Comparison of US and European Commission guidelines on Regulatory Impact Assessment/Analysis

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A great deal of additional information on the European Union is available on the internet. It can be accessed through the Europa server (http://europa.eu.int).

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Summary

This paper examines the United States Executive Branch and European Commission (EC) approaches to the impact analysis, based on a critical review of the two respective sets of guidelines – The U.S. Office of Management and Budget’s (OMB) Circular A-4, and the EC’s Impact Assessment (IA) Guidelines. The scope of this paper does not include a judgment on which approach leads to better decision making or policy outcomes; neither does the paper give direct recommendations on modifying, improving, or standardizing the guidelines. Instead, its purpose is to add to the general understanding of the two approaches by drawing out similarities and differences. The authors hope an objective accounting of these similarities and differences will prove useful in current and future study of the regulatory state.

The paper begins with a short description of the legislative and regulatory processes in the U.S. and the E.U., in order to emphasize the fundamental difference between the two sets of requirements. Whereas in the US an IA is produced in order to find the most efficient way of implementing laws passed by Congress in the form of a rule or a regulation, a Commission IA serves mainly to inform policy makers when deciding on what sort of legislative or non-legislative proposal to make. Created at different point in the process, the analyses that follow these guidelines necessarily serve different purposes.

Nevertheless, both approaches are based on a similar understanding of the need to provide good analysis to improve decision-making. The EC impact assessments are a fundamental part of the Better Regulation Agenda, which is a direct outcome of the Lisbon summit that established the goal of making Europe the most dynamic and competitive knowledge based economy by 2010. Better Regulation tools such as impact assessments are seen as crucial ingredients in the mix of policies that have since been set in motion. While both approaches have certain similarities, e.g. they stress the same issues that need to be considered, they differ in their emphasis on a number of important points.

The US approach emphasises cost-benefit analysis and cost-effectiveness analysis, and Circular A-4 therefore presents more detailed recommendations of these methods. The system adopted by the US assesses different options normally on the basis of a quantitative economic analysis. Economic impacts, while a prominent feature, are one area of impacts to which economic analysis is applied. Other impacts that are quantified and whose options undergo economic analysis include social and environmental impacts. Although the presumption is that costs and benefits can be expressed in figures, the US guidelines also recognise that it will not always be possible to quantify all impacts, and thus provide for the use of qualitative analysis where it can be reasonably argued that their costs or benefits are of such a magnitude that they would affect the choice of option.

The Commission has explicitly adopted an integrated approach, which establishes no ranking between economic, social and environmental impacts of policy options. The

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1 In fact, the common term used in the US guidelines, in order to avoid the confusion between “economic analysis” and analysis of economic impacts, is the term “regulatory impact analysis.”

2 This means that impacts that occur in any one of these three categories have no precedence over others. The magnitude of each impact is what is of significance, not the fact that a particular impact happens to fall within the sphere of the economic, environmental or social pillar. Although the impacts are reported separately, the final verdicts on a particular option takes into account all impacts, regardless of where they happen, i.e. which category they belong to. If there are marginally positive
The guidelines issued by the Commission in June 2005\(^3\) are less prescriptive in terms of the type of analysis that is required for assessing the impacts in each of those three pillars. A quantitative analysis of any of those impacts is as valid as is one based on a more qualitative assessment. While this gives officials in the Commission more leeway in their choice of analysis, bearing in mind the checks and balances that exist in the form of Interservice Steering Groups and the Secretariat General's oversight role and the recently created Impact Assessment Board, the guidelines were designed to ensure that all three pillars would receive equal consideration. It is also worth pointing out that Commission officials have a duty to ensure that their analysis is sound and of high quality, which means that quantitative analysis based on CBA is used when it is considered to be the most appropriate analytical method.

One may conclude that while many similarities exist, there are significant differences, particularly as regards the legal and institutional framework, the resulting different stages at which (R)IAs are produced, and the difference in purpose they serve in the two systems. Consequently, carrying out one ex-ante (R)IA on a comparable initiative that can be shared by US regulators and the Commission would at this moment in time be an immensely challenging task. Building on each separate analysis based on a better understanding of the other's system are likely to produce better results by way of regulatory cooperation.

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**Introduction**

impacts in two categories but significantly negative impacts in the third category, then this does not mean that an option receives a favourable assessment based of a score of 2 to 1. The essence of the integrated approach is that an option is assessed based on the overall magnitude of the likely impacts, regardless of where they arise.

\(^3\) The guidelines issued in June 2005 are generally referred to as the revised guidelines, reflecting the fact that they build on the previous set of guidelines. The statement in the text regarding their prescriptive nature, however, is equally valid for the previous guidelines.
Impact Assessments and Regulatory Impact Analysis are now carried out for the vast majority of new "economically significant regulatory proposals" in the US and for most items that are in the in the Legislative and Work Programme (CLWP) of the European Commission, barring a few exceptions. The US has been carrying out RIAs with some emphasis on Cost Benefit Analysis for the past two to three decades. As far as the European Commission is concerned, the previously sectoral impact analyses that were carried out, most notably in the area of environmental impacts, were combined by establishing integrated impact assessments in the early years of the new millennium in the context of the Lisbon Agenda (2000), the White Paper on Governance (2001), and the EU Sustainable Development Strategy (2001). There is now a recognition shared on both sides of the Atlantic that ex-ante analysis of likely impacts of regulatory actions are essential for good policy making. The ongoing regulatory dialogue between the world's two biggest economic areas is timely and important to ensure that regulatory action by both sides does not create unnecessary and thus detrimental economic and trade obstacles. In order to further the understanding of this regulatory dialogue a thorough knowledge of each other's ex ante impact analysis is essential.

This paper looks at the two sets of guidelines, Circular A-4 in the US and the Commission's Impact Assessment guidelines. Section one analyses some general issues, while Section two takes a look at the role of analysis of the impacts in both approaches. Section one begins with an assessment of the legislative backgrounds against which (R)IAs are produced in the US and at the EU level and includes a comparison of the legal or other bases that underpin ex-ante impact analysis in both systems. This section looks at how subsidiarity and federalism are handled, the role of consultation, the provisions that have been made for ensuring an efficient use of available resources and how impacts in and vis-à-vis third countries are taken into account. In addition, it touches upon some institutional aspects and the quality control checks and balances that exist within the Commission. Section two looks at the more technical aspects that an analysis of impacts includes. The role of cost benefit and cost effectiveness analyses is discussed, as well as how parameter values such as discount rates are dealt with. Assessing the impact of new proposals on administrative costs and monitoring and evaluation requirements, which are peculiar to the Commission's IA guidelines, is explained and there is a discussion of how risk and uncertainty analysis is handled. Section three concludes.

