Determining Compatible Regulatory Regimes between the U.S. and the EU

By: John Morrall III

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Executive Summary

As democratic, developed societies, the United States and the European Union strive for well-regulated market economies that provide their citizens high levels of protection for consumer welfare and safety, the environment and financial stability. With the U.S. and EU economies so highly integrated, however, differing U.S. and EU approaches to *domestic* regulation can actually reduce consumer welfare by creating unnecessary costs as companies modify products to meet different requirements that do not notably increase consumer protection. Among other things, these differences require regulatory agencies to devote scarce enforcement resources to policing high-volume but low-risk transatlantic trade, reducing their ability to adequately enforce regulatory requirements on imports from less well-regulated economies.

To overcome the costs of these unnecessary regulatory divergences, and to enhance the efficiency and effectiveness of our regulators, this paper advocates that the United States and European Union should:

- establish a process that should ultimately result in **mutual recognition of compatible regulatory regimes**, initially focusing on product safety in such pilot areas as automobiles, chemicals and pharmaceuticals; and,
- as a first step toward this goal, have corresponding regulatory agencies undertake **Transatlantic Regulatory Impact Assessments (TARIA)** on significant existing and pending product safety regulations in these sectors that have major impacts on the U.S.-EU economic relationship.

That U.S. and EU regulators strive for similar regulatory outcomes is well-established; a detailed study of 3,000 risk-reducing regulatory decisions in the U.S. and EU shows that overall risk stringency is about the same, while divergences stem largely from protectionism and local rent-seeking. Other studies cited herein highlight the existing and prospective overlap especially in the areas of automotive safety, chemicals and pharmaceuticals. The cost of divergent approaches is highlighted in a detailed study by ECORYS, which estimates that eliminating even half of the non-tariff barriers to trade caused by regulatory divergences could increase transatlantic GDP by half a percent, or $150 billion. Even more conservative estimates of economic gain imply the benefits of greater regulatory convergence through mutual recognition of compatible regimes and transatlantic regulatory impact analyses will far outweigh the costs.

[1] This paper was funded by the U.S. Chamber of Commerce's Global Regulatory Cooperation Project.

As regulators are often legally mandated to focus on their domestic responsibilities, regulators will need to be so convinced of these benefits that they will seek legislative authority to be able to recognize the product safety decisions of their transatlantic counterparts. As detailed in Annex A, such a process would build on, and build up, nearly two decades of cooperation between U.S. and EU regulatory agencies by studying whether outcomes are in fact similar, and then seek public comment on those studies. If regulators decide they do have compatible regimes, they would ask legislators for the ability to accept the product safety determinations of their transatlantic counterpart, while retaining the right to suspend this recognition for individual products where they have reason to believe a problem may exist. Such a determination would initiate consultations with their regulatory counterpart, which clearly would be interested in any evidence that its product safety ruling might be incorrect.

TARIA would help build regulator-to-regulator confidence by coupling existing U.S. and EU regulatory cooperation with domestic "better regulation" initiatives coordinated through the U.S.'s Office of Information and Regulatory Affairs (OIRA) and the EU Commission's Impact Assessment Board (IAB). The Transatlantic Regulatory Impact Assessments would help identify and justify divergences in existing and new "major" U.S. and EU product safety regulations, guided by the recently agreed common principles of transparency and stakeholder involvement, consideration of costs and benefits, analysis of alternatives, preference for the least burdensome approach, and use of flexible tools. We suggest ten specific questions each TARIA should answer, including identifying the specific problem to be addressed, the cost savings of complying with one set of regulations rather than two different ones, and the regulatory spillover benefits of similar approaches.

If properly done, these two initiatives should result in greater regulatory efficiency and effectiveness, enhanced consumer welfare and safer products, deeper transatlantic economic integration and competitiveness, and the added growth and jobs our two societies need. All that's required now is the political will to begin the process.

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Table of Contents

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By John F. Morrall III[2]

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative.

—President Obama (2011)[3]

Let's be clear: Trade is critical to American innovation and economic growth. It can expand opportunity for workers and entrepreneurs, both at home and abroad.

—Senators Baucus and Kerry (2011)[4]

This paper proposes a new approach to transatlantic regulatory cooperation aimed at improving regulator efficiency and effectiveness through U.S.-EU mutual recognition of "compatible regulatory regimes." As democratic societies at similar levels of economic development, the citizens of the United States and European Union seek the same protections and performance from their regulatory regimes, so U.S. and EU regulatory measures – especially in the area of product safety – often seek the same results, even if through different approaches.

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[3] President Barack Obama, Executive Order 13563: *Economic Growth and Public Protection*, January 18, 2011, Section 1, General Principles of Regulation.

[4] Senators Max Baucus and John Kerry in the *Wall Street Journal,* April 4, 2011.

By eliminating unnecessary regulatory divergences between us, we can also reduce existing, and prevent new, non-tariff barriers (NTBs) to transatlantic trade and investment, thereby generating growth, jobs and greater public protection in the world's largest economic partnership. An important study by ECORYS, funded by the European Commission, estimates that if 50% of the non-tariff barriers between the United States and the European Union were eliminated, combined transatlantic GDP would increased by half of a percent.[5] With a combined transatlantic GDP of $30 trillion, the modeled improvements to our regulatory regimes could promote economic growth of $150 billion per year in GDP while also enhancing public health and safety.[6]

Although the transatlantic regulatory cooperation effort of over twenty years has shown some progress — and potential for more — it has been slowed by agency inertia and resistance to policy concerns not directly related to agency mission. In a fiscally-constrained period when regulators must do more with less, when our societies must look for growth through efficiencies, we must redouble our efforts and undertake bolder approaches to improve the quality and protections of our regulations while expanding trade, investment and incomes. Specifically this paper proposes ***an approach that combines on-going regulator-to-regulator cooperation with the existing and reinvigorated central government coordination and quality control institutions. It will ensure that new and existing regulations take into account a beyond-the-border perspective grounded in the public interest approach to regulation.***

Regulatory reform at the national level has taken center stage again as both sides of the Atlantic seek ways to reestablish growth, job creation, innovation, and competiveness with dynamic emerging markets. At the same time the need for "better" or "smarter" regulation is more apparent now than ever before, at the international as well as the national level.[7]

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[5] ECORYS Nederland B.V. Non-Tariff Measures in EU-U.S. Trade (December 2009). A ten year "ambitious" but feasible (with high level political support) regulatory cooperation process was modeled. The EU would gain a permanent increase of 0.7% and the U.S. 0.3% of GDP. One half of a percent is 20% of the growth forecast of combined GDP by *Economist Magazine* for 2011 and 2012 on May 14, 2011.

