To compete or to cooperate? This is an Impact Assessment question

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**Introduction**

There is a fine line between regulatory competition and cooperation across the Atlantic. Whilst U.S. and European Union (EU) increasingly collaborate on a range of specific regulatory areas in an effort to remove tariff barriers and thus facilitate trade flows of about 620 billion Euros per year, they also compete in order to improve their internal markets, attract a higher number of investors, increase safety for their citizens and maintaining acceptable environmental standards (Vogel, 2001). When measuring the temperature of regulatory competition and cooperation between U.S. and the EU, a valid reading key is Impact Assessment (IA) (Löfstedt, et al, 2008). IAs are the main evidence-based policy-making instrument in place in both U.S. and EU and can help understand the rationales and justifications for policy and regulatory interventions.

There are various reasons why U.S. and EU should will to cooperate on IA. They rest on the benefits associated with common rules for trade; transparency for improving regulatory decisions; sharing burdens in the fight climate change; prevention of trade conflict; strategic partnership against regions. In this vein, a Forum for Regulatory Cooperation takes place twice a year and gathers together senior officials from both the U.S. Office of Management and Budget (OMB) and the European Commission (EC). Recently, the OMB and EC also produced a joint report to improve cooperation on trade and sustainability issues in IAs.

IA could also be used as an instrument for international regulatory competition, because of the need to attracting investors, as well as fostering the internal market especially in time of low economic growth. Both the EU (EC, 2005) and the U.S. Governments (OMB, 2007) have stated their ambition of improving economic methods for respectively enhancing and maintaining their regulatory competitive

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position. Cost-Benefit Analysis plays a pivotal role in determining the analytical effort made by governments in order to have policy outputs based on the costs and benefits estimates. Within Cost-Benefit Analysis decisions on whether to monetize health benefits or not mark the difference between the two continents.

The two conflicting approaches –competition versus cooperation- will be examined in this chapter, which aims to provide a framework for analysing the level of regulatory cooperation and competition through an analysis of the existing IA systems in the two continents.

This chapter commences by introducing the IA system in the European Union and the U.S. Regulatory Impact Analysis (RIA) system. It describes in parallel how IA and RIA systems were established, their main features and their respective developments and practices (section 2). It considers reasons in favour of the cooperative perspective. It examines the need for cooperation; the transatlantic forum for regulatory cooperation; the joint EU-U.S. report on IA for trade (section 3). It explores reasons for regulatory competition through reasons underpinning competition; different approaches on Cost-Benefit Analysis and evidence from individual IA reports (section 4).

2 Impact Assessment systems in EU and U.S.

2.1 The EU Impact Assessment system
2.1.1 The establishment of Impact Assessment in the European Union
The EU integrated IA system commenced in 2003. It is characterised by a broad focus on ‘major initiatives’, as opposed to regulations only, hence the choice of an integrated Impact Assessment (IA) system and not just Regulatory Impact Analysis (RIA) (Allio, 2007).

European national models of RIA which pre-date the EU one, namely UK, Finland and Sweden may indeed have had an influence on the EC, at least in the creation of the first EU guidelines and in the integrated approach which combines elements of health impact assessments, environmental impact assessments, social impact assessments and Cost-Benefit analysis. The integration of social and environmental
impact assessments is connected to the Sustainable Impact Assessment instrument, which has been explored in a body of literature focusing specifically on trade legislation (George and Kirkpatrick, 2004).

2.1.2 Impact Assessment in the European Union: main features
The EU IA procedure is based on two stages: roadmaps (EC, 2005) and IAs. Roadmaps are carried out on all legislative and non-legislative proposals and are published together with the Commission’s Legislative and Work Programme. The aim of roadmaps is to inform on the planned proposal; the policy options; likely impacts; the consultation to be undertaken; and its timing (Meuwese, 2008).

Its extended version, i.e. IA, is intended to be ‘a more in-depth analysis of the potential impacts on the economy, on society and on the environment’ (EC, 2005). The decision on the depth of the analysis required is left to the Directorate General officially entrusted with the preparation of the proposal, according to a principle of proportionality. It has been noted that the proportionality principle lacks concrete criteria (Nielsen et al, 2006).

The Directorate General responsible for leading the policy is also accountable for designing the process and carrying out the IA report. After adoption by the European Commission, the IA has to be sent along with the proposal to the European Council and the European Parliament. Hence, IA accompanies the proposal throughout the legislative process. Both the European Parliament and Council may amend an IA. However, it has been observed that due to the lower levels of expertise in these institutions, there are only few occasions where substantial amendments take place. As a consequence, when the proposal becomes law, the IA is usually still the same as at the time of the draft proposal, and may not reflect the changes that society and the market might have experienced in the intervening period.

2.1.3 Impact Assessment: development and practice
In principle, all EU IAs address the three pillars of economics, the environment and social issues. In practice, they use different methodologies deriving from Cost-Benefit Analysis to Sustainability Impact Assessment. As a result, their analytical weight and length of the reports differ considerably.
The quality of the more than 200 hundred IAs produced between 2003 and 2007 (see Figure 1) has varied significantly.

At the research level, it has been highlighted that the performance of IAs in most cases did not fulfil the expectations (Löfstedt, 2007). A number of evaluative studies, based on various scorecards, content and function tests, underline that existing EU IAs do not sufficiently quantify the benefits and costs of future legislation (Torriti, 2007); do not include sustainable development issues (Kirkpatrick and Franz, 2006; Opoku and Jordan, 2004; IEEP, 2004); and do not take into consideration a sufficiently wide range of policy alternatives (Renda, 2006).

At the institutional level, the acknowledged disputable quality of IAs (EP, 2007) has been taken care of by a sort of oversight unit the Impact Assessment Board (Alemanno, 2008). This Board is composed of five senior officials of European Commission. It might be seen as a step for closing the EU gap in having an oversight unit. However, unlike its U.S. counterpart -i.e. OIRA, as described in the next section-the EU Impact Assessment Board is not awarded any *veto* powers.
The EU IA system has been, in different ways compared with the U.S. Regulatory Impact Analysis (RIA) model (Renda, 2006; Wiener, 2006; Radaelli, 2003; Löfstedt, 2004). RIA was first established in the U.S. in 1981, by President Reagan’s executive order 12291. One of the first consequences was that major regulations (over $100 million annual impact) had to be accompanied by RIA. Originally the U.S. RIA was introduced in order to promote economic efficiency and therefore economic growth; to regulate only when the market fails; and to regulate by using cost-effective and market-based approaches. The Office of Information and Regulatory Affairs within the Office of Management and Budget was created with the aim of evaluating federal agencies, with the mandate to suspend regulatory proposals when the accompanying cost-benefit analysis was deemed inadequate.

The original RIA programme was criticised for being too secretive and closed to outsiders (Morral, 2001). Since its creation, the U.S. RIA has undergone some alterations. President Clinton, for instance, revised the system slightly by streamlining it and increasing the public consultation and transparency requirements.

Unlike EU IAs, RIA accompanies regulatory proposals only. The RIA procedure in the U.S. consists essentially of two stages. The federal agency drafts a preliminary RIA on the regulatory proposal (first stage). This preliminary RIA contains (i) a comparison of different regulatory alternatives, including the status quo option; (ii) a rough estimation of benefits and costs associated with each regulatory alternative and (iii) an indication of the relevance of the impact of the proposed regulation. Depending on the latter point, it will be decided whether an extensive RIA is necessary. After two months of consultation, the final RIA is completed and accompanies the final regulatory proposal for approval (stage two). OIRA has three months to approve or reject the regulatory proposal on the basis of the quality of cost-benefit analysis carried out by the agency.
OIRA can reject regulatory proposals until they are provided with an adequate cost-benefit analysis. The number of regulations withdrawn by OIRA has significantly increased under George W. Bush’s presidency as it is illustrated in Figure 2. Under Clinton’s presidency the number of annual withdrawn proposals on average was the lowest of the last three administrations.

