

# **EU-U.S. Horizontal Regulatory Cooperation**

*Two global regulatory powers converging on how to assess regulatory impacts?*

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## ***Introduction***

Anne-Marie Slaughter famously suggested that regulators are the new diplomats.<sup>1</sup> This invokes an image of decision-making by professionals in anonymous meeting rooms, rather than one of influence being exercised by aristocrats over a few glasses of champagne. What matters is whether this change of scene conveys a shift in power relations in global governance. In the seemingly technical but ultimately political realm of regulatory cooperation, pressing questions on sovereignty, delegation and accountability linger.<sup>2</sup>

Slaughter's phrase was meant to express the increasing prominence of regulation as a public activity and the necessary internationalization of forums in which it takes place. Regulators – in the sense of 'those involved in the setting, monitoring and enforcement of regulatory standards' – have to cross borders to solve with their foreign peers issues that used to fall within the exclusive domain of domestic policy-making. 'Cooperation' is no longer an activity related to military security, trade and development, but is becoming an important feature of regulation as well. Regulatory cooperation is now being seen as a priority in many business round tables and dialogues.<sup>3</sup> Transnational<sup>4</sup> dialogues about regulatory standards deal with a range of issues such as environmental standards, more technical areas such as food safety and apparent tabloid material such as the acceptability of non-metric measurements.<sup>5</sup> In

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<sup>1</sup> 'Regulators: The New Diplomats' is the title of the first chapter of her book 'A New World Order'. Slaughter, A.-M. (2004). *A New World Order*. Princeton/Oxford, Princeton University Press, p. 36.

<sup>2</sup> See a recent article by Lehmkuhl who argues that international relations scholars and regulation scholars should borrow and learn more from each other. Lehmkuhl, D. (2008). "Control Modes in the Age of Transnational Governance." *Law & Policy* 30(3), pp. 336-363.

<sup>3</sup> Allio, L. (2008). *The Emergence of Better Regulation in the EU*. PhD Thesis, King's College London, October 2008.

<sup>4</sup> The terms 'transgovernmental' and 'transnational' are often used as synonyms, to convey a level that transcends the domestic but without formal involvement at the level of (heads of) state. However, Pollack and Shaffer (2001) make a distinction: 'transgovernmental' refers to situations "where lower-level domestic officials work with their transatlantic counterparts on specific issues to coordinate and harmonize domestic policies" and 'transnational' to situations "where private actors, including business representatives and other constituents, coordinate efforts to advance their respective goals". Pollack, M. A., & Shaffer, G. C. (2001). *Transatlantic governance in the global economy*. Lanham, Md: Rowman & Littlefield, p. 5. This paper does not maintain a strict distinction.

<sup>5</sup> Raustiala, K. (2002). "The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law ." *Virginia Journal of International Law* 43. Lehmkuhl, D. (2008).

these regulatory dialogues, the nation state is still the most powerful but by no means the only actor in global regulatory games as self-regulatory organizations increase their influence in the epistemic communities that frame debates of regulatory design.<sup>6</sup> A supranational organization such as the EU can be seen as an instance of regulatory cooperation (heavily relying on one of the strongest modes of cooperation: harmonization), but it is also an actor *in* regulatory cooperation.

Zooming in on regulatory governance we find that increasing cooperation is not the only transformation that 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. As was already more common outside of the regulatory arena, performance-based regulatory management systems are being set up across the globe. We can also witness a tendency among regulators to think more reflexively about regulation and design 'horizontal' (i.e. non sector-specific) policies 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% by 2012, the introduction of impact assessment<sup>7</sup> as a systematic tool for European policy-making was a major component of this horizontal policy. In the United States the transformation towards ever more 'regulation of regulation' had already been underway for longer: for many decades broad delegated regulatory powers for federal agencies have been accompanied by heavy procedural protection,

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"Control Modes in the Age of Transnational Governance." *Law & Policy* 30(3): 336-363; Petersmann, E.-U. (2000). Globalization and transatlantic regulatory cooperation: proposals for EU-US initiatives to further constitutionalize international law. In: G. A. Bermann, M. Herdegen & P. L. Lindseth (Eds.), *Transatlantic Regulatory Cooperation*, Oxford: Oxford University Press.

<sup>6</sup> Braithwaite, J. & Drahos, P. (2000). *Global Business Regulation*, Cambridge, Cambridge University Press, p. 475 & 481.

<sup>7</sup> When this tool was introduced in 2002 (in the European Commission, Communication on Impact Assessment COM(2002) 276 final) the European Commission decided to drop the usual adjective 'regulatory' and speak of 'impact assessment' only. This was meant to emphasize that not only regulatory measures (or even more narrowly 'regulations', a term that refers to a specific type of binding legislative instrument in the EU context) are covered, but any 'policy initiative' by the European Commission.

both judicial (review) and non-judicial (hearings, regulatory impact analysis) in nature.

This paper investigates the intersection of these two trends. An explosion of 'Better Regulation' policies has taken place in many countries and as a consequence we have a new type 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,<sup>8</sup> with the OECD and certain think tanks such as the German Bertelsmann Foundation often playing a facilitating role. This general or 'horizontal' cooperation on regulation exists between quite a few states and not in the least among EU Member States through a type of open method of coordination.<sup>9</sup> But horizontal regulatory cooperation is most developed between the EU and the U.S. as exemplified by the EU-U.S. 'horizontal dialogue' on cross-cutting issues of regulatory cooperation. The direct partners here are the Secretariat-General of the European Commission and the Office of Management and Budget (OMB) at the U.S. side.

The main question addressed in this paper is to what extent this dialogue has indeed led to the emergence of shared norms for domestic standard-setting and/or for substantive regulatory cooperation.<sup>10</sup> The paper 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. The structure of this paper is as follows. After some general observations on the concepts of regulatory cooperation and horizontal regulatory policy, the development of

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<sup>8</sup> Jacobsson, B. (2006). Regulated regulators: Global trends of state transformation. In *Transnational Governance*. In: *Institutional Dynamics of Regulation*. M.-L. Djelic and K. Sahlin-Andersson. Cambridge, Cambridge University Press, pp. 205-224.