[6] Many studies have shown that higher income tends to lead to better health. *See* Randy Lutter and John Morrall, "Health-Health Analysis: A New Way to Evaluate Health and Safety Regulation," *Journal of Risk and Uncertainty* (1994). Based on estimates updated for inflation form this literature. *See* Randy Lutter, John Morrall, and Kip Viscusi, "The Cost-Per-Life-Saved Cutoff for Safety-Enhancing Regulation," *Economic Inquiry* (1999) a $150 billion increase in GDP could lead to an additional 6,000 lives saved per year.

[7] It is important to make clear that regulatory reform efforts designed to promote economic growth, job creation, innovation, and competiveness are not at odds with the need for regulation to be effective in achieving a desired regulatory outcome. In fact, it is just the opposite. Confidence in the quality and integrity of regulation remains the primary objective and taking into account international considerations only further underscores this mandate. Given

Increasingly, the domestic center-of-government regulatory oversight bodies, the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) which is part of the Office of the President, and the European Union's Impact Assessment Board (IAB), chaired by a Deputy Secretary General of the European Commission (EC), are being asked to expand and integrate their coordinating and quality control roles for domestic regulation with work in international regulatory cooperation. Regulator-to-regulator sector negotiations to eliminate regulatory divergence and to implement mutual recognition agreements must be given the same quality control and coordination from the central government as domestic rulemakings already receive. Additionally, these rulemakings must abide by the same principles as those used for domestic-focused regulation: transparency, open government and evidence-based benefit-cost analysis. As Cass Sunstein commented:

> *To understand the likely consequences of regulations, it is indispensable to use the best available techniques to project both benefits and costs, and to be as quantitative as possible.* [8]

Receptivity to a new approach that combines bottom-up reform with clearly needed top-down coordination and oversight appears ripe for consideration. In the United States alone, since 2005 OMB has co-chaired the U.S.-EU High-Level Regulatory Cooperation Forum (HLRCF), which now reports to the Cabinet-level Transatlantic Economic Council (TEC). In December 2010, OIRA agreed to consider new regulatory cooperation mechanisms. In its March 2011 *Draft Report to Congress on the Cost and Benefits of Federal Regulations*, OMB discussed various regulatory cooperation initiatives and asked for comments on whether OMB should recommend that agencies promote regulatory cooperation initiatives alongside their trading partners. When OMB recommends an agency practice, it monitors and oversees those actions. Also in March 2011, OMB established a new website on international regulatory cooperation with a special section devoted to the EU.[9] Similar developments are occurring in Brussels.

The paper proceeds as laid out in the following paragraph. Section 1 makes the case for a new approach for transatlantic regulatory cooperation through mutual recognition of compatible

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the complexity and interconnected nature of today's global economy, incongruent regulatory frameworks that fail to interrelate across borders can have the unintended consequence of exposing gaps in the integrity of the safeguard intended by the regulation.

[8] Cass R. Sunstein, Administrator of OIRA, Speech at NYU Law School, "Executive Order 13563, Economic Growth and Public Protection" on April 4, 2011.

[9] *See* http://www.whitehouse.gov/omb/oira_irc_europe.

regulatory regimes; this approach is presented in more detail in Annex A. Section 2 proposes building on the recently reinvigorated regulatory impact analysis (RIA) programs of evidence-based, public participation and impact analysis rulemaking by institutionalizing a transatlantic regulatory impact analysis process. Principles of analysis and specific requirements are presented, while a brief regulatory impact assessment, presented in Annex B, suggests the benefits of this new approach likely outweigh costs. Section 3 describes the slow progress of previous efforts at transatlantic regulatory cooperation and refers the reader to Annex C for the particulars of the attempts to establish meaningful mutual recognition agreements (MRAs) between the U.S. and the EU. It suggests that further steps to revise the OMB and EC regulatory impact analysis guidelines need to be taken, in order to better take into account trade and investment impacts. Annex D describes current requirements. Section 4 proposes a way forward by suggesting the program start with pilot sectors. Three key sectors/regulatory regimes appear most suitable for this pilot program, as they offer the greatest potential for advancing product safety and saving consumer and taxpayers' resources. These sectors include: the auto industry, chemicals and pharmaceuticals. Section 5 concludes with a summary of the findings and a call for a more ambitious approach to reducing regulatory divergences.

1. The Case for a New Compatible Regulatory Regime Approach

a. Better Regulation and Trade

Regulation is a necessary and accepted part of good governance. "Free" economies function most efficiently when all actors operate in the context of transparent, evidence-based, and enforced rules; rules which reflect societal norms for protecting consumer safety, the environment and financial prudence.

These rules and regulations naturally reflect *domestic* political desiderata, with regulatory agencies enforcing them on all products and services sold in their jurisdiction, whether produced domestically or abroad. But the regulators' ability to enforce these measures becomes increasingly strained in a highly globalized world, where international trade constitutes nearly a quarter of the goods and services available in such developed economies as the United States and European Union.

When regulatory agencies in two jurisdictions take different approaches, they can raise non-tariff barriers to trade between them, without necessarily enhancing social welfare. The net benefit to the public of reducing barriers to trade between nations has been recognized at least since the time of Adam Smith and David Ricardo; it is this benefit that has spurred globalization. Unfortunately, the benefit to narrower interests of resisting reductions in both tariff and non-tariff barriers to imports, also known as "rent seeking," boasts an equally long history. Especially since the end of World War II, countries have made significant progress in reducing tariff barriers; however non-tariff barriers continue to pose an impediment. Both political and economic efficiency reasons explain the differential rate of progress. A tariff is a tax, and voters do not normally vote to raise taxes. However, the cost to the public of non-tariff barriers is not as transparent, so those more concerned with their parochial interests can use the public's ignorance to their advantage.

