Managing risk through enhanced regulatory cooperation between the EU and the U.S.?

Abstract

Newfound recognition that regulatory problems, including risk issues, are of a cross-sector and cross-border nature has led to enhanced transnational dialogues on the most general level of regulatory policy (often labelled 'Better Regulation'). This horizontal regulatory cooperation is the most developed between the EU and the U.S., as exemplified by the recent attempts to achieve convergence on regulatory impact assessment through a horizontal dialogue between the European Commission and the Office of Management and Budget. On both sides of the Atlantic, regulatory impact assessment is an important tool for risk assessment.

Given the considerable differences in 'regulatory philosophies' and institutional contexts, substantive agreement (e.g. methodology and the policy objectives of regulatory analysis) is hard to achieve, making common procedural principles (e.g. early notice of planned regulatory initiatives and transparency) the preferred route. The two global powers mainly seem to 'agree to disagree'. However, the explicit nature of their current dialogue forces them to take an explicit stance on pivotal issues of regulatory management. It also means that what is not being said can contribute to the picture of the current state of transnational regulatory convergence. This paper analyzes the impact of the enhanced horizontal regulatory cooperation on the traditional transatlantic divide on the analytical basis for regulatory standards.

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Introduction

Conflicts between states are more often than not about trade. With explicit barriers to international trade occurring less and less frequently, partly due to WTO involvement, regulatory differences are the next great battleground. The most famous example is the regulatory dispute between the U.S. and the EU on GM foods and crops, and the resulting Biotech dispute at the WTO. Since diverging views on how to regulate best – for instance how to deal with risk - have been an important factor in disputes arising, the importance of regulatory cooperation has grown. More generally, the recognition that 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 has also led to increased transnational regulatory cooperation: regulators are crossing borders to solve with their foreign peers issues that used to fall within the exclusive domain of domestic policy-making. Transnational dialogues about regulatory standards deal with a range of issues such as the rather technical area of food safety but also tabloid material such as the acceptability of non-metric measurements.

Increasing cooperation is not the only transformation contemporary regulatory governance underwent. A more strategic approach to regulation has been the result of the recognition that it has a major impact on economic and social well-being. In analogy to other instruments, such as government spending, tools like performance-based regulatory systems are being set up across the globe. We can also witness a tendency among regulators (used here in the broadest sense of the word to encompass all actors involved in the setting, monitoring and enforcement of regulatory standards) to think more reflexively about regulation and design dedicated policies to help them regulate 'better'. In other words, regulators – actors involved in the setting, monitoring and enforcement of regulatory standards – find that in order to solve today's economic and societal problems they have to cross borders to discuss with their foreign peers regulatory issues which a) no longer exclusively fall within the domain of domestic policy-making and b) often transgress the boundaries of traditional substantive areas of policy and law.

These simultaneous trends have led to a new type of regulatory cooperation: dialogues on the 'meta-level' of regulatory policy, or what we shall call 'transnational horizontal regulatory cooperation'. The term 'transnational' is used here to convey that non-state actors can be included, thus going beyond the

'intergovernmental' or the 'transgovernmental' (Pollack and Shaffer 2001). 'Horizontal' indicates that these dialogues are part of a tendency among regulators to think more reflexively and strategically about regulation and design dedicated policies to help them regulate 'better'. One intra-European example is the informal dialogue between senior civil servants from EU Member States who meet regularly as the 'Directors of Better Regulation'. The transatlantic example that is the subject of this paper is the horizontal dialogue taking place between the European Commission and the Office of Management and Budget (OMB).

There are 'regulatory dialogues' specifically dealing with risk assessment too: the 'Global risk assessment dialogue' and the 'Transatlantic Risk Assessment Dialogue' between the European Commission, the U.S. and Canada. However, since in the European context the normal task division is that the European Commission engages in risk management and leaves risk assessment to the agencies, it is argued here that the 'general' horizontal dialogue on regulation is relevant for risk issues too. Although cooperation on *assessment* is easier to implement and possibly more productive because of its claim to universality (Alemanno 2008) the *management* part is needed to complete the picture of transatlantic cooperation on risk analysis.

