Comments of the United States Government on the 2014 Revision of the European Commission Impact Assessment Guidelines Public Consultation Document September 30th, 2014

The United States welcomes the opportunity to provide comments on the European Commission's "preliminary revision" to its impact assessment guidelines ("proposed Guidelines"). The United States agrees with the revision's underlying premise, i.e., that "better informed policy-making contributes to better policies."[1] As noted in U.S. comments on the Commission's Better Regulation Package over a decade ago, as a major economic and political partner of the European Union, the United States has a substantial interest in the EU's regulatory process and activities, given that EU regulations can have significant upstream and downstream effects across a broad variety of actors inside and outside EU territory. The United States is encouraged that the Commission is revising its Guidelines and has provided all interested parties of the public with an opportunity to provide comments.

The European Commission and the United States have had extensive discussions on these issues in the High Level Regulatory Cooperation Forum over many years.[2] All regulatory systems tend to grapple with similar issues, so it can be useful to learn from the experiences of others. While each regulatory system presents unique challenges, the EU and United States share the view that enhancing implementation of certain good regulatory practice ("GRP") principles will improve the quality of regulations in any regulatory system, helping regulators to achieve their legitimate public policy objectives more effectively, and increase public acceptance of those regulations.

This submission addresses:

1. the value of permitting the public to critique draft impact assessments (IAs);
2. the overall approach to, and purpose of, conducting an IA;
3. the scope of coverage of proposals subject to IA;
4. clarifications to specific questions to be answered in conducting an IA;
5. evidence-based decision-making, stakeholder consultations and transparency; and

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[1] *2014 Revision of the European Commission Impact Assessment Guidelines: Public Consultation Document*, [*Consultation Document*], 2, available at http://ec.europa.eu/smart-regulation/impact/docs/iag_pc_questionnaire_en.pdf.

[2] For example, see *Common Understanding on Regulatory Principles and Best Practices*, 2011, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/common-understanding-on-regulatory-principles-and-best-practices.pdf.

6. documents describing the U.S. approach to sound science, regulatory analysis and oversight.

1. The value of permitting the public to critique draft impact assessments (IAs)

The experiences of many countries, including the United States, have demonstrated the value of public consultations on draft impact assessments; and that there is a mutually reinforcing link between public consultations, the completeness and accuracy of impact assessments, and the quality of the science and data underlying the assessments, on the one hand, and the resulting quality of the regulation on the other. With higher quality regulations, regulators can better protect the health, safety, and security of their citizens and the environment.

As provided in the 2012 OECD Recommendation, good regulatory practices include "providing meaningful opportunities (including online) for the public to contribute to the process of preparing draft regulatory proposals and to the quality of the supporting analysis."[3] "Regulatory Impact Analysis should as far as possible be made publicly available along with regulatory proposals . . . and within adequate time to gain input from stakeholders and assist political decision making."[4] Moreover, the OECD noted that:

> "Impact assessment processes should be closely linked with general consultation processes for the development of new regulations through for example, roadmaps, giving early notice of possible regulatory initiatives and related consultation and impact assessment work and the use of a consultation stage Regulatory Impact Assessment. The results of the consultations, together with individual contributions, should as far as possible be made publicly available (including online where appropriate) in order to ensure a high level of transparency and reduce the risks of regulatory capture."[5]

Conducting regulatory impact assessments ("RIA") to enhance transparency and improve regulatory quality has been the practice in many OECD countries for many years. In 1997, the OECD observed that:

> "Consultation, in fact, is often built around RIA documents that state the goal and effects of proposed rules. Incorporation of RIA into consultation has enhanced the transparency of regulatory processes, provided quality control for impact statements, and improved the information on which decisions are based. In some countries, such as Australia, RIA is justified in

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[3] *See* OECD, 2012, *Recommendation of the Council on Regulatory Policy and Governance*, 4, available at http://www.oecd.org/gov/regulatory-policy/49990817.pdf.

[4] *Id.* at 10.

[5] *Id.* at 26. Additionally, the 2014 OECD *Compliance Cost Study* states that "Consulting on compliance cost estimates . . . a significant element of Regulatory Impact Analysis . . . can further improve the quality of final CCA [Compliance Cost Assessment] – and of the resulting regulations – by enabling stakeholders to critique the analysis undertaken and providing a source of additional data and analytical input." OECD, 2014, *Regulatory Compliance Cost Assessment Guidance*, 7, available at http://www.oecd-ilibrary.org/governance/oecd-regulatory-compliance-cost-assessment-guidance_9789264209657-en.