1 General Issues
1.1 The two legislative processes

Before looking at the two sets of analytical requirements in more detail, it is important to appreciate that there are significant differences in the legislative process between the US and the EU. Awareness of these differences is essential for an understanding of the reasonings that underpin the two sets of guidelines. In the US, Article I, Section 1, of the Constitution gives the Congress the sole power to make laws. Laws must be passed in identical form in both the House of Representatives and the Senate, and must be signed by the President in order to take effect. Over time, Congress has passed a number of laws authorizing the creation of and assigning a mission to executive branch regulatory agencies. There are over 100 federal agencies and subagencies with regulatory mandates from Congress, such as the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency. One of the primary tools these agencies use to fulfill their mission is a “rule” or “regulation” which, when finalized, have the effect of law. Regulations are almost always much more detailed than the laws passed authorizing their issuance; in fact, that is often one of the justifications used for employing the use of regulations. In fulfilling their mission, the regulatory agencies have an obligation (partly created by statute, partly created by direction from the President, who is head of the executive branch) to show that their rules have a sound reasonable basis.

In the US, the RIA is produced by the regulatory agency granted authority through legislation to regulate a particular subject. The RIA has a goal to assess how regulations can be done in the most efficient way for society, and also can be used as evidence in court (discussed in more detail below) to prove that the final regulation has a reasonable basis. Regulatory agencies produce a full RIA for proposed rules, which then may be modified, along with the rule itself, after public comment and republished as a final rule.

The most common procedure under which EU legislation is devised is the so-called co-decision procedure. Under this procedure, the Commission puts forward a legislative proposal, which is sent to the European Parliament (EP) and the Council. The EP discusses the proposal and can make amendments for the Commission to include in the version to be decided on in the Council. The Council will then accept it or adopt a

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4 It is, of course, beyond the scope of this paper to cover all the different aspects of the two political and legislative systems. For a more elaborate discussion on this please see http://europe.eu.int/eur-lex/en/about/pap/process_and_players3.html.

5 The paper uses the term 'regulation' at this point in the US sense of the word. It should be noted that a regulation in the Commission/EU context has a different meaning and refers to a type of legislative instrument. A regulation in the EU is a legal act that is obligatory and directly applicable for all EU member states. It is much more prescriptive than a Directive, which gives more leeway with regard to how its objectives are achieved.

6 For a more elaborate discussion on this please see http://ec.europa.eu/codecision/procedure/index_en.htm. It should be noted an account of all the different ways in which legislation takes place would involve an examination of the different procedures under which the three EU institutions – the European Parliament, the Council and the Commission – work with one another, which is beyond the scope of this paper.
“common position”. If the Council accepts, the act is adopted and published in the Official Journal at which point it becomes law. Thus, although the Commission is the initiator of legislation, it is not the legislator/legislative and it does not normally determine the final version of a piece of legislation.

Thus, the main difference between the role of the EC Impact Assessment and the US Regulatory Impact Analysis is that the EC IA is produced prior to the proposal being debated by the legislators, whereas in the US an agency is normally tasked with devising the most efficient way for society of regulating a subject by Congress. Created at different point in the process, the analyses that follow these guidelines necessarily serve different purposes.

The Commission Impact Assessment guidelines and the Commission's Work and Legislative Programme state that an IA is needed for 'items on the Commission's Work Programme, which means all regulatory proposals, white papers, expenditure programmes and negotiating guidelines for international agreements (with an economic, social or environmental impacts)'. The Commission's IA accompanies the proposed legislation on its way to Parliament and Council, where it is used to inform legislative and public debate and aims to show that new legislation that is proposed by the Commission is based on a sound analysis of all its economic, social and environmental impacts, and that due consideration was given to feasible alternatives to legislation when developing the proposal.

The final form that a particular piece of legislation takes is determined by the legislator, who, of course, remains at liberty to amend legislative proposals. The Commission does not view its IAs as substitutes for the need for political decisions, but rather as something that helps inform the debate, including inside the Commission so that overall better quality legislation is produced. When the EP or Council amend proposals, there is recognition that where either of them make substantial amendments, further IA work is required. Through an Interinstitutional 'Common Approach to Impact Assessment' (2005) between the EP, Council and the Commission, a commitment to such further IA work has been made, with the EP and the Council being responsible for doing that work based on the Commission's earlier impact assessment.

The Commission's IA first and foremost serves to help the Commission draft proposals that take account of sound analysis. In practice an IA that produces a 'preferred option'

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7 The Council will normally take its decision by a qualified majority, except when its position differs from that of the Commission or if the Commission has not incorporated the Parliament's amendments in its proposal; in those cases, unanimity is required.

8 If not, its common position is sent to Parliament which can accept it, reject it or propose amendments at "second reading". In the latter case, the text is sent to Council for a second reading, which in turn, can approve the amended common position or not. If Council refuses to approve, the Conciliation Committee is convened, which must try to find a compromise and produce a "joint text", submitted to a "third reading".


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should base that decision on what the most efficient option is in terms of its economic, social and environmental impacts. But there is no automatic link between the IA and the final policy outcome, nor is there any possibility for legal appeal. Secondly, because of the Commission's commitment to producing an IA for most items on the CLWP (see above) there is, in addition to legislative proposals, a need for IAs to be prepared for documents that may be of broad policy orientation. It is clear that the analysis accompanying these documents will be of a more general nature.

1.2 The underpinnings: legal and otherwise

To highlight in more detail the requirements in the US, and a few of the differences touched on above, in the US regulatory analysis is required by Executive Order¹¹ (EO) 12866 for all significant regulatory actions (rules and regulations), and more significant analysis that has to comply with OMB Circular A-4 is required for all economically significant regulatory actions, where “economic significance” is primarily defined as a rule that has an impact on the economy (costs, benefits, or transfers) of greater than $100 million in any one year. The EO also establishes the procedures by which OMB reviews significant proposed and final agency regulations. In other words, not all regulations in the U.S. are accompanied by a regulatory impact analysis. In fact, OMB reviews approximately 600 proposed and final regulations per year, and only roughly 10-15 percent of the regulations are economically significant. These regulations, however, are responsible for almost all of the benefits and costs of all regulations reviewed by OMB¹².

To a lesser extent, various US laws also require some aspects of regulatory analysis. For example, the US National Environmental Policy Act (NEPA) requires federal agencies to consider the environmental impacts of their proposed regulatory actions and reasonable alternatives to those actions. To meet this requirement, federal agencies prepare an Environmental Impact Statement (EIS). In addition, the Unfunded Mandates Reform Act requires cost-benefit analysis of all rules imposing expenditures on state or local governments or the private sector of greater than $100 million a year (adjusted for inflation). The “Regulatory Right-to-Know Act” (Section 624 of the Treasury and General Government Appropriations Act of 2001, Public Law 106-554, 31 U.S.C. 1105 note), obliges OMB to report yearly on the total costs and benefits of federal regulation, which implies an analysis of those costs and benefits. In addition, the Regulatory Flexibility Act requires an impact analysis for any rule expected to have a significant impact on small businesses. Finally, under the US Administrative Procedures Act, which is the major statute governing the process by which agencies develop regulations, agencies have an obligation to provide a “reasonable basis” for their decisions. Although this requirement can be met without providing a complete impact analysis compliant with all aspects of OMB’s Circular A-4, EO 12866 and other statutory requirements, RIAs in the

¹¹ An Executive Order is not a law; it is issued by the President as a direction to the federal government agencies on how to conduct their business. Eos do not expire at the end of a particular Presidency; in fact, EO 12866 was issued by President Clinton. Not only does EO 12866 define in general terms the type of analysis required for regulations in the US, it also establishes the procedures under which OMB exercises oversight of the regulatory process, including reviewing regulations and developing detailed analysis guidelines such as OMB Circular A-4.