<sup>9</sup> Radaelli, C. M. (2007). Whither Better Regulation for the Lisbon Agenda? *Journal of European Public Policy*, 14(2), 190-207; Radaelli, C. M., & De Francesco, F. (2007). *Regulatory Quality in Europe: Concepts, Measures, and Policy Processes*. Manchester: Manchester University Press. The Directors of Better Regulation is an informal network of high and medium level civil servants from EU Member States charged with general regulatory policies that exists outside the supranational EU structure. It serves as a forum for exchanges of best practices and coordination of activities in the field of 'Better Regulation'.

<sup>10</sup> The legally neutral concept of 'standard-setting' will be used as much as possible in this paper to avoid confusion by choosing either the American term 'rule-making' or the more European expression 'law-making'. It also fits well with fact that current Better Regulation debates focus mainly on the 'standard-setting' phase of the regulatory process, rather than on monitoring, implementation or enforcement'.

horizontal regulatory cooperation over the past decade is set out, ending with how (regulatory) impact assessment came to be the most recent focus of this transatlantic dialogue. Then the paper goes on to zoom in on EU-U.S. cooperation on impact assessment and concludes by some recommendations.

## ***Regulatory cooperation and horizontal regulatory policy***

### ***What is regulatory cooperation?***

Across the globe, regulatory policies are increasingly interdependent. This is the case first of all because many regulatory problems – problems regulation is aiming to address as well as problems caused by regulation – are of a cross-sector and cross-border nature. If a government wants to improve air quality or stabilize the financial system it has to find a way to get foreign governments on board. Increasingly regulatory cooperation is preferred to the traditional route of concluding a multilateral treaty. Secondly, there is a strong link between regulatory standards and trade disputes.<sup>11</sup> Looking at the matter strategically, governments can deliberately make use of regulation as a strategic weapon in international competition.<sup>12</sup> If a country is assertive in promoting its regulatory standards and succeeds in persuading others to adopt them, it gives a competitive edge to domestic industry (cf. the much discussed ‘California effect’). Or, in the passive-aggressive version, domestic regulation can serve as an obstacle to trade. With explicit barriers to international trade occurring less and less frequently, due to WTO involvement, regulatory differences are the next great battleground and regulatory cooperation is often hailed as the solution. It should be noted that, seen in this light, regulatory competition and regulatory cooperation are two sides of the same global regulatory game.

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<sup>11</sup> Bermann, G. A. (1996). “Regulatory Cooperation between the European Commission and US Administrative Agencies.” *Administrative Law Journal of American University*, 9, p. 957.

<sup>12</sup> Majone, G. D. (2000). *International Regulatory Cooperation*. In: *Transatlantic Regulatory Cooperation*. G. A. Bermann, M. Herdegen and P. Lindseth. Oxford, Oxford University Press, pp. 119-145, p. 129.

The combination of the two functions of regulatory cooperation – as a direct rule-making strategy and as a way to ease trade disputes<sup>13</sup> – has thrown the concept into the limelight in recent years. Regulatory convergence can occur both within and outside of institutionalized contexts.<sup>14</sup> First, there is parametric adjustment, which is an umbrella term for forms of unilateral harmonization and policy imitation. This does not need to occur between nation states necessarily: it is also possible that private companies adopt public standards from overseas. For example, American company HP is adopting requirements from several EU directives and regulations, such as REACH and the Restriction of Hazardous Substances (RoHS) directive, which restricts the use of certain heavy metals.<sup>15</sup> The second mode is information exchange, such as provided for in the EC directive on the exchange of information related to the assessment of taxes. Thirdly, 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 foreign norms of one legal system by another and vice versa, without incorporating them 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 concerning conformity assessment<sup>16</sup> – is achieved through the conclusion of Mutual Recognition Agreements (MRAs) on the basis of Article 133 of the Treaty. Harmonization – ensuring norms are compatible if not similar – is possibly the most far-going mode. Finally, we find a mode that can operate in varying degrees of

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<sup>13</sup> Bermann (1996), *supra* n. 11 adds a third category: regulatory cooperation in aid of mutual assistance in enforcement.

<sup>14</sup> The following list of modes of regulatory convergence is based on Majone (2000), *supra* n. 12 but does not maintain his sharp distinction between spontaneous and institutionalized modes.

<sup>15</sup> <http://www.hp.com/hpinfo/globalcitizenship/environment/productdesign/materialuse.html>.

<sup>16</sup> European Commission, Third strategic review of Better Regulation in the European Union Commission communication, COM(2009)15, 28 January 2009.

formality: transnational or transgovernmental regulatory networks. Examples are the Basel Committee on Banking Supervision, the International Association of Insurance Supervisors (IAIS) and the informal international networks in the field of competition law. An example of a more informal network is the Informal Financial Markets Regulatory Dialogue, led by the Treasury Department and the Commission's DG Internal Market, in which the Federal Reserve Board and Securities and Exchange Commission also participate. The dialogues that take place in these networks are instrumental to broadening the outlook of regulatory officials. Through cross-border dialogues, officials get to see their own roles in a comparative light. They help to redefine issues and to rearrange priorities. Finally, such dialogues foster normative commitments by institutionalizing social mechanisms such as peer pressure and praise.<sup>17</sup> As shown by the illustrations above, many of these modes of regulatory convergence have been turned into operational mechanisms which are undertaken to increase regulatory co-operation.

How trade, regulation and risk management interrelate can well be illustrated with an example from environmental policy. In this policy area regulation is always controversial because of the high stakes on both the cost side and the benefit side. Seen in the light of regulatory cooperation the contention heightens because of the impact of the differences in those regulations across jurisdictions on each other's producers and consumers. The U.S. and Europe historically adopted contrasting approaches to the regulation of environmental and health risks, resulting in diverging regulatory outcomes which posed *de facto* obstacles to transatlantic trade. To be more specific, the alleged European weariness of new technologies for food production and preservation, voiced through a more centralized and political type of decision-making that allows for plenty of room to interpret the precautionary principle, resulted in a more prohibitive approach to genetic modification of organisms (GMO). In the US, decentralized, more scientific, decision-making – which fitted with its more open attitude towards new technologies – led to regulatory facilitation of GM products.<sup>18</sup> However the latter is not of much use to American

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<sup>17</sup> Braithwaite & Drahos (2000), *supra* n. 6.

<sup>18</sup> See other papers prepared for this research project, notably the one by Alemanno.

firms who want to do business in Europe. After a lengthy battle at the WTO, the question is not whether both sides will give regulatory cooperation another try.