> terms of its utility in informing the consultation process as well as a decision tool in its own right."[6]

The OECD has also reported that Denmark, among other OECD Members, publishes both draft regulations and draft impact assessments for comment by the public before sending proposals to its parliament.[7]

More recently, in September 2012, a position paper developed by five EU Member State independent advisory bodies made recommendations to the Commission along similar lines:

> "Stakeholders should be involved as early as possible, in particular before the decision of the Commission, i.e. when the working level preparation of the draft legislative proposal and of the impact assessment has been finalised. They should also be consulted when identifying areas for ex-post evaluation and fitness checks...
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> The Commission should produce "consultation stage" impact assessments, i.e. draft impact assessments with a preliminary assessment of the expected costs, which should be published – e.g. in form of a standard template – along with the legislative proposals in the consultation process. This would systematically allow consultees to comment on the evidence base, serious alternative options, and assumed costs and benefits and to enable the final impact assessment to be robust."[8]

For many years, the United States has followed an analogous approach.[9]

An important step toward improving regulatory quality is providing the public the opportunity to understand and comment on draft impact assessments at a time when comments can be taken into account, and where appropriate, regulators can revise their analysis before making any final choices. The opportunity for public scrutiny would include permitting the public to comment on the Commission's supporting information and analysis, including the methodology, the assumptions made, conclusions drawn and the comparison of and selection among the alternatives.

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[6] *See* OECD, 1997, *Regulatory Impact Analysis: Best Practices in OECD Countries*, 17, available at http://www.oecd.org/gov/regulatory-policy/35258828.pdf.

[7] *See* OECD, 2009, *Indicators of Regulatory Management Systems*, Regulatory Policy Committee, available at http://www.oecd.org/gov/regulatory-policy/44294427.pdf.

[8] *See* Adviescollege toetsing regeldruk (ACTAL, the Netherlands); Nationaler Normenkontrollrat (NKR, Germany); Regelradet (Sweden); Regulatory Impact Assessment Board (RIAB, Czech Republic) and Regulatory Policy Committee (RPC, United Kingdom), 2012, *Common Position Paper of the Five European Independent Advisory Boards for Cutting Red Tape and Better Regulation*, 4, available at http://ec.europa.eu/smart-regulation/consultation_2012/docs/public_authority/common_position_paper_en.pdf.

[9] In the U.S. context, the combination of the requirements for notice and comment rulemaking under the Administrative Procedure Act (APA) (1946) and such later measures as Executive Order 12866, Regulatory Planning and Review (1993), Information Quality Guidelines (2002), Circular A-4, Regulatory Analysis (2003), and Executive Order 13563, Improving Regulation and Regulatory Review (2011), have steadily strengthened that link with public consultation and each element of the process. For example, the APA ensures that all interested parties are given notice of proposed rules and the supporting research, data and analysis; Executive Order 12866, together with Circular A-4, along with the Information Quality Guidelines, provide objective criteria to guide the agencies in determining the type and extent of analysis to be performed for a particular proposal and in promoting reliance on sound science in their regulatory decision-making.

Providing the opportunity for public comment on draft impact assessments, followed by making any appropriate revisions to the analysis or otherwise taking the comments into account before making any final choices, would help ensure that draft regulations are supported by robust analysis and information and fully understood and accepted by the public. Providing the opportunity for public comment on draft impact assessments complements another critical component of meaningful public consultations: publication of the preliminary text of regulatory proposals for public comment. These opportunities for comment allow any member of the public to test, critique and provide information to support regulatory outcomes that most effectively meet regulatory objectives. Together, these opportunities to submit comments, along with a commitment to take such comments into account in making regulatory choices and to explain the rationale and support for such choices, both improve regulatory quality and strengthen the legitimacy and acceptance of the regulatory choices.

