

***Review of the Application of EU and US Regulatory Impact  
Assessment Guidelines on the Analysis of Impacts on International  
Trade and Investment***

**Final Report and Conclusions**

**Prepared by the Office of Management and Budget and the Secretariat  
General of the European Commission**

Brussels/Washington DC, May 2008

## **Introduction**

This paper has been drafted by the Secretariat General of the European Commission and the U.S. Office of Management and Budget as part of the dialogue between the European Commission services and the Office of Management and Budget on methodological issues as agreed in the "Framework for advancing Transatlantic Economic Integration between the European Union and the United States of America", signed at the EU-US summit on 30 April 2007.

It reviews the application of the Office of Management and Budget's Circular A-4, regulatory analysis guidance, and the European Commission's Impact Assessment Guidelines, with the goal of ensuring that assessment of future regulations takes due account of their impacts on international trade and investment.

It contains two separate reports on existing methodology and practices on both sides of the Atlantic, and suggests possible ways forward in the concluding chapter.

This paper was presented in draft form at the High Level Regulatory Forum held in Washington, DC, on November 7, 2008. In addition, both the Office of Management and Budget and the Secretariat General solicited comments from the general public on the draft version of this report. The public comments were generally positive, and made many suggestions for improving the final report and our accompanying conclusions. This final report responds to the public comments.

## **A.1. Methodology for international trade and investment in the European Commission Impact Assessment system**

### **General context**

The methodology for international trade and investment in the European Commission's system for impact assessment (IA) should be seen in its general context.

The legislative process in the EU gives a particular role to each institutional actor. Under the most common procedure for the adoption of EU legislation, the co-decision procedure, the European Commission puts forward a legislative proposal which may subsequently be modified by the two legislative bodies, the European Parliament and the Council. Since the Commission is the initiator of legislation, its Impact Assessments are produced prior to the proposal being examined by the legislators, which means that the timing of any assessment is not entirely comparable to its US equivalent. It should be noted that the Council and the EP have committed to carry out their own impact assessments on amendments that would entail significant modifications to the Commission's original proposals.

Another essential difference concerns the type of initiatives for which an assessment is carried out: European Commission Impact Assessments are carried out for a broad range of policy initiatives, only half of which in 2007 were legislative proposals. The broad scope of the initiatives complicates the task of applying uniform guidelines and criteria. The Commission's Impact Assessment Guidelines therefore strive to be sufficiently coherent and unequivocal to help guarantee the desired quality standards, while retaining the necessary flexibility to apply them to a great variety of initiatives.

Probably the most distinguishing feature of the European Commission's impact assessment system is its integrated approach. It requires a comprehensive analysis, in which all relevant impacts are assessed in one single framework identifying trade-offs and synergies that may result as a consequence of some of the identified policy options. Analysis of specific or partial impacts always needs to be placed in a more general context: the valuation (quantitative where possible) of alternative options is never based on one individual issue or partial analysis, but always needs to represent the outcome of weighing all expected positive and negative impacts against pre-defined criteria.

It should be emphasised that it is always the lead service (Directorate General) in the European Commission that is responsible for the quality of the analysis, as well as for the preparatory process by which the work is carried out. In a very early stage this service will need to enlist the cooperation of other services to ensure a balanced assessment of all relevant economic, social and environmental impacts.

Finally the importance of adequate and timely consultation of stakeholders at an early stage of the assessment should be stressed, for which the European Commission has adopted strict Minimum Standards. These consultations are fully open to all interested parties; third country stakeholders frequently contribute. The impact assessment needs to reflect the contributions made in the consultations, and indicate what the impact has been on the final proposal.

## **The Impact Assessment Guidelines**

The Impact Assessment Guidelines have been prepared under the coordination of the Secretariat General of the European Commission, and contain guidance material that clearly sets out what impacts should be analysed as well as more technical and methodological support for the services. The Guidelines were revised and extended in 2005, drawing extensively on input from the other Institutions and stakeholders, with strong emphasis on the strengthening of the analysis of economic impacts, especially in the context of global economic relations.

In their current form the Impact Assessment Guidelines require that all impacts be assessed, regardless of where they are likely to materialise or whom they are likely to affect. More specifically, they ask that impacts on international trade and relations, and impacts on third countries or international agreements, are taken into account. Amongst other things, this requires an assessment of whether the proposal places EU companies at an advantage or disadvantage vis-à-vis external competitors, or how trade and cross-border investment will be affected.

The relevant guideline reads as follows:

### ***"Impacts on international trade and cross-border investments***

*Proposals may have consequences for the conditions under which European enterprises operate in comparison with their main competitors in non-EU countries. These consequences may differ between the short and the long term. Awareness of the main characteristics of the regime that these foreign competitors face is an essential element for the scrutiny of economic impacts.*

*In the context of likely impacts on trade and cross-border investments, will the proposal:*

- *Increase or reduce differences between the regulatory regime faced by EU companies and competitors in non-EU countries?*
- *Place EU firms at an advantage or disadvantage compared to their international competitors?*
- *Will cleaner companies and sectors be boosted either directly or indirectly through shift of demand away from polluting companies and sectors?*
- *Help or hinder trade and cross-border investment into the EU or from the EU to third countries?*
- *Contribute to the relocation of economic activity to or from non-EU countries?*
- *Will a 'first-mover' advantage be generated with other countries likely to follow?"* (source: Annex to IA Guidelines, p. 29)

This is complemented by the following text – in a more general perspective:

### ***"Impacts on third countries and overseas relations***

*Certain proposals may have an impact on third countries and overseas relations in general. In this case, consideration should be given to whether the proposal will have an impact on:*

- *International agreements and alliances (e.g. WTO rules)?*
- *Enlargement and/or neighbouring countries?*

- *Developing countries?*
- *Other countries?"* (source: ibid. p. 33)

### **Dealing with impacts on international trade and investment in other contexts**

Apart from Impact Assessments, the European Commission has a number of other instruments at its disposal to prepare policy initiatives in an open and constructive consultative dialogue with stakeholders and other interested parties. Often these have the format of Green Papers inviting all such parties to contribute to a preparatory discussion ahead of the more definitive formulation of the policy initiative in question.

In the context of the European Commission's responsibility for external trade relations, a specific type of consultation has been developed, the so called Sustainability Impact Assessment (SIA). For these assessments, which are made when preparing external trade policy initiatives, an external study is often made to support a public discussion - involving stakeholders and NGOs – as input for the formulation of negotiation mandates.