The growing prominence of regulatory cooperation has triggered calls for constitutional rules and principles,<sup>19</sup> or even for facilitating institutions that are capable of taking into account the broader community of states affected by the regulatory standards in question.<sup>20</sup> The following proposal for a set of constitutional principles for transgovernmental networks has been made by Slaughter: the principle of legitimate difference, the principle of positive comity and the principle of positive conflict.<sup>21</sup> The principle of legitimate difference would set the bar for rejecting foreign standards higher than it is currently usually set, without going as far as a 'blanket' acceptance of foreign regulatory standards. Mere national interests are not accepted as an argument against recognition of foreign or transnational standards. The principle of legitimate difference requires the balance of interests to include values of constitutional magnitude. The principle would further entail a great degree of respect for 'different' standards and for the officials who advocate it, in the sense that these should not be presumed to "chauvinistically privilege their own citizens".<sup>22</sup> The principle of positive comity would stimulate active consultation and assistance by turning dialogue into the main mode of regulatory cooperation, rather than the passive 'deference'.<sup>23</sup> The final suggested principle is the one of positive conflict: if we embrace 'conflict' in transatlantic regulatory relations, it can serve as a positive engine of change and as something that can be managed through the gradual development of procedures and principles.<sup>24</sup>

These principles are not meant to be operational. They express the most fundamental values underlying transatlantic regulatory cooperation and they entrench the idea of regulatory cooperation as a mode of governance that is far

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<sup>19</sup> Petersmann (2000) *supra* n. 5, p. 615.

<sup>20</sup> Lazer, D. (2006). "Global and Domestic Governance: Modes of Interdependence in Regulatory Policymaking" *European Law Journal* 12(4), p. 468.

<sup>21</sup> Slaughter, A.-M. (2000). Agencies on the loose? Holding government networks accountable. In: *Transatlantic Regulatory Cooperation*. G. A. Bermann, M. Herdegen and P. Lindseth. Oxford, Oxford University Press, p. 535.

<sup>22</sup> *Ibid.*, p. 536.

<sup>23</sup> *Ibid.*, p. 539.

<sup>24</sup> *Ibid.*, p. 544.

removed from the usual bargaining of trade negotiations. However, we will see below how principles such as these can acquire an operational relevance for the conditions under which regulatory dialogues operate.

### ***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 such as the United States, where the conditions for regulation itself are regulated in many cases, this is often remarkably unclear. The European Union has a few broadly defined regulatory *objectives* in the Treaty, delineating its competences vis-à-vis the Member States, but 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<sup>25</sup> – as an analytical framework for the preparation and deliberation of European legislation. The core of IA is to assess the environmental, social and economic impacts of proposed regulatory interventions on various societal groups. It is not just a document, but a highly structured process of policy formulation and, importantly, coordination between different parts of the Commission services. However, this process 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, which is used as a means for controlling delegation *away from* the core legislature.

Institutional differences account for most of the differences in 'regulatory philosophies' across the Atlantic,<sup>26</sup> such as contention over the precautionary

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<sup>25</sup> 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 amending Directive 85/337 on the assessment of the effects of certain public and private projects on the environment, and Directive 2001/42 of the European Parliament and of the Council on the Assessment of the Effects of Certain Plans and Programmes on the Environment.

<sup>26</sup> Löfstedt, Ragnar E. and D. Vogel (2001) "The changing character of regulation: a Comparison of Europe and the United States" *Risk Analysis*, 23(2), pp. 411-421.

principle, which has been repeatedly asserted<sup>27</sup> and equally frequently been played down.<sup>28</sup> Some have detected a wave of convergence in U.S. and European regulatory approaches.<sup>29</sup> Impact assessment provides a useful lense for capturing the remaining differences. Although impact assessment is increasingly regarded as a global standard,<sup>30</sup> it is commonly acknowledged that the U.S. system of 'regulatory impact analysis' (RIA) and the EU counterpart 'impact assessment' (IA) differ in scope, objectives, stringency, enforceability and methodology. To borrow from Scott Jacobs a concise way of summing up the differences: U.S. RIA has flexibility in design of the assessment, including what impacts to asses but is rigid in terms of decision criteria; EU IA features rigidity as to what impacts to consider but great flexibility in choosing decision criteria.

A point of convergence between the U.S. and the EU impact assessment systems is actually that both comprise 'integrated' assessment of economic, social and environmental impacts. If anything, the European system is the narrower one, with its recent focus on cutting administrative burdens as opposed to investing in 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.<sup>31</sup>

A recent evaluation of the quality of European IAs concluded that they have become more informative since moving out of the pilot phase, but claims that quite a few IAs are still missing important pieces of economic information such as the

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<sup>27</sup> Löfstedt, R. E. (2004). "The Swing of the Regulatory Pendulum in Europe : From Precautionary Principle to (Regulatory) Impact Analysis" *Journal of Risk and Uncertainty* 28(3), pp. 237-260.

<sup>28</sup> Wiener, J. B. (2006). "Better Regulation in Europe" *Current Legal Problems* 59, pp. 447-518.

<sup>29</sup> Wiener, J. B. (2003). "Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems" *Duke Journal of Comparative & International Law*, 13, pp. 207-262. Lofstedt & Vogel (2001), *supra* n. 26.

<sup>30</sup> Jacobs, S. (2006). *Current Trends in Regulatory Impact Analysis: The Challenges of Mainstreaming RIA into Policy-making*. Jacobs & Associates. Washington.

<sup>31</sup> Wiener (2006), *supra* n. 28.

monetization of benefits.<sup>32</sup> The study also found that the quality of EU impact assessments on measures that are estimated to cost more than \$100m is similar to that of regulatory impact analyses in the U.S.<sup>33</sup> It also points to the fact that the range of initiatives that are scrutinized in Europe is much broader and asks whether it is not time for the U.S. to expand the scope of RIA to include laws, policies, and smaller regulations. However, one of the main points of discussion in the EU at the moment is whether the scope should be narrowed because the current regime is 'suffering from its own success' producing too huge a flood of IAs.

## ***A brief history of EU-U.S. horizontal regulatory cooperation***

The EU's Better Regulation strategy includes a number of cooperative dialogues with other global regulatory powers, such as Japan, China and Canada but *horizontal* regulatory cooperation is the most developed with the U.S. For more than a decade various steps have been taken, each with a different focus and a different degree of formality.