This paper analyzes the enhanced horizontal regulatory cooperation against the background of the traditional transatlantic divide on how to go about setting regulatory standards. Judging by the content of the horizontal dialogue, are regulatory styles across the transatlantic converging? The paper also draws on empirical findings from a case study on REACH, the colossal chemicals regulation that the EU enacted in 2006.

The structure of this paper is as follows: first of all the transatlantic differences as to the analytical base for regulation are briefly sketched. Then the development of 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. The third section contains an analysis of the fairly new impact assessment system in the EU, which is explained in relation to the precautionary principle in particular. Then the paper goes on to zoom in on EU-U.S. cooperation on impact assessment and finishes by some concluding remarks.

Horizontal regulatory policy: the transatlantic divide

At least for those dealing with the subject in Europe the horizontalization of regulatory governance is often captured by the label 'Better Regulation', after the general regulatory policy that the European Commission put into place in 2002. The political orientation of better regulation policies in Europe fluctuates (Radaelli and Meuwese 2009). In some cases better regulation amounts to classical deregulation, in other instances it favours reduction of administrative burdens over other considerations, and in yet other manifestations it entails an exercise in open governance (Radaelli 2007; Lynch-Fannon 2009). Much of the better regulation debate is about how to best produce regulation under conditions of uncertainty. Aside from a simplification programme and a plan to reduce administrative burdens by 25% by 2012, the introduction of impact assessment[1]

as a systematic tool for European policy-making was a major component of this horizontal policy.[2]

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, both judicial (review) and non-judicial (hearings, regulatory impact analysis) in nature. The European Commission, in its efforts to facilitate multilateral and bilateral dialogues on regulatory policies and best practices, decided to give particular emphasis to the transatlantic dimension (Allio 2008). The EU's Better Regulation strategy includes a number of cooperative dialogues with other global regulatory powers, but regulatory cooperation with the U.S. is by far the most developed and institutionalized. For more than a decade various steps have been taken, each with a different focus and a different degree of formality.

A lot has been written about differences in 'regulatory philosophies' across the Atlantic (Wiener and Rogers 2002; Lofstedt and Vogel 2001). First of all, the diverging approaches to risk analysis and the application of the precautionary principle in particular are sources of friction between the U.S. and the EU. Although there is increasing evidence that the gap is not as wide as often presumed (Wiener and Rogers 2002) there is still a difference ingrained in the regulatory culture: European regulators are more inclined to act in the face of insecurity, whereas American regulators would only act if there is at least some evidence available. Diagnoses of the underlying causes vary from different degrees of tolerance towards risks, and different emphasizes in what people worry about, to different institutional set-ups. A less obviously visible, but equally important transatlantic difference relates to the use of cost-benefit analysis (CBA). In the U.S. the use of CBA is regulated: in some cases it is mandatory for federal agencies, in some cases restricted and in other cases forbidden. In the EU regulatory context the role of CBA is mostly played down, the official line being that it should be used 'where appropriate' but it should never replaces political decision-making. A final issue to be touched upon in this paper in the light of the enhanced transatlantic dialogue is the degree and style of public participation.[3] Again, the U.S. has many more requirements regarding consultation of stakeholders. Most importantly there tends to be a (judicial) sanction for regulators who fail to consult (properly) while this is usually not the case in the European context.

These three issues – precautionary principle, cost-benefit analysis and consultation – culminate in the new impact assessment system the European Commission has put in place. This latter system has now become the focal point of horizontal regulatory cooperation, as the brief historical overview below will show.

Enhanced horizontal regulatory cooperation

The Transatlantic Declaration of 22 November 1990 already contained an implicit reference to transatlantic regulatory cooperation: 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".[4] In 1994 the so-called Sub-Cabinet Group issued a declaration endorsing U.S.-E.C. bilateral regulatory cooperation (Vogel 1997). 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-U.S. Summit on 3 December 1995 in Madrid, where the idea of a 'New Transatlantic Marketplace' was launched. This would have to be achieved by progressively reducing or eliminating barriers that hinder the flow of goods, services and capital between the EU and the U.S. More specifically, the commitment was to "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 thus 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. Regulatory cooperation was put to the service of the '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.