Unlike with tariffs, a non-tariff barrier arising from a regulatory measure may sometimes be in the "public interest," meaning that the benefits to the public exceed the costs to the public. This might be the case if the measure corrects a significant market failure, such as unequal information between parties to transactions or externalities imposed on third parties.[10] Moreover, because of differences in situations and needs among countries, regulations designed to maximize economic efficiency and net benefits are likely to diverge as long as a purely domestic perspective is used. A benefit-cost analysis performed on the same regulation in two different economies may produce varying results since social benefits (measured generally by willingness-to-pay) and social costs (generally measured by the opportunity costs of the capital, labor, and natural resources used for compliance) often fluctuate depending upon a variety of factors. Nonetheless, economies with similar per capita incomes and values, such as the U.S. and the EU, should produce more similar results and should possess more comparable regulatory regimes.

Even when an international perspective is used so that, among other concerns, compliance costs of conforming to more than one standard are factored in, economically efficient

[10] The third type of market failure, "market power," is not likely to be corrected by a NTB since its solution is to allow entry and promote competition. Indeed OMB's Circular A-4, "Regulatory Analysis" guidance on market failure states that: "Government action can be a source of market power, such as when regulatory actions exclude low-cost imports [p. 4.] http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf>.

regulations may still legitimately differ between countries. In international trade parlance, this situation is commonly referred to as "necessary" or "justifiable" regulatory divergence. But it is also true that particular interests often use this possibility to their advantage by arguing that a specific regulatory measure directly beneficial to them is in the public interest, while also allying with those advocating a legitimate public interest.[11] Debate about whether a divergent regulation is "unnecessary" or not can be endless and extremely political. Negotiations can also drag on even when the original reason for the divergence, legitimate or not, no longer exists.

Talk among the regulators of trading partners on specific non-tariff barriers is not generally aimed at determining whether elimination of a non-tariff barrier is economically efficient from a combined trading-partner perspective. Indeed, experts on domestic regulation have observed that regulators are motivated by a complex set of factors, including their agencies' missions and their own interests, as well as the public's broader welfare. In this sense, one should "never underestimate the power of inertia."[12] So even when agency missions and mandates across the Atlantic match, as recent studies indicate,[13] a nudge from the center may be necessary.[14]

In the specific case of the U.S. and the EU, as noted above, the cost of unnecessary regulatory divergences is substantial. According to ECORYS, eliminating all non-tariff barriers could increase transatlantic GDP as much as 2.5% to 3%, if higher compliance costs and the economic rents resulting from lessened competition are both counted. The ECORYS study is rigorous, detailed and carefully qualified, combining sophisticated economic modeling and extensive trade and investment data with survey results from government, industry and academic experts. This method allows ECORYS to present several more likely estimates that distinguish between the short and long term (ten years), partial and general equilibrium, sector and

[11] This is sometimes termed the "Bootleggers and Baptist" theory of regulation after Bruce Yandle pointed out that these two groups were allied in their opposition of easing alcohol restrictions during prohibition. *See* "Bootleggers and Baptists: the Education of a Regulatory Economist," *Regulation* 7 (1983).
[12] Richard H. Thaler and Cass R. Sunstein, *Nudge, Improving Decisions about Health, Wealth, and Happiness*, Penguin (2009) p.8.
[13] *See* for example *The Reality of Precaution*: *Comparing Risk Regulation in the United States and Europe* Edited By Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand, RFF Press (December 2010).
[14] This was the conclusion of John Graham, Administrator of OIRA from 2001 to 2006, in "Saving Lives through Administrative Law and Economics," *University of Pennsylvania Law Review*, V 157, 2 (December 2008), p.540.

interaction impacts, and social and transfer costs (economic rents).[15] Using the more realistic scenarios, the gain to transatlantic GDP varies between .08% and 0.5%; nonetheless, even the low estimates are in the tens of billions of dollars per year and of course are ongoing unless reversed by later policy choices.[16]

b. U.S. and EU Regulatory Compatibility

However different U.S. and EU regulations may be, with increasing convergence and interconnection between the two sides of the Atlantic, moving beyond national interest to an even broader trading-partnership perspective is a logical step. The EU and U.S. are each others' largest trading and investment partners and their trade combined internationally accounts for 40% of world trade.[17] Perhaps more significantly, U.S. and EU companies have each invested well over €1 trillion on "the other side of the pond," so that they are major employers in each other's jurisdiction; indeed, nearly 40% of bilateral U.S.-EU trade occurs within the same firm. They also share many of the same cultural, social, legal and political traditions. The U.S. and EU members (when weighted by population) have about the same percentile ranking (90%) on the World Bank's Regulatory Quality world governance indicator,[18] and the millions of Europeans and Americans visiting each other's attractions show little concern for the safety of the cars they rent, the products they buy or the food they eat.

A recent Resources for the Future study analyzed a dozen detailed case studies of a wide array of U.S. and European measures to regulate risks to health, safety, environment, and security, and concluded that:

> *The authors rebut the rhetoric of divergence or reversal in European and American approaches to risk regulation, and show that the reality has been general parity, combined with the selective application of precaution to particular risks on both sides of*

[15] ECORYS Nederland B.V. Non-Tariff Measures in EU-U.S. Trade (December 2009). For 23 sectors, ECORYS first estimates the tariff equivalence cost of NTBs and then determines the percentage of NTBs are "actionable." It estimates that on average about 50% of the cost of NTBs could be eliminated in ten years through transatlantic regulatory dialogues and cooperation assuming the political will exists. The estimates are based on business survey results and expert opinion by sectors which are plugged into a "gravity" model of trade and investment flows. For the longer run dynamic interactions that take into account expanded trade and investment flows, these sectoral data are plugged into computable general equilibrium (CGE) model of world economies.

[16] ECORYS table 1. ECORYS also points out that a 2005 OECD study estimated potential gains in GDP of between 3.0% and 3.5%.

[17] http://www.eurunion.org/eu/EU-U.S.-Relations/EU-U.S.-Facts-Figures.html.