### ***1990s: Calls for explicit cooperation***

The Transatlantic Declaration of 22 November 1990 contained what could be called an implicit reference to transatlantic regulatory cooperation:<sup>34</sup> it states that the EU and the U.S. "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."<sup>35</sup> In 1994 the so-called Sub-Cabinet Group issued a declaration endorsing U.S.-E.C. bilateral

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<sup>32</sup> Cecot, C., R. W. Hahn, et al. (2008). "An evaluation of the quality of impact assessment in the European Union with lessons for the US and the EU." *Regulation & Governance* 2, p. 420.

<sup>33</sup> *Ibid.*

<sup>34</sup> Bermann (1996), *supra* n. 11.

<sup>35</sup> Bulletin of the European Communities, vol. 23, no. 11, point 1.5.3 (1990). The official title is Declaration on Relations between the European Economic Community and the United States. See E.C. and U.S. Reinforce Transatlantic Partnership, *European Community News*, No. 41/90 (Nov. 27, 1990), p. 91

regulatory cooperation.<sup>36</sup> 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.”<sup>37</sup> More high-level political support followed in a joint declaration that was part of the New Transatlantic Agenda at the EU-U.S. 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.”

Regulatory cooperation was put to the service of creating a ‘New Transatlantic Market Place’ and the call for strengthened cooperation was repeated in a Joint Statement on Regulatory Cooperation in December 1997. At the EU-U.S. London Summit of May 1998, the European Union and the United States launched the Transatlantic Economic Partnership (TEP) and enhanced regulatory cooperation was made one of its cornerstones.

Regulatory cooperation was and is mainly envisaged as happening between agencies, although agencies are relatively rare in the EU context and almost always lack regulatory powers, in the sense of standard-setting powers. Instead, U.S. agencies will often find Directorates General (DGs) of the European Commission at the dialogue table, raising the issue of ‘institutional mismatch’.<sup>38</sup> The question of whether U.S. agencies and EC Commission divisions bring comparable political

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<sup>36</sup> Vogel, D. (1997). *Barriers Or Benefits?: Regulation in Transatlantic Trade*. Washington D.C.: Brookings Institution Press, p. 10.

<sup>37</sup> Bermann (1996), *supra* n. 11.

<sup>38</sup> Macey, J. R. (2000). US and EU structures of governance as barriers to transatlantic regulatory cooperation. In: *Transnational Regulatory Cooperation*. G. A. Bermann, M. Herdegen and P. L. Lindseth. Oxford, Oxford University Press, pp. 357-371. Bermann (1996), *supra* n. 11; Bermann, G. A., M. Herdegen, et al. (2000). *Transatlantic Regulatory Cooperation*. Oxford, Oxford University Press.

authority to the dialogue,<sup>39</sup> is newly relevant in the current horizontal version of the transatlantic regulatory dialogue, in which the Office of Management and Budget is talking to the Secretariat-General.

### ***2002: Guidance on regulatory cooperation and transparency***

The ‘Guidelines on EU-U.S. regulatory cooperation and transparency’ (hereafter: Guidelines) were drafted and negotiated on the basis of the TEP Action Plan, first published in 2002 and politically endorsed at the EU-U.S. 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. The ‘operational elements’ of the Guidelines are split in two: one part deals with ‘regulatory cooperation’, the other with ‘transparency’. Although the term ‘impact assessment’ is not mentioned – understandable given that in 2002 the European Commission had not even started its pilot project on IA – 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.”<sup>40</sup>

Regulators are also encouraged to aid public commenters 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”.<sup>41</sup>

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<sup>39</sup> Bermann (1996), *supra* n. 11, p. 980.

<sup>40</sup> Guidelines for EU-U.S. regulatory cooperation and transparency (2002), p. 4.

<sup>41</sup> *Ibid.*, p. 6.

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 U.S. regulators.”<sup>42</sup> On the other hand, these Guidelines worried the French government enough to fight the Commission on the legality of the Guidelines in front of 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 U.S.-E.C. competition law agreement.<sup>43</sup> 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 E.C. Treaty*.<sup>44</sup> The second, lesser known, case concerning the Guidelines on regulatory cooperation and transparency was decided by the ECJ in 2004.<sup>45</sup> France brought an action under Article 230 EC for annulment of the decision by which the Commission of the European Communities concluded these Guidelines. Among the provisions that the French government considered problematic were:

- “ - identification and implementation of jointly defined general principles/ guidelines for effective regulatory cooperation;
- joint review of mutually agreed issues, notably access to each others’ regulatory procedures with respect to transparency and public participation - including the opportunity for all interested parties to ‘have meaningful input’ in those procedures and to receive reasonable consideration of their views;

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<sup>42</sup> DG Enterprise and Industry, International Affairs website, [http://ec.europa.eu/enterprise/international\\_relations/cooperating\\_governments/usa/usa\\_reg\\_en.htm](http://ec.europa.eu/enterprise/international_relations/cooperating_governments/usa/usa_reg_en.htm).

<sup>43</sup> Horizontal cooperation on competition is largely left aside in this contribution, because it mainly concerns cooperation on *cases* whereas this contribution exclusively deals with *regulatory* cooperation.

<sup>44</sup> Case C-327/91, France v. Commission, [1994] ECR. I-3641. See also Bermann (1996), *supra* n. 11, p. 960.

<sup>45</sup> Case C-233/02, France v. Commission, [2004] ECR I-2759.

– on the basis of that review, identification of ways and means to improve access to each other’s regulatory procedures and development of jointly agreed general principles/ guidelines on such procedures, while preserving the independence of domestic regulatory authorities.”<sup>46</sup>

France claimed that this step in transatlantic regulatory cooperation was illegal for similar reasons as the ones that 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”, 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. However, the ECJ first of all established that the Guidelines do not have legally binding effect, pinning this on the “intentions of the parties”. It 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”. Whilst acknowledging that the Commission had taken upon itself an obligation to take the Guidelines into account, the ECJ ruled that the Guidelines provided mere possibilities such as engaging in prior consultation and gathering all necessary information before submitting appropriate proposals. According to the ECJ these possibilities “cannot be alleged to undermine the Commission’s power of initiative” since they are part of it.