The 'Guidelines on EU-U.S. regulatory cooperation and transparency' (hereafter: Guidelines) were the next big milestone on the road of horizontal regulatory cooperation. They 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."[5]

Regulators are also encouraged to aid public commentators 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" .[6]

The significance of these Guidelines is hard to assess. 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."[7] 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 Court of Justice. France brought an action under Article 230 EC for annulment of the decision by which the Commission of the European Communities concluded these Guidelines. France had two different legal grounds for opposing the guidelines: a) it contested the competence of the Commission to adopt this decision since the Guidelines amount to a binding international agreement, the conclusion of which falls within the competence of the Council and b) asserted that the Guidelines could undermine the European Commission's exclusive right of initiative in initiating legislative proposals. The Court dismissed both pleas, stating 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". This case is not the only example of France fighting the extension of horizontal regulatory cooperation between the EU and the U.S. before the European Court of Justice (ECJ). In a landmark case from 1994 the French Government contested the legality of the U.S.-E.C. competition law agreement.[8] The Court 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.[9] In terms of EU law, the way to express legitimacy concerns and present them before the court, is to phrase them as competence problems, as the French government did. The French fear that an explicit call to 'improve access to each other's regulatory procedures'[10] will amount to illegitimate influence of one institutional actor over another has in no way been recognized by the Court of Justice in its formalistic approach.

In the next 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 (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" (Ahearn 2008). A more formal

governmental 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.[11] 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).[12] 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 next to 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.[13] One of the main functions of the Forum is to lend senior level support and visibility to the concrete activities of the former.

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 U.S. 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.[14]

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.[15] 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".[16] 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."

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.[17]

The most concrete outcome of dialogue, agreed in the "Framework for advancing Transatlantic Economic Integration, between the European Commission services and the Office of Management and Budget on methodological issues is the joint review of impact assessment guidelines by the Secretariat General of the European Commission and the U.S. Office of Management and Budget. This joint review was meant specifically to highlight how both sides deal with impact on trade and investments in their (regulatory) impact assessments. The review does not include a 'common approach', but is aimed at fostering mutual awareness. Before setting out what concrete 'shared norms' arise out of this most concrete instance of horizontal regulatory cooperation, the section below will focus on some specificities of the European impact assessment system and clarify its relationship with the precautionary principle.

The coming of age of European impact assessment

This section introduces the impact assessment system by the European Commission in 2002 and in part does so by illustrating its interaction with the precautionary principle, as this will probably be more familiar to the current readership. The precautionary principle essentially advocates (regulatory) action that could prevent or minimize possible harm, also in situations in which there is great scientific uncertainty regarding the magnitude or likelihood of that harm. The EU impact assessment is essentially an analytical framework for the

preparation and deliberation of European legislation and as such could steer towards or away from trade-off devices such as the precautionary principle.

Impact assessment in the European Union

Impact assessment provides a format for assessing *ex ante* a range of regulatory activities. The core of IA is to assess the environmental, social and/or economic impacts of proposed regulatory interventions various societal groups. It is important to stress that although cost-benefit analysis (CBA) is an important component of many types of IA, IA does not equal CBA. CBA is a method for decision-making; impact assessment is a highly structured process of policy formulation which shows the methods adopted to assess different options and the test used for comparing them (which could be a net-benefit test, but not necessarily so) and possibly reaching a decision, who was consulted and what type of evidence was collected.

Another common misunderstanding is that 'an IA' is a document. However, IA is first and foremost a process that forces or encourages decision-makers to follow certain analytical steps. True, an IA document which documents the process and its findings is a crucial element which guarantees the transparency of the process. The absence of such a comprehensive, public, IA report has even led experts to question whether certain national ex ante assessment frameworks the label 'impact assessment' (Jacob et al., 2008). But the opposite situation: a tangible IA report which contains nothing more than a checklist or which only pays lip-service to an otherwise highly politicized process is worse on all accounts. In the strongest, and some would argue 'original' type of IA, we often find a legal requirement that only regulation which passes a cost-benefit test can be enacted. This means that maximization of net benefits decision criterion has been laid down in a statutory provision beforehand. Often, this type of strong IA is meant to compensate for the delegation of regulatory power and to exercise a control function over, for example, US federal agencies. The type of impact assessment that the European Commission put in place differs markedly from this.