Studies that the Commission has drawn upon in developing the proposed Guidelines[10] also appear to support making a draft version of the IA available for public comment in order to allow stakeholders to have the opportunity for meaningful input[11] into the process of developing the proposed regulation. The OECD 2011 *Sustainability in IA* study states that "[o]verall, the whole process is very transparent . . . according to the TEP evaluation there have been stakeholder consultation in 90% of the IAs."[12] Nevertheless, the 2007 "TEP" study commissioned by the Commission also revealed that "stakeholders were very critical with the points of time during the IA process at which input was sought" and "57% disagreed that there was enough time and opportunities to provide input."[13] A 2011 study commissioned by the European Parliament observed that: "One would expect that consultation, if it were to be effective, should take place throughout the policy process, starting with providing input into the problem definition and selection of policy options, and ending with consultation on the draft IA report."[14] The study noted "scope for improvement" in that "[c]onsultation conducted throughout the RIA process also appears not to be used to its full potential."[15] The study's suggestions for improvements include "ensuring that consultation input can be used to inform all stages of the IA including in

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[10] *See Consultation Document*, *supra* at 2 n.2, 3 n.6-9.

[11] A meaningful opportunity to comment is one of the most important concepts in the U.S. rulemaking process. This "means that interested persons should be provided with an opportunity to challenge the factual assumptions on which the agency is proceeding and to show in what respect such assumptions are erroneous." *See* American Bar Association, *A Guide to Federal Agency Rulemaking*, 298 (4th ed. 2006). The concept means further that: 1) comments are invited from all interested parties at an early stage (which is typically after a detailed proposal has been developed, but still early enough that changes or modifications can be made; 2) timely notice and availability to commenters and the general public of the key data, analyses, assumptions and other information underlying the proposal; and 3) written, reasoned agency response to the comments, explaining the basis for the agency's agreement or disagreement with them.

[12] OECD, 2011, *Sustainability in Impact Assessment – A Review of Impact Assessment Systems in Selected OECD Countries and the European Commission*, 28, available at http://www.oecd.org/gov/regulatory-policy/Sustainability%20in%20impact%20assessment%20SG-SD(2011)6-FINAL.pdf.

[13] The Evaluation Partnership (TEP), 2007, *Evaluation of the Commission's Impact Assessment System*, 48, available at *http://ec.europa.eu/smart-regulation/impact/key_docs/docs/tep_eias_final_report.pdf*.

[14] European Parliament, 2011, *Comparative Study on the Purpose, Scope and Procedures of Impact Assessment Carried Out in the Member States of the EU*, 39, available at http://www.europarl.europa.eu/RegData/etudes/etudes/join/2011/453179/IPOL-JURI_ET(2011)453179_EN.pdf.

[15] *Id*. at 64.

particular the selection and appraisal of policy options;" and "improving the effect of 'feedback' mechanisms and scrutiny by providing greater transparency around revisions of proposals based on RIA."[16]

Other comprehensive evaluations, reports, and studies also support the Commission's not waiting until it issues a final IA and proposal for Council and Parliament consideration to allow stakeholders to contribute to regulatory development:

- A 2012 paper by CEPS/University of Exeter observed: "In fairness, parts of the European Commission's work on IAs take place behind closed doors: the Commission only publishes final versions of the IAs, together with the IAB opinion on previous drafts and the corresponding legislative proposal. Earlier draft IAs, by contrast, are not made public."[17]

- A European Court of Auditors' evaluation stated that: "consultations with stakeholders were not carried out on draft IA reports. As a result, the potential benefits of public scrutiny before the proposal is finalized (i.e. gathering the views of all parties concerned at an early stage and the increased acceptance of the resulting legislative proposal) have not fully materialized." The evaluation further recommends that the Commission should "publis[h], for information and comment, interim documents (such as roadmaps and a draft version of the IA report)."[18]

- The most recent annual Impact Assessment Board Report also found that "stakeholders' views could still be better reflected in the IA report."[19] The IAB also noted that "stakeholder consultation is an essential tool for producing high-quality and credible policy proposals" and observed that "many impact assessments fail to properly integrate views and report them in an unbiased way."[20]

In sum, there appear to be good reasons, and both internal and external recommendations, supporting the use of a "consultation phase IA" that could be published by the Commission for public comment before finalizing its text and IA for transmission to the Council and Parliament.

