussion on) shared underlying principles (Meuwese, 2008, p. 182).

Binding transnational agreements on horizontal issues, such as how to use impact assessment,^{xlvii} would not be legally possible, because the better regulation initiative continues to be seen as mostly an internal matter for the EU institutions. In these two respects horizontal regulatory cooperation differs from regulatory cooperation on competition policy, since the latter is an area in which the EU has wide competences and there is much less disagreement as to the underlying principles. The horizontal dialogue could usefully be refocused on general principles for sector-specific regulatory cooperation. Arguably, some high-profile attempts, such as those on genetically modified organisms and REACH, have shown that regulatory convergence, still officially mentioned as a goal,^{xlviii} is unattainable. But there are alternatives along the lines of discussing further what count as *legitimate* differences in regulation. On the procedural side, the EU and US should practise positive comity, in the sense that they should commit to active mutual consultation and assistance by turning dialogue into the main mode of regulatory cooperation (Slaughter, 2000, p. 539). Finally, the positive role of conflict ought to be pointed out here. As Braithwaite and Drahos put it, ‘international fora must be constituted in ways that allow for the possibility of contest’ (2000, p. 516). Mutual recognition in substantive areas of regulation means that a framework of general rules is in place within which different regulatory approaches can compete (Majone, 2000). Perhaps this can be translated into horizontal regulatory cooperation, and the OMB–European Commission dialogue can work more explicitly towards “mutual recognition” of certain horizontal norms.

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ⁱ ‘Regulators: The New Diplomats’ is the title of the first chapter in Slaughter (2004), p. 36.

ⁱⁱ This chapter does not maintain a strict distinction between the terms “transgovernmental” and “transnational” as proposed in Pollack and Shaffer (2001), p. 5.

ⁱⁱⁱ When this tool was introduced in 2002 (in the European Commission’s (2002) Communication on Impact Assessment), the European Commission decided to drop the usual adjective “regulatory” and speak of solely of “impact assessment”. This was meant to emphasize that not only are regulatory measures covered, but also any policy initiative by the European Commission.

^{iv} The legally neutral concept of “standard-setting” is used as much as possible in this chapter to avoid confusion by choosing either the American term “rule-making” or the more European expression “law-making”.

^v See the chapter ‘How to get out of the transatlantic regulatory deadlock over GMOs?’ by Alberto Alemanno in this volume.

^{vi} Bermann (1996) adds a third category: regulatory cooperation in aid of mutual assistance in enforcement.

^{vii} The following list of modes of regulatory convergence is based on Majone (2000), but does not maintain his sharp distinction between spontaneous and institutionalized modes.

^{viii} More specifically, this is not to be confused with the Community law obligation for member states to carry out “environmental impact assessments” on projects or plans. See Council Directive 97/11/EC of 3 March 1997 amending Directive 85/337/EEC on the assessment of the effects of certain public and private projects on the environment, OJ L 073, 14.03.1997, and Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment, OJ L 197, 21.7.2001.

^{ix} See *Bulletin of the European Communities*, **23** (11), point 1.5.3 (1990). The official title is the Declaration on Relations between the European Economic Community and the United States. See also ‘E.C. and US Reinforce Transatlantic Partnership’, *European Community News*, No. 41/90, 27 November 1990, p. 91.

^x See the *Guidelines for EU–US Regulatory Cooperation and Transparency*, 2002, p. 4.

^{xi} *Ibid.*, p. 6.

^{xii} Refer to the website of European Commission’s Directorate-General for Enterprise and Industry, ‘EU–US Regulatory Cooperation’, available at http://ec.europa.eu/enterprise/policies/international/cooperating-governments/usa/regulatory-cooperation/index_en.htm (accessed 2 July 2009).

^{xiii} Transatlantic cooperation on competition policy is largely left aside in this chapter, because it mainly concerns cooperation on *cases* whereas this chapter exclusively deals with *regulatory* cooperation.

^{xiv} Refer to Case C-327/91, *France v. Commission* [1994] ECR I-3641. See also Bermann (1996), p. 960.

^{xv} See Case C-233/02, *France v. Commission* [2004] ECR I-2759.

^{xvi} See paragraph 3.1.1 of the 2002 Guidelines, *op. cit.*

^{xvii} Case C-233/02 *France v Commission*, *op. cit.*

^{xviii} Case C-233/02 *France v Commission*, *op. cit.*

^{xix} Case C-233/02 *France v Commission*, *op. cit.*

^{xx} For the legal limitations on the US side, particularly when state governments engage in regulatory cooperation directly, see the chapter ‘Legal guidelines for cooperation between the EU and American state governments’ by Daniel Farber in this volume.

^{xxi} A leaflet describes its scope as follows: ‘It covers discussions between the Commission and the US government on general regulatory policy issues, such as comparing the EU and US regulatory systems, and approaches to impact and risk assessments.’

^{xxii} There is some confusion as to whether the Forum members are limited to senior US officials and senior officials at the European Commission or also includes academics, think tanks and private stakeholders. The answer is that the permanent members of the Forum are solely the senior officials and heads of relevant regulatory agencies; however, the Forum also facilitates events where the circle of participants is wider. This blending of networks from the government and private spheres is typical in transnational governance.