[18] http://info.worldbank.org/governance/wgi/mc_chart.asp.

the Atlantic, as well as a constructive exchange of policy ideas toward "better regulation."[19]

Clearly there are strong indications that at least several "compatible regulatory regimes" exist across the Atlantic. Yet our regulatory agencies are currently required by our domestic laws to scrutinize products and services emanating from the other side as though they were as high-risk as any other import. This undermines the effectiveness of our regulators, forcing them to use their limited enforcement resources to police low-risk but very high volume transatlantic sources of supply when imports from other less-well-regulated jurisdictions are rapidly rising.[20]

As dedicated as our respective regulatory agencies are, legally requiring them to indiscriminately police hundreds of billions of dollars and euros of imports from a similarly-regulated jurisdiction places them in a "no-win" situation. This situation could be changed, however, by creating a process that would allow our regulators to seek legislative authority to recognize their transatlantic counterparts as possessing a "compatible regulatory regime."

Such a process[21] would build on — and build up — cooperation between paired transatlantic regulatory agencies, focusing initially on product safety, where the outcomes our regulators seek appear nearly identical. The first step would be to study whether these outcomes are in fact similar, to then seek public comment on those studies, and finally to determine whether we have compatible regulatory regimes. If so, regulators would ask their legislators for the ability to generally accept the product safety determinations of their transatlantic counterpart, while retaining the right to suspend this recognition for individual products where they have reason to believe a problem may exist. Such a determination would initiate consultations with their regulatory counterpart, who would clearly be interested in any evidence that their product safety ruling might be incorrect.

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[19] Promotion for *The Reality of Precaution*: *Comparing Risk Regulation in the United States and Europe* Edited By Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand RFF Press (December 2010).

[20] There is significant potential for budgetary savings for more efficient rulemaking, inspection, and enforcement based on U.S. data alone. In 2010, $43.7 billion and 233,610 FTEs were dedicated to health, safety, environmental and security regulation. Another $8.2 billion was spent by the U.S. federal government on economic and financial regulation. *See* Susan Dudley and Melinda Warren, *Regulator's Budget Report*, May 11, 2011, http://www.regulatorystudies.gwu.edu/images/pdf/2012_regulators_budget.pdf.

[21] *See* Annex A for a more detailed break-down of the process.

2. Building on the RIA Model to Transatlantic Regulatory Cooperation: TARIA

To use an evidenced-based approach to determine which EU-U.S. regulatory regimes are sufficiently compatible for full mutual recognition, we should build on the existing EU and U.S. regulatory review programs, and move one level higher in regulatory impact assessment, coordination and quality control. This paper proposes a "Trans-Atlantic Regulatory Impact Analysis" (TARIA) program for this purpose. TARIA would (1) require transparent, open, and evidenced-based prospective and retrospective analysis of regulations from a transatlantic perspective as well as (2) assure participation and follow-up by the regulators and the regulatory oversight bodies of both specific regulations and regulatory sectors, in order to determine the compatibility of regulatory regimes.

The Transatlantic Regulatory Impact Analysis would almost certainly produce significant benefits that exceed the costs of the additional analysis. Both the EU and the U.S. have recently reevaluated and moved to reaffirm and strengthen their domestic RIA programs. The essence of the program is to ask agencies "to look before they leap," and after they have leapt to see where they have landed. This approach force agencies to answer with multiple complex questions, including: why take the leap at all? Does a significant market failure or some other compelling public need require action? Have costs and benefits of the proposal and its reasonable alternatives been estimated? Do the benefits of the intended regulation (including hard-to-quantify social values) justify its costs? The EU for over ten years and the U.S. for over 30 have made steady progress in developing transparent and evidence-based regulatory review mechanisms to coordinate and improve the quality of regulations but they have done so primarily using a domestic perspective;[22] TARIA expands this into the international arena.

The TARIA approach aims to further build the trust and confidence required from regulators, while also guiding them toward priorities and solutions. The essence of the TARIA process is to augment agency RIAs by including a section evaluating differences in comparable product safety regulatory decisions on the other side of the Atlantic, where regulatory

[22] In benefit-cost analysis this issue is known as determining who has "standing."

cooperation is strongest.[23] These analyses would be used to establish a database that would form the basis for determining compatible regulatory regimes.

Once agencies and services prepare and submit impact analyses with a transatlantic perspective to OMB and the EU Impact Assessment Board as part of their reviews under EO 13563 and the EU Better Regulation program, the growing database of impacts by regulatory programs can be used to select "compatible regulatory regimes" and to establish roadmaps with clear objectives and fixed timetables for implementing full Mutual Recognition Agreements. The TARIA approach should also focus on specific regulatory regimes and sectors and will combine prospective and retrospective analysis. Sectors that are good candidates for pilot programs include automotives, chemicals, and pharmaceuticals.

OMB and the EC also need to move forward to issue and enforce agency guidance on estimating the full international costs and benefits of regulations, rather than just the domestic consequences. Single mission agencies such as OSHA or functional Commission Directorates General understandably do not routinely consider the broader impacts on the economy of their own regulations. That is the concern of the President and his White House advisors and of the European Commission's Secretariat General. OMB, OIRA, and the USTR were established to take into account and to represent the broader national and international interests. They are located in the Executive Office for the President, the only elected official who represents all the people, for that purpose. The IAB was also established in the Secretariat-General of the Commission, in turn part of the Office of the President of the Commission, to reflect broader Commission interests than that of the individual service or Directorates-General proposing the regulatory policy.[24] The common purpose of these two offices in overseeing better regulation in their respective jurisdictions makes them natural partners in bringing greater international efficiency between our regulators as well. Indeed the success of their efforts to improve regulation using shared methods and principles of better regulation should itself move regulatory regimes overtime toward greater compatibility.

[23] It is precisely because U.S.-EU regulatory cooperation has progressed so far over the past years that we recommend this process focus initially on transatlantic collaboration, although it can – and should – be extended to other regulators as appropriate.

[24] For a history and comparison of OIRA and the IAB, *see* Jonathan B. Weiner and Alberto Alemanno, "Comparing Regulatory Oversight Bodies across the Atlantic: The Office of Information and Regulatory Affairs in the U.S. and the Impact Assessment Board in the EU" (2010) in Susan Rose-Ackerman & Peter Lindseth, eds., *Comparative Administrative Law* (Edward Elgar).

a. Guiding Principles for Analysis

TARIA guidance should be consistent with the new regulatory programs recently announced by the U.S. and the EC and should build on the five common core regulatory principles set forth at the December 16, 2010 TEC meeting in Washington:

(1) **Transparency and openness**, allowing participation by stakeholders and the public;

(2) **Consideration of costs and benefits**;

(3) **Careful analysis of alternatives**, including those more and less stringent;

(4) **Selection of the least burdensome approach**; and

(5) **Use of flexible tools**, promoting freedom of choice and free markets.