According to the guidance material produced by the responsible service, these SIAs 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, as well as a full package of complementary policies;*
- *build an open process of consultation around trade policy creating a basis for an informed discussion with a broad range of stakeholders, including civil society;*
- *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;*
- *propose ex-post monitoring measures to be put in place during the trade agreement's implementation."*

## **A.2. Dealing with impacts on international trade and investment in practice: recent developments and experiences**

### **Recent developments**

The Impact Assessments produced by services of the European Commission over the five years since the introduction of the system are assessing international impacts more and more rigorously and systematically, both due to a progressive development of impact assessment rules and practice as well as the increased awareness of globalisation and focus on EU competitiveness. The focus of the analysis of international impacts depends on the specific context in which the policy initiatives are developed. In some cases regulatory arrangements in the EU are compared with those in third countries, seen both as major trading partners and – where relevant - as competitors. In other cases developments in existing regulatory dialogues are taken as a starting point. Other proposals pay considerable attention to the impacts on developing countries and the consistency of proposed initiatives with the EU's development policy. Finally, in specific cases the interests of certain third countries may be affected by proposed EU actions. Generally speaking there always needs to be consistency with the EU's foreign and neighbourhood policies.

The reinforcement of the analysis of international impacts received more impetus after the fundamental revision of the Impact Assessment guidelines in 2005. A further stimulus was given in 2006 by the creation of the Impact Assessment Board, an internal group of high-level officials with IA experience acting in a personal capacity under the authority of the European Commission President, and chaired by a Deputy Secretary General. This Board provides not only quality support but also reviews, independently from the author services, draft Impact Assessments with a view to assess the quality of the analysis and the coverage of all relevant impacts. In the opinions that have so far been issued by the Board it has frequently emphasised the need to strengthen the analysis of international impacts. Board opinions are generally reflected into the final Impact Assessments and may also influence the corresponding proposals.

The Impact Assessment Board has consistently checked the submitted impact assessments for adequate reference to regulatory dialogues with third countries, including the United States, and where necessary encourages the responsible Directorates General to take issues arising from these dialogues properly into account.

Generally speaking, until now more attention has been paid to issues of international competitiveness and barriers to international trade than to the impacts on cross-border investment. However, as indicated below, an ongoing Impact Assessment concerning the insurance sector now also develops this issue more.

### **Some concrete examples**

The cases presented here are but illustrative of the various ways in which impacts on international trade and investment are dealt with in Commission Impact Assessments. They also give an impression of the development over time: an increasing proportion of recent Impact Assessments reflect a growing awareness of the international context.

Some early examples of Impact Assessments that addressed international impacts more thoroughly deserve to be mentioned here. The first was the Impact Assessment for **The Communication on a Thematic Strategy on Air Pollution** (combined with the **Directive on “Ambient Air Quality and Cleaner Air for Europe”**), for which an in-depth preparatory study was carried out that compared the costs for business of the EU and US approaches. For the final version of the Impact Assessment this analysis was complemented with a model-based analysis to incorporate the effects on relative competitiveness (using the RAINS model for specific environmental aspects and GEM-E3 to assess the consequences for competitiveness).

In the area of agricultural policy reform, the general context of world markets has typically been a key element of the analysis. The impact of EU reform initiatives on third countries was analysed in great depth in the 2003 Impact Assessment for the **Review of the Tobacco Regime**. A series of impact assessments have been carried out since then for a considerable number of specific agricultural markets; one of the most recent examples can be found in the assessment concerning the **Common organisation of the market in wine**.

More recent Impact Assessments show a much broader range of issues playing an important role in the argument. In the Impact Assessment concerning **Units of measurement** one of the core arguments reflected a long-standing and ongoing dialogue with the US concerning requirements with regard to the use of metric versus imperial measures.

In another example, the Impact Assessment concerning **Defence Procurement** (expected by the end of 2007), the analysis explicitly took into account that any rules the EU would introduce should stay within the general parameters of existing WTO rules, which would guarantee that no unnecessary barriers would result for suppliers from third countries.

The value added of the Impact Assessment Board is reflected in its opinions, which increasingly cover the perspective of the analysis of the impacts that the proposed actions can be expected to have on international trade and investment. A recent example can be found in the discussion of two impact assessments carried out on a review of food and nutrition labelling legislation **Regulation on horizontal food labelling** and **Regulation on nutrition labelling** (publication of impact assessment and IA Board opinion forthcoming) in which a considerable part of discussions focused on the comparison of regulatory regimes in the EU and its main trading partners, as well as on the outcome of discussions in the relevant international forums.

Less explicit attention has been given to date to the influence of proposals on international investment flows. However, a recent example of a case in which this was an important consideration is **Solvency II**: for this impact assessment an international comparison has been made, and the consequences of the approach to convergence towards international standards have been analysed in depth.

All European Commission impact assessments are published on the *Europa* website ([http://ec.europa.eu/governance/impact/practice\\_en.htm](http://ec.europa.eu/governance/impact/practice_en.htm)) after adoption of the corresponding proposal by the College of Commissioners, so as to be available for the further discussions of the initiative by the European Parliament and the Council. This site also gives access to the Commission's Work Programme that shows for which forthcoming proposals impact assessment work is in progress.

## Appendix A.1. Examples of European Commission Impact Assessments

<i>Impact Assessment</i>	<i>Brief description of proposal</i>	<i>International trade and investment impacts</i>	<i>Document number and link</i>	<i>IAB opinion</i>
Review of the Tobacco Regime	Reform of tobacco policy, abolishes price support and opens up for imports, provides for support to reorientation in affected regions	Effects on third countries' exports assessed.	SEC(2003)1023 <a href="http://ec.europa.eu/governance/impact/docs/ia_2003/sec_2003_1023_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2003/sec_2003_1023_en.pdf</a>	n/a
Communication on a Thematic Strategy on Air Pollution	Set out main elements of broad EU strategy to improve air quality.	Costs for business of EU and US approaches compared. Model-based analysis (RAINS for environmental effects, complemented by GEM-E3 to assess the consequences for competitiveness).	SEC(2005)1133 <a href="http://ec.europa.eu/governance/impact/docs/ia_2005/sec_2005_1133_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2005/sec_2005_1133_en.pdf</a>	n/a
Directive on units of measurement	Withdraws existing sunset clause to allow for a limited number of exceptions on general principle to adopt metric standards in the interest of international trade and of consumers in two member states	International (transatlantic) dialogue explicitly mentioned. Costs for exporters/importers of alternative regulatory requirements estimated.	SEC(2007)1136 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1136_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1136_en.pdf</a> and SEC(2007)1137 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1137_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1137_en.pdf</a>	Final IAB Opinion <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/d_6572_iab_opinion_units_of_measurement.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/d_6572_iab_opinion_units_of_measurement.pdf</a>
Common organisation of the market in wine	Reform of wine regime, aims at improving the sector's competitiveness and to eliminate overproduction	Impacts on the competitive position of EU wine sector; convergence to evolution of WTO discussions. Assessed for all relevant measures of proposed reformed regime.	SEC(2007)893 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0893_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0893_en.pdf</a> and SEC(2007)894 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0894_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0894_en.pdf</a>	SEC(2007)895 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0895_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0895_en.pdf</a>