Figure 2-Number of regulatory proposals returned or withdrawn by OIRA on average, per year

2.2.3 U.S. Regulatory Impact Analysis: development and practice

The OMB yearly Report to Congress on the Costs and Benefits of Federal Regulations consists of a yearly calculation of total costs and benefits of regulatory proposals.

To date the OMB has evaluated more than 1,000 Regulatory Impact Analyses. Obviously the results vary according to many factors and are difficult to interpret univocally. Where data are missing in general the OMB has criticized the lack of quantitative and monetary evaluations in most of federal agencies’ RIAs. Where data are available in no year costs were significantly greater than benefits, even though benefits are likely understated because agencies estimate costs but not benefits for some of the rules reviewed by OMB over this time period. Figure 3 shows the benefits
and costs of federal regulations (OMB, 2007). This means that the annualized benefits of major U.S. federal regulations between 1996 and 2006 significantly outweigh the costs, with benefits ranging from $99 billion to $484 billion (in 2001 dollars) and costs ranging from $40 billion to $46 billion.

Figure 3- Benefits and Costs of Federal regulations between 1992 and 2006 in billion dollars (OMB, 2007)

Non-institutional evaluations of U.S. RIAs and Cost-Benefit Analyses accompanying regulatory proposals also highlight interesting features. A study by Hahn and Litan (2000) on 48 proposed regulations subject to RIA between 1996 and 1999 showed that only in one third of the cases agencies had quantified costs and benefits of proposed regulations and calculated the net present value of the regulatory intervention. Another study by Hahn and Dudley (2004) examined 55 RIAs and pointed out similar problems. Some analysts also used econometric methods on a database, first developed by the OMB (Morrall, 1986) on health and safety regulations. Farrow (2001), for instance, has used multivariate regression methods to examine a database of 69 regulations proposed by several U.S. agencies and reviewed by the OMB, of which seven were rejected (i.e., sent back to the agency for further consideration).
2.4 Comparison: similarities and differences
Comparative analyses between the U.S. and both EU institutions (Hahn and Litan, 2005 and Renda, 2006) and Member States (Radaelli, 2001) have highlighted procedural similarities and differences. Certain of these features are related to different approaches to risk regulation (Löfstedt and Vogel, 2001; Wiener and Rogers, 2002) and also different regulatory areas (Vogel 2001). What these valid contributions have not looked at is ways in which IAs can explain reasons for regulatory cooperation and competition across the Atlantic. The remainder of the chapter will address this elusive and yet crucial issue by first exploring reasons for regulatory cooperation and then reasons for competition.

3 Cooperative perspective: the institutional endeavour for cooperation
Reasons for cooperation in the IA area rest on both institutional and academic motivations. First, it will be explained why there is a need to increase the cooperation between EU and U.S. on regulatory affairs and how IAs might function as a tool to increase cooperation across the Atlantic. Second, it will be described how this cooperation is taking place at the institutional level, within the framework of the forum for regulatory cooperation and the joint report on EU-U.S. IA guidelines.

3.1 Need for cooperation
The first reason why EU and U.S. need cooperation on regulatory affairs is that trade benefits from cooperation. The EU-U.S. trading partnership is the largest bilateral trade and investment relationship in the world. Trade flows across the Atlantic run at around € 620 billion per year. In addition, 14 million jobs depend on these bilateral investment flows, making up to 57% of world GDP. Close to a quarter of all EU-U.S. trade consists of transactions within firms based on their investments on either side of the Atlantic. Hence, the two economies are highly interdependent and seek to maximise the advantages of the existing trading partnership. In order to improve trade between macro regions such as EU and U.S. a shared set of rules is vital. This might result difficult due to many reasons: a number of monetary and labour market issues may work against a fully shared set of rules across the ocean. However, where having the same rules is impossible, EU and U.S. will aim to share the same approach to making those rules. If they share the same method (e.g. IA) for assessing regulations, it does not mean that they necessarily share the same rules, but at least the same
approach for making rules. A common approach for rule-making is a key starting point for consolidating trade in sectors where it is already taking place and setting up the conditions for commerce in new sectors. Moreover, a shared method for rule-making facilitates communication with mutual stakeholders.

The second reason is that the exchange of data is vital for improving regulatory decisions. The core of an IA consists of data estimates on costs, benefits and risks (Torriti, 2007). These are analysed and weighed taking into account economic, social and environmental impacts (EC, 2005). Optimal regulatory choices are made when policy-makers – be either the European Commission or any federal agency- have precise information about exactly what will occur under any choice made. Alternatively, policy-makers may have a reliable probability describing what will happen under any choice made. This means that the analysis of impacts by the European Commission and U.S. agencies can pursue optimal decisions only if precise information is available about what exactly will occur, in terms of costs, benefits and risks, as a consequence of any policy alternative. The exchange of information across the Atlantic improves the awareness of data available for regulatory decisions. There is a wealth of examples especially of EU IAs using U.S. data and case studies. The IA on Sustainable Use of Pesticides produced by the European Commission relied on previous EPA studies to understand the epidemiological health risks of pesticides (BiPRO, 2004). In the IA on the liberalisation of energy markets (so-called “Third Package”), a case study is based on the U.S. experience with Information System Operators (EC, 2007). The IA for a regulation concerning the use of biometrics for Visa systems is based on the U.S. costs of installing biometric mechanisms (EC, 2004). If both sides of the Atlantic produce IAs of high technical standards, regulators and policy-makers are to benefit enormously.

The third reason is the need for harmonized regulation to fight climate change. The need for cooperative action to address climate change has been stated in several policy documents (e.g. UNFCCC, 2008). On the one hand, the need to measure, report and verify initiatives aimed at reducing climate change may arguably find an adequate analytical location in IA reports, where individual regulatory proposals are weighed according to the expected changes to levels of CO2 emissions. This occurs, for instance, in the template for IA established in 2007 by the UK Government. On
the other hand the regulatory cooperation across the major bilateral economic partnership (EU-U.S.) is crucial to any hope of planning and implementation of reduction targets on a global scale. For example, the Italian Economy Minister argued that an effective tax on profits by oil companies could only prove effective if proposed by both sides of the Atlantic.‡

The fourth reason is the prevention of trade conflicts. Regulatory cooperation has proven an effective means to avert potential trade conflicts, as different standards and regulations are the main obstacles to trade between the U.S. and the EU today. Hence regulatory cooperation is aimed at minimising the negative economic impacts of trade disputes due to diverging regulation. In fact, several trade-related disputes which regularly hit the headlines impact around 2% of EU-U.S. trade.

The fifth reason is strategic partnership before the economic threat posed by other regions. IAs could also be seen as a way for preserving competitive advantage against other economies. China and India, for instance, not only are capable of producing and exporting goods to the rest of the world, they have seen their economies expanding at a rate at times up to ten times higher than some EU countries over the last ten years. In order to consolidate the western trade partnership, as well as strengthening the opportunities represented by ever-growing Asian buyers, cooperation becomes crucial. In the past, risk assessments helped the European and North American regulators to keep out of the western markets specific items made in Asia. For example, the European thresholds for content of chemical substances such as Bisphenol A and toxins in toys represent a threat of ban for a wide range of Chinese products, ranging from toys to toothpaste. However, decisions about acceptable levels of risk are not taken by scientists only. The risk management part of an IA will play a key role in deciding how certain substance will be banned or heavily regulated. IAs could also be seen as a systematic way for preserving competitive advantage against other economies.

3.2 Forum for regulatory cooperation
A so-called 'High-Level Forum for Regulatory Cooperation' takes place twice a year and gathers together senior officials from both the U.S. OMB and the European

‡ http://www.eubusiness.com/news-eu/1211995022.01
Commission. The Forum aims to help avoid unnecessary divergences in the way the EU and U.S. regulate.

The forum’s deliberations provide input to the Transatlantic Economic Council, which gathers in Washington or Brussels once a year. The last meeting held on 18th May 2008 focused on strengthening transatlantic cooperation on the safety of imported products. Business and consumer representatives are also involved in the discussion on how the EU and the U.S. consult the public when developing regulation.