The TARIA should be performed on economically significant regulations[25] by the agencies and services as a component of the RIA, and submitted to OMB in the U.S. and the Impact Assessment Board in the EU as part of the existing coordination and quality control process. It should have a stand-alone summary section focused equally on costs and benefits. In keeping with the first core principle, the TARIA should be transparent and open to comment and consideration from the transatlantic partner governments, public and stakeholders. Dedicated TARIA websites should be established on both sides of the Atlantic to promote openness on a transatlantic scale. The TARIA is not confined to specific regulation, but should include a broad overview by regulatory regime and sector.

The second principle requires consideration of all costs and benefits, which the TARIA would extend to benefits and costs impacting both sides of the Atlantic. Among other things, this would necessarily entail discussions among the regulatory agencies on specific decisions made or considered by their counterparts on similar product safety issues. TARIA would further the third principle by carefully analyzing a scenario of no divergence. Principle (4), selection of the least burdensome approach to achieve a given objective, would now include consideration of an alternative with minimum divergence, such as MRAs. Principle (5), use of flexible tools, would be informed by the TARIA, in comparison to the basic RIA providing domestic considerations. Expansion of markets generally improves the cost-effectiveness of using flexible

[25] An "economically significant" regulatory action is defined in the U.S. by Executive Order 12866 Section 3(f)(1) as that which has "an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." The European Commission does not set a specific threshold for economically significant impact assessments, but instead establishes a consultative process to determine what is covered and what "proportionate" level of effort should be devoted to it.

tools such as market incentives, performance standards and information policies. The increased competition resulting from market openness, combined with the added elasticity to comply with protective regulations, both drives and permits firms to reduce costs and/or produce higher quality and safer products.

b. Content of TARIAs

TARIA guidance should ask agencies to answer specific questions based on a default assumption of no regulatory divergence between the actions proposed by the EC and the U.S. The analysis needs to show why regulatory divergence would be in the combined public interest of the transatlantic partnership. TARIA, like the U.S. RIA process, should be about prospective economic efficiency impacts ("maximizing net benefits"), not a rationalization of a political decision already made. Decisions will ultimately be finalized on political grounds, as they should be in democratic societies like the U.S. and EU,[26] but they should be made transparently, with full information regarding the transatlantic welfare implications. In this manner, even if the instant regulatory action is not impacted by the analysis, a long-run case may be made to the public and legislatures that may lead to future regulatory improvements.

The following ten questions should be answered for regulations flagged for their international impacts and for retrospective analyses by sectors/regulatory regimes:

1. What is the market failure or compelling national need that requires a divergent regulation?
2. Does a statute or other legal impediment prevent an administrative mutual recognition agreement that would permit the reduction of the divergent regulation?
3. What are the costs/savings to the private sector (if any) of complying with a single set of regulations compared to the costs of complying with two or more sets of divergent regulations?

[26] Indeed, this is explicitly stated by European Commission as follows: "*Impact assessment is an aid to political decision-making, not a substitute for it.* The impact assessment informs the political decision-makers of the likely impacts of proposed measures to tackle an identified problem, but leaves it to them to decide if and how to proceed." (emphasis added). http://ec.europa.eu/governance/better_regulation/impact_en.htm.

4. What are the budgetary savings to the two regulatory authorities of developing, inspecting, and enforcing two sets of regulations compared to one?
5. How much is transatlantic trade likely to increase as a result of the lower transaction costs from the elimination of the divergent rules?
6. How much would estimated benefits increase if regulatory spillover benefits to the transatlantic partner are included in the benefit estimates?
7. Would there be a change in the regulatory alternative recommended if the net-benefits are increased relative to the baseline of divergent regulations?
8. What are the quantitative and qualitative benefits of a transatlantic regulatory alternative compared to the domestic-oriented regulation?
9. Taking into account the factors above, do the benefits of divergent regulations compared to the costs justify two separate regulatory regimes?
10. If legal, political, or pragmatic factors currently compel divergent regulations, are there reasons to believe that these regulatory regimes are compatible and that pursuit of a long run strategy to overcome the identified obstacles should be bilaterally pursued?

This analysis is aimed at moving toward smarter transatlantic regulation, which could lead to either more regulatory benefits (greater protections) and/or less burdensome regulation. Reductions in divergences should decrease costs to consumers, as lessened compliance costs and increased competition result in lower prices and budgetary savings for the agencies and services. In addition, consumers could benefit from greater protections newly "justified" by including transatlantic-wide benefits in the analysis.

c. Database and Decision Making

TARIAs should be tracked by annual reporting of the results of the OIRA and IAB analyses at the HLRCFs, and a joint report modeled after the joint OMB EC report on guidance should be published. For OMB this could be published in a chapter on TARIA results, along with the results of other international cooperative efforts, in its annual report to Congress on the Cost and Benefits of Federal Regulations. OMB publishes this report first for comment and then in final form. The OMB report is also required by statute to suggest improvements and modifications in specific regulations and the rulemaking process. A section should report on the

analyses of trade impacts as a database, as well as the progress on the sector negotiations proposed below as pilots. Recommendations to the legislative branch can be made by the regulatory regime for the sectors determined to be mutually "compatible."

3. Building the Foundation for a Successful Implementation of TARIA

In the past 15 years, contacts between U.S. and EU regulators have significantly expanded, increasing trust and collaboration among counterpart agencies. As one example, the Food and Drug Administration, which once strongly resisted having "trade concerns" injected into its work through transatlantic regulatory cooperation, now has dozens of contacts each week with its EU counterparts (the European Medicines Agency (EMEA) and the European Food Safety Authority (EFSA)), in addition to stationing attaches in Europe to facilitate these exchanges.