Directive on Defence Procurement	Aims to establish a properly functioning regulatory framework for award of contracts for defence and security, implementing Internal Market principles as well as ensuring Member States security interests. Majority of defence and security contracts (incl. procurement of arms, munitions, war material), to be awarded on the basis of EC rules.	Assessed size and nature of extra-EU imports of defence and security products falling within the scope of this proposal. Concluded that specific defence and security rules would not change the situation for arms trade with third countries, as this remained governed by WTO rules (GPA).	SEC(2007)1598 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1598_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1598_en.pdf</a> and SEC(2007)1599 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1599_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1599_en.pdf</a>	SEC(2007)1602 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1602_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_1602_en.pdf</a>
Regulation on horizontal food labelling and Regulation on nutrition labelling	Revision of Directive 2000/13/EC providing for compulsory information on the label of pre-packed foods. Most of the provisions date back to 1978. Simplification proposal, developed in parallel with a proposal on nutrition labelling (separate impact assessment), provisions in that area mostly voluntary.	In the Impact Assessment Board, the issue of the relation with existing international dialogues was assessed. The preferred option was shown to have no significant impact on international trade flows, also because the elements addressed in the proposed legislation were not the subject of agreed positions in the relevant forums.	SEC(2008)92 <a href="http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0092_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0092_en.pdf</a> and SEC(2008)93/2 <a href="http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0093_2_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0093_2_en.pdf</a> SEC(2008)94 <a href="http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0094_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0094_en.pdf</a> and SEC(2008)95/2 <a href="http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0095_2_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0095_2_en.pdf</a>	SEC(2008)97 <a href="http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0097_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0097_en.pdf</a> and SEC(2008)96 <a href="http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0096_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2008/sec_2008_0096_en.pdf</a>
Taking-up and pursuit of the business of Insurance and	Aims at bringing the regulatory environment concerning prudential supervision more in line with developments in the industry, to	Promotion of international convergence was one of the explicit objectives of the new policy; underlining EU commitment to the	SEC(2007)871 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0871_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0871_en.pdf</a>	SEC(2007)872 <a href="http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0872_en.pdf">http://ec.europa.eu/governance/impact/docs/ia_2007/sec_2007_0872_en.pdf</a>

Reinsurance Solvency II	- make the system more risk-sensitive and improve the functioning of the single market.	opening of global financial markets. Compatibility with current and future international standards (IASB, IAIS), further international convergence used as key criteria. Commission conducted a comparative analysis of insurance solvency regimes.		
----------------------------	---	---	--	--

## **B. The Impact of United States Regulation on International Trade and Investment**

The United States has been collaborating with the European Union, several countries and international organizations in an effort to reduce regulatory barriers to trade and to promote efficient regulatory systems. Recent regulatory reforms in the form of revised guidelines from the European Commission and Canada, as well as the clear and increasingly important spill-over effects of regulations in global markets, suggest the US might usefully consider providing further guidance on our approach to regulatory impact analysis. This report identifies current U.S. practices for the analysis of international impacts of regulations. The draft version of this report, release in November, 2007, also requested comment on options for improving the analysis of the effects of regulations on international trade and investment.

### **United States Regulatory Framework**

In the U.S., Article I, Section 1, of the Constitution gives the Congress the sole power to make laws. 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, has the force and 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 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 particular, Executive Order (EO) No. 12866, Regulatory Planning and Review, issued in 1993, directs federal agencies to promulgate regulations that increase the well-being of the American people. Specifically, it asks executive branch agencies to assess all costs and benefits of available regulatory alternatives, select the approach that maximizes net benefits unless not permitted by law, and send significant regulatory actions to the Office of Management and Budget (OMB) for review. Although largely geared towards domestic impacts of regulations, the EO does require consideration of international trade impacts for economically significant rules (generally those rules that have an effect of at least \$100 million in any one year). The EO states in its introduction, that “private sector and private markets are the best engine for economic growth.” In Section 6 (a)(3)(C)(ii), the EO also states that agencies, for economically significant regulatory actions under Section 3(f)(1) of the EO, have an obligation to provide an assessment of “any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs.”<sup>1</sup> As international trade is a key component of the efficient functioning of private markets, agencies do have an obligation to consider such trade impacts in their EO 12866 analyses for economically significant rulemakings.

---

<sup>1</sup> Executive Order 12866, as amended by Executive Order 13422, is available at [http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866\\_amended\\_01-2007.pdf](http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf)

OMB Circular A-4, Regulatory Analysis, issued by OMB in 2003 elaborates on this requirement established by the Executive Order for economically significant rules. Specifically, it states that:

*“The role of Federal regulation in facilitating U. S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.”*<sup>2</sup>

However, Circular A-4 does not offer clear guidance on how to consider the international trade and investment effects of US regulation. The EO does ask for a description of distributional effects (i.e. how benefits, costs, and transfers are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency; however, this discussion usually focuses on domestic rather than international effects.

Circular A-4 is designed to inform the public and federal agencies (both those issuing the proposals and those impacted by it) of the effects of alternative options. Regulatory options are to be evaluated in a rigorous way, including an analysis of social benefits and costs, and transfer payments (payments from one group in society that do not reflect real resource use), in order to understand their effects on U.S. society. Specifically, A-4 currently states that the analysis:

*“should focus on benefits and costs that accrue to citizens and residents of the United States. Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately.”*<sup>3</sup>

The analysis called for in A-4 follows several steps, starting with the requirement established by EO 12866 to “identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.” Relying on markets where they work is the key principle behind the US approach to regulatory development; however, A-4 also discusses other possible reasons for regulation, such as “improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.”<sup>4</sup>

If the regulatory agency determines that federal regulation is needed for one of these reasons, and that it will be economically significant, it then proceeds with a comprehensive cost-benefit analysis. All impacts should be quantified and monetized, to the extent feasible, into an overall assessment of the costs and benefits of the proposed and alternative regulatory actions. A-4 requires analyses to evaluate the distributional impacts of alternative approaches; in addition, other stakeholder analyses that outline impacts—on small businesses, state and local and tribal governments, for example—are often conducted separately.

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

---

<sup>2</sup> Circular A-4, p 6.

<sup>3</sup> Circular A-4, p 15.

<sup>4</sup> Circular A-4, p 4.

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.<sup>5</sup>

---

<sup>5</sup> 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 EC guidelines. Circular A-4 is not explicit about the form this analysis may take.

## **The Importance of Considering the Impact of Regulation on International Trade and Investment**

As explicit barriers, such as tariffs, to international trade fall, in an increasingly global marketplace, domestic policies are more likely to affect trading partners. Because of this, OMB and the European Commission are considering whether our respective regulatory analysis approaches should be modified to better incorporate international trade impacts into the analysis of regulation. An evaluation of the effect of regulation on trade may help to ensure that regulatory policy does not become a tool for establishing unnecessary barriers to trade.