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 monetization of benefits. 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. (Cecot et al. 2008). 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 large a flood of IAs.

Impact assessment vs. the precautionary principle?

Löfstedt has argued that impact assessment has overtaken the precautionary principle as the main tool for regulatory analysis in Europe (Löfstedt 2004).

Others have played down this assertion (Wiener 2006, Meuwese 2008). Since there is not one precautionary principle in Europe, but rather many variations of it, operationalized in many different ways and legal contexts (Fisher 2007), it is difficult to pin down its significance in terms of regulatory outcomes. It is illustrative that opinions can vary significantly as to what extent certain legislative proposals are 'precautionary'. This is the case for instance with the European REACH regulation which deals with the registration of chemicals: whereas some find the very fact that chemicals which are potentially dangerous have to be registered evidence of a precautionary approach (Eckley and Selin 2004), others require even more action because the system does not ensure that all substances that pose a risk are caught (Hey et al. 2006). One finding by De Sadeleer is that the European legislator has been applying the precautionary principle more widely in the area of health protection than in the area of environmental law and policy (De Sadeleer 2006). Now, does the introduction of a fully-fledged impact assessment in Europe mean that the precautionary principle gets an 'institutional vehicle' and thus will have more effect on actual policy-making or has it simply been replaced?

The differences between the two "regulatory philosophies" (as implemented in the EU) are in fact not so great. Both tools are used in the EU context as attempts to objectify 'common sense' rather than as strict 'decision generators'. The similarity with IA becomes clear where the Communication on the Precautionary Principle clarifies the requirement that precautionary measures must be "based on an examination of the potential benefits and costs".[18] Wiener views this as a redefinition of the precautionary principle by the Commission and seems to see a link with the introduction of IA, but it should be noted that the 2000 Communication predates the Action Plan on Better Regulation.(Wiener 2006)

> "Examination of the pros and cons cannot be reduced to an economic cost-benefit analysis. It is wider in scope and includes non-economic considerations. However, examination of the pros and cons should include an economic cost-benefit analysis where this is appropriate and possible."[19]

This wording is by no means in contradiction with the IA framework.[20] On the contrary, the language is reminiscent of the only very light steer in the direction of cost-benefit analysis in the Impact Assessment Guidelines. The Guidelines for their part merely invoke and summarize the Communication in an Annex, without adding concrete clues as to how to combine IA and policy-making on the basis of the precautionary principle.[21] The Communication is also keen to anticipate the fears of opponents of the precautionary principles by stressing that "the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions".[22]

So if the key is that the principle should only be invoked after every attempt has been made to gather evidence is the link between the two tools that IA triggers the precautionary principle? In that model, the precautionary principle would enter the scene if an IA has shown that the evidence available is inconclusive or insufficient. That way the two would work together to achieve the optimally "structured decision making process with detailed scientific and other objective information".[23]

However, not all tension between the two can be neutralized completely by the flexibility of the respective frameworks. Whereas on the level of providing a structure for lawmaking, IA and the precautionary principle can be complementary, two problems remain:

1) It may be just more convenient to resort to precautionary measures rather than going through the effort of trying to collect more scientific data, especially when these measures are likely to be quite popular with European citizens. This concern is also present in the Report on 'Evaluation and Transparency' by one of the Governance Working Groups, which – as part of a plea that impact assessment should ask the right questions at the right time – states that "the precautionary principle, as necessary and as modern as it may seem, should not preclude serious risk assessment balancing all costs and benefits of new legislation".[24] Therefore the issue of the need to provide institutional incentives to carry out serious impact assessments remains.

2) At the level of implementing measures the precautionary principle – on one interpretation – can steer clearly in one substantive direction (namely giving the burden of proof to the industry), a direction that is not necessarily in line with better regulation and the IA framework. Of course this observation critically depends on a certain – more political – conception of better regulation, but one that is hard to deny. This is the tension that played out in the REACH case, as mentioned above.