This increased collaboration suggests that the trust and confidence needed to encourage U.S. and EU regulators to generally work toward compatible regulatory outcomes, even where their procedures may differ, is growing. But it is not there yet**.** Recently Ambassador Sapiro, put it this way:

Historically, NTBs have proven to be thorny issues. Many of them are rooted in differences in the way we regulate our economies – differences that are not easily narrowed around the negotiating table. We've had some successes in achieving greater regulatory compatibility in specific sectors, but it is painstaking and slow work. We have learned that it can be especially difficult to align our approaches more closely after we have both already adopted our own regulations.

We have also learned that regulatory cooperation is not something that regulators can do by themselves. Success requires input from private sector stakeholders and economic policy officials on priorities and proposed solutions."[27]

a. Regulatory Cooperation and Early Steps toward TARIA

Starting in 2005, OMB and the Secretary General of the EC have worked cooperatively to make their RIA procedures and guidance more consistent and incorporate international trade

[27] Ambassador Miriam Sapiro, U.S. Deputy Trade Representative, Remarks before the European Policy Centre, Brussels, February 10, 2011.

impacts into their requirements.[28] In May of 2008,[29] they published a joint report comparing guidance and stating:

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.

However progress has been uneven. In OMB's *2008 Draft Report to Congress on the Costs and Benefits of Federal Regulation*s, it proposed to provide guidance to the agencies on how to incorporate trade impacts into their analysis of regulations and asked for public comments. Also in 2008 OMB added an "international flag" to the *Unified Agenda* and *Regulatory Plan.*[30] This established a potential mechanism that agencies, OMB and the public could use to monitor and review whether international impacts, particularly for economically significant rules, were being adequately addressed. [31]

In its reporting to the December 2008 TEC meeting, the HLRCF pointed out that, with respect to international impact guidance:

> *For the U.S., the report concluded that "regulatory agencies face both statutory and executive obligations to take international trade impacts into account when developing regulatory proposals." Specifically, OMB guidance states that "Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully." (OMB Circular A-4, p. 6) The Report also recommended that "guidance should be provided on the type of analysis needed to provide decision makers with information on international trade and investment impacts.*[32]

b. Taking the Next Step toward TARIA

[28] Annex C presents a comparison of the two sets of requirements for trade impacts.
[29] In full disclosure while at OMB, I worked on these negotiations and the report. *See* http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/sg-omb_final.pdf.
[30] These semi-annual (*Agenda*) and annual (*Plan*) U.S. Government publications provide uniform reporting of data on regulatory and deregulatory actions under development throughout the Federal Government, covering over 60 departments, agencies, and commissions. *See* http://www.whitehouse.gov/sites/default/files/omb/oira/irc/HLRCF%20Summary%20Report%20October%202008.pdf.
[31] As of April 1, 2011, 32 "economically significant" regulations reviewed by OIRA out of 136 had been flagged as having an international impact. Also on that date, OIRA listed six regulations as under review.
[32] Direct quote from U.S.-EU High-Level Regulatory Cooperation Forum Report to the Trans-Atlantic Economic Council on the Fifth Meeting of the Forum Held October15, 2008, Washington DC.

On May 19, 2011, Deputy USTR Miriam Sapiro and Administrator of OIRA Cass Sunstein issued a joint Memorandum on Export and Trade Promotion, Public Participation, and Rulemaking.[33] The purpose of the Memorandum was to draw agencies' attention to several existing obligations, such as the Regulatory Impact Analysis, the openness requirements of Executive Order 13563 and the Trade Act of 1979 requirement that prohibits agencies from engaging in "any standard-related activity that creates unnecessary obstacles to the foreign commerce of the United States." The Memorandum also encourages agencies to coordinate and share information on regulatory activities with other governments, and to set regulatory schedules to allow for sufficient time to consider the regulatory approaches of other countries.

The Memorandum points out that good regulatory practices, such as consideration of both costs and benefits based on the best available scientific and technical information, should promote U.S. exports and trade by reducing unnecessary regulatory divergences, lead to reductions in regulatory costs and improve the quality of foreign health, safety and environmental measures. Note that the Memorandum still reflects a domestic perspective.

Although OMB has recently issued a checklist and Q&As for agencies on how to complete Regulatory Impact Analysis, it has not issued further agency guidance on how to take into account international impacts in a RIA since the issuance of Circular A-4 in 2003.[34] The European Impact guidance described in Annex D, even though modified in 2009, still stresses domestic competitiveness concerns over a more transatlantic perspective.

The TARIA approach may also meet concerns expressed by advocates of greater regulatory protections that the "excessive" trade concerns apparently inherent in regulatory cooperation efforts might undermine such protections. For example, the Trans-Atlantic Consumer Dialogue expressed caution about the need for and costs of the OMB/EC proposal for updating regulatory guidance on international impacts to take into account certain regulations'

[33] *See* http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-23.pdf.
[34] The two HLRCFs held in 2010 did not mention any future steps, or the status of its reflections on international impact analysis guidance.

impacts on trade and investment, saying that so doing would only add to the cost side of a cost-benefit analysis, thereby undermining any protections.[35]

To the extent that these comments are reflective of the view that consideration of costs and benefits by the agencies, and coordination and quality control from the center of government, is not in the public interest because the agencies and services know best, the TARIA proposal will continue to meet resistance from certain interests at least until the program establishes a record of maintaining and improving public protection and environmental benefits. It may also not sway concerns of interests that are philosophically opposed to any regulation because the transatlantic benefits analyses will likely increase benefit estimates.[36] The philosophical debate, however, appears to have been recently settled for now by the U.S. President and the European Commission with separate announcements of "smart" regulatory programs that emphasize benefit-cost analysis, coordination and quality control.

c. Utilizing TARIA for Retrospective Reviews

The EC and U.S. have both recently made *ex post* or retrospective analysis a key part of their reform efforts and in fact announced this at the HLRCF in Washington, D.C. in December, 2010.[37] These retrospective analyses should include international impacts of the measures being reviewed. Where there is an international impact, the TARIA approach outlined above could be used, and agencies and OMB should integrate these considerations into their review and any modifications to the regulations. This will also add to the data set and aid future efforts to determine compatible regulatory regimes and MRAs. In addition, some of the retrospective analyses chosen should be focused on regulatory regimes and sectors where there is evidence that they are compatible across the Atlantic. In a May 26, 2011 report about the initial results of the U.S. retrospective reviews, Administrator Sunstein highlighted an Occupational Safety and Health Administration rule about to be finalized that would harmonize U.S. hazard classifications and labels with the Globally Harmonized System agreed to at the UN in 2002. It