¹² These totals are derived from OMB’s Reports to Congress on the Costs and Benefits of Federal Regulation, which present the aggregate costs and benefits of regulations introduced in the last ten years.
US can be used as evidence to show that agencies did in fact provide a reasonable basis for their regulations. This means that analysis has a legal status significantly different from that in the EU.

The European Commission's impact assessment system is not determined by legal requirements. Instead, it is based on political commitments made by the Commission in a range of documents, e.g. the Lisbon Agenda (2000), the Gothenborg Council Conclusions (2001), the White Paper on Governance (2001), the Sustainable Development Strategy (2001), the New Initiative for Growth and Jobs (2005), and the Interinstitutional 'Common Approach to Impact Assessment' (2005) between the Commission, the Council and the European Parliament, which also aims to ensure that substantial amendments made by the Council or the European Parliament are informed by impact assessments. Although different from the more legalistic basis that impact analysis enjoys in the US, these repeated explicit commitments to the Better Regulation Agenda and, in the context of this paper, specifically the need for new legislative proposals to be informed by impact assessments, mean that there is a strong political expectation on the Commission to deliver.

In addition, there is the EU Treaty obligation that has already been alluded to above, which requires that in preparing its policy on the environment, the Community shall take account of the potential benefits and costs of action or lack of action and therefore necessitates some form of cost/benefit impact analysis in this policy area, without further specifying the exact form it should take. This requirement, together with the added emphasis on evidence based policy making since 2000, means, for instance, that in practice most EU Directives that shape EU environmental legislation are accompanied by cost benefit analyses in the form of an IA.

1.3 The Basic Framework of Impact Assessments and Regulatory Impact Analyses

The Commission has explicitly adopted an integrated approach, giving equal consideration to environmental, social and economic impacts. Prior to the first set of IA guidelines, which were put in place in 2003 the Commission had made extensive use of single sector type impact assessments. The integrated approach combined the then existing separate IA mechanisms into one IA. The Commission has stated that it views the integrated approach as essential for assessing trade-offs and synergies, which was difficult under the sectoral approach that existed before 2002.

Secondly, the Lisbon Agenda established the goal of making the EU the most dynamic, knowledge based economy in the world by 2010, and reaffirmed the EU’s commitment to sustainable development. The Commission has structured the analytical requirements in this way because it believes that any particular set of impacts should not take preference over others, regardless of whether they are of an economic, social or environmental nature. The integrated approach has a stated goal of ensuring that the three pillars of sustainable development are assessed on an equal basis. One of the main purposes of the IA is to clearly identify impacts in each of the pillars, and to show any likely trade-offs and synergies across the three pillars so that one can make an assessment that takes all impacts into account.

The US approach also takes these impacts into account, but integrates environmental, economic, and social impacts within a cost-benefit analysis (CBA) or cost-effectiveness
analyses (CEA). Similar to the EU guidelines, A-4 derives its approach from the stated goals of the Executive Order, which states that the goal of regulation should be to maximize the net benefits to society. A-4 states that “where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society.” A-4 certainly does not preclude an analysis from identifying, for example, environmental impacts separately. A-4, however, requires that CBA and CEA are the primary way in which analyses present results. In an analogous way, the EC Impact Assessment guidelines do not preclude a CBA or CEA in the A-4 mould; however, it specifies that the primary presentation of impact should separate out social, environmental, and economic impacts.

In practice, however, there are often benefits (and sometimes costs) that are difficult, if not impossible, to monetize. In cases such as this, there is no prejudice against costs and benefits that cannot be quantified, as according to A-4, officials should use their professional judgement in deciding whether there are significant non-quantifiable costs and benefits that could change the outcome of the analysis based on what is quantifiable. Thus, it is feasible in the US that qualitative environmental or social (or indeed, even economic) impacts can lead to choosing an option that would not be chosen if only quantified and monetized impacts where taken into consideration. In theory therefore, the US approach does not differ significantly from the Commission in considering all the potential impacts of regulation.

1.4 Federalism and Subsidiarity

The Commission guidelines require verification of the need for EU level action under the concept of subsidiarity. According to the subsidiarity principle, even in cases in which the EU has the authority to legislate, action should be taken at the lowest level possible and only at the EU level if there is evidence that this would provide added value.

A US agency has what appears to be a less strict obligation to assess whether ‘Federal regulation is the best solution’ and to also ‘consider regulation at the State or local level’. US agencies have an additional obligation under Executive Order 13132 to consult state and local governments when pursuing a regulations that may significantly impact them; for example, if a federal regulation pre-empted similar state level requirements. These obligations try to ensure that regulation at federal level only take place if the federal regulation is the appropriate level of government to undertake the task.

1.5 Ensuring the Efficient Use of Resources

The principle of proportionate analysis applies to the Commission's IAs which means that any analysis should not go beyond what is needed to have a reasonable assessment of the likely impact. Due to the commitment to accompany all items that are on the Commission’s Legislative Work Programme by an Impact Assessment, there is a need to ensure that resources are used efficiently. Expending a great deal of effort on proposed policy actions that are likely to have only a limited economic, social or environmental impact would be an inefficient use of limited resources.

The $100m threshold for economic significance, and therefore expanded regulatory analysis in Executive Order 12866, is a type of proportionate analysis test as it also tries to ensure that resources are directed to those rules that have the potential to more seriously affect the US economy. In addition, Circular A-4 also asks officials to ensure
that there is a ‘balance’ between thoroughness, particularly with regard to considering alternatives to regulation, and ‘the practical limits on one’s analytical capacity’. However, the obligation to quantify impacts in a certain way, and to use CBA, prescribes a minimum amount of analysis that is always required for economically significant rulemakings. It seems that there is more leeway in the Commission’s guidelines for choosing the level of analysis that an individual IA requires, but not to the extent that the lead Directorate-General drafting the IA is completely at liberty to decide what is the appropriate degree of analysis or quantification.