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[16] *Id*. at 64-5.
[17] CEPS/University of Exeter, *Regulatory Quality in the European Commission and the UK: Old Questions and New Findings*, 1-2, available at http://www.ceps.eu/book/regulatory-quality-european-commission-and-uk-old-questions-and-new-findings.
[18] European Court of Auditors (ECA), 2010, *Impact Assessments in the EU Institutions: Do They Support Decision-Making?* Special Report No. 3, 46, available at http://ec.europa.eu/smart-regulation/impact/docs/coa_report_3_2010_en.pdf.
[19] European Commission, *Impact Assessment Board Report for 2013*, 8, available at http://ec.europa.eu/smart-regulation/impact/key_docs/docs/iab_report_2013_en.pdf.
[20] European Commission, *Impact Assessment Board Report for 2012*, 25-6, available at http://ec.europa.eu/smart-regulation/impact/key_docs/docs/iab_report_2012_en.pdf.

2. The overall approach to, and purpose of, conducting an IA

Question 6 on page 21 of the Public Consultation Document states that "at the end of this process the IA should present the relevant information for policy makers to make a choice and, where appropriate, suggest a preferred option."[21] As a document intended to provide operational guidance, however, the proposed Guidelines could benefit from greater specificity and more detailed guidance on economic and scientific analysis and the use of data, so that analysts across the Directorates General have a common framework that provides a starting point for their work and that informs the answers to "Key Impact Identification Questions" on pages 41-46.

For example, the Guidelines mention cost-benefit analyses, cost-effectiveness analysis, compliance cost analysis, and multi-criteria analysis, but do not actually define them, nor provide guidance as to when they should be used—thus leaving large discretion to the individual analyst. More specific guidance could produce greater consistency in analytical approaches across both regulations and agencies. Notably, the Guidelines make no mention of a fundamental regulatory analysis concept, the basis for valuing changes in risks to life (i.e., the "value of a statistical life" (VSL)), and make only brief mention of at least two other key concepts--discounting, which is required to make proper comparisons of costs and benefits over time; and the concept of uncertainty and the appropriate way to treat uncertainty (e.g., sensitivity and/or probabilistic uncertainty analysis). These analytical issues are generally relevant to impact analyses of many programs and policies.

Some of the language pertaining to methodologies could be specifically clarified in this regard. In the first paragraph of the background discussion, the Document indicates the Commission's determination "to meet <u>policy goals at minimum costs</u>, ensuring maximum benefit to citizens, businesses and workers while avoiding all unnecessary regulatory burdens."[22] In the paragraph immediately thereafter, the proposed Guidelines caution that "EU legislation must be smart in achieving its objectives: demonstrating clear added value, delivering <u>full benefits at minimum cost.</u>"[23] These formulations do not clearly lay out the decision rule under which policy can be evaluated. In effect, there is no indication of the decision-making criterion or analytical methodology that should be used to assess a regulatory approach, nor ultimately, what level of stringency would produce "full benefits." Instead, the approach in the Guidelines selects, on an *a priori* basis, a set level of output (benefit to be achieved) and then uses cost minimization analysis (i.e., minimizing cost for that set level of output). The Commission may instead wish to consider using a benefit-cost analysis approach, since it would enable staff to identify the regulatory approach and levels of stringency for which benefits justify costs, including where net benefits would be maximized, thus promoting an efficient allocation of societal resources.

The United States concurs that, in general, a regulatory impact assessment should be "integrated" to capture all meaningful effects. The U.S. approach is to examine all meaningful primary and

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[21] To be consistent, on page 6 the Guidelines could be clarified to state that impact assessment is about gathering and analyzing evidence "to inform policy making" rather than "to support" policy making.
[22] *Id.* at 2 (emphasis added).
[23] *Id.* (emphasis added).

ancillary effects.[24] However, encouraging analysts to examine a pre-determined list of effects that may or may not be meaningful for a particular policy could lead to an incomplete assessment of the impacts of policymaking. The guidance should ensure that analysts have the flexibility to examine all meaningful effects of a particular regulatory measure, whether or not they are on the list.

To address these and other issues, it may be advisable to submit the proposed Guidelines to a peer review process. Guidance that is likely to significantly affect policy choices should be peer reviewed to ensure that the guidance is of sound quality. For example, OMB Circular A-4, which provides guidance for U.S. agencies on how to conduct benefit-cost analysis, was subject to an external peer review process, in addition to interagency review and public comment, prior to its adoption. The reviewers, whose names are provided in the Circular, were chosen based on their expertise in economics and benefit-cost analysis methods. Significant updates to the guidance should also be subject to peer review.