Allegedly, given the supremacy of U.S. Government in implementing a number of economic instruments for regulatory economics (Hahn and Titlock, 2008), the Forum may prove an arena for fostering the use of Cost-Benefit Analysis in Europe. Wiener (2006) notes that the EU borrowed not only the notions of Impact Assessment and 'better regulation' from the North American legal system, but has also taken on board the idea that institutional features are influenced by inter-institutional dialogues.


Recently, the European Commission and OMB carried out a joint report to improve cooperation on trade and sustainability issues in IAs. The review does not introduce a transatlantic integrated approach for the future, but rather presents separately what work the Office of Management and Budget and the European Commission are doing in terms of IAs on trade and investment. In addition, the two parts are not balanced because the European Commission describes how IA guidelines address the trade and investment issue, whereas the OMB presents cases where this issue was dealt within individual IAs. The EU section provides a rather generous self-evaluation of the consultation process. For instance, the joint report states that the EC “has adopted strict minimum standards” on stakeholder consultation. Minimum standards are by definition not strict, compared for instance with consultation codes. The EU consultation regime is less stringent than in Member States and has been criticized for not allowing enough time -8 weeks compared to 12 weeks in the UK- and for its lack of transparency (Löfstedt, 2007; Torriti, 2007).
The joint report foresees a crucial role by the recently established EU Impact Assessment Board in improving the quality of the analyses. However, it is not clear how the EU Impact Assessment Board actually increases the focus of IAs on trade and investment. No examples are made to strengthen the concept that the Board improves the analysis of international impacts within specific IAs. Yet, the comments of the Board are normally made available and published.

The confidence showed in the review by the European Commission regarding the suitability of the IA system for addressing international trade and investment issues is not shared by academic studies. A study by Opoku and Jordan (2005) finds that the IA procedure does not function as an effective instrument for the implementation of the Union’s commitment to promoting sustainability in non-European countries. For instance, they believe that IA on the Reform of the Tobacco Regime, also mentioned in the review, entirely ignores the external impacts on the economies of non-EU tobacco growing countries through market distortions. While this IA touches on external dimensions, it would be done in a vague and somewhat abstract manner, as it results in the evaluation score illustrated in the graph below.

*Figure 4-Impact Assessment on the Reform of the Tobacco Regime: Evaluation of the consideration of effects on non-EU countries (4 = Good, 3 = satisfactory, 2 = unsatisfactory, 1 = little attention, 0 = no mention) from Opoku and Jordan (2005)*
4 Competition perspective
The previous section examined the benefits related to regulatory cooperation and common IA settings across the Atlantic. To these benefits one needs to add competition reasons.

4.1 Need for competition
Both European Commission and U.S. Government have valid reasons for competing on regulatory issues. In the regulatory realm public institutions compete in order to have the most attractive, investor-friendly and secure business environment. Having the best regulatory framework equals attracting investors as well as fostering the internal market.

At the EU level, the need for improving methods for regulatory competition was established in the Communication on Growth and Jobs (EC, 2005), which asserted that the EU economy was lagging behind in achieving the goals of the Lisbon Agenda, partly due to excessive 'red tape'. Much of the policy literature on “better regulation” refers to the Lisbon agenda as an essential objective for improving the EU economy against other economies.

The U.S. Government is conscious of leading the way (at least in comparison to the EU) in the use of economic analysis for regulatory purposes (OMB, 2007). On this matter, Cost-Benefit Analysis is seen as the instrument predisposed at delivering regulatory outputs analytically grounded on cost and benefit estimates. It is a form of expressing all the potential in terms of regulatory economics expertise in U.S. administrations.

4.2 Different approaches on Cost-Benefit Analysis
One key aspect for understanding the importance of competition in a regulatory system is Cost-Benefit Analysis. A functioning Cost-Benefit Analysis system may assure investors that regulatory interventions in the market are pondered and justified (Genschel and Plumper, 1997). Hence, the use of Cost-Benefit Analysis has the double aim of increasing market competitiveness, i.e. guaranteeing the correct running and maximising the efficiency of the internal market, and at the same time
improving international regulatory competition, i.e. the institutional endeavour to obtain a more significant share of multi-national investments.

The application of cost-benefit analysis changes significantly across the Atlantic. The U.S. have been defined as a Cost-Benefit state (Sunstein, 1996), the European Commission has been repeatedly blamed for the absence of quantitative cost-benefit analysis in its IAs (Vibert, 2004; Hahn and Litan, 2004).

There are reasons for this difference as it is explained below.

The first reason is the institutional history of the oversight bodies. A regulatory oversight has been in place in the U.S. since the 1970s. One of its functions is to guarantee that the government disseminates information on the reasons for regulatory intervention. As a result of the oversight’s work, it is common practice in the U.S. that government agencies routinely assess the risks and benefits of various kinds of hazards and estimate the costs to industry (Viscusi et al, 2005). In Europe the only body that resembles the Office of Management and Budget is the Impact Assessment Board, whose power can be hardly compared to its U.S. equivalent.

The second reason is institutional pressure to carry out Cost-Benefit Analysis. In the U.S. since President Reagan’s Executive Order 12291, the Office of Management and Budget has required regulatory agencies to assess the costs and benefits of regulation, and to attempt to ensure that the benefits justify the costs. Although levels of compliance by federal agencies vary significantly (Hahn and Sunstein, 2002), the pressure to do Cost-Benefit Analysis remains high. The European Impact Assessment Board on paper has the power to reject IAs on the bases of insufficient analysis. However, rarely an IA has been rejected on the basis of inadequate estimation of costs and benefits (Alemanno, 2008)

The third reason is methodological. Whilst in federal agencies’ Cost-Benefit Analyses the use of Value of Statistical Life techniques is common practice in order to monetise certain categories of benefits, in Europe such practice is not common. Moreover, the European Commission guidelines provide an interesting account of how Value of Statistical life techniques should (not) be employed:

“The Commission cannot – and does not seek to – place a monetary value on our own lives or on other individuals’ lives. However, changes in risks are a different matter. While no one would trade their life for a sum
of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street compared to the saving of time.”

(EC, 2005: p. 44)

This statement has significant consequences on cost-benefit analysis, as only in very few instances is it possible to give a monetary value to a health and environmental benefit without using the value of statistical life, as it is demonstrated in the next section.

The fourth reason is academic. Unlike in Europe, in the U.S. at least part of the academic literature is deemed influential, in relation to the increasing demands from government for economic expertise even in social regulation sectors (Ogus, 2004). The protagonists of the ‘New Haven’ or Progressive School’ of law-and-economics are similar to the Chicagoans in recognising both the value of markets in promoting efficiency and also the importance of economic incentives in both the private and public sectors (Rose-Ackerman, 1988). The main input of this School to policy-making has been through the medium of Regulatory Impact Analysis, which relies heavily on Cost-Benefit Analysis.

The fifth reason is cultural. Works on the oversight process in the U.S. date back to before 1997. The existence of a body of literature and also the systematic appraisal of RIAs by federal agencies has facilitated the creation of an analytical culture on costs and benefits which is missing in the EU. Although the notion of analytical culture entails a ‘black box’ dimension which is difficult to measure, its positive consequences have been conceptually identified in the framework of a policy-learning process (Majone, 1989). Furthermore, to understand where the EU version of IA comes from, one should keep in mind that IA instruments have been used by the European Commission largely in the environmental field over the last twenty years, as has been thoroughly discussed in the literature on EU environmental impact assessments (Canter 1996). Even if it was demonstrated that many of the key features of the U.S. approach served as major influences on environmental assessments worldwide (Lee, 1995), the EU has adopted a completely different system that has potential repercussions on forthcoming strategic planning for IAs (Canter 1996). According to Wood, according to Wood,⁸ the current EU system of integrated IAs is a direct descendant

of previous environmental IA systems. This interesting observation has not been
developed thoroughly in the literature, but may indeed explain why the focus of the
EU integrated IA system is not centred on Cost-Benefit Analysis.