1.6 Quality control

There are various mechanisms in place in the Commission to ensure that the greater leeway that the guidelines accord officials does not undermine the quality of IAs and that the appropriate amount of analysis is carried out. Every Commission IA should be steered by an Interservcies Steering Group (ISSG) which brings together all DGs that are affected by the proposal or that have a stated interest in it. The Secretariat General of the European Commission as the guardian of the IA system is always invited to send a representative. The number of times the ISSG meets varies and depends upon such things as the level of agreement/disagreement regarding the options to be examined, the type of analysis to be carried out and the significance of the impacts. By taking part in the ISSGs DGs can ensure that any impacts specific to the policy areas they represent are sufficiently analysed, for example by requesting more thorough quantification. The Secretariat-General ensures that the IA guidelines are adhered to, which also includes the right application of the criterion of proportionate analysis. For the lead DG the benefit of having an ISSG consists of achieving greater buy-in earlier on, thus reducing the scope for unexpected difficulties to emerge further on in the process, and to make use of other DG's expert knowledge in order to improve the robustness of the IA. A further of the ISSGs is to ensure that legislation is consistent and complementary across the Directorates-General.

In order to further strengthen the quality control functions within the Commission, an Impact Assessment Board (IAB) was set up at the end of 2006. This board consists of five high-ranking Commission officials who are acting in their personal capacities. The IAB's tasks consist of scrutinising IAs before finalisation, offering a quality support role to Commission services and screening upcoming items that may not require an IA but for which an IA would add value.

The IAB issues an opinion on all IAs produced in the Commission. These opinions may be negative if the IA is deemed too weak and may involve a request for resubmission, or positive, which in practice includes some recommendations for improvement. In its deliberations, the IAB also takes into account whether the level of analysis that is presented is adequate, given the type of proposal, i.e. whether legislative or non-legislative, and its likely impacts. The mandate of the IAB furthermore foresees the possibility of issuing so-called 'prompt' letters to DGs for proposals that strictly speaking do not require an IA, when it believes that carrying out impact analysis would provide useful value added. 13

1.7 Stakeholder consultation

13 In the US, OMB occasionally issues prompt letters in order to encourage agencies to perform additional analysis on a subject or to consider a rulemaking on a particular policy.
The Commission’s IA guidelines ask officials to consult as much and as widely as possible. It states that consultation should not be restricted to those stakeholders who are easy to engage and to experts. Officials are expected to proactively identify all stakeholders and to ensure that each group of stakeholders is engaged in what is the most suitable way for them. A reactive approach based on publishing a consultation on the internet and waiting for responses may not always be sufficient or appropriate. The Commission guidelines emphasise the importance of consultation for reducing the likelihood of ignoring important aspects of the proposed action that may otherwise be overlooked and in increasing stakeholder buy-in. There is ample guidance on consultation apart from what is in the guidelines, including minimum standards that all services are expected to adhere to in their IA work. Moreover, all consultations have to be published on the webportal 'your voice in Europe' www.europa.eu.int/yourvoice/consultations/index_en.htm and stakeholders can foresee possible contributions by looking at the Commission's Legislative and Work Programme, which includes the publication of roadmaps outlining upcoming impact assessments.

Consultation requirements are not specifically spelled out in Circular A-4, but are governed by other statutory and OMB requirements. For example, the US Administrative Procedure Act established the “notice and comment” rulemaking process, where all regulations (not only significant regulations) and their analyses must be first published in proposed form in order to give the public a chance to comment. The public can find all regulations currently out for comment on the website http://www.regulations.gov. OMB also put in place guidelines establishing requirements for the peer review of influential scientific documents before they are disseminated by the agency.

There is an understanding that the agency will use high quality information and expert advice if appropriate. A-4 states that “Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data.” There is no requirement, however, for officials to approach this topic proactively. In addition, there is no explicit requirement to seek interservice/agency advice. Agencies with knowledge or a stake in another agency’s regulation will review the rule during the OMB review process, and often participate during rule development, but there is no specific process requiring this type of interagency or expert consultation.

1.8 Taking account of international impacts (third countries, trade issues, international competitiveness, etc)

Legislation and regulations passed in the EU or the US can often have a significant impact on third country exporters to the US/EU markets and affect the conditions under which home country firms compete with external producers. The EC impact assessment guidelines require all impacts to be assessed, regardless of where they are likely to materialise or whom they are likely to affect. In addition, the annex to the EC Guidelines specifically asks for impacts on international trade and relations, and impacts on third countries or international agreements, to be taken into account\(^\text{14}\). Amongst other things, this requires an assessment of whether the proposal places EU companies at an advantage or disadvantage vis-à-vis external competitors, whether consumer demand will shift away from polluting industries or how trade and cross-border investment will be affected.

\(^{14}\) Annex to IA Guidelines, pages 29 and 33
The Commission is committed to promoting sustainable development at home and abroad. When negotiating international trade agreements a Trade Sustainability Impact Assessment (Trade SIA) is carried out by DG Trade. Trade SIAs may build on a previous IA carried out in relation to preparing the EU negotiators mandate. They aim to: provide an in-depth assessment of likely changes caused by the trade agreement on economies, social development and the environment in any potentially affected geographical area; provide information to help clarify trade-offs derived from trade liberalisation and the limits of trade negotiating positions; build an open process of consultation around trade policy creating a basis for an informed discussion with a broad range of stakeholders; improve the EU’s institutional and political dialogue on sustainable development with its trading partners; shed light on how trade policy can contribute to internationally agreed processes on sustainable development, in particular the Millennium Development Goals and the targets set by the 2002 World Summit on Sustainable Development in Johannesburg; and propose ex-post monitoring measures to be put in place during the trade agreement’s implementation.

In a bit of a contrast, Circular A-4 states that a regulatory impact analysis “should focus on benefits and costs that accrue to citizens and residents of the United States.” Although analyzing the impacts to non-citizens or residents is often undertaken, analyzing the impact on foreign entities not directly conducting business in the U.S. economy is not required by the Circular. Circular A-4 also states that transfers (monetary payments from one group to another that do not affect total resources available to society) between foreign and domestic producers or consumers should be considered costs and benefits of a rulemaking. If the transfer occurred between domestic entities, only the net change in the total surplus should be counted is a real cost or benefit to society.

In practice, US Regulatory Impact Analyses often acknowledge that many direct impacts on foreign entities are passed on to the U.S. economy, and these impacts should be taken into account. For example, if a regulation raises the cost of importing a product, and therefore raises domestic prices, the costs to domestic consumers or intermediate producers due to those price increases should be considered in the impact analysis. Depending on market structure, a significant portion of the direct cost of the rulemaking imposed on foreign entities may be felt in the U.S. economy. Therefore, an analysis of the direct costs on foreign entities is often a useful if conservative proxy of the costs on the U.S. economy, and many U.S. analyses incorporate this approach in order not to underestimate the costs of their rulemakings.