[35] *See* comments of TACD on the draft report from the OMB/EC High Level Regulatory Forum on regulatory impact assessment (IA) and the analysis of impacts on international trade and investment.
[36] It should be noted that the U.S. EPA, DOT, and DOE have recently issued regulations that include worldwide benefit estimates of a reduction in CO_2 emissions based on a U.S. Working Group's estimates. *See* Interagency Working Group on Social Cost of Carbon. 2010. *Social Cost of Carbon for Regulatory Impact Analysis under Executive Order 12866*. United States Government.
[37] http://www2.eere.energy.gov/buildings/appliance_standards/commercial/pdfs/sem_finalrule_appendix15a.pdf.

is expected to save employers $585 million in costs per year as well as to provide safer workplaces.[38]

d. Explaining the Lack of Success of MRA Efforts in the Past

The U.S. and EU have been engaged in regulatory cooperation efforts to reduce possible non-tariff barriers arising from unnecessary regulatory divergences at least since the adoption of the Transatlantic Declaration in 1990.[39] Dialogues with the goals of reducing non-tariff barriers have continued with varying levels of alacrity and with different structures, frameworks and roadmaps since that time.[40] A review of the official statements from U.S.-EU summits and high level meetings shows progress in exchanging information, but binding agreements have generally been indefinitely postponed.[41] Since progress is more likely with high level political attention, the two transitions in Administrations since the 1990s, especially on the U.S. side, appear to have slowed down transatlantic progress while the new Administration confirmed new officials and determined its priorities. Cycles in information exchanges on regulatory processes and principles, with some limited progress on regulatory agreements, appear to mirror transitional cycles. Recent activity indicates we may be in an upward swing. However, a review of past efforts indicates that an upward swing may not be enough to achieve meaningful MRAs. A new approach more rigorously led by central oversight units is called for. Annex C describes the slow progress of past efforts.

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[38] *See* speech of Cass Sunstein prepared for delivery at AEI in Washington May 26, 2011. http://www.whitehouse.gov/sites/default/files/omb/inforeg/speeches/oira-administrator-lookback-at-federal-regulation-05262011.pdf. OSHA first placed this rulemaking on its regulatory agenda in 2005. The original 1983 OSHA Hazard Communication rule's preamble promised that the agency would work toward international harmonization in the future.

[39] The Declaration states on Economic Cooperation: "Both sides recognize the importance of strengthening the multilateral trading system. They will support further steps towards liberalization, transparency, and the implementation of GATT and OECD principles concerning both trade in goods and services and investment. They will further develop their dialogue, which is already under way, on other matters such as technical and non-tariff barriers to industrial and agricultural trade, services, competition policy, transportation policy, standards, telecommunications, high technology and other relevant areas."

[40] In full disclosure, as an OMB regulatory official this period until 2008, I participated in numerous meetings on regulatory cooperation on both sides of the Atlantic and with numerous stakeholders.

[41] By my count there have been seven frameworks, all usually with "transatlantic" in the name: Transatlantic Declaration, 1990; New Transatlantic Agenda, 1995; Transatlantic Partnership, 1998; Guidelines for Regulatory Cooperation and Transparency, 2003; Roadmap for EU-U.S. Cooperation and Transparency, 2004; Framework for Advancing Transatlantic Economic Integration, 2005 and Transatlantic Economic Council (TEC), 2007. There were five TEC meetings between 2007 and 2010 with two in 2008: one before and one after the U.S. election.

4. A Way Forward

a. Considerations in Choosing Pilot Sectors

Although the case for striving toward compatible regulatory regimes, including through implementing a comprehensive TARIA program, is strong, the more prudent approach is to pilot a limited program in regulatory regimes (composed of sectors and their regulatory agencies) where the payoff is likely to be the most rewarding.[42] Payoffs should be the higher because of the greater the potential for:

1. Cost savings from reducing non-tariff barriers, which depend on the degree of economically inefficient divergence in regulatory regimes and the compliance cost savings due to scale economies.
2. Cost savings to the regulators from economies of scale and duplication of effort in research, standards development, inspection, and enforcement.
3. Additional regulatory benefits from safer products, which are made possible by more efficient and cost-effective regulatory compliance by firms and administration by regulators.
4. The potential to reduce divergences and align the regulatory regime, which depends on the interplay between the public interest, narrow interests, and the administrative process governing the regulatory regime.[43] The theory of the TARIA is to determine what the public interest is, make it transparent, and hold the agencies accountable by changing the administrative process.
5. Increases in transatlantic trade and investment for the sector or regulatory regime, as well as positive impacts on overall global trade and investment.

[42] In the AEI speech cited above, Sunstein states that one of the lessons learned about regulation is: "We know that intuitions and anecdotes are both unreliable, and that advance testing of the effects of rules, as through pilot programs or randomized controlled experiments, can be highly illuminating."

[43] *See* Steven P. Croley, Regulation and Public Interest: the Possibility of Good Regulatory Government, (Princeton University Press: Princeton and Oxford, 2008) for a thorough discussion of the competing theories of regulation. Croley argues that to fully understand regulatory outcomes, more than the public interest and public choice explanations of regulation is needed. More important are the rules governing agency decision-making, or what he calls the administrative process theory of regulation. Croley's thesis is that administrative rulemaking is more likely to be in the public interest than regulatory legislation, because it is more responsive to the President and the Judiciary.

The ECORYS study provides a comprehensive set of data and estimates of the cost savings from reductions in "actionable" non-tariff measures (NTMs) for 23 sectors in the EU and U.S. and thus is a good attempt at taking into account factors 1, 4 and 5. For each sector, the study uses estimates based on business surveys of the percentage cost increase that non-tariff barriers add for trade from the EU to the U.S. and from the U.S. to the EU, percentage estimates of the possible reductions that serious negotiations could produce over ten years, and the size of the markets and expected growth in trade and investment that should result to estimate the total gains if each sector separately reduced divergences. The study finds that 75% of total potential benefit (combined cost reductions for the EU and U.S. by reducing divergence and partially aligning regulatory regimes) are in four sectors: motor vehicles (31%); chemicals, cosmetics, and pharmaceuticals (19%); food and beverages (14%) and electrical machinery (11%).[44]

To account for factor 2 above, a notion of the budget efficiency gains may be derived by using Dudley and Warren's *Regulator's Budget Report*, which is published each year and provides data on fiscal expenditures by regulatory regime.[45] There is significant potential for budgetary savings for more efficient rulemaking, inspection, and enforcement based on U.S. data alone. They estimate that in 2010 $43.7 billion and 233,610 full federal workers were dedicated to health, safety, environmental and security regulation.