More fundamentally, while the IA questions are extensive and include topics such as international trade effects, the economic analysis of those effects as part of an impact assessment analysis cannot be a replacement for a coherent policy process that includes a legal analysis assessing and ensuring compliance with WTO and other international obligations such as non-discrimination, basing food safety regulations on sound science, and avoiding unnecessary obstacles to trade. The considerations underlying those obligations should not be traded off, for example, against other factors listed, such as specific effects in EU Member States or the sectoral competitiveness of EU companies in third markets. Further specificity could help analysts address the situation where the analysis of different factors points in different directions. Moreover, in order to better guard against the possibility that a potential regulation could raise international trade concerns, and to better understand the options for mitigation, it would seem prudent, even necessary, to enable those outside the policy-making process, including third-country interests, to see the draft analysis and details of the preferred option or options (i.e., via publishing for comment a preliminary text of the regulation). Those parties may well be able to offer perspectives and data that may not otherwise be readily available to the Commission.

3. The scope of proposals subject to IAs

The scope of proposals requiring an impact assessment appears largely limited to "primary" regulations, while "secondary" measures are only subject to such analysis when "significant." In the U.S. experience with EU comitology, this lack of coverage has led to some inconsistencies and a lack of predictability.

Moreover, the proposed Guidelines effectively remove from the scope of the IA requirement any potential measure having expected significant economic, environmental or social effects because

[24] OMB Circular A-4 states: "an ancillary benefit is a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking…while countervailing risk is an adverse economic, health, safety, or environmental concerns that occurs due to a rule and is not already accounted for in the direct cost of the rule…." OMB, *Circular A-4*, 26 (Sep. 17, 2003), available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf.

the regulator determines that there are no "choices among noticeably different policy alternatives."[25] This prong would seem to provide too much scope to allow a regulator to prejudge the outcome and avoid any serious policy analysis. A public consultation regarding such measures might well lead to the identification of noticeably different policy alternatives. Accordingly, it should perhaps be clarified that such instances where there are "no choices" are likely to be rare and what such instances may include.

At a minimum, the European Commission should develop clear and objective criteria, such as numerical thresholds, for determining when an impact assessment is required.[26] The criteria would increase consistency in the determinations by different Directorate Generals and by even the same Directorate General whether to prepare an IA. That determination would subsequently inform the degree and extent of analysis that a Directorate General should undertake for a particular proposal.

4. Clarification of the questions to be answered in conducting an IA

Part III sets out the key questions to be pursued in an impact assessment. While these are, generally speaking, fundamental areas of inquiry, the guidance could benefit from clarity in a few notable areas.

Any analysis of the likely consequences of a policy will have uncertainty associated with the assumptions of the statistical or physical model, the input data, and the scenarios modeled. As such, it is important to provide guidance about how to characterize the uncertainty inherent in the analysis conducted, including the need to clearly describe the assumptions and limitations, as well as to quantify the amount of uncertainty to the extent feasible and practicable. There are varying degrees of uncertainties, including "known-unknowns" and "unknown-unknowns." Uncertainty assessment is critical to inform the policymakers on how much confidence they should place on the estimated outcomes of a policy. Uncertainty assessment is a key component to transparent regulatory process.

In addition, the guidance for Question 4, concerning the ways to achieve regulatory objectives, could benefit from some clarifications.

- The boxed guidance on page 13 states that "at the end of this process you should have isolated those alternative policy options that are truly relevant for political decision-making." The meaning of "truly relevant" is unclear, and could risk regulators' prejudgment of options. Perhaps the guidance could be clarified to require the analysts to identify those alternative policy options that are "available to address the problem identified" or "available to achieve the objectives." Public comments on the identified options would aid in determining which options are "truly relevant."

[25] *Consultation Document*, *supra* at 6.
[26] For example, under Executive Order 12,866, any rule having an annual effect on the economy of $100 million or more is an economically significant rule and sets forth the additional type and extent of analysis that must be performed for rules meeting or exceeding that threshold.

- Further, the guidance with respect to small businesses appears to establish a presumption to exclude them from the regulation, *a priori*. This may not be the best approach to policy because, for example, small businesses may be the primary source of the problem that has been identified – for instance, microenterprises could be the major contributor of the emissions of relevant chemicals to be regulated. The United States maintains numerous protections for small businesses in regulatory development, but the U.S. approach is flexible in encouraging policy options that reduce potential economic impacts on small businesses. U.S. regulators are required to look at whether small businesses are significantly impacted, and if so, the next task is to consider a variety of ways to reduce those potential effects, including exclusion.