### ***2005: Formalizing horizontal regulatory networks***

A two-day event on ‘Better Regulation: the EU and the Transatlantic Dialogue’ held in March 2005, hosted by the European Policy Centre (EPC) and bringing together officials and stakeholders, concluded that approaches to standard-setting on both sides were converging rather than diverging but not necessarily to a substantive or sufficient degree.<sup>47</sup> In this phase of institutionalization of the transatlantic horizontal dialogue, the emphasis was on formalizing networks. Transatlantic stakeholder

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<sup>46</sup> Paragraph 3.1.1 of the Guidelines, *supra* n. 40.

<sup>47</sup> European Policy Centre (2005). Minutes of the Conference ‘Better regulation: the EU and the transatlantic dialogue’. Brussels.

dialogues were already in place, notably the Transatlantic Business Dialogue and the Transatlantic Consumer Dialogue (TABD and TACD). In particular the TABD, 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.”<sup>48</sup>

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-U.S. Summit in order to encourage EU and U.S. senior regulators to exchange views, share experiences and learn from each other.<sup>49</sup> This Forum is essentially a more institutionalized dialogue on good regulatory practices between the European Commission and the U.S. Office of Information and Regulatory Affairs, part of the Office of Management and Budget (OIRA/OMB).<sup>50</sup> The Forum meets twice a year and its deliberations provide input to the Transatlantic Economic Council (TEC). A more informal EC-OMB dialogue on methodological issues takes place alongside the Forum’s activities. In this dialogue good regulatory practices are being discussed, with a focus on transparency provisions and public consultation and the respective impact assessment methodologies (see dedicated section below).<sup>51</sup> One of the main functions of the Forum is to lend senior level support and visibility to the concrete activities of the former.

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<sup>48</sup> Ahearn, R. J. (2008). *Transatlantic Regulatory Cooperation: Background and Analysis* (CRS Report for Congress). Washington D.C., p. 17, citing Maria Green Cowles, “Calming the Waters: The Rebirth of the Transatlantic Business Dialogue,” p. 278.

<sup>49</sup> A leaflet describes its scope as follows: “It covers discussions between the Commission and the U.S. government on general regulatory policy issues, such as comparing the EU and U.S. regulatory systems, and approaches to impact and risk assessments.” There is also a Canada-EU Joint Action Plan Regulatory Dialogue and Cooperation, launched in the spring of 2003.

<sup>50</sup> There is some confusion as to whether the Forum members are U.S. and European Commission senior officials only, or also includes academics, think tanks and private stakeholders. The answer is that the permanent members of the Forum are senior officials and heads of appropriate regulatory agencies only. However, the Forum also facilitates events such as where the circle of participants is wider. This blending of governmental networks and private sphere networks is typical for transnational governance.

<sup>51</sup> Joint Report on the Roadmap for EU-US Regulatory Cooperation, June 2006.

Better Regulation was a topic of discussion at the U.S.-EU summit in Washington D.C. on 20 June 2005, followed by several renewed calls for closer cooperation. In the same year, the U.S. and the EU agreed on a Roadmap for Regulatory Cooperation and the Commission issued a Communication on 'A stronger EU-U.S. Partnership and a more open market for the 21st century' which suggested a 'reinforced approach' to regulatory policy cooperation. This reinforced approach was envisaged to entail 'enhanced upstream cooperation'. Concretely, this comprises the following elements:

“(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 at the final bullet point are specified as 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;
- development of common standards, where appropriate.”

Finally, a guidebook for regulators, intended to complement the EU-U.S. Guidelines on Regulatory Cooperation and Transparency appeared in June 2006, but seems to lead a dormant existence.<sup>52</sup>

### ***2007: Operationalizing regulatory cooperation***

Upon concluding that the declarations and guidelines mentioned above had made little impact, the transatlantic partners again called for a more explicit and structural cooperation in April 2007.<sup>53</sup> 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”.<sup>54</sup> At the EU-U.S. Summit in Slovenia on 10 June 2008 political leaders stated that:

“We expect that improvements to our respective regulatory processes will benefit stakeholders and help diminish unnecessary regulatory divergences. In this respect, we will continue our efforts via the High Level Regulatory Cooperation Forum and the European Commission - U.S. Office of Management and Budget dialogue to address methodological issues regarding regulatory impact assessment and risk analysis.”

Achievements of the sector-specific and horizontal dialogues are documented in progress reports by the Transatlantic Economic Council.<sup>55</sup> The profile of the ‘High-Level Regulatory Cooperation Forum’ has been on the rise, as testified also by the fact that Member States have asked for greater participation in the Regulatory Cooperation Forum events.<sup>56</sup> A final development to mention is the increasing intensity in regular informal contacts between the European Commission and the

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<sup>52</sup> EU-US Regulatory Cooperation, Best Cooperative Practices.

<sup>53</sup> The 2007 EU-U.S. Summit Economic Progress Report mentions “deepening the dialogue on good regulatory practices between the U.S. Office of Management and Budget (OMB) and the European Commission”, p. 2.

<sup>54</sup> Joint Statement of the European Commission and the United States following the second meeting of the Transatlantic Economic Council (No. 47/08, May 13, 2008).

<sup>55</sup> Transatlantic Economic Council, Review of Progress under the Framework for Advancing Transatlantic Economic Integration between the United States of America and the European Union.

<sup>56</sup> Group of High Level National Regulatory Expert, Minutes of the meeting, Brussels, 27 June 2006.

U.S. Office of Management and Budget with the aim of sharing experiences and best practices.<sup>57</sup>

### ***Zooming in on impact assessment***

Recently the Forum focused on 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 ‘Review of the application of EU and U.S. regulatory impact assessment guidelines on the analysis of impacts on international trade and investment’ (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”.<sup>58</sup>

In impact assessment we find again the double layer: it is seen as a means to achieve regulatory cooperation but it has also become an object of transatlantic regulatory cooperation itself. This section analyzes what horizontal norms are currently in place or envisaged by the dialogue and it does so for two categories: substantive norms and procedural norms. For each category a lighter and a heavier variant is discussed; the lighter one can often more or less be deducted from the current framework, whereas the heavier versions are more controversial but nonetheless present in the policy discourse.

### ***Substantive horizontal-norms***

#### ***Light: Requirements to assess extra-territorial impacts***

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<sup>57</sup> Allio (2008), *supra* note 3.

<sup>58</sup> Review of the Application of EU and U.S. Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment, Final Report and Conclusions, Prepared by the Office of Management and Budget and the Secretariat General of the European Commission, Brussels/Washington DC, 13 May 2008.