Recent studies demonstrate the correlation between efficient regulations and economic growth<sup>6</sup>. They suggest that a regulatory regime that offers transparent rules based on technical requirements increases investment, economic growth, and consumer welfare. In addition to increasing productivity and flexibility in the labor and product markets, flexible, performance and market-based regulatory systems that preserve liberal trade lead to higher employment, improvement in social indicators and innovation<sup>7</sup>. Open markets may also lead to regulatory reforms as nations strive for efficiency and productivity to stay competitive in global markets. Reports from the Organization for Economic Cooperation and Development (OECD), for example, found that unnecessary regulation in services markets have a large negative impact on market entry, which also lead to negative impacts on trade flows. Ultimately, local services sectors' export performance will suffer due to a lack of competition, and consumers will be worse off. All of these advantages to flexible economies and open markets should be considered when designing new regulatory approaches to emerging issues.

### **Appendix B1: Discussion of Incorporating Trade Impacts into Benefit-Cost Analysis**

OMB Circular A-4 states that benefit-cost analysis is a primary tool used for regulatory analysis, as it provides decision makers with a clear indication of the regulatory alternative that generates the largest net benefits to society. Even if economic efficiency is not the only or primary public policy objective, an understanding of the costs and benefits of a regulatory action is important for decision makers and the public.

Further, EO 12866 states regulatory policies should recognize that “the private sector and private markets are the best engine for economic growth.” Although regulations typically impose limitations on the functioning of the private market, a subset of those regulations may affect international trade, which is the subject of this discussion. International trade is simply a private market where economic exchange takes place across national boundaries. Therefore, in the absence of a market failure, trade itself presumptively increases the net benefits to each nation involved in the trading, in the same way trade increases welfare when taking place between individual private parties.

Just as a regulation may impose costs on private domestic markets, a regulation may have the effect of interfering with, and shrinking, the level of trade. Since this aspect of regulation is presumptively harmful to overall economic welfare in each nation, the size of this harmful effect should be considered in regulatory analysis and compared, along with other regulatory costs, to the benefits generated by the regulation to determine whether regulations maximize the net benefits to society. It is important to emphasize: this discussion is not meant to

---

<sup>6</sup> For example, Djankov, McLiesh, and Romalho. *Regulation and Growth*. World Bank. 2006.

<sup>7</sup> See the World Bank's Doing Business annual volumes. <http://www.doingbusiness.org/>

convey that a regulation with such a trade impact cannot have net benefits. It merely points to a cost that should be assessed and compared with the estimated benefits of a regulation.

How might this cost be considered? Circular A-4 states that the analysis “should focus on benefits and costs that accrue to citizens and residents of the United States.” An example of how a trade impact could lead to an impact on U.S. citizens is the following. A regulation is introduced which leads the United States to stop or restrict the import of a particular product. U.S. citizens that used to consume this product now turn to a substitute product, which is produced domestically. To simplify, suppose the two products are identical, but the production of the domestically produced product uses more resources than the imported product and sells at a higher price. One effect of this regulation, therefore, is to induce a pure uncompensated cost, which is roughly equal to the average of the pre- and post-regulation quantity consumed multiplied by the price increase.<sup>8</sup>

There is another possible cost. Since the regulation may reduce the number of competing suppliers of the product that was imported before the regulation, a benefit-cost analysis may also need to assess whether or not market-power-based price increases will occur as a result of the regulation. In this case, it may be difficult to estimate both the size of the price increase and the fraction of the market-power-based price increase which constitutes a net cost to a country, as opposed to a simple wealth transfer from consumers to producers within that country.<sup>9</sup> As Circular A-4 states, “distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation.”<sup>10</sup> Nevertheless, benefit and cost estimates should reflect real resource use.

Using this approach, regulators may more easily distinguish a regulation affecting trade which benefits the producers in their country at the expense of the consumers in their country, from a regulation that retains welfare-enhancing trade where possible and only restricts trade, either indirectly or directly, in cases where the benefits outweigh the costs.

*The Role of Regulation:* Just as domestic markets can fail to work properly, international markets can fail as well. Externalities, public goods, market power, and informational imperfections know no national boundaries. Consequently, the costs and benefits enjoyed by engaging in unregulated trade between nations may be enhanced through regulation in certain situations. For example, international trade certainly includes products traded in the presence of information asymmetry; products may suffer from negative attributes that may be unknown or unknowable at the time of purchase. Of course, the existence of information asymmetry itself does not establish a need for regulation. In private markets for these types of products, firms often invest substantial sums to develop a strong brand reputation to convey that their products contain positive attributes, such as safety for food. The products being imported into a country, however, may suffer greater information asymmetries than those products that are domestically produced, especially if such products do not carry strong brands. In addition, common property resources such as fisheries may not be effectively managed under a single

---

<sup>8</sup>This cost would be exactly equal where price equals average cost for domestic suppliers. In the case where the producers of the domestic product sell at a post-regulation competitive price equal to their marginal cost, which lies on the upward sloping portion of their supply curves and at a price above their average cost, the cost of the regulation is less than is stated in the text. It is less by the excess of the domestic producers' total revenues above their total costs.

<sup>9</sup>Rent seeking behavior by producers and consumers has long been known to erode the wealth value of monopoly and turn a pure transfer into a loss of resources to the economy. The argument dates back at least to James Buchanan. An oft cited article is Richard Posner, *Journal of Political Economy*, 1974.

<sup>10</sup> Circular A-4, p 38.

national jurisdiction. International regulatory mechanisms may be the most efficient approach to managing such resources.

In the draft version of this report, OMB presented the discussion above as a step towards considering how U.S. agencies may consider a more extensive analysis of the impact of their regulation on international trade. The case studies presented here and in the draft version of this report identified that U.S. agencies do identify various types of international impacts in order to satisfy their obligations to do so under OMB Circular A-4.



## **Appendix B2: Case Studies**

This section summarizes several recent proposed and final U.S. regulations affecting non-US firms and individuals. This is a preliminary list; and we will continue to study the current practices of agencies in analyzing international impacts. In the limited examples OMB has examined, most agencies have examined the impacts of their regulations on foreign entities. The most common approach in these case studies is to simply assume the impact of a regulation on non-US firms or individuals is a cost of the rule to be compared against benefits. In addition, with the exception of USDA rulemakings considering whether to allow imports of a particular commodity, we have found few examples of U.S. regulations that have analyzed an explicit impact of a regulation on international trade.