4.3 Examples from individual Impact Assessment reports
A few examples are provided here in order to illustrate differences in the use of Cost-
Benefit Analysis within IA reports across the Atlantic. The IA produced in 2006 by
the European Commission on the Directive for a Sustainable Use of Pesticides is a
valid example of how the EU does not make use of the full potential of Cost-Benefit
Analysis. The IA quantifies how much the directive would help decrease the use of
pesticides from 31,000 to 44,000 tonnes per year, mainly by reduction of unintended
losses, overuses more efficient applications of plant protection products. The IAs does
not establish how much this decrease would be worth in monetary terms. This means
that it is not specified how much removing each ton of pesticide is worth in € in terms
of lives saved. The IA does not include a full Cost-Benefit Analysis because of the
refusal by the EU to use the Value of Statistical Life technique, i.e., to place a
numerical value on the life saved or health benefits per tonne of pesticide not used.
The reasons for this refusal rest on the difficulty in the use of pricing techniques even
with market goods, where social and environmental matters are involved. The use of
common market-based and/or non-market based methodologies of monetisation
would have obviated this problem. However, on principled grounds, the EU
guidelines (EC, 2005) object to the notion that a ‘value’ can be associated to life.

The famous example of U.S. RIA on the regulation phasing lead out of gasoline
demonstrates how health benefits related to human health can have a decisive role in
determining the benefits of saving human health (Hahn and Tetlock, 2008). The most
important benefits from the Cost-Benefit Analysis were associated with the lower
blood pressure in adults resulting from lower blood lead levels. This effect, which was
quantified, was then translated into a monetary value using medical costs, lost wages,
and mortality. Benefits amounted to $18 billion (in 1983 dollars). The same category
of health benefits, by summing avoided costs of medical treatment and remedial
education foresaw $2 billion for reduced levels of lead in children’s blood.
These examples show how US Government and the EU put different emphasis on Cost-Benefit Analysis especially with regards to the monetarization of health benefits, a topic treated in various chapter of this book.

5 Conclusions
The chapter presented reasons for cooperation and competition on regulatory issues across the Atlantic. It described IA as an instrument capable of facilitating the comprehension of the level of cooperation and competition between U.S. Government and the EU.

On the one hand, IAs can be instrumental in a cooperative agenda because they enable settling common rules for trade; increasing the level of data exchange between U.S. and EU; providing a common platform for tackling climate change and sharing the burdens associated with it; strengthening partnership against other economic macro-regions; preventing trade conflicts. On the other hand, IAs may advance regulatory competition because they represent opportunities for attracting investors and fostering the internal market.

It is suggested in this chapter that EU and U.S. are to cooperate in order to maintain high standards of environmental and health regulation; exchanging information on health and safety data and ensuring that trade continues despite lower economic growth. In this regard the Transatlantic Forum and the OMB-EU joint report on IAs might play significant roles. Furthermore, EU and U.S. are expected to compete on IA issues to have the most attractive, investor-friendly and secure internal market. In this sense, from an IA perspective, the focus is on Cost-Benefit Analysis: the U.S. will persevere in using their competitive advantage, whereas the EU will have to re-think about its approach for monetizing benefits.

The reader will have noticed that this chapter intentionally does not take a position about whether the cooperative reasons shall prevail over competitive reasons or vice versa. Indeed, it is extremely difficult to predict which approach the two continents will undertake in the nearest future, given the change in leadership in the U.S. and the global economic downturn. Much will depend on factors which are out of IA control, such as the level of protectionism in internal markets and amount of priority given to
climate change policies. What is more, we are aware that IAs themselves are not likely to change the equilibrium. In fact, they rarely have much weight in actual policy decisions (Torriti, 2007). Rather, we argue that IAs will be an instrument through which it will be possible to read the level of cooperation and competition across the Atlantic.

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TO COMPETE OR TO COOPERATE? THIS IS AN IMPACT ASSESSMENT QUESTION

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INTRODUCTION
There is a fine line between regulatory competition and cooperation across the Atlantic. Whilst U.S. and European Union (EU) increasingly collaborate on a range of specific regulatory areas in an effort to remove tariff barriers and thus facilitate trade flows of about 620 billion Euros per year, they also compete in order to improve their internal markets, attract a higher number of investors, increase safety for their citizens and maintaining acceptable environmental standards (Vogel, 2001). When measuring the temperature of regulatory competition and cooperation between U.S. and the EU, a valid reading key is Impact Assessment (IA) (Löfstedt, et al, 2008). IA is the main evidence-based policy-making instrument in place in both U.S. and EU and can help understand the rationales and justifications for policy and regulatory interventions.

There are various reasons why U.S. and EU should cooperate on IA issues. Common approaches on IA would also imply joint rules for trade; enhanced transparency for regulatory decisions; sharing in the informational costs associated with the fight climate change; prevention of trade conflict; and strategic partnership against regions. In this vein, a Forum for Regulatory Cooperation takes place twice a year and gathers together senior officials from both the U.S. Office of Management and Budget (OMB) and the European Commission (EC). Recently, the OMB and EC also produced a joint report to improve cooperation on trade and sustainability issues in IAs.

IA could also be used as an instrument for international regulatory competition, because of the need to attracting investors, as well as fostering the internal market, especially in times of low economic growth. Both the EU (EC, 2005) and the U.S. Governments (OMB, 2007) have stated their ambition of improving economic methods for respectively enhancing and maintaining their regulatory competitive

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position. Cost-Benefit Analysis is the main economic tool within IA and plays a pivotal role in determining the analytical effort produced by governments when it comes to estimating the future economic impacts of policy proposals.

The two conflicting approaches –competition versus cooperation- will be examined in this chapter, which aims to provide a framework for analysing the level of regulatory cooperation and competition through an analysis of the existing IA systems in the two continents.

The chapter commences by introducing the IA system in the European Union and the U.S. Regulatory Impact Analysis (RIA) system. It describes in parallel the contexts in which IA and RIA systems were established, their main features and their respective developments and practices. It considers reasons in favour of the cooperative perspective. It examines the need for cooperation; the transatlantic forum for regulatory cooperation; and the joint EU-U.S. report on IA for trade. It explores the main reasons for regulatory competition, the different approaches on Cost-Benefit Analysis and empirically substantiates competition arguments with evidence from individual IA reports. The paper concludes by providing some recommendations to policy-makers for enhancing cooperation on IA across the Atlantic.

THE EU IMPACT ASSESSMENT SYSTEM

The establishment of Impact Assessment in the European Union

The increase in the number of directives, decisions and regulations produced by the European Union over the last few years has been an argument for discussion in both institutional and academic settings.

“By the year 1970, the average was twenty-five directives and six hundred regulations per year; by 1975, this figure had risen to fifty and one thousand respectively; between 1985 and the early 1990s, eighty directives and one a half thousand regulations per year”

(Majone, 1996: 57).

The supposed proliferation of EC legislation has generated discussion about both quantity (Robinson, 2004) and quality (Welch, 2007). As for the increase in quantity, this is often subject to misinterpretations. Figure 1 shows that, in fact, some of these remarks are misplaced, since no significant increase occurred in the number of
legislative instruments, i.e. regulations, decisions and directives, between 1992 and 2005. Data supporting Figure 1 originate from a report by the House of Commons (2006).

**Figure 1-Amount of legislation from the European Commission (1992-2005)**

(Source: House of Commons, 2006)

The notion of quality in the framework of management of regulation has been envisaged as the main reason for the introduction of a ‘better regulation’ agenda (OECD, 1995). The concept of ‘better regulation’ is a form of meta-policy, applied to the whole spectrum of policy areas, encompassing a range of tools. These tools include simplification of existing policies, consultation, Standard Cost Model for reducing administrative burdens and IA. The latter was introduced under Romano Prodi’s presidency of the European Commission in 2003 and was partly revised under the Barroso presidency (2004-2009).

The IA system consists of the most important aid to policy-making within the EU ‘Better Regulation’ agenda. At the EU level the broad focus on ‘major initiatives’, as opposed to regulations only, explains why the choice was for ‘Impact Assessment’ instead of ‘Regulatory Impact Analysis’ (Allio, 2007). Since 2003 the European Commission has employed IAs to estimate *ex ante* the impacts of its policy and regulatory proposals.