^{xxiii} Refer to the Group of High-Level National Regulatory Experts, ‘Minutes of the meeting’, Brussels, 27 June 2006.

^{xxiv} Refer also to the *Joint Report on the Roadmap for EU–US Regulatory Cooperation*, June 2006.

^{xxv} The guidebook is entitled *EU–US Regulatory Cooperation, Best Cooperative Practices*, June 2006.

^{xxvi} The *2007 EU–US Summit Economic Progress Report*, mentions ‘deepening the dialogue on good regulatory practices between the US Office of Management and Budget (OMB) and the European Commission’, 2007, p. 2.

^{xxvii} Refer to the Joint Statement of the European Commission and the United States following the second meeting of the Transatlantic Economic Council, No. 47/08, 13 May 2008.

^{xxviii} In this discussion the Commission practice of trade impact assessment, which has been in place longer than the general impact assessment requirement and which confusingly goes by the name of “sustainability impact assessment”, is sometimes mentioned. Sustainability impact assessment is not going to help because it is solely limited to trade negotiations, whereas what we are trying to tackle here are the side effects of regulation on trade.

^{xxix} This flaw was also pointed out by Torriti, Boudier and Lofstedt in their reaction to the draft Review: ‘The two parts are not balanced because the EC describes how IA [impact assessment] guidelines address the trade and investment issue, whereas the OMB presents cases where this issue was dealt with in individual IAs.’ See ‘Comments on the Joint draft report prepared by the Office of Management and Budget and the Secretariat General of the European Commission: “Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment”, 14 August 2008, http://ec.europa.eu/governance/better_regulation/documents/eu_us_consult/comment_on_omb_eu.pdf.

^{xxx} German trade and industry association (BDI), reaction to consultation on the Review, 8 February 2008, http://ec.europa.eu/governance/better_regulation/documents/eu_us_consult/bdi_public_comment_on_omb_ec_joint_draft_report.pdf

^{xxxi} German trade and industry association (BDI), reaction to consultation on the Review, *op. cit.*

^{xxxi} AmCham EU’s comments on the EC-OMB Joint Draft Report on the Review of the application of EU and US regulatory impact assessment guidelines on the analysis of impacts on international trade and investment, reaction to consultation on the Review, http://ec.europa.eu/governance/better_regulation/documents/eu_us_consult/ec_omb_final.pdf.

^{xxxi} AmCham EU’s reaction to consultation on the Review, *op. cit.*

^{xxxi} AmCham EU’s reaction to consultation on the Review, *op. cit.*

^{xxxi} Comments of the Transatlantic Consumers Dialogue on Draft OMB-EC

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http://ec.europa.eu/governance/better_regulation/documents/eu_us_consult/tacd_comments_on_ec_omb_report.pdf.

^{xxxvi} Transatlantic Business Dialogue, reaction to consultation on the Review, 7 February 2008.

^{xxxvii} Refer to the Guidelines (2002), *op. cit.*, p. 3.

^{xxxviii} See the example of REACH later discussed.

^{xxxix} The US Mission to the European Union in Brussels also organized a seminar entitled ‘Better Regulation: The EU and the Transatlantic Dialogue’, which brought together 20 regulatory representatives from the new EU member states to Brussels for a day of training in EU approaches to regulation, followed by a second day of comparative approaches to regulation focusing on how the US approaches it.

^{xl} On 17-18 March 2005 a conference was held on ‘Better Regulation: The EU and the Transatlantic Dialogue’ co-sponsored by the European Policy Centre, the European Commission and the US Mission to the EU. The US Mission to the EU continues to regularly host seminars on better regulation, often co-organized with Brussels-based think tanks.

^{xli} See the website link of the Center for Regulatory Effectiveness to the document ‘Comments of the United States Government on the European Commission’s Better Regulation Package’, available at <http://www.thecre.com/eu-oira/comments.htm>.

^{xlii} Refer to the Guidelines (2002), *op. cit.*, p. 1.

^{xliii} Derived from German trade and industry association (BDI), reaction to consultation on the Review, *op. cit.*

^{xliv} Because a ‘non-paper’ is defined by the fact that no governmental organisation formally wants to take responsibility for it, it was impossible to track down the definite document, but various sources have confirmed its existence and content in interviews, see also Meuwese 2008.

^{xlv} This point was also made by the Transatlantic Consumer Dialogue in their reaction to the Review.

^{xlvi} For instance, according to Ahearn (2008, p. 8), ‘[u]ntil the regulatory structures themselves become more convergent or aligned, the major divergences in regulatory policies are unlikely to disappear’.

^{xlvii} AmCham, following the US Chamber of Commerce, advocates the concept of a legally binding agreement on regulatory cooperation.

^{xlviii} Refer to the 2008 Joint Statement of the European Commission and the United States following the second meeting of the Transatlantic Economic Council (No. 47/08), *op. cit.*