## **Reduction of Fuel Tank Flammability in Transport Category Airplanes, Proposed Rule**

**Summary of Rulemaking:** On November 23, 2005, the US Federal Aviation Administration (FAA) published a Notice of Proposed Rulemaking (NPRM) in the Federal Register<sup>11</sup> titled “Reduction of Fuel Tank Flammability in Transport Category Airplanes.” This NPRM is designed to alleviate a risk that has led to several fatal airplane accidents caused by fuel tank explosions, including the Boeing 747 TWA Flight 800 explosion off of Long Island, New York in 1996. It proposes new rules that will require operators and manufacturers of all transport-category airplanes in operation in the United States, including airplanes manufactured by Airbus, to take steps to prevent electrical and other systems from igniting flammable vapors in the fuel tank. The rule would cover both new airplanes and retrofits of existing airplanes over the next few years. FAA has not yet published a final rule based on this NPRM, and this analysis is subject to change based on public comment.

**Analysis of Impacts:** Since FAA determined this rule to be economically significant according to Executive Order 12866, it provided a Regulatory Impact Analysis for public comment, as required by OMB Circular A-4<sup>12</sup>. Because the rulemaking allows for a very long phase-in, FAA analyzes the impact of the rule over the next 50 years.

*Costs:* FAA estimates the rule would lead to present value compliance costs of \$808 million, in 2005 dollars, at a 7% discount rate. The main components of costs are for retrofitting, which is usually more expensive than new model design, and additional operational costs such as maintenance and fuel. Of these costs, FAA estimated a direct regulatory impact to Airbus aircraft of approximately \$436 million in present value. FAA assumes these costs will be borne primarily by aircraft operators in the case of retrofitting, and aircraft producers in the case of new production. In both cases, however, some of the direct regulatory impact could be felt outside of the United States. For example, Airbus production costs may increase for new aircraft, while Airbus sales of aftermarket fuel tank inertion systems may increase as well. FAA did not perform a separate analysis of the trade impacts of this rulemaking, but did assume that all of these costs were direct costs of the regulation to be compared against benefits.

*Benefits:* FAA estimates that fuel tank flammability reduction would prevent 4.2 catastrophic explosions, which has a present value of \$495 million, at a 7% discount rate. Benefits estimates are based on loss of life, property damage, and resources devoted to accident response.

*Sensitivity Analysis:* FAA performed a sensitivity analysis varying several of the parameters that were the major driver of costs and benefits. By varying the Value of a Statistical Life, the effectiveness of the regulation in lowering the risk of an accident, and the discount rate, FAA estimated that costs ranged between \$800 million and \$1.2 billion, while benefits ranged between \$250 million and \$2.7 billion.

*Alternatives:* FAA analyzed the alternative of requiring cargo airplanes to comply with the requirements of the NPRM. This provision would cost approximately \$111 million more in present value and would have no effect on the estimated quantified benefits, primarily because FAA projected a low probability of any accidents of cargo airplanes due to fuel tank

---

<sup>11</sup> *US Federal Register*: Volume 71, Page 70921.

<sup>12</sup> The full RIA is available at [http://dmses.dot.gov/docimages/pdf94/370618\\_web.pdf](http://dmses.dot.gov/docimages/pdf94/370618_web.pdf)

flammability. FAA also partially analyzed whether the rule should cover Airbus aircraft<sup>13</sup>. Although an Airbus aircraft has never suffered an accident due to this risk, FAA concluded from engineering studies that the average risk of 1 event per 60 million flight hours was approximately equal across Boeing and Airbus. In addition, FAA studied the total cumulative flight hours operated by all Airbus aircraft to date, and concluded that given this estimated risk, there is an approximately 40 percent chance that no Airbus accidents would have occurred to date. FAA took comment on both of these conclusions.

**Other International Considerations:** In addition to the analysis summarized above, FAA also considered the interaction of this rulemaking with international standards. Specifically, in keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to this NPRM.

---

<sup>13</sup> This consideration was not based on whether Airbus was a foreign firm, but whether the characteristics of Airbus aircraft made them more or less vulnerable to fuel tank flammability.

## **Advance Electronic Transmission of Passenger and Crew Member Manifests For Commercial Aircraft and Vessels**

**Summary of Rulemaking:** On August 23, 2007, the U.S. Customs and Border Protection (CBP) of the Department of Homeland Security (DHS) published a final rule in the Federal Register<sup>14</sup> titled “Advance Electronic Transmission of Passenger and Crew Member Manifests for Commercial Aircraft and Vessels.” This final rule requires electronic manifest transmission to CBP of passenger and crew member information for those onboard international commercial flights and voyages to and from the United States.

The final rule allows two options for data transmission in the air environment: (1) transmission of passenger manifests in batch form no later than 30 minutes prior to securing the aircraft doors; (2) transmission of individual passenger manifest information as each passenger checks in for the flight.<sup>15</sup> This information will be vetted against a government-established and maintained terrorist watch list prior to departure of the aircraft or vessel. These changes were proposed by CBP in a notice of proposed rulemaking published in the Federal Register<sup>16</sup> on July 14, 2006.

**Analysis of Impacts:** Since CBP determined this rule to be economically significant according to Executive Order 12866, they provided a Regulatory Impact Analysis, as required by OMB Circular A-4<sup>17</sup>.

*Costs:* CBP estimates the rule would impose present value compliance costs of \$827 million to \$1.2 billion over 10 years. The final rule will affect primarily large air carriers (those that employ over 1,500 employees), and CBP includes both U.S. and non-U.S. air carriers in this estimate. The rulemaking does not impose different requirements for U.S. and non-U.S. carriers; however, because the rule affects more non-U.S. carriers, as a group they bear a higher cost.

The major costs are for software and process upgrades by the air carriers, and the opportunity cost of passenger time due to the possibility of missing connecting flights. CBP monetizes this opportunity cost of time using standard U.S. wage rates. CBP based their passenger cost estimate on total passenger counts, including foreign passengers. In practice, it would have been very difficult to separate out U.S. and non-U.S. citizens on all international flights. CBP also assumes a “transaction cost” for each manifest transmission. The range of costs presented depends on the uncertain number of airlines choosing each transmission method, the uncertain amount of software updating required by each airline, and uncertain estimates of the number of passenger delays caused by the rule.

*Benefits:* CBP estimates quantified and non-quantified benefits. Under previous CBP rules, passenger manifest information could have been submitted after the aircraft departed for the U.S. If a passenger subsequently matched a name on the watch list, CBP would likely have needed to conduct interviews, deport a percentage of these individuals, and delay or reroute

---

<sup>14</sup> *US Federal Register*: Volume 72, Page 48319.

<sup>15</sup> The rule also establishes requirements for sea travel. CBP will require vessel carriers to transmit passenger and crew manifests for vessels departing from the United States no later than 60 minutes prior to departure. CBP estimates, however, that the impacts to sea travel will be minimal. Therefore, the rest of this case study focuses on the air environment.

<sup>16</sup> *US Federal Register*: Volume 71, Page 40035.

<sup>17</sup> The full RIA is available at <http://www.regulations.gov>, under docket number USCBP-2005-0003.

some of the aircraft. Based on historical data on the average number of incidents of this type, CBP estimates present value avoided costs of \$105 million over the 10 years of the analysis.