Common norms for impact assessment?

Instigated by the OECD, the idea came in vogue that political systems with different institutional set-ups still have common objectives and that these are translatable to a set of good practices in regulatory policy-making. A few years down the line, attention for the specific institutional restraints returned in literature on Better Regulation (Jacob et al. 2008). In the policy world, the constant tension between adapting to the specific domestic circumstances and complying with the global standard for good regulation is acknowledged, but pressure to strive for the latter is rising.[25]

Some have detected a wave of convergence in U.S. and European regulatory approaches (Wiener 2003; Lofstedt and Vogel 2001). Impact assessment provides a useful lense for capturing the remaining differences. Although impact assessment is increasingly regarded as a global standard (Jacobs 2006), it is commonly acknowledged that the U.S. system of 'regulatory impact analysis' (RIA) and the EU counterpart 'impact assessment' (IA) still 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 (European Policy Centre 2005).

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 (Wiener 2006). 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 (Wiener 2006) because cheap norms in terms of measurable burdens are often vague norms, which in turn tend to be more precautionary.

Since the ex ante analysis of regulatory impacts is often seen as the most tangible element of a general regulatory policy and the one tool that is capable of improving the regulatory environment, it should come as no surprise that the efforts towards regulatory cooperation focus on this topic (Office of Management and Budget and the Secretariat General of the European Commission 2007). Below, the main issues on which the parties are explicitly trying to achieve convergence – or in some cases at least mutual understanding – are discussed.

Requirements to assess extra-territorial impacts[26]

Both systems include encouragements, if not obligations, to assess extra-territorial impacts in as far as they affect trade and investment. Interestingly the Review justifies the assessment of trade and investment impacts[27] mainly in terms of national benefits (Office of Management and Budget and the Secretariat General of the European Commission 2007). The review of the European Commission Guidelines concludes that they require that "all impacts be assessed, regardless of where they are likely to materialize 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" (p. 4). 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, by checking that European impact assessments contain adequate references to regulatory dialogues with third countries" (p. 6). On the U.S. side, the Review reiterates that the OMB Circular A-4 on Regulatory Analysis contains guidance stipulating that new U.S. rules that could act as non-tariff barriers to imported goods should be evaluated carefully.

However, the Review goes on to state that there is no clear guidance on *how* to consider the international trade and investment effects of U.S. 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" (p. 12).

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" (p. 14). 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 a reluctance on the part of the OMB to commit to changes in its Guidelines.[28]

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.[29] 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 labelled 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 one-off errors such due to mix-ups in specifications."[30] 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 (still a problematic method in the EU context, see above), 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 'foreigners' count as heavily as impacts on 'citizens' (Meuwese 2009).

Data sharing on and for impact assessment

An issue that has been on the agenda for a few years[31] 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."

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."[32] 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.[33] 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 effect produces a list of rulemakings with effects outside the U.S.

Torriti & Lofstedt mention some examples European impact assessments using U.S. regulatory data. For instance, the EU IA on Sustainable Use of Pesticides built on a previous study on epidemiological health risks of pesticides by the U.S. Environment Protection Agency (EPA), the EU IA on the liberalization of energy markets includes, a case study on the American experience with Information System Operators and the IA for a regulation concerning the use of biometrics for visa systems makes use of the U.S. figures on the costs of installing biometric mechanisms (Torriti and Löfstedt 2008).

Mutual access to regulatory processes

The idea that 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) has been fully embraced in the EU-U.S. horizontal dialogue. But these potential mechanisms can be put on a spectrum that goes from 'informing' to 'co-decision-making'. Currently, the EU treats the U.S. government officially as a regular stakeholder' and all the encouragements to engage in an early stage with transatlantic peers are phrased as belonging in the sphere of friendly cooperation. Business stakeholders have also argued that the regulatory process should allow for "some measure of participation by 'the other side'".[34] However, experience has shown that participation by the U.S. government in policy-processes can lead to confusion as to the nature of the authority exercised, especially when impact assessment is used as the means. In the decision-making process that led to the adoption of the major chemicals regulation REACH by the EU, the U.S. government engaged with the IA process as an alternative to the (struggling) formal regulatory cooperation (Meuwese 2008). The main concern of the U.S. Government has always been the timing of consultation and publication of

assessments by the European Commission. This is for instance apparent in its comments on the European Commission's Better Regulation Package.[35]