16 Circular A-4, Page 15.
17 Note that Circular A-4 makes no distinctions between foreign or domestic firms operating in the U.S. For example, in the U.S. Department of Transportation’s rulemakings establishing corporate average fuel economy standards, the impacts on foreign firms such as Toyota are analyzed in an identical manner as the impacts on domestic firms such as General Motors. In addition, if agencies, OMB, or the U.S. Trade Representative have a concern that a regulation may act as a non-tariff barrier, the agency will conduct a trade impact analysis likely similar to the analysis required by the IA guidelines. Circular A-4 is not explicit about the form this analysis may take.
2 The role of the analysis of impacts

2.1 Key Elements of Regulatory Analysis

The IA Guidelines specify that an IA should consist of the following sections: 1) identification of the problem, 2) definition of the objectives, 3) development of the main policy options, 4) analysis of their impacts, 5) comparison of the options and 6) an outline of how the policy will be monitored and evaluated.

The introduction to the US guidelines takes a similar approach; a good regulatory analysis consists of 1) a statement of the need for proposed action, 2) an examination of alternative approaches and 3) an evaluation of the costs and benefits – quantitative and qualitative – of the proposed action and the main alternatives.

A notable difference in emphasis in the guidelines is that A-4 states that the evaluation of costs and benefits is not restricted to the preferred option but that it is required for all reasonable alternatives – indeed, there is an expectation that CBA will be done for more than one policy option. While the EC guidelines also clearly support this CBA approach, it is often limited to the preferred option, with a less fully developed CBA being produced for the other options which have been found to be less efficient.

Both guidelines specify that analyses should develop a baseline scenario against which all other options have to be compared. However, comparing other options against the no-change option in the US means that the costs and benefits of the baseline option are quantified and projected into the future. This requirement is less pronounced in the EC guidelines, where often a qualitative assessment that concludes that existing problems are likely to remain is sufficient, although the guidelines do require one to look at how the problem is likely to evolve over time. The baselines scenario as understood in the Commission IA system does include taking into account developments, such as existing policies already decided and in the pipeline and predictable technological progress. Part of the raison de etre of the IA is to show that another option would lead to net social benefits vis-à-vis the baseline option. If the IA cannot show that, the baseline option should be the preferred option, something which has happened on some occasions.

A-4 does not obligate RIAs to examine a certain number of options, and a US agency is allowed to dismiss some options without much analytical work if they are clearly not genuine options. There is an expectation that serious analysis is done on several alternatives. The Commission’s IA are expected to look into a range of options, usually three to five in total.

An important difference, however, is that the alternatives available and expected to be considered in the EU are often wider in scope than in the US. The term “regulatory alternatives” is used in the US, whereas the EC guidelines discuss “alternatives to regulation.” The EC guidelines state, and strongly recommend, that all analyses should consider alternatives to regulation, such as co- and self-regulation or other market based implementation instruments, within the impact assessment. Typical alternative regulatory approaches in the US may include some EC “alternatives to regulation”, but others are narrower in scope than what typically would be considered an EC alternative, such as different compliance dates, levels of stringency, enforcement methods and different requirements for small firms. This is almost certainly due to the wider scope of the legislative and regulatory actions covered by the EC guidelines. Remember that the scope
of a U.S. regulatory agency to consider non-regulatory alternatives is limited by the authority granted by previous statutes (or primary legislation). For example, although resource-based taxes are often considered a viable alternative to direct pollution regulation, the EPA, as well as the Commission, does not have the statutory authority to impose taxes to meet their regulatory objectives.

Both A-4 and the Impact Assessment guidelines have transparency as a major goal. A-4 states that third parties should be able to see clearly how estimates of costs and benefits are arrived at and be able to reproduce any calculations with the information that is given in the impact assessment. The Impact Assessment guidelines state that the analysis and conclusions should be transparent to a non-specialist and clearly presented in a standardized format. Both guidelines require that analyses use clear language that does not obfuscate results.

2.2 Reasons for Intervention

Almost every regulation is an intervention in the functioning of markets. Markets are generally efficient, but sometimes fail in a way that intervention, including regulation, may be able to address. Both guidelines discuss externalities, public goods, and inadequate or asymmetric information as typical market failures that may require intervention. In addition, both systems allow for intervention on the grounds of other compelling public needs, such as distributional equity and fairness, or rectifying other undesirable social outcomes. Regardless of the need for the intervention, both guidelines state that the rationale should be clearly presented and as concrete as possible.

While there is a great deal of similarity on the rationale for intervention between the two systems, the identification of the market failure argument appears to be given more prominence in Circular A-4 in the US. A-4 presents a fuller discussion of the types of market failures that regulations may address, and includes the direction that agencies should have a presumption against “economic regulation,” or using such regulatory mechanisms as price and wage controls or entry restrictions to accomplish their regulatory objectives.

The IA guidelines, however, have a fuller discussion of how to frame a problem well, or in such a way that it lends itself to appropriate policy alternatives. For instance, the guidelines suggest a problem tree approach, which maps out major problems and how they relate to each other. The IA guidelines state that this is a useful tool for focusing on the core problem that actually needs to be addressed by a regulation.

The slight difference in emphasis between the two approaches to discussing the reasons for an intervention may be due to the wider applicability of the IA guidelines. By its nature, for example, some of the items requiring an IA under the Commission’s existing rules may address issues that lend themselves less to a categorisation into what economists would consider classic market failures.

2.3 Analytical Methods

As stated above, A-4 states that the evaluation of how best to achieve the objectives of a regulation is done within the framework of cost-benefit and cost-effectiveness analysis (CBA and CEA respectively). The US guidelines give considerable detail on how to use the two methods. The Commission’s guidelines, on the other hand, see CBA and cost-effectiveness analysis as valuable methodologies that can add value when assessing likely
impacts. They are not compulsory and a qualitative analysis is often equally valid. In practice, however, almost all regulatory impact analyses in the U.S. and impact assessments in the EU will contain both qualitative and quantitative components.

The IA guidelines provide greater guidance on the specific impacts particular regulations may have. For example, it provides an impacts menu tool, which is “meant as an aid for you to use in developing your thinking about a wider range of potential impacts for the policy options.” This reasoning behind the menu approach chosen by the Commission to identifying impacts may be twofold. It tries to take account of the various limitations of these types of analysis, where obstacles such as a lack of data often allow for only partial monetisation or quantification. Moreover, the proportionate analysis criterion of the EC guidelines often limits the amount of effort that should be expended on an IA that analyses a policy with a relatively small impact, which can favour qualitative analysis since it is generally less resource intense. Both guidelines stress that analysis should be proportional to the size and importance of the regulation; therefore, in practice both guidelines support greater analytical rigor when it is especially relevant for decision making. Finally, as explained above, the role of the IA in the EU policy making process is to provide additional information for decision makers to consult when developing policy legislation (and not a replacement for policy decisions). As such, there may be instances in which this information is just as easily, or even better, disseminated by a qualitative discussion of likely impacts rather than by detailed quantitative work.