The Review justifies the assessment of trade and investment impacts<sup>59</sup> mainly in terms of national benefits.<sup>60</sup> The part that deals with the European Commission 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.”<sup>61</sup>

The Review also emphasizes the role of the Impact Assessment Board – a recently established 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.”<sup>62</sup>

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.”<sup>63</sup>

However, the Review goes on to state that there is no clear guidance on *how* to consider the international trade and investment effects of US regulation, since the

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<sup>59</sup> 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’ (SIA), is sometimes mentioned. SIA is not going to help because it is limited to trade negotiations only, whereas what we are trying to tackle here are side-effects of regulation on trade.

<sup>60</sup> Review, *supra* n. 58, pp. 14-15.

<sup>61</sup> *Ibid.*, p. 4.

<sup>62</sup> *Ibid.*, p. 6.

<sup>63</sup> *Ibid.*, p. 12.

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”.<sup>64</sup>

So there is some encouragement of 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”.<sup>65</sup> The final version of the Review contained more analysis of the OMB guidance on 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.<sup>66</sup>

One example of a European Commission IA that took trade impacts fully into account is impact assessment accompanying the Proposal for a Directive on the approximation of the laws of the Member States relating to units of measurement.<sup>67</sup> Under the threat of a sunset clause that would end the current exemption for supplementary indications in non-metric measurement units from 2009, the European Commission had to propose a solution: its choices were to either take no action (allowing metric units only), repeal the directive (leaving Member States free to deregulate or adopt international standards, as long as they mutually recognize the standards set by other Member States) or adapt the directive to indefinitely allowing supplementary indications. An important reason to choose the latter option was that the former two would cause high (and difficult to estimate) costs for both EU and non-EU exporters: metric-only would mean that many products would have to be labeled separately and de-regulation would incur “risks of high costs due to permanent confusion in cross-border trade and transactions and high costs due to

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<sup>64</sup> *Ibid.*

<sup>65</sup> *Ibid.*, p. 14.

<sup>66</sup> This flaw was also pointed out by Torriti, Boudier and Lofstedt in their reaction to the draft Review: “[t]he two parts are not balanced because the EC describes how IA guidelines address the trade and investment issue, whereas the OMB presents cases where this issue was dealt with in individual IAs”.

<sup>67</sup> This example is also mentioned in the Review, *supra* n. 58 p. 7.

one-off errors such due to mix-ups in specifications.”<sup>68</sup> The conclusion stated that although the option of indefinitely allowing for non-metric measurement units would generate no benefits, the costs were considerable lower than those involved in the other options. Interestingly, in the tables presenting the disaggregate results of the (rough) cost-benefit analysis, non-EU industry was mentioned as a specific group. However, since the preferred policy option was not arrived at by a monetary comparison of net benefits – a controversial method in the EU context – but by a political judgment that the costs of the other options was simply too high, this does not tell us anything about to what extent the EU is prepared to let impacts on third countries count.

### ***Heavy: A common methodology***

The impression has arisen that the U.S.-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.”<sup>69</sup> The example above illustrates why a shared methodology is quite a different matter from a shared acknowledgement that trade and possibly other extra-territorial impacts should be assessed. ‘Assessing’ is relatively harmless and the potential harmful effect of interfering with trade on the “overall economic welfare in each nation” is easy to acknowledge. How to take these impacts into account when reaching the final decision is the hard question here.<sup>70</sup> 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.”<sup>71</sup>

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<sup>68</sup> SEC(2007) 1136, p. 8.

<sup>69</sup> Ahearn (2008), *supra* note 48, p. 18.

<sup>70</sup> Radaelli, C.M. and A.C.M. Meuwese (forthcoming). “Hard questions, and equally hard solutions? Explaining proceduralisation in impact assessment”, accepted for publication pending minor revisions, West European Politics, forthcoming in 2010.

<sup>71</sup> Review, *supra* n. 58, pp. 14-15.

A real common methodology includes some kind 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 Office of Management and Budget 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.”<sup>72</sup>

Yet, 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, that “should give due weight to the burden anticipated for affected companies”. Furthermore, it puts forward the far-reaching and unrealistic suggestion that “U.S. 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”. The American chamber of commerce to the European Union (AmCham) proposes that “common regulatory methodologies should be created in the long run.” The note contains an accurate analysis of the differences between the EU and the U.S. impact assessment systems:

“European impact assessments appear to be a tool for informing legislators about, and legitimising, the Commission’s choices in formulating legislative proposals. However, in the U.S. – 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.”

However, the conclusion drawn from this analysis 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

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<sup>72</sup> Review, *supra* n. 58, p. 14.

help ensure the comparability of the EU and U.S. impact assessment systems.”

The suggestion that institutional differences can be overcome by convergence on methodology is interesting but worrying. ‘Institutional spill-over’ 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 Consumers Dialogue (TACD) indeed explicitly reproaches the Commission and the OMB to mask institutional engineering under the guise of ‘exchanging good practices on methodology’. In the TACD’s words 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 to the impact on trade and investment relative to other impacts on other factors”.

### ***An alternative: Bringing the international into the consideration of alternatives***

An alternative horizontal norm that has recently been floated in the Better Regulation community, is the principle that international standards should be considered by regulators on a preferential basis. This is another horror scenario for TACD which states:

“International standards cannot be a basis for good policy making so long as the international standardsetting fora are undemocratic institutions that all too often fail to incorporate meaningful consumer participation, are dominated by industry interests, and cannot be held accountable by the public.”

The Review is nuanced and non-committal on this point. The OMB in its reaction to the consultation points out that its Circular A-4’s already requires “that such alternatives be fully analyzed” and that “[a]lthough OMB disagrees with Commenter 8’s characterization of international standard setting organizations, the concern regarding the impact on U.S. citizens if international standards were automatically adopted, is not without merit.”<sup>73</sup> “[A] recommendation that existing international standards or regulatory approaches, if applicable, should be analyzed as an explicit

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<sup>73</sup> Review, *supra* n. 13, p. 29

regulatory alternative” is very carefully mentioned as one of the “possible ways forward”.<sup>74</sup> The real point that proponents of this horizontal norm want to make of course is the *preferential* treatment of international norms, requiring a sound justification from the regulator if it wants to initiate special domestic norms.