In addition, since security benefits are a function of the likelihood and severity of a hypothetical future terrorist attack, they are very difficult to forecast, quantify, and monetize. Therefore, CBP conducted a “break even” analysis. Given the estimated damages possible from a hypothetical future attack, the break even analysis identifies the change this rule would need to have on the probability of an attack in order for the benefits of the rule to exceed the costs. CBP presented many different break-even scenarios. For example, CBP estimated that if the rule reduced the probability of a 500 casualty terrorist attack by greater than 3 to 9 percent, the benefits of the rule would exceed the costs.

*Alternatives:* CBP quantified two regulatory alternatives: a requirement for non-interactive data transmission no later than 60 minutes prior to departure, and a requirement for non-interactive data transmission no later than 120 minutes prior to departure. CBP estimated a 10-year present value cost of \$2.7 billion for the 60-minute alternative, and a 10-year present value cost of \$33.8 billion for the 120-minute alternative. CBP estimated that benefits were not appreciably larger under either of the alternatives, since the ability to intercept passengers if needed was only slightly higher.

**Other International Considerations:** CBP policies allow data transmission under this rule to follow the UN/EDIFACT (United Nations/Electrical Data Interchange for Administration, Commerce, and Trade), an international electronic data interchange standard developed under the United Nations. The final rule does not change this practice.

## **Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act, Interim Final Rule**

**Summary of Rulemaking:** On October 10, 2003, the US Food and Drug Administration (FDA) issued an interim final regulation<sup>18</sup> that required domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with FDA. The interim final rule implemented the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). FDA's registration requirements are one of several rulemakings required by the Bioterrorism Act, all of which are designed to allow FDA to better respond to a deliberate contamination of the U.S. food supply. In the event of an outbreak of food-borne illness, registration information should help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be affected by the outbreak.

The major components of the Bioterrorism Act implemented through this rulemaking are as follows:

- Each facility must obtain a separate registration, even if owned by the same firm. The registration for foreign facilities must include the name of the U.S. agent for the facility.
- Foreign facilities that manufacture/process, pack, or hold food that is exported for consumption in the United States are required to register unless the food undergoes further processing or packaging at another facility outside the United States.
- Some establishments are excluded from the registration requirement, including farms and restaurants.
- Registered facilities must notify FDA in a timely manner of changes to their registration information.

**Analysis of Impacts:** Since FDA determined this rule to be economically significant according to Executive Order 12866, they provided a Regulatory Impact Analysis for public comment, as required by OMB Circular A-4<sup>19</sup>. FDA analyzed the impact of the rule over 20 years.

*Costs:* FDA estimates that the rule would lead to present value compliance costs of \$2.9 billion. The main component of the cost estimate was the opportunity cost of the time facilities would need to spend complying with the regulation, and the cost for foreign firms to obtain the services of a U.S. agent. For domestic facilities, FDA's estimate considered the time for the facility to learn about the requirements and fill out a registration form. In addition, FDA estimated additional costs for foreign facilities to perform the registration, and time to find and then hire a U.S. agent. FDA estimated the largest single component of cost is the agent requirement for foreign facilities. Note that an agent was specifically required by the Bioterrorism Act.

FDA also considered, qualitatively, the potential costs associated with port delays due to foreign facilities not being aware of the registration requirement until their shipment reaches

---

<sup>18</sup> An Interim Final Regulation is a stage of rulemaking where an agency publishes a final rule that is binding, but also continues to solicit public comment on a particular set of issues. In this case, part of the rationale for issuing an interim final rule, instead of a final rule, was to gather more information regarding the impact of the "Agent" requirement described later in this case study.

<sup>19</sup> The full RIA was published with the rulemaking in the *Federal Register*: Volume 68, page 58894.

the U.S. This included costs such as lost value of perishables, storage costs, and transaction costs.

*Benefits:* FDA did not quantitatively analyze benefits. A qualitative discussion of benefits was provided whereby FDA stated that requiring registration of manufacturers, processors, packers, and holders of food would aid in deterring and limiting the effects of food-borne outbreaks in four ways: (1) by requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain. (2) If FDA is aware of a specific food threat, a registration database would make FDA better able to inform the facilities potentially affected by the threat. (3) FDA would be able to deploy more efficiently its domestic compliance and regulatory resources. (4) FDA inspectors, using registration and other regulations required by the Bioterrorism Act, would be better able to identify shipments for inspection. Registering with FDA creates a paper trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the false registrant.

*Sensitivity Analysis:* FDA re-estimated the total costs under alternative assumptions, using the chosen option for comparison. The big drivers of cost were the number of firms, the amount of time firms needed to learn about and understand compliance obligations, and the cost to foreign firms of obtaining a U.S. agent. The lowest cost combination of assumptions gives a total cost of \$220 million for the first year and \$140 million in subsequent years. The highest cost combination gives a total cost of \$360 million in the first year and \$270 million annually.

*Alternatives:* In this interim final rule, FDA analyzed and quantified three options: 1) Longer periods of time allowed between updates of registration information, 2) No requirement to include product category information in the registration, and 3) No requirement for foreign firms to obtain a U.S. agent. Present value compliance costs could have been lowered to \$400 million had FDA chosen not to adopt the U.S. agent requirement. However, the agency felt that this would have significantly lowered the benefits of the rule, which it was unable to quantify, and would have been a violation of the Bioterrorism Act.

**Other International Considerations:** FDA considered and states it complied with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Act agreements.

## **Mexican Hass Avocado Import Program**

**Summary of Rulemaking:** On November 30, 2004, the U.S. Department of Agriculture (USDA) issued a final regulation in the Federal Register<sup>20</sup> with the title, the “Mexican Hass Avocado Import Program.” This final rule expanded the number of States in which fresh Hass avocado fruit grown in approved orchards in approved municipalities in Michoacan, Mexico, may be distributed. The final rule also allowed the distribution of the avocados during all months of the year, and removed restrictions on the ports through which the avocados may enter the U.S. and the corridor through which the avocados must transit the U.S. This regulatory action was based on a request from the Government of Mexico, and a finding that the phytosanitary measures described in the final rule will reduce the risk of introducing plant pests associated with Mexican Hass avocados into the U.S.

**Analysis of Impacts:** Since USDA determined this rule to be economically significant according to Executive Order 12866, as amended, they provided a Regulatory Impact Analysis for public comment, as required by OMB Circular A-4<sup>21</sup>.

*Costs:* USDA used an economic model that divided the U.S. into three “demand regions.” Since the previous rule allowed Mexican avocados into parts of the U.S. during part of the year, one demand region was defined as this area. The other two regions were California, Hawaii, and Florida, which are the major domestic avocado producing regions in the U.S. (dominated by California, with 96% of domestic production), and the rest of the U.S. The model also defines three supply regions: California, Mexico and Chile. Using this model, USDA estimates costs of \$70 to \$110 million per year. The largest component of cost is a welfare loss to California growers due to an approximately 7% drop in demand. The range of estimates is based on the uncertainty in the U.S. demand and supply of avocados, and the uncertain quantity of avocados imported under the new rule.