European national models of RIA which pre-date the EU one, namely UK, Finland and Sweden may indeed have had an influence on the EC system, at least in the creation of the first EU guidelines and in the integrated approach which combines elements of health impact assessments, environmental impact assessments, social impact assessments and Cost-Benefit analysis. The integration of social and
environmental impact assessments is connected to the Sustainable Impact Assessment instrument, which has been explored in a body of literature focusing specifically on trade legislation (George and Kirkpatrick, 2004).

**Impact Assessment in the European Union: main features**
The EU IA procedure entails a two-step approach, consisting of roadmaps first and then IAs. Roadmaps are carried out on all legislative and non-legislative proposals and are published together with the Commission’s Legislative and Work Programme. The aim of roadmaps is to provide information about the planned proposal; what policy options are being considered; what impacts are likely to occur; and which parties will be consulted. IAs are in-depth analyses of the potential impacts of policy proposals on the economy, on society and on the environment’ (EC, 2005). The decision on the actual depth of the analysis is left to the Directorate General officially entrusted with the preparation of the proposal, according to a principle of proportionality. It has been noted that this application of the proportionality principle lacks concrete criteria and generates confusion about the extent to which the analysis needs to be detailed or can remain at a superficial level (Nielsen et al, 2006).

The Directorate General responsible for leading the policy is also accountable for designing the process and carrying out the IA report. After adoption by the European Commission, the IA has to be sent along with the proposal to the European Council and the European Parliament. Hence, IA accompanies the proposal throughout the legislative process. Both the European Parliament and Council may amend an IA. However, it has been observed that due to the lower levels of expertise in these institutions, there are only few occasions where substantial amendments take place. As a consequence, when the proposal becomes law, the IA is usually still the same as at the time of the draft proposal, and may not reflect the changes that society and the market might have experienced in the intervening period.

**EU Impact Assessment: development and practice**
In principle, all EU IAs address the three pillars of economics, the environment and social issues. In practice, they use different methodologies ranging from Cost-Benefit
Analysis to Sustainability Impact Assessment. As a result, their analytical weight and length of the reports differ considerably.

**Figure 2-Number of EU IAs from 2003 to 2007 (Torriti, 2008a)**

The quality of the more than 200 hundred IAs produced between 2003 and 2007 (see Figure 2) has varied significantly.

At the research level, it has been highlighted that the performance of IAs in most cases did not fulfil the expectations (Löfstedt, 2007). A number of evaluative studies, based on various scorecards, content and function tests, underline that existing EU IAs do not sufficiently quantify the benefits and costs of future legislation (Torriti, 2007); do not include sustainable development issues (Kirkpatrick and Franz, 2006; Opoku and Jordan, 2004; IEEP, 2004); and do not take into consideration a sufficiently wide range of policy alternatives (Renda, 2006).

At the institutional level, the acknowledged disputable quality of IAs (EP, 2007) has been taken care of by a sort of oversight unit, the Impact Assessment Board (Alemanno, 2008). This Board is composed of five senior officials of European Commission. It might be seen as a step for closing the EU gap in having an oversight
unit. However, unlike its U.S. counterpart - i.e. OIRA, as described in the next section - the EU Impact Assessment Board is not awarded any veto powers. Recent empirical studies explored the reliance of IAs on the knowledge and expertise of those officials responsible for carrying them out (Hertin et al, 2007). Some of the cultural resistance to IAs is based on the newness of these tools, but also on the ethical rejection of using Value of Statistical Life techniques for monetising the benefits of health and environmental policies.

Besides the issue of quality, IAs play an important role in explaining changes in risk analysis. It has been argued that IAs might represent a shift from the precautionary principle to risk-based regulation (Löfstedt, 2004). In the past, EU regulation has been characterised by the extensive adoption of precautionary measures aimed at preventing and mitigating hazards in various fields of risk regulation, including genetically modified foods, climate change, and chemicals (Wiener, 2006). Emerging technologies, for instance, have been a specific target area for the precautionary principle (Jasanoff, 2005). Existing research considers the precautionary principle in terms of the final regulatory decision, which tends to be characterised by a preventative approach to the regulated subject (Goldstein, 2002). If IAs implied a shift away from the precautionary principle, Europe would get closer to the risk-based approach featuring in the U.S. However, Löfstedt (2007) notices that the introduction of IA did not lead to a simultaneous withdrawal of the precautionary principle with attention dedicated to the use of risk-risk and risk-benefit techniques.

THE U.S. REGULATORY IMPACT ANALYSIS SYSTEM

The establishment of Regulatory Impact Analysis in the U.S.

Before the 1980s, federal agencies did not systematically rely on RIA when evaluating regulations and other projects (Adler and Posner, 1999). RIA was first established in the U.S. in 1981, by President Reagan’s executive order 12291. One of the first consequences was that major regulations (over $100 million annual impact) had to be accompanied by RIA. Originally the U.S. RIA was introduced in order to promote economic efficiency and therefore economic growth; to regulate only when the market fails; and to regulate by using cost-effective and market-based approaches. The Office of Information and Regulatory Affairs within the Office of Management and Budget was created with the aim of evaluating federal agencies, with the mandate
to suspend regulatory proposals when the accompanying cost-benefit analysis was deemed inadequate.

The original RIA programme was criticised for being too secretive and closed to outsiders (Morral, 2001). Since its creation, the U.S. RIA has undergone some alterations. President Clinton, for instance, revised the system slightly by streamlining it and increasing the public consultation and transparency requirements.

**Regulatory Impact Analysis in the U.S.: main features**

RIAs accompany regulatory proposals only, unlike EU IAs which also encompass policies. The RIA process commences when federal agencies draft preliminary RIAs on regulatory proposals. This preliminary RIA contains (i) a comparison of different regulatory alternatives, including the *status quo* option; (ii) a rough estimation of benefits and costs associated with each regulatory alternative and (iii) an indication of the relevance of the impact of the proposed regulation. Depending on the latter point, it is decided whether an extensive RIA is necessary. After two months of consultation, the final RIA is completed and accompanies the final regulatory proposal for approval. The Office of Information and Regulatory Affairs (OIRA) has three months to approve or reject the regulatory proposal on the basis of the quality of cost-benefit analysis carried out by the agency.

OIRA can reject regulatory proposals until they are provided with an adequate Cost-Benefit Analysis. The number of regulations withdrawn by OIRA has significantly increased under the last Bush administration, as it is illustrated in Figure 3. What is more, the same administration introduced the use of “prompt letters” which increased the power of OIRA in terms of rejection of regulatory proposals. As a consequence, the most significant regulatory growth during John Graham’s tenure at OIRA was homeland security. It is unlikely that any radical change in the use of Cost-Benefit Analysis will take place under Cass Sunstein, who was recently appointed to run OIRA.
Figure 3-Number of regulatory proposals returned or withdrawn by OIRA on average, per year

U.S. Regulatory Impact Analysis: development and practice
The OMB yearly Report to Congress on the Costs and Benefits of Federal Regulations consists of a yearly calculation of total costs and benefits of regulatory proposals. To date the OMB has evaluated more than 1,000 RIAs. Obviously the results vary according to many factors and are difficult to interpret univocally. In general, where data are missing the OMB has criticized the lack of quantitative and monetary evaluations in most of RIAs carried out by federal agencies. Where data are available, there is not a single year when costs were significantly greater than benefits. This occurs even though often benefits are likely to be understated, because agencies estimate costs but not benefits for some of the rules reviewed by OMB over this time period. Figure 4 shows the benefits and costs of federal regulations (OMB, 2007). This means that the annualized benefits of major U.S. federal regulations between 1996 and 2006 significantly outweigh the costs, with benefits ranging from $99 billion to $484 billion (in 2001 dollars) and costs ranging from $40 billion to $46 billion.
Some of the existing non-institutional evaluations of U.S. RIAs and Cost-Benefit Analyses accompanying regulatory proposals also highlight interesting features. A study by Hahn and Litan (2000) on 48 proposed regulations subject to RIA between 1996 and 1999 showed that only in one third of the cases agencies had quantified costs and benefits of proposed regulations and calculated the net present value of the regulatory intervention. Another study by Hahn and Dudley (2004) examined 55 RIAs and pointed out similar problems. Some analysts also used econometric methods on a database, first developed by the OMB (Morrall, 2001) on health and safety regulations. Farrow (2001), for instance, has used multivariate regression methods to examine a database of 69 regulations proposed by several U.S. agencies and reviewed by the OMB, of which seven were rejected (i.e., sent back to the agency for further consideration).