An example of a horizontal norm containing the preferential treatment and designed to encourage transnational standards, even at the expense of national sovereignty is a new Canadian provision in the Cabinet Directive on Streamlining Regulation. This Directive came into effect on 1 April 2007 and replaced the 1999 Government of Canada Regulatory Policy. This provision, designed to limit the number of specific Canadian regulatory standards, essentially places a burden of proof on the national regulator if it wants to introduce or even retain domestic regulation. The innovation in these guidelines is that a justification for not using international standards is now required, a principle that goes quite a bit further than just asking regulators to assess impacts on trade and/or third countries.<sup>75</sup>

## ***Procedural horizontal norms***

### ***Light: Data sharing on and for impact assessment***

An issue that has been on the agenda for a few years<sup>76</sup> 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 it expects significant international trade and investment issues. 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 via a “common, publicly available EU-U.S. website or online platform for proposals with transatlantic impacts”. The Transatlantic Business Dialogue concurs: “[i]deally the regulatory co-operation process should be entirely visible on line from the earliest stages of impact assessment and cost benefit analysis.”

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<sup>74</sup> Review, *supra* n. 58, p. 26.

<sup>75</sup> The Directive can be downloaded at <http://www.regulation.gc.ca/directive/directive01-eng.asp>.

<sup>76</sup> AmCham Position Paper on Advancing Transatlantic Economic Integration dated 26 October 2007.

The idea behind sharing IA is that data on costs and benefits of regulatory options can be valuable to others. However, 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. In order for shared data to be useful, in view of the scientific principle of reproducibility applies, *all* data have to be available, down to the micro-level. But the more details will be published, the harder it will be to convince stakeholders – still the primary data source for European Commission IA at least – to disclose them. This explains why the Guidelines can only be vague on this: “[r]egulators may share non-public information to the extent such information may be shared with foreign governments in accordance with applicable rules.”<sup>77</sup> Another reason why 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.

These objections mainly apply to sharing information *ex ante*. Sharing information *ex post* is less problematic. An example of good practice here is the U.S. Department of Transport, regarded as a ‘leader among U.S. departments’ has a lot of regulatory data available from its ‘Regulatory Information’ website.<sup>78</sup> The website contains information ranging from an explanation of the agency's authority to issue legislative rules to a list of the economic values used for analysis. It also allows the user to generate reports listing rulemakings with a certain effects. Among the effects to choose from are ‘privacy’ and ‘economically significant’, but also ‘EU’ and ‘foreign’; selecting the latter produces a list of rulemakings with effects outside the U.S.

### ***Heavy: Mutual access to regulatory processes***

Regulatory cooperation triggers tensions between the role of ‘stakeholder’ and that of ‘government’. The U.S. government has presented itself as a ‘stakeholder’ (a stakeholder in a process is someone who has to win or lose from the outcome of that process) in EU Better Regulation from the beginning. Apart from the horizontal

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<sup>77</sup> Guidelines, *supra* n. 58, p. 3.

<sup>78</sup> <http://regs.dot.gov/index.htm>.

dialogue that is the object of this paper, the U.S. government has been commenting on policy documents, getting involved in concrete IA procedures<sup>79</sup> and organizing training<sup>80</sup> and seminars.<sup>81</sup> The timing of consultation and publication of assessments by the European Commission has long been a major concern for the U.S. Government.<sup>82</sup> In fact, on the part of the U.S. government the Guidelines are apparently seen as a means to address the concern “[t]hat EU regulatory processes still are not always transparent”.<sup>83</sup> Here lies the root of the French fear that an explicit call to ‘improve access to each other’s regulatory procedures’<sup>84</sup> is part of an attempt to foster institutional change by actors who are not constitutionally mandated to initiate that.

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-U.S. 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.”<sup>85</sup> Business stakeholders have

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<sup>79</sup> See the example of REACH below.

<sup>80</sup> The US Mission to the European Union in Brussels also organized a seminar entitled ‘Better Regulation: The EU and the Transatlantic Dialogue’ which brought 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 which focuses on how the United States approaches regulation.

<sup>81</sup> 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.

<sup>82</sup> <http://www.thecre.com/eu-oira/comments.htm>.

<sup>83</sup> Ahearn (2008), *supra* n. 48, p. 10.

<sup>84</sup> Guidelines, *supra* n. 58, p. 1.

<sup>85</sup> Vogel, D. Can it be done? Suggestions for better regulatory cooperation between the US and Europe, Transatlantic Thinkers #7, Bertelsmann Foundation. Downloadable from [http://www.euractiv.com/29/images/TT%20Part%207\\_tcm29-163946.pdf](http://www.euractiv.com/29/images/TT%20Part%207_tcm29-163946.pdf).

also argued that the regulatory process should allow for “some measure of participation by ‘the other side’”.<sup>86</sup>

However, experience has 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 U.S. government via the language and framework of impact assessment. Because of the huge implications for the American chemicals industry – who would have to have their chemicals tested and registered in order to do business in Europe – the REACH proposal stirred up a big transatlantic regulatory clash. Having raising some concerns for the implications of REACH for U.S. businesses at an early stage without finding a listening ear, the U.S. Trade Representative circulated a so-called ‘non-paper’ – meaning that no public body takes direct responsibility for it – in 2002 which argued that REACH raised important concerns regarding compliance with the WTO’s ‘least trade restrictive’ requirement’. The content of this paper was very close to an impact study by the American Chemistry Council. Also the arguments against REACH that were put forward at the highest political level almost literally reiterated the industry concerns.<sup>87</sup> Even the ‘meta’-argument that the Commission’s impact assessment was insufficient was echoed by the U.S. Secretary of State at the time, 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<sup>88</sup>

However, 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 type of joint ‘pre-assessment’ to screen for trade impacts, could easily lead to preliminary negotiations,<sup>89</sup> putting too much political pressure

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<sup>86</sup> German trade and industry association (BDI), reaction to consultation on the Review.

<sup>87</sup> Waxman (2004). "A special interest case study: The Chemical Industry, the Bush Administration, and European Efforts to Regulate Chemicals", in US House of Representatives Committee on Government Reform - Minority Staff Special Investigations Division (ed.) Washington, USA.

<sup>88</sup> Meuwese, A. C. M. (2008). Impact Assessment in EU Lawmaking. The Hague: Kluwer Law International, p. 193.