However, in spite of the absence of an obligation to quantifying and monetising where possible, there is of course recognition in the Commission that public funds have to be used in accordance with sound financial management, and that [AI: private mandates?] should be imposed only when necessary and that they should be efficient. Interventions should therefore be achieved in a cost efficient manner. The EC guidelines state that efficiency goals of an intervention are met "if its set of objectives are achieved at least cost, or if its desired impact is maximised at a given level of resources." For highly focused regulatory proposals, those that are likely to have significant economic, social or environmental impacts and where good data exists, using CBA and/or CEA techniques is common and encouraged.

2.4 CBA and CEA

A-4 states that CBA should be carried out for all rulemakings and for all options considered in a regulatory analysis. Moreover, overall as well as incremental costs and benefits have to be calculated. Agencies are not entirely free in their choice of how to do CBAs as there is some requirement for consistency across regulations. Circular A-4 introduces the tools of CBA and CEA, such as opportunity cost, willingness to pay and accept, contingent valuation and revealed preference, Quality Adjusted Life Years, discount rates, etc. and discusses their limitations.

18 IA guidelines, pg 28

19 Moreover, the same page in the guidelines states that "all proposals with financial implications for the Community budget must also be accompanied by a legislative financial statement that includes a detailed calculation of the financial and human resources to be allocation to the intervention" (IA guidelines, pg. 26).
The main feature of a CBA is that costs and benefits are expressed in monetary terms to the extent feasible, which allows for a direct comparison and evaluation of the different policy options. This policy represents a significantly stronger reliance on CBA than that adopted by the Commission. Taking the net benefit measure as the evaluation indicator may favour options with large costs as long as they are exceeded by high benefit estimates. The EC guidelines are clear in stating that a qualitative approach to impact assessment is appropriate in many circumstances. This may be a reflection of the difference in purpose of IAs compared with the US and a recognition that CBA for a broad policy outline would not be sensible, and takes account of the proportionate analysis criterion, but it is also likely that it reflects a slight difference in the perceived limitations of quantitative analysis in some instances.

Circular A-4, although requiring CBA if feasible, recognizes that monetized CBA, in practice, is not the only consideration in a decision, as many costs and benefits simply cannot be monetised. The US official is encouraged to quantify where possible in such instances, and if that is not possible to present a qualitative discussion of the costs and benefits. In situations such as this A-4 encourages a “threshold” or “break-even” analysis. This analysis answers the following question, “How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?” In addition to threshold analysis, A-4 indicated that the agency “should indicate, where possible, which non-quantified effects are most important and why.”

In addition, A-4 encourages CEA for all rules and requires it for rules in which the primary benefit is an improvement in health or safety. In CEA, a set of regulatory actions with the same outcome(s) is compared (e.g. construction of an index on units of health improvement). CEA should lead to the identification of the most efficient way of achieving a regulatory outcome in the absence of complete monetisation of benefits. Circular A-4 gives considerable detail on pitfalls and things that have to be kept in mind for making CEA successful - for example, the need to look at incremental cost-effectiveness and how to construct the cost-effectiveness ratios. A-4 encourages the use of an integrated measure of effectiveness, such as Quality Adjusted Life Years, but does not take a position on what measure of health improvement or other unit of benefit to use, stating that lives saved, life years saved, or a measure such as Quality Adjusted Life Years may all lend a useful perspective to the decision-makers. CEA is a relatively new requirement for RIAs, and the US Institute of Medicine of the National Academy of Sciences recently published a report called “Valuing Health for Regulatory Cost-Effectiveness Analysis” that studies the issue in more detail.

The EC guidelines stress that CEA offers a good alternative to CBA, particularly in cases in which the full monetisation of all costs and benefits is not possible. It explains that CEA leads one to calculate the costs of a desired outcome for several options and allows one to rank them based on ‘cost per unit of effectiveness’. According to the guidelines CEA can be useful when several options all lead to more or less the same outcome.

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20 This report is available at http://www.iom.edu/CMS/3809/19739/32029.aspx
It is clear that Circular A4 itself give more detail as regards, for example, CBA and CEA than the EC guidelines do. This is, of course, a reflection of the stronger requirement for CBA/CEA that exists in the US system, which itself is a reflection of the slightly different purposes the two (R)IA systems fulfil. It should be stressed that as in the EC some IAs may be prepared for broad policy documents, communications that summarise a consultation outcome or are of a very general nature and thus do not propose concrete policy steps, any analysis that simply compares the proportion of IAs that use quantitative analysis, as has been done by some scholars, would be misleading. For policy proposals that are likely to have significant impacts, the level of detailed quantitative analysis, and hence the use of CBA, CEA, etc, is by and large comparable. Good examples of this can be found is the area of environmental legislation.

2.5 Administrative Costs

Measuring the likely administrative costs of legislation is a requirement unique to the Commission's IA guidelines, although A-4 would consider any impacts of this nature legitimate costs and would require their analysis. The Commission has recently developed a model for measuring net administrative costs. These costs can be considerable burden on business, voluntary organisations and the public sector. They affect small to medium size enterprises (SMEs) more than larger organisations and can pose a serious hindrance to a competitive, productive and innovative economic environment. Given the commitments the Commission made in Lisbon 2000 to making the EU the most dynamic, knowledge-based economic area by 2010, their potential to weigh down economic progress by slowing down productivity growth and innovation can be directly at odds with overall Commission policy. The other side of the coin is that data collection, labelling of products and so on often fulfils a very useful and necessary requirement. One only needs to think about the confidence consumers would have in unlabelled products or imagine a world without data collection. In order to strike a balance between the necessity and usefulness of labelling and data collection on the one hand, and ensuring a competitive market economy framework on the other, it is essential to be aware of administrative costs that a given piece of legislation is likely to cause.

The guidelines suggest measuring administrative costs by multiplying the average cost of an action (price) by the total number of actions performed (quantity). The core equation is the following: \( P \times Q \) (Price = tariff x time; Quantity = no. of businesses x frequency)

21 “Administrative costs are defined as the costs incurred by enterprises the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties. Information is to be taken in a broad sense, including costs of labelling, reporting, and monitoring to provide the information and registration.” (Annexes to guidelines, pg. 35)

22 In addition, the U.S. does require a separate analysis of the “paperwork burden” of regulations and, more generally, information collections, under the Paperwork Reduction Act, which was discussed in more detail above. OMB also tracks and reports to Congress yearly, called the Information Collection Budget, on the total paperwork burden imposed by U.S. agencies. This process and analysis, however is not covered in Circular A-4.

23 Net administrative costs are defined as: costs introduced by the legislation minus the costs suppressed by legislation at EU and/or national level.
The tariff is based on labour cost and overheads, which are normally the main cost factors of meeting administrative obligations.

Since the recent amendment to the guidelines, taking account of administrative costs has been made obligatory. However, these costs were also taken into consideration for some of the most far-reaching IAs the Commission has done so far. In the IA supporting the REACH\textsuperscript{24} proposal, the administrative costs of each man-day required for meeting the obligations were calculated to be EUR 1000. This figure includes overheads which in the case of chemical laboratory work can be quite substantial.