In addition to these evaluative studies, a large literature has followed and discussed various aspects of the development and practice of U.S. RIAs for the last thirty years. A significant body of literature contests the excessive employment of Cost-Benefit Analysis in RIA. Ackerman and Heinzerling (2004), for instance, regard these tools as morally obtuse, a recipe for capitulation to powerful industries and ultimately for
deregulation. They believe that it is a form of pseudo-science, with the pernicious effect of blinding us to the real values at stake. According to them, human lives are priceless, and deaths are not mere costs. Much of the literature advocating for Cost-Benefit Analysis is devoted to defending the use of the value of statistical life to assess health risk reductions from government regulations (Viscusi, 2006). The same authors also support the continued use of stated preference approaches to valuing environmental benefits, which is in contrast to the critiques of stated preference analyses by those who consider environmental resources to be priceless (Ackerman and Heinzerling, 2004) and by those who believe that all non-use values of environmental benefits are zero (Martelli, 2001). Critics, especially on the left, present the monetisation of certain values as morally indefensible, an obstacle to the creation of an equal distribution of public resources:

“The kind of economic thinking [behind monetisation] is ascendant in public-policy circles today. If the advocates of free market economic theory get their way, the simplistic use of economics will become even more prominent; in fact, it will become the way of making critical policy decisions.”

(Ackerman and Heinzerling, 2004: 11)

Advocates of Cost-Benefit Analysis have at times directly addressed the points raised by their opponents, most usually by defending the legitimacy of quantification as a way of knowing, not of organising a polity and a culture:

“From an economic standpoint, the advantages of monetizing benefits are quite strong because establishing this kind of metric makes it much easier to compare benefits with costs and make choices across various policy alternatives. [...] Monetisation also has an additional practical benefit in a world of regulatory impact analysis. Costs are quantifiable in dollar terms, as are many benefits components, so failing to place a monetary value on seemingly intangible benefits such as environmental amenities may lead to inadequate attention to intangible benefits in the policy choice process. Monetizing these benefits puts them on equal footing with benefits that are perceived to have real economic value because they can be quantified in dollar terms.”

(Viscusi, 2006: 4-5)

The use of Cost-Benefit Analysis within RIA has been discussed from several disciplinary perspectives. Methodological problems have been debated by economists since the New Deal government initiated the use of CBA in 1936, when Congress ordered agencies to weigh costs and benefits when evaluating projects designed for
flood control (Porter, 1996). The legal literature questions whether, despite large Government practice, such tool is legal or not (Zerbe, 2007). Ethical concerns have been raised on social grounds with regard to the lack of consideration of distributional impacts (Sunstein, 1996). There are also arguments against the ability of RIA to include some of environmental benefits because of the inappropriate appraisals of some levels of costs (Stirling, 1997).

THE COOPERATIVE PERSPECTIVE: THE INSTITUTIONAL ENDEAVOUR FOR COOPERATION

The need for cooperation

Reasons for cooperation in the IA area rest on both institutional and academic motivations. First, it will be explained why there is a need to increase the cooperation between EU and U.S. on regulatory affairs and how IAs might function as a tool to increase cooperation across the Atlantic. Second, it will be described how this cooperation is taking place at the institutional level, within the framework of the forum for regulatory cooperation and the joint report on EU-U.S. IA guidelines.

The first reason why EU and U.S. need cooperation on regulatory affairs is that trade benefits from cooperation. The EU-U.S. trading partnership is the largest bilateral trade and investment relationship in the world. Trade flows across the Atlantic run at around € 620 billion per year. In addition, 14 million jobs depend on these bilateral investment flows, making up to 57% of world GDP. Close to a quarter of all EU-U.S. trade consists of transactions within firms based on their investments on either side of the Atlantic. Hence, the two economies are highly interdependent and seek to maximise the advantages of the existing trading partnership. In order to improve trade between macro regions such as EU and U.S. a shared set of rules is vital. This might result difficult due to many reasons: a number of monetary and labour market issues may work against a fully shared set of rules across the ocean. However, where having the same rules is impossible, EU and U.S. will aim to share the same approach to making those rules. If they share the same method (e.g. IA) for assessing regulations, it does not mean that they necessarily share the same rules, but at least the same approach for making rules. A common approach for rule-making is a key starting point for consolidating trade in sectors where it is already taking place and setting up
the conditions for commerce in new sectors. Moreover, a shared method for rule-making facilitates communication with mutual stakeholders.

The second reason is that the exchange of data is vital for improving regulatory decisions. The core of an IA consists of data estimates on costs, benefits and risks (Torriti, 2007). These are analysed and weighed taking into account economic, social and environmental impacts (EC, 2005). Optimal regulatory choices are made when policy-makers –be either the European Commission or any federal agency- have precise information about exactly what will occur under any choice made. Alternatively, policy-makers may have a reliable probability describing what will happen under any choice made. This means that the analysis of impacts by the European Commission and U.S. agencies can pursue optimal decisions only if precise information is available about what exactly will occur, in terms of costs, benefits and risks, as a consequence of any policy alternative. The exchange of information across the Atlantic improves the awareness of data available for regulatory decisions. There is a wealth of examples especially of EU IAs using U.S. data and case studies. The IA on Sustainable Use of Pesticides produced by the European Commission relied on previous EPA studies to understand the epidemiological health risks of pesticides (BiPRO, 2004). In the IA on the liberalisation of energy markets (so-called “Third Package”), a case study is based on the U.S. experience with Information System Operators (EC, 2007). The IA for a regulation concerning the use of biometrics for Visa systems is based on the U.S. costs of installing biometric mechanisms (EC, 2004). If both sides of the Atlantic produce IAs of high technical standards, regulators and policy-makers are to benefit enormously.

The third reason is the need for harmonized regulation to fight climate change. The need for cooperative action to address climate change has been stated in several policy documents (e.g. UNFCCC, 2008). On the one hand, the need to measure, report and verify initiatives aimed at reducing climate change may arguably find an adequate analytical location in IA reports, where individual regulatory proposals are weighed according to the expected changes to levels of CO2 emissions. This occurs, for instance, in the template for IA established in 2007 by the UK Government. On the other hand the regulatory cooperation across the major bilateral economic
partnership (EU-U.S.) is crucial to any hope of planning and implementation of reduction targets on a global scale.

The fourth reason is the prevention of trade conflicts. Regulatory cooperation has proven an effective means to avert potential trade conflicts, as different standards and regulations are the main obstacles to trade between the U.S. and the EU today. Hence regulatory cooperation is aimed at minimising the negative economic impacts of trade disputes due to diverging regulation. In fact, several trade-related disputes which regularly hit the headlines impact around 2% of EU-U.S. trade.

The fifth reason is strategic partnership before the economic threat posed by other regions. IAs could also be seen as a way for preserving competitive advantage against other economies. China and India, for instance, not only are capable of producing and exporting goods to the rest of the world, they have seen their economies expanding at a rate at times up to ten times higher than some EU countries over the last ten years. In order to consolidate the western trade partnership, as well as strengthening the opportunities represented by ever-growing Asian buyers, cooperation becomes crucial. In the past, risk assessments helped the European and North American regulators to keep out of the western markets specific items made in Asia. For example, the European thresholds for content of chemical substances such as Bisphenol A and toxins in toys represent a threat of ban for a wide range of Chinese products, ranging from toys to toothpaste. However, decisions about acceptable levels of risk are not taken by scientists only. The risk management part of an IA will play a key role in deciding how certain substance will be banned or heavily regulated. IAs could also be seen as a systematic way for preserving competitive advantage against other economies.