USDA also analyzed the risk of the introduction of quarantine pests into the U.S., and concluded there was no such additional risk due to expanded trade in avocados. The risk assessment prepared by USDA established that the annual number of avocados infested by quarantine pests imported into the U.S. is zero.

USDA did not estimate the cost of the phytosanitary measures that Mexican growers would be required to put in place in order to export to the U.S.; however, they stated the costs related to these changes were expected to be small and not significantly influence the supply or price of Mexican avocados. The measures did not differ substantially from current practice.

*Benefits:* Using the same model, USDA estimated benefits of approximately \$120 - \$180 million per year, primarily in U.S. consumer welfare gains due to an increased supply of avocados. The range of benefits is based on the same uncertain parameters as the range of cost. USDA did not provide an estimate of the gain in the producer welfare of Mexican avocado producers, but did analyze the Mexican response to the lifting of these restrictions in order to calculate the change in consumer prices expected due to the rulemaking.

---

<sup>20</sup> *US Federal Register*: Volume 69, page 69748.

<sup>21</sup> The full RIA is available at <http://www.aphis.usda.gov/ppq/avocados/>



*Alternatives:* The final rule delayed lifting the avocado import restrictions into California, Hawaii, and Florida for two years. The main alternative analyzed by USDA would have lifted the restrictions immediately. USDA calculated that the net benefits would have been approximately \$20 million higher per year for the two years the restriction would be in place. USDA decided, however, to include the two year delay for a couple of reasons. First, they stated the transition would provide an opportunity for the efficacy of the rule's risk-mitigating safeguards to be demonstrated through year-round distribution to the remaining 47 States. In addition, they concluded a transition would be less disruptive to domestic avocado farmers, the majority of which are small businesses.

## C. Conclusions and ways forward

From the above methodological study concerning the impacts on trade and investment in impact assessments, OMB and the Secretariat General of the European Commission have identified a number of conclusions and possible ways forward. They have invited and received comments from a number of interested organisations and parties (listed in Section D) on the following topics:

- 1) The value of timely announcement of planned legislative and regulatory initiatives, and of transparency in the analysis presented by the associated impact assessments. In this context, it is desirable to evaluate whether a planned regulatory or legislative initiative might have an impact on international trade or investment, or might otherwise be of interest to U.S., EU, or third countries.
- 2) The importance of having transparent impact assessment methodologies and procedures incorporated within clear rules or guidelines that are accessible to the public, accompanied by a rigorous system of quality control. Public consultation and notice and comment mechanisms will help to provide better quality of agency impact assessments and analyses. These mechanisms give the governments, businesses, and citizens of the EU, U.S. and third countries the opportunity to voice solicited or unsolicited comments on planned initiatives and to reflect their input in impact assessment and impact analysis reports.
- 3) The importance of making policy proposals and accompanying impact assessments public, which will allow governments and stakeholders in other countries to respond if they expect international trade and investment issues to be significant. Relevant underlying technical analysis and data should generally be published or otherwise made available to assure the transparency of these assessments.
- 4) With respect to the evaluations of the impact of a regulation on trade and investment, guidance should be provided on the type of analysis needed to provide decision makers with information on international trade and investment impacts and their multilateral context. This could include:
  - an analysis demonstrating the need for any proposed regulation that might directly impede international trade or investment,
  - an analysis of the degree to which different groups (foreign and domestic businesses and consumers) are affected by such a proposal or
  - a recommendation that existing international standards or regulatory approaches, if applicable, should be analysed as an explicit regulatory alternative.

Over and above these general conclusions and possible ways forward, both sides stress the usefulness of raising issues having a potential impact on international trade and investment in the existing forums for regulatory cooperation; this may also comprise exchange of preliminary results and technical studies. Where issues of a horizontal nature arise they can be brought to the attention of, and addressed in, the horizontal EC-OMB dialogue.

## **Response to Public Comment on the Conclusions and Ways Forward**

On item 1, most respondents supported transparency and the timely announcement of planned legislative and regulatory initiatives. For example, comment 1 stated that agencies should undertake “an ex ante thorough screening and scoping of IAs [Impact Assessments] on proposals related to trade.” Similarly, comment 4 also recommended a “Preliminary assessment of potential trade and investment impacts at the earliest stage in policy-making.” A few respondents made specific suggestions. For example, on the U.S. side, commenter 5 noted that the U.S. Department of Transportation (DOT) maintains a database identifying regulations that may have impacts to trade or be of interest to major trading partners, including the EU. They also stated this database could serve as a government-wide model on both sides. OMB agrees that the DOT database is a promising step in providing more timely notice of planned regulatory initiatives to our international trading partners, and intends to ask that all U.S. agencies include such indications in the fall, 2008 Regulatory Agenda.

On item 2, most respondents found valuable the opportunity to voice solicited or unsolicited comments on planned regulatory initiatives, and to have their input reflected in impact assessment and impact analysis reports. A typical response was that of comment 4, which stated that “All policies and assessments must be publicly available. Likewise, all peer reviewed scientific information and technical analyses that form the basis of the assessments should be required to meet the same levels of transparency.” A few respondents (3, 4, 6, 7) also made reference to the GUIDELINES ON REGULATORY COOPERATION AND TRANSPARENCY of April 2002, that call on “both sides to identify and implement jointly defined general government Guidelines for effective regulatory co-operation and for improving access to each other’s regulatory procedures, including the opportunity for all interested parties to have meaningful input in regulatory procedures and receive reasonable consideration of their views.” OMB and the Secretariat General reiterate their support for the goals of the 2002 Guidelines and agree their consistent application would further the goals identified in this joint Report.

In addition, respondents (4, 5) stated that impact analyses and impact assessments should be available even before a regulation is issued in proposed form. Although this may not always be possible in the U.S., as OMB reviews Regulatory Impact Analyses at the same time as proposed regulations, OMB does support the general principle of releasing the analyses supporting a regulatory decision as early as possible in the policy development process. This would help to ensure that stakeholders and the public have an adequate chance to comment on such assessments and analyses, and to ensure that the regulatory alternative finally adopted to implement the policy objectives reflects such input.

The Secretariat General underlines that stakeholder consultation by the Commission is often an iterative process and that impact assessments are made available as soon as the Commission submits a proposal for legislation to the legislative bodies in the EU.

On item 3, many comments supported these goals. In particular, many respondents (4, 5, 6, 7) would welcome the creation of a joint website to inform the public and stakeholders from the very earliest stage of policy preparation. In particular, respondent 6, the TABD, restated its previous offer to facilitate such a website:

“We reiterate our recommendation that annual work plans should be published on horizontal and sector priorities, together with a timetable towards resolution and results. All known proposals with potential transatlantic impacts should be included, and based on early assessments of trade and investment impacts in impact assessments and cost benefit analyses. As you know we have in the past offered to host on our website a common

calendar of transatlantic meetings of regulators, to help enhance transparency. Ideally the regulatory co-operation process should be entirely visible on line from the earliest stages of impact assessment and cost benefit analysis."