2.6 Required Parameter Values

For the most part, neither document requires that analyses use particular values for parameters of interest. The two exceptions are the value of risk and discount rates. First, A-4 discusses the methods and economic research on the value individuals place on risk reduction in some detail. The guidelines do not come to a definitive conclusion on a specific value, but they do recommend a range. A-4 states that “A substantial majority of the resulting estimates of VSL (the “value of a statistical life”, or the monetized value of small changes in fatality risk that when summed up equal one life saved) vary from roughly $1 million to $10 million per statistical life.”\textsuperscript{25} In practice, these values are widely used in US RIAs in many different regulatory contexts that involve small changes in risk. A-4 also discusses the value agencies may place on interventions that change the risks faced by children. Although research on this point is inconclusive, A-4 states that agencies should place at least as high a value on a child’s statistical risk as they do to an equivalent risk faced by an adult.

The EC guidelines discuss VSL in the context of environmental policy. They recommend a value €1.0 million ($1.2 million at current exchange rates) as a best estimate when monetizing benefits, and between €0.65 ($0.78) million and €2.5 ($3.0) million as upper and lower bounds in sensitivity analysis. The EC guidelines state that these figures are “applicable to deaths in a largely elderly population where the reduction in life expectancy is likely to be short – maybe one year or less.”\textsuperscript{26} They are not the default choice when monetising the value of life. Depending on the individual case, different methodologies have been used within the Commission, bearing in mind the relatively low number of EC IAs that have attempted monetisation in the context of value of life. Although both A-4 and the EC guidelines are clear that these values are only applicable to interventions resulting in small changes in risk, in practice it is more common to quantify risks and not monetize them in Commission IAs. Nevertheless, the EC guidelines support monetization of this type, stating that “any decision in this context means placing an implicit monetary value on health benefits. Decision-making will be easier and become more consistent if we

\textsuperscript{24} The European Commission has proposed a new EU regulatory framework for chemicals called REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). More information is available at: http://ec.europa.eu/enterprise/reach/index_en.htm

\textsuperscript{25} Circular A-4, Page 30.

\textsuperscript{26} IA guidelines, pg 38
have a monetary estimate of the value of health benefits. The monetary value represents the strengths of society’s preferences.27

Both guidelines also specify discount rates which should be used in all impact analyses to adjust benefits and costs when they do not take place in the same time period. The EC guidelines state that all analyses should use a discount rate of 4%, while A-4 requires that all analyses use discount rates of both 3% and 7%. Both are real rates of return, which means that they do not include inflation, which should be accounted for with an expected inflation rate. The EC guidelines state that 4% “broadly corresponds to the average real yield on longer-term government debt in the EU over a period since the early 1980s.”28 A-4 provides a detailed discussion of the rationale for the different discount rates. The 7% rate approximates the average before-tax rate of return to private capital in the U.S. economy, and represents the opportunity cost of capital in the U.S. A-4 states, however, that when regulation primarily and directly affects private consumption, a lower discount rate is appropriate. The alternative most often used is sometimes called the social rate of time preference, which may be fairly approximated by the historical real rate of return on long term government debt, which is around 3%.29 Thus, the rationale for A-4’s lower rate of return also applies to the EC’s required rate of return of 4%. A-4 requires both rates for all analysis, stating a rationale that, in practice, it is difficult to determine the distribution of cost in the market and on consumers.

2.7 Uncertainty Analysis

Both guidelines discuss uncertainty analysis. Specifically, the EC guidelines state that “it is important to remember that in some cases, the level of uncertainty may be too high to make precise quantified estimates. In these cases, ranges of plausible values or different scenarios should be given…”30 The guidelines provide a brief introduction outlining the importance of dealing with uncertainty by analysing its potential impacts. For more detail on how to do this type of work and techniques, the EC guidelines provide a web link to the Commission’s Joint Research Centre (JRC).31 Circular A-4 requires agencies to

27 EC Guidelines Annexes, Pages 37 - 38

28 EC Guidelines Annexes, Page 39. Essentially, the EC believes that the average rate of return on government bonds should be the only proxy used as it more accurately reflects the opportunity cost of public investments. The US argues that the opportunity cost is more accurately reflected by the private sector rate of return, but that the private personal time preference may be approximated by the same government bond returns recommended by the EC. The US uses two discount rates reflecting these two different opportunity costs.

29 The SRTP is calculated in the following way: \( r = \bullet + g \), where \( r = \text{SRTP}, \) \( \bullet \) - discount rate of future consumption over present consumption with no change in per capita consumption, \( g \) - elasticity of marginal utility of consumption with respect to utility, \( g \) - annual growth in per capita consumption. Studies have shown the value for \( \bullet \) to lie between 1.0 and 1.6 (e.g. OXERA 2002), for \( g \) to be around 1 with a range of +/− 0.3-0.5 (e.g. OXERA 2002; Cowell and Gardiner 199; Pearce and Ulph 1995). A good estimate of \( g \) is generally around 2-2.5% (e.g. various studies, for UK Madison 2001). When substituting these values into the equation one obtains \( r = 3-4\% \).

30 EC guidelines, Page 37 - 38.

31 http://sensitivity-analysis.irc.cec.eu.int

The JRC is an institution that all Commission services (the DGs) can draw on for expertise, particularly on the use of quantitative techniques such as sensitivity analysis.
characterize in some way the uncertainty inherent in the analysis. “The important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis.”

In both cases, the analysis often takes the form of sensitivity analysis of one or more important or particularly uncertain parameters. The EC guidelines identify sensitivity analysis as an especially useful and relatively easy approach. The EC guidelines may be understood as encouraging a discussion of both variability- uncertainty for which probabilities or distribution functions exist - and uncertainty, for which no probabilities are available. As both normally go hand in hand, obtaining a good idea of those uncertainties with known probabilities alone is not enough. Dealing with uncertainties without known probabilities generally requires a case-by-case or scenario approach, often comprising a qualitative approach describing different plausible scenarios. The application of uncertainty analysis in the EC is of course also subject to the proportionate analysis criterion. A-4, however, goes further with specific requirements: for rules involving annual impacts of $1 billion or more, A-4 requires agencies to conduct what the guidance calls a “formal quantitative analysis” of the relevant uncertainties about benefits and costs. In practice, this will often take the form of a Monte-Carlo analysis, which assumes a distribution around many of the uncertain variables in order to estimate an uncertainty interval around net benefits. For rules with annual impacts under $1 billion, the guidance does not require as in-depth an analysis, and in practice sensitivity analysis is probably the most common approach. A-4 also encourages, similar to the EC guidance, a scenario approach to discussing uncertainty where the agency cannot estimate the probability of a particular impact.