**Forum for regulatory cooperation**
A so-called 'High-Level Forum for Regulatory Cooperation' takes place twice a year and gathers together senior officials from both the U.S. OMB and the European Commission. The Forum aims to help avoid unnecessary divergences in the way the EU and U.S. regulate.
The forum’s deliberations provide input to the Transatlantic Economic Council, which gathers in Washington or Brussels once a year. The last meeting held on 18th May 2008 focused on strengthening transatlantic cooperation on the safety of imported products. Business and consumer representatives are also involved in the discussion on how the EU and the U.S. consult the public when developing regulation.

Allegedly, given the supremacy of U.S. Government in implementing a number of economic instruments for regulatory economics (Hahn and Titlock, 2008), the Forum may prove an arena for fostering the use of Cost-Benefit Analysis in Europe. Wiener (2006) notes that the EU borrowed not only the notions of Impact Assessment and 'better regulation' from the North American legal system, but has also taken on board the idea that institutional features are influenced by inter-institutional dialogues.


Recently, the European Commission and OMB carried out a joint report to improve cooperation on trade and sustainability issues in IAs. The review does not introduce a transatlantic integrated approach for the future, but rather presents separately what work the Office of Management and Budget and the European Commission are doing in terms of IAs on trade and investment. In addition, the two parts are not balanced because the European Commission describes how IA guidelines address the trade and investment issue, whereas the OMB presents cases where this issue was dealt within individual IAs. The EU section provides a rather generous self-evaluation of the consultation process. For instance, the joint report states that the EC “has adopted strict minimum standards” on stakeholder consultation. Minimum standards are by definition not strict, compared for instance with consultation codes. The EU consultation regime is less stringent than in Member States and has been criticized for not allowing enough time -8 weeks compared to 12 weeks in the UK- and for its lack of transparency (Löfstedt, 2007; Torriti, 2007).

The joint report foresees a crucial role by the recently established EU Impact Assessment Board in improving the quality of the analyses. However, it is not clear
how the EU Impact Assessment Board actually increases the focus of IAs on trade and investment. No examples are made to strengthen the concept that the Board improves the analysis of international impacts within specific IAs. Yet, the comments of the Board are normally made available and published.

The confidence showed in the review by the European Commission regarding the suitability of the IA system for addressing international trade and investment issues is not shared by academic studies. A study by Opoku and Jordan (2005) finds that the IA procedure does not function as an effective instrument for the implementation of the Union’s commitment to promoting sustainability in non-European countries. For instance, they believe that IA on the Reform of the Tobacco Regime, also mentioned in the review, entirely ignores the external impacts on the economies of non-EU tobacco growing countries through market distortions. While this IA touches on external dimensions, it would be done in a vague and somewhat abstract manner, as it results in the evaluation score illustrated in the graph below.

![Figure 5-Impact Assessment on the Reform of the Tobacco Regime: Evaluation of the consideration of effects on non-EU countries (4 = Good, 3 = satisfactory, 2 = unsatisfactory, 1 = little attention, 0 = no mention) from Opoku and Jordan (2005)](image)

**THE COMPETITION PERSPECTIVE**

**The need for competition**
Both European Commission and U.S. Government have valid reasons for competing on regulatory issues. In the regulatory realm public institutions compete in order to have the most attractive, investor-friendly and secure business environment. Having
the best regulatory framework equals attracting investors as well as fostering the internal market.

At the EU level, the need for improving methods for regulatory competition was established in the Communication on Growth and Jobs (EC, 2005), which asserted that the EU economy was lagging behind in achieving the goals of the Lisbon Agenda, partly due to excessive 'red tape'. Much of the policy literature on “better regulation” refers to the Lisbon agenda as an essential objective for improving the EU economy against other economies.

The U.S. Government is conscious of leading the way (at least in comparison to the EU) in the use of economic analysis for regulatory purposes (OMB, 2007). On this matter, Cost-Benefit Analysis is seen as the instrument predisposed at delivering regulatory outputs analytically grounded on cost and benefit estimates. It is a form of expressing all the potential in terms of regulatory economics expertise in U.S. administrations.

**Different approaches to Cost-Benefit Analysis**

One key aspect for understanding the importance of competition in a regulatory system is Cost-Benefit Analysis. A functioning Cost-Benefit Analysis system may assure investors that regulatory interventions in the market are pondered and justified (Genschel and Plumper, 1997). Hence, the use of Cost-Benefit Analysis has the double aim of increasing market competitiveness, i.e. guaranteeing the correct running and maximising the efficiency of the internal market, and at the same time improving international regulatory competition, i.e. the institutional endeavour to obtain a more significant share of multi-national investments.

The application of cost-benefit analysis changes significantly across the Atlantic. The U.S. have been defined as a Cost-Benefit state (Sunstein, 1996), the European Commission has been repeatedly blamed for the absence of quantitative cost-benefit analysis in its IAs (Vibert, 2004; Hahn and Litan, 2004). There are reasons for this difference as it is explained below.
The first reason is the institutional history of the oversight bodies. A regulatory oversight has been in place in the U.S. since the 1970s. One of its functions is to guarantee that the government disseminates information on the reasons for regulatory intervention. As a result of the oversight’s work, it is common practice in the U.S. that government agencies routinely assess the risks and benefits of various kinds of hazards and estimate the costs to industry. In Europe the only body that resembles the Office of Management and Budget is the Impact Assessment Board, whose power can be hardly compared to its U.S. equivalent.

The second reason is institutional pressure to carry out Cost-Benefit Analysis. In the U.S. since President Reagan’s Executive Order 12291, the Office of Management and Budget has required regulatory agencies to assess the costs and benefits of regulation, and to attempt to ensure that the benefits justify the costs. Although levels of compliance by federal agencies vary significantly (Hahn and Sunstein, 2002) and policy space for conducting Cost-Benefit Analysis is limited by the fact that it is not applied in areas such as pharmaceutical regulation or terrorism law, however the pressure to do Cost-Benefit Analysis remains high. The European Impact Assessment Board on paper has the power to reject IAs on the bases of insufficient analysis. However, rarely an IA has been rejected on the basis of inadequate estimation of costs and benefits (Alemanno, 2008)

The third reason is methodological. Whilst in Cost-Benefit Analyses by federal agencies the use of Value of Statistical Life techniques is common practice in order to monetise certain categories of benefits, in Europe such practice is not common. Moreover, the European Commission guidelines provide an interesting account of how Value of Statistical life techniques should (not) be employed:

“The Commission cannot – and does not seek to – place a monetary value on our own lives or on other individuals’ lives. However, changes in risks are a different matter. While no one would trade their life for a sum of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street compared to the saving of time.”

(EC, 2005: p. 44)

This statement has significant consequences on cost-benefit analysis, as only in very few instances is it possible to give a monetary value to a health and environmental benefit without using the value of statistical life, as it is demonstrated in the next section.
The fourth reason is academic. Unlike in Europe, in the U.S. at least part of the academic literature is deemed influential, in relation to the increasing demands from government for economic expertise even in social regulation sectors (Ogus, 2004). The protagonists of the ‘New Haven’ or Progressive School’ of law-and-economics are similar to the Chicagoans in recognising both the value of markets in promoting efficiency and also the importance of economic incentives in both the private and public sectors (Rose-Ackerman, 1988). The main input of this School to policy-making has been through the medium of Regulatory Impact Analysis, which relies heavily on Cost-Benefit Analysis.