Lack of norms here seems a risk, since we are dealing with a very special type of stakeholder. However, creating some form of special forum of participation for the transatlantic partner, is not without risks either. Once again, the reason why increasing the mutual access to regulatory processes is potentially far-reaching, is nicely expressed by the TACD, claiming that the Review

> "[s]eems to envisage a preliminary analysis or preassessment of the impact on trade and investment, and even preliminary negotiations between EU and U.S., before proceeding to a full impact assessment of all relevant factors."

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 dialogue that is the object of this paper, the U.S. government has been commenting on policy documents, getting involved in training[36] and seminars,[37] but also in concrete IA procedures. 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. After some early concern for the implications of REACH for U.S. businesses, 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 (Waxman 2004). 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 (Meuwese 2008).

What is the legitimate attitude of participating actors when it comes to their constitutional roles? On the one hand it is considered not legitimate that they are not accountable to their domestic constituencies (Slaughter 2000), 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. Who should the participating governments be assumed to be representing and does this matter? This is a matter of trust that is needed anyhow for regulatory cooperation. 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? [38] Past positive behaviour can be one reason, but

institutionalization and socialization through regulatory networks is a more pressing one.

A common methodology?

The impression had 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" (Ahearn 2008). This paper illustrates why a shared methodology is quite a different matter from – for instance - 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 (Radaelli & Meuwese 2009a). 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."[39]

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."[40]

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 and/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 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 decided to seek judicial recourse (without success, see above). The Transatlantic Consumers Dialogue (TACD) indeed explicitly reproaches the Commission and the OMB to mask grand politico-constitutional 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".

More commitment to shared norms, let alone 'hard law',[41] would not be desirable because of a lack of shared underlying principles for regulatory cooperation nor would they be legally possible. Binding rules on regulatory cooperation will be much more difficult to adopt than rules on competition cooperation (an area in which the EU has wide competences anyway) as general regulatory policy touches core institutional provision as well as constitutional values. When trying to cooperate and converge on an issue as fundamental as standard-setting, the question whether the constitutional and legal systems of the U.S. can be compared to the EU, and if so at what level, suddenly acquires a much greater relevance than just an academic one. Questions that Bermann asked about transatlantic regulatory cooperation in 1996 are still relevant here: "do U.S. agencies and EC Commission divisions bring comparable political authority to the dialogue?" and "how do differing attitudes toward transparency affect conduct of the U.S.-EC regulatory dialogue?" (Bermann 1996).

Conclusion

Across nations, regulation is more and more conceived of as a policy area in its own right (Radaelli 2007), as an object of strategic management and as an activity that can be regulated too. This paper has analyzed one of the concrete manifestations of this trend: the recent attempts to achieve convergence on norms for regulatory impact assessment through the enhanced dialogue between the European Commission and the Office of Management and Budget.

There has been a gradual shift in the overall aim of transatlantic cooperation: whereas before convergence (by means of harmonization or mutual recognition) was often aimed for, the more recent emphasis has come to be on promoting mutual understanding of different regulatory regimes and approaches. But this shift has brought about new questions and the need for a common frame of

reference. The OMB-European Commission dialogue on impact assessment can be seen as an attempt to build this common frame of reference.

One problematic aspect of this process is that at times impact assessment seems to mean 'all things to all men' in the EU policy-making process (Meuwese 2008). In fact, as we have seen above, the European system for impact assessment is kept malleable on purpose. Better regulation did however help forge a change in regulatory habits to Europe in the sense that it has now become more normal to 'regulate only after reflection', as then British Prime Minister Tony Blair once put it (Wiener 2006).