- The guidance also instructs analysts to "consider those options which have strong outside support."[27] While this will typically be done as a matter of course, the phrase should perhaps be qualified to recognize that the degree of outside support for, or opposition to, a particular option is not dispositive to the analysis and does not override the principles set out in the guidance.

Regarding question 5, which covers the impacts of different policy options and who will be affected, the classifications to be used when describing identified impacts appear to be overlapping. The distinction between "broad nature: economic, social and environmental" impacts (the first classification) and "specific nature… gains (or falls) in market efficiency, competitiveness, innovation, impacts on health, quality of the environment etc." (the third classification) is unclear. The line between the third classification and "relation with the underlying initiative: direct impacts … [and] indirect impacts" (the second classification) is similarly blurry. It appears that the first three classifications could be combined under one heading "economic, social, and environmental impacts, both direct and indirect." In addition, to aid the assessment of impacts pursuant to these Guidelines, specific guidance might be provided for EU regulators to do so in a quantitative manner. Such guidance should also indicate that the degree of analysis will vary depending on the significance of the proposed regulation, and include a statement recognizing that not all costs and benefits can be quantified.

With respect to question 7, pertaining to future monitoring and evaluation, the requirements for data collection concerning future implementation could be built into the regulation through requirements, for example, on Member States in their enforcement of directives on their respective territories. In addition to helping to ensure that regulations are enforced and legitimate policy objectives are achieved, collecting and maintaining such data in electronic format is critically important for gauging the success of a particular regulatory approach as part of any retrospective review process, and for purposes of ongoing and future regulatory cooperation with trading partners.

5. Evidence-based decision-making, stakeholder consultations, and transparency

Evidence-based decision-making, stakeholder consultations, and transparency are key governing principles for any regulatory system, since robust implementation will improve the quality,

[27] *Id*. at 14.

predictability, and legitimacy of regulation; help regulators to achieve their objectives of, e.g., protecting health, safety, and the environment; and minimize the potential for the creation of trade barriers and unnecessary differences with trading partners. While the Document does not appear to ask specifically for comment on the proposed Guidelines' descriptions of Fundamental Principles of Impact Assessment that are set out on page 8, including Annex II.A, which lay out guidance on the evidence base, stakeholder consultations, and transparency, U.S. observations and suggestions on these issues are set out below.

Evidence-based

On page 8, the Commission calls for IA analysis to be "based on the best available evidence and scientific advice, or a transparent explanation of why some evidence is not available and why it is still considered appropriate to act." It is important to provide analysts with further technical guidance on how to ensure reliance on high quality data – for example, by using peer reviewed studies -- and how to use scientific analysis in the IA. Without such guidance, the quality and utility of IAs will vary considerably.

In the United States, for example, specific guidance has been provided to regulators on the use of science in regulatory decision-making. This includes OMB's 2002 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, which are aimed at enhancing the quality of information -- including scientific and analytic information -- which federal agencies disseminate to the public and use in policy making. OMB, along with the Office of Science and Technology Policy, also published Updated Principles for Risk Analysis in 2007, a document that sets out general principles for risk analysis, principles for risk assessment, principles for risk management, principles for risk communication, and principles for priority setting.[28]

The IA should also explain how that evidence and advice supports the key aspects of the proposal. In situations in which available evidence may be insufficient, but it is still considered appropriate to act, the impact assessment should clearly identify what additional information the Commission staff believes is necessary and what steps will be undertaken to obtain that information.

Lastly, the quality of the evidentiary and analytic basis for a proposed regulatory measure could be significantly strengthened by simultaneously publishing draft versions of detailed regulatory text for that measure and of an impact assessment analyzing, explaining and justifying that text, inviting public comment, and then issuing revised versions of those two documents, along with a written explanation of the basis for which the Commission agreed or disagreed with the comments.