OMB expects that the information on regulations of international interest provided in the fall 2008 regulatory agenda of the U.S., which will be publicly available, will help to facilitate a web site such as the one described here. The Secretariat General is ready to provide relevant links to its own website, notably as regards planned initiatives. OMB and the Secretariat General underline there is no systematic record kept of transatlantic meetings of regulators, as these contacts are often informal by nature.

In addition, several respondents (3, 4, 5) supported the premise that underlying technical analysis should be made available for the public. Comment 3 stated that a process for peer review may aid in ensuring the information regulations are based on is "credible, accurate, objective, complete, and verifiable." Comment 5 also suggested that the U.S. Information Quality Act is a useful tool for ensuring this in the U.S.

On Item 4, most respondents, with one exception, supported the goal of more clearly and systematically including international trade and investment effects in regulatory assessments and analyses. For example, respondent 2 "commended OMB and the Secretariat General of the EC for proposing analysis of impact of regulation on international trade and investment." Likewise, respondent 4 stated that "The recommendation that international standards or regulatory approaches should be considered is particularly useful. This should be extended to require regulators explicitly to consider policy options already chosen by major trading partners as alternatives in the IA/CBA, as well as international approaches". In addition, respondent 7 stated that "it should be ensured that all assessments take due account of the regulations' impact on international trade and investment." This respondent also recommended that both the US and the EC explicitly compare their regulatory approaches to those of their major trading partners, and require an analysis of whether any particular regulation was consistent with a country's WTO obligations.

One commenter, however, expressed concern that the consideration of international trade impacts in regulatory assessments and analyses might be given excessive attention, to the detriment of other valid considerations in favour of specific regulatory initiatives. Commenter 8 stated that "there is insufficient evidence from the narrative of the Draft Report that there is any need whatsoever to pursue these regulatory process changes." OMB and the Secretariat General understand but do not fully share the concerns of this commenter; they believe that the other respondents to the draft report have provided strong arguments in favour of ensuring that these potential impacts of regulation be more systematically taken into account, within the existing framework that requires assessment of all significant impacts, including those on domestic consumers. Moreover, regulations that unnecessarily restrict international trade and investment reduce competition, thereby harming consumers through higher prices and reductions in incentives for producers to innovate and increase productivity.

Several respondents expressed their support for continuing this dialogue through both future meetings of the High-Level Regulatory Cooperation Forum, and the Transatlantic Economic Council. The Secretariat General and OMB appreciate these comments, and intend to continue our productive dialogue on these and other topics.

## **Response to Comments on the Consideration of International Trade and Investment Impacts in U.S. Regulatory Impact Analysis**

Several respondents (2, 4, 5, 7) stated that U.S. agencies already have an obligation to analyze the impacts of proposed regulations on international trade. For example, respondent 4 stated that “It is encouraging to see that there are already existing commitments on both sides to deal with international impacts. As the report notes, the European Commission’s Impact Assessment Guidelines and the US Office of Management and Budget’s Circular A-4, Regulatory Analysis contains relatively clear instructions on the matter.” Respondent 4 also recommended that “Both the EU and the US should improve the enforcement of their existing impact assessment commitments.” Comment 5 stated “OMB should underscore with U.S. agencies the importance of its Circular A-4 on Regulatory Analysis issued in 2003 that raises consideration of regulations as potential non-tariff barriers.” Furthermore, comment 7 observed that both EO 12866 and Circular A-4 “although largely geared towards domestic impacts of regulations, do require consideration of international trade impacts for economically significant rules.”

Comment 9 stated that the use of private sector standards is the best way to achieve cross-border compatibility of rules. This respondent observed that private sector standards “facilitate the alignment of regulatory criteria across borders. The most effective mechanism of harmonizing cross-border requirements (technical regulations and standards) is when regulators around the world reference private sector standards.” In the U.S., OMB Circular A-119 and the National Technology Transfer and Investment Act oblige agencies to use existing private sector standards, including private sector international standards, as the basis for regulations, or present a justification for not doing so. Comment 8, however, objected to this requirement, stating that international standard setting bodies are undemocratic, biased forums.

OMB agrees with commenter 9 that U.S. agencies are obliged to evaluate and consider private sector standards as one alternative when developing regulations, and to justify cases when they have not adopted a private sector standard. In fact, the original recommendation in conclusion 4, that agencies should consider existing international standards or regulatory approaches as an explicit regulatory alternative, coupled with OMB Circular A-4’s requirement that such alternatives be fully analyzed, satisfies a U.S. agency’s obligation to consider standards under Circular A-119 and the National Technology Transfer and Investment Act. Although OMB disagrees with Commenter 8’s characterization of international standard setting organizations, the concern regarding the impact on US citizens if international standards were automatically adopted, is not without merit. However, in the U.S., were an agency to use an international or other private sector standard as the basis for a regulation, the U.S. agency would still be required to conduct a regulatory impact analysis and to determine the best approach to regulation under Executive Order 12866. Furthermore, the U.S. agency would still be required to publish any such proposed regulation for open public comment under the Administrative Procedure Act. Therefore, OMB does not believe that the use of a private sector standard in a regulation makes the process less transparent than other methods for developing regulations.

In conclusion, in the US, regulatory agencies face both statutory and executive obligations to take international trade impacts into account when developing regulatory proposals. The examples provided in this report illustrate how agencies are fulfilling these obligations. To clarify these current obligations and responsibilities, OMB will be reminding agencies of the

importance of their taking into appropriate consideration, in preparing their impact analyses for draft regulations, the impact that the intended regulation would have on trade and cross-border investment between the United States and other countries.

#### **D. Public Comments on the Draft Report**

Below is a list of public comments to the Draft Report. The full comments are available at: [http://www.whitehouse.gov/omb/inforeg/trade/index\\_trade.html](http://www.whitehouse.gov/omb/inforeg/trade/index_trade.html) and [http://ec.europa.eu/governance/better\\_regulation/impact\\_en.htm#\\_EU\\_US](http://ec.europa.eu/governance/better_regulation/impact_en.htm#_EU_US)

1. Jacopo Torriti, Frederic Boudier, and Prof. Ragnar Lofstedt
2. Association of American Publishers and The Washington DC Principles for Free Access to Science
3. Federation of German Industries
4. BUSINESSEUROPE
5. Chamber of Commerce of the United States of America
6. TransAtlantic Business Dialogue
7. American Chamber of Commerce to the European Union
8. Transatlantic Consumers Dialogue
9. Chamber of Commerce of the United States of America: Supplemental Comment