<sup>89</sup> This point was also made by the TACD in their reaction to the Review.

on the early stages of the policy-making process and possibly trespassing the legal limits set by the European Court of Justice. A more fundamental reason why 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,<sup>90</sup> on the other regulators need to trust their foreign peers not to arrive at the dialogue table with the exclusive aim to represent its domestic stakeholders and voters. What leads a regulator from one country to believe that his peer in another country will cooperate even though this peer is part of a different political and administrative system?<sup>91</sup> Past positive behavior can be one reason, but institutionalization and socialization through regulatory networks is a more pressing one.

### ***Policy implications and concluding remarks***

If regulation is more and more conceived of as a policy area in its own right,<sup>92</sup> as an object of strategic management and as an activity that can be regulated too, the image of regulators as diplomats takes on a different significance. This paper has analyzed 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 Office of Management and Budget. We have taken a step back from the grand theorizing on transnational governance and regulatory networks and looked at EU-U.S. horizontal regulatory cooperation as a concrete manifestation of this.

We have seen that most transatlantic learning to date has taken place in the realm of procedures. The European Institutions have now internalized the practice of consulting stakeholders much more than before and the Minimum Standards on

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<sup>90</sup> Slaughter (2000) *supra* n. 21, p. 522.

<sup>91</sup> Bignami also raises this question and answers it for the regulatory relations between 'old' Member States and Central and Eastern European Regulators. Bignami, F. (2004). The Challenge of Cooperative Regulatory Relations after Enlargement. In: Law and Governance in an Enlarged European Union. G. A. Bermann and K. Pistor. Oxford, Hart Publishing, p. 98.

<sup>92</sup> Radaelli, C. M. (2007). "Whither Better Regulation for the Lisbon Agenda?" *Journal of European Public Policy* 14(2), p. 195.

Consultation have been integrated with the impact assessment framework. On the U.S. side, actors are starting to realize that there is a different way of conducting impact assessment. Also, the development of a common vocabulary and frame of reference has been an important achievement. We can characterize the learning in the EU-U.S. horizontal dialogue as the exchange and promotion of potentially far-reaching horizontal norms, with actors underlining the non-binding nature. However, the 'soft law' status of norms floated in the dialogue can contribute to normative commitments on the part of individual actors, who are more motivated by the desire to be innovative than by legal constraints.

The paper has identified two different faces of the European Commission-OMB horizontal dialogue:

- 1) The learning face: how is 'regulation regulated' on the two sides of the Atlantic and what 'best practices' can be used to improve the quality of domestic regulation?
- 2) The facilitative face: how can sector-specific regulatory cooperation run more smoothly and be put to the service of reducing trade obstacles?

These faces correspond to the two distinct directions in which the transnational horizontal phenomenon can develop: 1) the emergence of transnational dialogues on how to better regulate (domestically) and 2) regulation of the very practice of regulatory cooperation.<sup>93</sup> The analysis has shown that the emphasis has come to be more on the former. In particular, the recent 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.<sup>94</sup>

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<sup>93</sup> This distinction more or less corresponds to what Bermann has called "Regulatory Cooperation as a Direct Rulemaking Strategy: Programmatic Cooperation" (p. 961) and "Regulatory Cooperation as a Means of Addressing Bilateral Trade Conflicts: Problem-Solving" (p. 966) . He also distinguishes "Regulatory Cooperation in Aid of Mutual Assistance in Enforcement" (p. 970), but we will leave this category aside in this paper as it is of less significance in the current context. Bermann (1996), *supra* n. 11.

<sup>94</sup> E.g. Ahearn (2008), *supra* n.48, p. 8: "Until the regulatory structures themselves become more convergent or aligned, the major divergences in regulatory policies are unlikely to disappear".

It is important for policy-makers to underline the limits of the horizontal dialogue and yet to 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 U.S. and the 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 one bridge too far for EU-U.S. regulatory cooperation.<sup>95</sup>

More explicit shared norms for impact assessment specifically,<sup>96</sup> would not be desirable because of a lack of shared underlying principles for regulatory cooperation. Binding transnational agreements on how to use impact assessment would not be legally possible, exactly because Better Regulation is still 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 this is an area in which the EU has wide competences and since 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 on GMOs and REACH, have shown that regulatory convergence, still officially mentioned as a goal,<sup>97</sup> is unattainable. But as the paper has shown there are alternatives along the lines of discussing further what count as *legitimate* differences in regulation and practicing positive comity.

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<sup>95</sup> Meuwese (2008), *supra* n. 88, p. 182.

<sup>96</sup> AmCham, following the US Chamber of Commerce, advocates the concept of a legally binding Agreement on Regulatory Cooperation.

<sup>97</sup> Joint Statement, *supra* n. of the European Commission and the United States following the second meeting of the Transatlantic Economic Council (No. 47/08, May 13, 2008).

Finally, the positive role of conflict ought to be pointed out here. As Braithwaite & Drahos put it “international fora must be constituted in ways that allow for the possibility of contest”.<sup>98</sup> Mutual recognition in substantive areas of regulation means that a framework of general rules is in place within which different regulatory approaches can compete.<sup>99</sup> Perhaps this can be translated to horizontal regulatory cooperation, and the OMB-EC dialogue can work more explicitly towards ‘mutual recognition’ of certain horizontal norms.

One specific mechanism that could contribute to further transatlantic learning and coordination in the area of horizontal regulatory policy is the inclusion of the legislators’ voice in this dialogue is an issue that deserves more attention.<sup>100</sup> In fact, a ‘Transatlantic Legislators’ Dialogue’ (TLD) does exist, as the formal response of the European Parliament and the U.S. Congress to the commitment in the New Transatlantic Agenda (NTA) of 1995, but seems to lead a rather dormant existence.<sup>101</sup> Tapping into the TLD could be a good starting point, but on the European side the Council (where the Member States are represented) would somehow have to be involved; all the more so because horizontal regulatory policy touches on core institutional provisions as well as constitutional values such as sovereignty, economic justice and accountability.

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<sup>98</sup> Braithwaite & Drahos (2000), *supra* n. 6, p. 516.

<sup>99</sup> Majone (2000), *supra* n. 12.

<sup>100</sup> It was also remarked upon by the German trade and industry association BDI in its reaction to the Draft Joint Review where it recommends to involve ‘legislators’ in the dialogue, as opposed to just ‘regulatory experts’.

<sup>101</sup> [http://www.europarl.europa.eu/intcoop/tld/default\\_en.htm](http://www.europarl.europa.eu/intcoop/tld/default_en.htm)

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