Concrete shared norms for standard-setting, certainly substantive ones, are one bridge too far for EU-U.S. regulatory cooperation. Although risk issues have traditionally been the heart of many transatlantic regulatory disputes, this new, horizontal type of dialogue does not directly discuss the issue of how to assess and manage risks. As the REACH example has illustrated, the conflict takes place in the sectoral dialogues. The horizontal dialogue could have a role in managing that conflict by debating its premises. However, the current strategy - countering the 'negotiation mode' of sectoral dialogues by glossing over fundamental differences by presenting regulatory policy as a set of best practices that can be transplanted – is a high-risk one. Because the European impact assessment system is as malleable as the American one is regulated, even simple forms of cooperation such as the exchange of information can have unintended side-effects.

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Endnotes

1 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.

2 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.

3 As a mild illustration: 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". See Ahearn, R. J. (2008). "Transatlantic Regulatory Cooperation: Background and Analysis (CRS Report for Congress)", Washington D.C. Ahearn 2008 Ahearn, R. J. (2008). "Transatlantic Regulatory Cooperation: Background and Analysis (CRS Report for Congress)", Washington D.C.

4 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

5 Guidelines for EU-U.S. regulatory cooperation and transparency (2002), p. 4.

6 Guidelines, supra n. 19, p. 6.

7 DG Enterprise and Industry, International Affairs website, http://ec.europa.eu/enterprise/international_relations/cooperating_governments/usa/usa_reg_en.htm.

8 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.

9 Case C-327/91, France v. Commission, [1994] ECR. I-3641. See also Bermann (1996), supra n. 8, p. 960.

10 Guidelines, supra n. 19, p. 1.

11 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.

12 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.

13 Joint Report on the Roadmap for EU-US Regulatory Cooperation, June 2006.

14 EU-US Regulatory Cooperation, Best Cooperative Practices.

15 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.

16 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).

17 Group of High Level National Regulatory Expert, Minutes of the meeting, Brussels, 27 June 2006.

18 European Commission (2000). "Communication from the Commission on the precautionary principle", Brussels.

19 Ibid.

20 It is also in line with the Court of First Instance's decision in the Pfizer case (Case T-13/99 Pfizer Animal Health v Council [2002] ECR II-3305) which stipulated that some economic assessments is required, the Institutions still have a rather large degree of discretion in carrying out theses assessments. See also De Sadeleer, N. (2006). The Precautionary Principle in EC Health and Environmental Law. European Law Journal, 12:2, 139-172.

21 European Commission (2005). "Annexes to Impact Assessment Guidelines", Brussels. Annex 15.

22 European Commission (2000). "Communication from the Commission on the precautionary principle", Brussels.

23 Ibid.

24 European Commission (2001). "Report on 'Evaluation and Transparency'", in Working Group 2b (ed.) Brussels.

25 The side-comment offered by the US Government in its Comments on the European Commission's Better Regulation Package is typical in this respect: "We recognize of course that practices that have worked well in the U.S. are not necessarily appropriate in the EU context and vice versa. However, the comments below are generally consistent with previous reports by international bodies on regulatory governance prepared by the OECD and other organizations."

26 The following four sub-sections are from my paper 'EU-US Horizontal Regulatory Cooperation: Two global regulatory powers converging on how to assess regulatory impacts?', Workshop – Managing Biosafety and Biodiversity in a Global World – EU, US, California and Comparative Perspectives (special focus on Biodiversity), 15-16 January 2009, Leuven, see also Acknowledgements.

27 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.

28 This flaw was also pointed out by Torriti, Bouder 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".

29 This example is also mentioned in the Review, supra n. 13 p. 7.

30 SEC(2007) 1136, p. 8.

31 AmCham Position Paper on Advancing Transatlantic Economic Integration dated 26 October 2007.

32 Guidelines, supra n. 19, p. 3.

33 http://regs.dot.gov/index.htm.

34 German trade and industry association (BDI), reaction to consultation on the Review.

35 http://www.thecre.com/eu-oira/comments.htm.

36 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.

37 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-organised with Brussels-based think tanks.

38 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.

39 Review, supra n. 13, pp. 14-15.

40 Review, supra n. 13, p. 14.

41 AmCham, following the US Chamber of Commerce, advocates the concept of a legally binding Agreement on Regulatory Cooperation.