Stakeholder views

On page 8 of the Document, the Commission notes that "[s]takeholders' views must be collected on all key issues and reported on in the IA Report. Every effort should be made to ensure that the Commission has sought and considered a wide and balanced range of views. The reasons for

[28] Available at http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/m07-24.pdf.

disagreeing with dissenting views must be explained." Further, on page 27 of the Document, the Commission states that "[n]o one knows more about a problem and about possible solutions than those concerned. Consulting those who will be affected by a new policy or initiative is a Treaty obligation and a mandatory component of all IAs." The Commission also states that:

> "Experience shows that the quality of the public consultation process is very important for the value of an IA and its credibility vis-à-vis the external stakeholders. A poor public consultation inevitably weakens the Commission's case. Stakeholder consultations should be used to gather relevant information and test initial views and estimates. It should not be approached as formal requirement or seen as a tool to gather support for preconceived views."[29]

The United States generally agrees with these strong affirmations of the value of seeking outside views. However, success hinges on the consistency and manner of implementation. The best way to seek and consider a wide and balanced range of views is to ask for comment from the public on a specific consultation document. It is preferable to allow stakeholders to decide for themselves whether to submit comments instead of selecting the stakeholders from which views are solicited. This will ensure that any stakeholder with a view can contribute to the process and that no stakeholder views are inadvertently left out of consideration. Second, the most effective way to become informed of what the supporting or dissenting views are is to seek consultation at a more advanced stage, on the draft regulatory text. If a regulatory authority only seeks such views when its thinking about a regulatory measure is still very general and it has not yet made a tentative selection of a specific regulatory option, the type of information that stakeholders can provide will tend likewise to be general and thus of more limited utility.

Improving stakeholder consultation would also facilitate realization of one of the main objectives of the Commission's "better regulation" efforts, namely to reduce regulatory red tape. In addition to addressing red tape problems stemming from existing regulations, good regulatory practice also requires efforts to avoid the creation of future red tape in the first instance. Additional consultations could help guard against the creation of new red tape if stakeholders are given the opportunity to comment on draft regulatory text and the Commission is still prepared to consider public comments and revise its proposal accordingly.

6. Documents describing the U.S. approach to sound science and regulatory analysis and oversight

Below are links to documents providing additional background material on the U.S. approach to sound science and regulatory analysis and oversight.

1. Presidential Executive Order 12866 -- Regulatory Planning and Review (58 Federal Register 51735, October 4, 1993). This Executive Order lays out the principles and procedures that govern centralized regulatory oversight in the United States. (Available at http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf)

2. Presidential Executive Order 13563 -- Improving Regulation and Regulatory Review (76 Federal Register 3821, January 21, 2011). This Executive Order reaffirms Executive Order

[29] *Id*. at 27.

12866. It also addresses public participation (including the length of comment periods), integration and innovation, flexible approaches and measures to be taken to ensure the objectivity of scientific and technological information used to support rulemaking actions. (Available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo13563_01182011.pdf)

3. U.S. Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (67 Federal Register 8452, February 22, 2002). These OMB guidelines are aimed at enhancing the quality of information -- including scientific and analytic information -- which federal agencies disseminate to the public and use in policy making. (Available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf)

4. The Regulatory Flexibility Act of 1980, 5 United States Code chapter 6. The purpose of this statute is to establish a principle that Federal agencies endeavor, consistent with the objectives of applicable law, to fit regulatory and informational requirements to the scale of entities subject to a regulation. To demonstrate this effort, Federal agencies are required to solicit and consider flexible regulatory proposals, and explain the rationale for their actions to assure that flexible regulatory proposals are given serious consideration.

5. U.S. Office of Management and Budget, Draft 2014 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities (May 2014), (79 Federal Register 37776, July 2, 2014). This draft report, now being revised in response to public comment, describes recent regulatory reform activities of the Obama Administration. (Available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/2014_cb/draft_2014_cost_benefit_report-updated.pdf)

6. U .S. Office of Management and Budget, Circular A-4, Regulatory Analysis (September 17, 2003) (Available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf); Agency Checklist: Regulatory Impact Analysis (October 28, 2010) (Available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA_Checklist.pdf); Regulatory Impact Analysis: Frequently Asked Questions (FAQs) (February 7, 2011) (Available at http://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a004/a-4_FAQ.pdf); Regulatory Impact Analysis: A Primer (August 15, 2011) (Available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf). These documents are the technical guidance that OMB provides to federal agencies on how to perform regulatory impact analysis.

7. U.S. Office of Management and Budget and U.S. Office of Science and Technology Policy, M-07-24, Updated Principles for Risk Analysis (September 19, 2007) (Available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-24.pdf).