2.8 Future Monitoring and Evaluation of Programs

The EC's guidelines stipulate that an IA has to include information on how achieving the policy objectives will be monitored. There is a specific requirement for evaluating the effectiveness of expenditure programs, including generating data on the basis of carefully designed indicators. The IA itself must discuss the method by which a programme will collect data or how its effectiveness after implementation will be verified. Although this is an important part of the IA, the guidelines recognise that the final form that evaluation and monitoring takes can only be determined after the proposal has been through the Council and Parliament. Officials are therefore required 'to provide a broad outline of possible monitoring' and '…evaluation arrangements' and to identify core progress indicators.

The evaluation and monitoring requirements in the Commission's IA system have a goal of providing policymakers with a way of verifying whether a policy is achieving its objectives. Many of the indicators that are needed for expenditure programmes can also be applied to regulatory proposals. A distinction is made in terms of outputs between expenditure programmes and purely regulatory (policy) proposals, and the EC guidelines acknowledge that it can be much more difficult to develop indicators for the latter. For

32 Circular A-4, Page 38.

33 EC guidelines, Page 45.

34 Ibid, page 45; with italics by authors.
example, if money is spent on building a road, it is relatively easy to come up with indicators, e.g. miles of road build after x months. For a Directive, however, this is more difficult: transposition into national law or adoption by the European Parliament cannot be considered an as output. The guidelines suggest that "outputs at EU level could in such a case be based on a typology of the 'key types of measures' adopted by the Member States in order to comply with the Directive". Any indicators in this context should be "RACER: relevant, accepted; credible, easy to monitor and robust.”

There is no equivalent requirement for an RIA to include performance indicators, or for post implementation validation or effectiveness analysis in the U.S. under Circular A-4 or EO 12866. Often the effects of regulations in the U.S. will be validated by outside parties, or will be re-evaluated in the context of adopting regulatory reforms, but there is no proactive requirement. In the 2005 Report to Congress on the Costs and Benefits of Federal Regulation35, OMB studied the extent to which the *ex-ante* regulatory analysis published by agencies before a rule is finalized are validated for their accuracy after the rule has been put in place. OMB found that only a small fraction of the rules reviewed by OMB before publication have been validated *ex-post*. The only proactive requirement in the U.S. for post-regulatory analysis is under the Regulatory Flexibility Act, Section 61036, which obliges agencies to revisit the regulations they passed that significantly impact small businesses. This analysis must take place within 10 years following the original final rule, however, the analysis need not be quantitative and the agency is not required to consider changing a regulation as a result of this review, even if the review concluded that the regulation is not acting as intended.

### 3 Conclusion

This paper began by stressing the different purposes the two IA systems serve and hence for which the two sets of guidelines have to cater. Due to the differences in the legislative systems, or more specifically how laws and regulations are made, impact analysis is produced at different stages in the process. In the US, an RIA is produced by an agency tasked by Executive Order 12866 with implementing laws or primary legislation in the most cost-beneficial way. The formal OMB Circular A-4 applies to “economically significant” proposed and final rules whose annual costs or benefits are likely to exceed the threshold of US$ 100 million. Since agencies have a statutory obligation to show that proposed regulation has a reasonable basis, US RIAs may be drawn upon in court cases.

The Commission's IAs fulfil the purpose of providing additional information internally and to policy makers on its regulatory or legislative proposals, and are prepared for all items on its legislative and work programme, barring some items of consultative nature which are exempted, such as Green Papers. Although external parties also use the IAs, e.g. the European Parliament and the Council of Ministers, they are mainly prepared as an input for internal Commission political decision-making. Thus, in the EU decision making process the final legislative product may be less strongly linked to the Commission IA, bearing in mind that the EP and the Council are committed to conducting additional

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35 Available at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html

36 *(Will add reference)*
impact analysis of substantial amendments they propose. Moreover, the Commission prepares IAs for a variety of documents and general policy orientation proposals that do not require RIAs in the US system. Hence, one may conclude that the Commission guidelines have to be more flexible and less prescriptive in its analytical requirements than Circular A-4, in order to apply in a meaningful way to CLWP items that are of a more general nature.

These differences manifest themselves in the level of detailed advice that is given in both sets of guidelines on quantitative analysis. In the US, there clearly is a stronger obligation to do cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA) of an economically significant proposed regulatory action and a reasonable set of alternative regulatory approaches. This must not be confused, however with there being no demands for detailed CBA (or CEA) for Commission proposals of similar economic, social and environmental impacts as the US$ 100 million threshold. The Commission guidelines clearly state that proportionate analysis is required, which by implication means more detailed, and thus often more quantitative, analysis if the likely impacts are sufficiently large and lend themselves to analysis.

A defining feature of the Commission IA system is the integrated approach, taking into account all economic, social and environmental impacts. The US does take account of economic, social, and environmental impacts, but within a CBA framework. Concluding from this that the US IA system is biased against impacts that cannot be quantified, whereas the Commission pays more attention to these impacts, perhaps at the expense of quantification, may be misleading. There is an obligation in the US guidelines to take account of non-quantifiable impacts and to provide thorough qualitative analysis. The demands for detailed quantitative analysis in the Commission were described above. In reality, the authors believe the differences in the guidelines regarding the ability of the two systems to take account of qualitative impacts and to conduct quantitative analysis are less straightforward than often thought.

One may conclude that while many similarities exist, there are significant differences, particularly as regards the legal and institutional framework, the resulting different stages at which (R)IAs are produced, and the difference in purpose they serve in the two systems. Consequently, carrying out one ex-ante (R)IA on a comparable initiative that can be shared by US regulators and the Commission would at this moment in time be an immensely challenging task. Building on each separate analysis based on a better understanding of the other's system are likely to produce better results by way of regulatory cooperation.

The next step in this line of analysis should include a more detailed investigation into how these differences or similarities in the guidelines translate into practice, or rather how Impact Assessments and Regulatory Impact Analyses compare that analyse impacts of a comparable policy or regulatory initiative. It should hopefully be clear from this paper that such an investigation cannot simply compare the proportion of analyses that quantify impacts, evaluate adequate alternatives, or perform sensitivity analysis in the two systems, but rather would have to respect the different contexts and requirements, as expressed by, for example, the different proportionality criteria, the narrower applicability of the U.S. Circular, and the relatively short time that the Commission Impact Assessment guidance has been in place.
Reference Documents

European Commission documents:

European Commission Impact Assessment Guidelines:

Gothenburg Council Conclusions (2001):
http://ec.europa.eu/governance/impact/docs/key_docs/goteborg_concl_en.pdf


The EU Sustainable development Strategy (2001):

See also: http://ec.europa.eu/environment/eussd/

The Interinstitutional 'Common Approach to Impact Assessments':
http://ec.europa.eu/governance/impact/docs/key_docs/ii_common_approach_to_ia_en.pdf

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http://ec.europa.eu/governance/impact/key_en.htm

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