The fifth reason is cultural. Works on the oversight process in the U.S. date back to before 1997. The existence of a body of literature and also the systematic appraisal of RIAs by federal agencies has facilitated the creation of an analytical culture on costs and benefits which is missing in the EU. Although the notion of analytical culture entails a ‘black box’ dimension which is difficult to measure, its positive consequences have been conceptually identified in the framework of a policy-learning process (Majone, 1996). Furthermore, to understand where the EU version of IA comes from, one should keep in mind that IA instruments have been used by the European Commission largely in the environmental field over the last twenty years, as has been thoroughly discussed in the literature on EU environmental impact assessments (Canter 1996). Even if it was demonstrated that many of the key features of the U.S. approach served as major influences on environmental assessments worldwide (Lee, 1995), the EU has adopted a completely different system that has potential repercussions on forthcoming strategic planning for IAs (Canter 1996). The current EU system of integrated IAs might be considered as a direct descendant of previous environmental IA systems. This might indeed explain why the focus of the EU integrated IA system is not centred on Cost-Benefit Analysis.

**Examples from individual Impact Assessment reports**

A few examples are provided here in order to illustrate differences in the use of Cost-Benefit Analysis within IA reports across the Atlantic. The IA produced in 2006 by the European Commission on the Directive for a Sustainable Use of Pesticides is a valid example of how the EU does not make use of the full potential of Cost-Benefit
Analysis. The IA quantifies how much the directive would help decrease the use of pesticides from 31,000 to 44,000 tonnes per year, mainly by reduction of unintended losses, overuses more efficient applications of plant protection products. The IAs does not establish how much this decrease would be worth in monetary terms. This means that it is not specified how much removing each ton of pesticide is worth in € in terms of lives saved. The IA does not include a full Cost-Benefit Analysis because of the refusal by the EU to use the Value of Statistical Life technique, i.e., to place a numerical value on the life saved or health benefits per tonne of pesticide not used. The reasons for this refusal rest on the difficulty in the use of pricing techniques even with market goods, where social and environmental matters are involved. The use of common market-based and/or non-market based methodologies of monetisation would have obviated this problem. However, on principled grounds, the EU guidelines (EC, 2005) object to the notion that a ‘value’ can be associated to life.

The famous example of U.S. RIA on the regulation phasing lead out of gasoline demonstrates how health benefits related to human health can have a decisive role in determining the benefits of saving human health (Hahn and Tetlock, 2008). The most important benefits from the Cost-Benefit Analysis were associated with the lower blood pressure in adults resulting from lower blood lead levels. This effect, which was quantified, was then translated into a monetary value using medical costs, lost wages, and mortality. Benefits amounted to $18 billion (in 1983 dollars). The same category of health benefits, by summing avoided costs of medical treatment and remedial education foresaw $2 billion for reduced levels of lead in children’s blood.

It was mentioned above that the U.S. might benefit from keeping their analytical advantage on IA. The following example on biometrics demonstrates that there are times when the EU IA reports lag behind in analytical terms compared to the U.S. While the U.S. RIA is based on net present value estimates (GOA, 2002), the IA estimating the costs and benefits of introducing biometrics for VISA-entry system in the EU is funded on a rather dubious “cost transfer” exercise (EPEC, 2004). The estimate of the financial costs for Member States associated with introducing biometrics (in Table 1) is based on the average of the only two member states that did provide cost estimates, i.e., Sweden and France. The starting assumption is that
France is a large issuer of visas, whereas Sweden is smaller. This calculation of financial costs goes against the concept of differential costs and the estimate of expenses for individual national systems and is therefore statistically insignificant. Indeed, this does not seem the type of ideal example to be presented in guidelines.

**Table 1—Financial costs of VISAs with biometrics (EPEC, 2004)**

<table>
<thead>
<tr>
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<th>‘VIS without biometrics’</th>
<th>‘VIS with biometrics’</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One-off investment costs</td>
<td>Annual operational costs</td>
</tr>
<tr>
<td>Costs for the Community</td>
<td>€30 million</td>
<td>€8 million</td>
</tr>
<tr>
<td>Costs for the Member States</td>
<td>No estimates</td>
<td>No estimates</td>
</tr>
<tr>
<td>(national systems)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total costs</td>
<td></td>
<td>€246-256 million</td>
</tr>
</tbody>
</table>

Other examples from emerging technologies demonstrate that there are times when the EU makes use of existing U.S. cost-benefit data for IA purposes (Torriti, 2008b). These cases show how US Government and the EU put different emphasis on Cost-Benefit Analysis especially with regards to the monetization of health benefits, a topic treated in various chapter of this book.

**CONCLUSIONS AND RECOMMENDATIONS**

The chapter presented some of the reasons why the EU and U.S. would gain from either cooperating or competing on regulatory issues. It described IA as an instrument which facilitates the comprehension of the level of cooperation and competition between the U.S. Government and the EU.

On the one hand, IAs can play a crucial role in a cooperative agenda because they create the conditions for (i) settling common rules for trade; (ii) increasing data exchange; (iii) providing a common platform for tackling climate change and sharing the burdens associated with environmental regulation; (iv) strengthening partnership against other economic macro-regions; and (v) preventing trade conflicts. On the
other hand, IAs may advance regulatory competition because they represent opportunities for attracting investors and fostering the internal market.

It is suggested in this chapter that IAs can play a key role in regulatory cooperation between EU and U.S. should they both aspire to maintain high standards of environmental and health regulation; exchange information on health and safety data; and ensure that trade continues despite lower economic growth. In this regard, both the Transatlantic Forum and the OMB-EU joint report on IAs are potentially important venues. It is also argued that EU and U.S. are expected to compete to have the most attractive, investor-friendly and secure internal market. The U.S. are likely to maintain their comparative advantage in the use of cost-benefit and risk-benefit analysis, whereas the EU will have to re-consider its approach for monetizing benefits, which so far has limited the level of quantification of IAs thus far.

The reader will have noticed by now that these authors intentionally do not take a position on whether the cooperative reasons shall prevail over competitive reasons or vice versa. Indeed, it is extremely difficult to predict which approach the two continents will undertake in the nearest future, given the change in leadership in the U.S. and the global economic downturn. Much will depend on factors which are out of IA control, such as the level of protectionism in internal markets and amount of priority given to climate change policies. What is more, we are aware that IAs themselves are not likely to change the equilibrium. In fact, they rarely have much weight in decision-making (Torriti, 2007) and seldom change the policy output (Baldwin, 2008). Rather, we argue that IAs will be an instrument through which it will be possible to read the level of cooperation and competition across the Atlantic.

Finally, on the basis of the discussion above, we present four recommendations to EU and U.S. policy-makers.

First, if EU and U.S. are willing to cooperate in a set of policy areas, they need a common analytical instrument to assess the potential impacts of their policies. IAs at EU level and RIA in the U.S. are common policy appraisals which have been in use for some time. IAs have potential, but also incongruities and pitfalls. The first recommendation is that EU and U.S. should find common grounds to share as much
as possible technical experience on *ex ante* assessments, more than it occurs at the moment within the Transatlantic Forum or the EC-OMB joint report on IA on trade and investment.

Second, evidence shows that much more work is needed to achieve the arduous task of foreseeing the impacts of future policies and regulations both in the U.S. and in the EU. Getting the estimates right means that doing IAs might cost less than ignoring the consequences of legislative proposals. However, wrong estimates on costs, benefits and risks may have devastating consequences for the European Commission as well as federal agencies. Hence, the second recommendation is that if U.S. and EU are to cooperate in order to maintain high standards of environmental and health regulation, exchange information on health and safety data, and ensure that trade and investments are not undermined by low economic growth, they will need to produce high-level Impact Assessments.

Third, the different approaches in estimating health and environmental benefits are enrooted in ethical and methodological discrepancies between EU and U.S. There are robust reasons why Value of Statistical Life techniques are explicitly not welcome in IA guidelines by the European Commission. The third recommendation is that on the one hand the EU should re-consider its stand on monetizing health and environmental benefits; on the other hand the U.S. should not use their competitive advantage in the use of Value of Statistical Life techniques to convince their European counterparts that their approach is flooded.

Fourth, researchers willing to compare policy and regulatory approaches in Europe and North America should bear in mind that IAs are attractive units of analysis, because they enable comparisons between the analytical input and political output for similar policy areas across the Atlantic. However, the fourth recommendation is to recall the contextual differences and rationales between U.S. and EU which were highlighted in this chapter. This fourth recommendation is meant for researchers carrying out comparative work on policy issues.
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