The 2011 OMB Report to Congress on benefit estimates by program over the last ten years can be used to account for factor 4 above by showing the potential health, safety and environmental benefits that can result from better transatlantic regulation. According to this data, 89% of the benefits of 106 major regulations that had reasonably complete cost and benefit analyses were produced by 59 regulations from the six primary regulators for these sectors: EPA's AIR office, the DOT's National Highway Traffic Safety Administration (NHTSA), HHS's Food and Drug Administration, DOE's Energy Efficiency and Renewable Energy office, the EPA's Office of Chemical Safety and Pollution Prevention, and the DOL's Occupational

[44] These estimates are based on the ambitious NTM reduction scenario that does not take into account long run dynamic interactions. The total welfare is $66 billion converting the euro estimates at the $1.48 April 2011 exchange rate. ECORYS Nederland B.V. Non-Tariff Measures in EU-U.S. Trade (December 2009).
[45] *See* Susan Dudley and Melinda Warren. *Regulator's Budget Report*, May 11, 2011, http://www.regulatorystudies.gwu.edu/images/pdf/2012_regulators_budget.pdf.

Safety and Health Administration.[46] This suggests that in addition to the high potential cost savings in the EC study's identified sectors and regulatory regimes, there is significant potential for health, safety, energy, and environmental benefits from the better, shared, and broader analysis of a TARIA program overseen by OMB and the IAB. The fact that these agencies already possess the capability to do quality analysis of benefits and costs, as shown by making the OMB list, also bodes well for the success of the TARIA program, as long as there is political will at the top.

b. Product Safety through Precautionary Regulation

The potential net benefits identified from a combined top-down and bottom-up transatlantic regulatory cooperation program are obviously significant. That said, it is prudent to proceed by piloting the TARIA program on compatible regulatory regimes in a few sectors over a three year period with a sunset provision and retrospective evaluation built-in at the end. This review suggests that regulatory regimes that produce high benefits and costs, and offer the potential for significant cost savings and public benefit increases in the future, are likely to be the most successful. Evidence indicates that regulatory regimes and sectors that have the potential to provide the highest level of benefits and cost savings are likely to be regulatory regimes in the product safety area. Moreover, there is strong evidence that U.S. and EU product safety regulation is likely to be deemed "compatible".

The U.S. and the EU enjoy comparable income levels, economies, values and customs, and have similar public health and safety goals. Indeed, the recent work by RFF researchers found that the U.S. and EU generally demand, and their regulators supply, similar levels of regulatory precaution.[47] This finding counters the perception by some observers, who may have been overly influenced by the availability of a few highly publicized differences in risk perceptions,[48] that the U.S. and EU have fundamentally different regulatory regimes and product

[46] Most of these benefits were produced by the fine particulate matter regulations by EPA's Air office a point emphasized by the OMB report. OMB also emphasizes the uncertainty of the benefit estimates used for fine pm regulation and in particular, "(1) the uncertainty in the reduction of premature deaths associated with reduction in particulate matter and (2) the uncertainty in the monetary value of reducing mortality risk." (OMB 2011 Report p.15-16).

[47] *See* Weiner (2010). Op. cit.

[48] In behavioral economics this is known as the "availability heuristic." People tend to worry more about risks that have recently been in the news. *See* Richard H. Thaler and Cass R. Sunstein, *Nudge, Improving Decisions about Health, Wealth, and Happiness*, Penguin (2009).

safety demands. The evidence is to the contrary; there are particular differences in products due to regulatory divergence but no systemic difference in riskiness.

Weiner concludes based on 20 case studies and 3,000 observations of risk-reducing regulatory decisions in the U.S. and EU that overall risk stringency is about the same, with several of the case studies showing divergence explained by protectionism and local rent seeking.[49]

Since oversight from the top is likely to be essential for success, regulatory regimes successfully overseen by the coordination procedures and quality control programs of OMB and the IAB are strong candidates. These sectors are motor vehicles, chemicals, and pharmaceuticals. In the U.S., the primary regulators are NHTSA, EPA, and FDA and in the EU, the key regulators are Directorates General Enterprise, Environment and Consumer Safety, European Chemicals Agency, European Medicines Agency and European Food Safety Agency. These agencies have strong public interest motivations, are experienced in analyzing the costs and benefits of their regulations, and have a history of working with OIRA and fellow agencies.

One mechanism that OMB/OIRA could use to initiate these studies is to use "prompt" letters to the agencies informing them that OMB believes these sectors are worthy of agency priority and analyses. Rather than being sent in response to an agency's submission of a draft rule for OIRA review, a prompt letter is sent on OMB's initiative and contains suggestions for how an agency could improve its regulations, including conducting specific research or analysis. Prompt letters have been widely praised by a variety of legal scholars.[50] The Economic Commission has similar authority to initiate such reviews and analysis. The HLRCF could facilitate coordination of the two announcements.

1. Automotive Safety Regulation

According to the ECORYS sectoral estimates, a reduction in the "actionable" divergent NTMs in the motor vehicle sector would provide about 31% of total benefits provided by the 23 sectors analyzed.[51] This finding is not surprising. The two motor vehicles industries represent

[49] *See* Weiner (2010). Op. cit.
[50] John D. Graham "Saving Lives through Administrative Law and Economics," *University of Pennsylvania Law Review* 157/2 (December 2008). p. 460-463.
[51] *See* ECORYS, chapter 6 as well as the technical appendix.

major contributors to the two economies (about 7% of GDP), are important players in the trade and investment between the two countries (40% of EU auto exports go to the U.S. and 16% of U.S. auto exports go to the EU) and both industries are regulated through diverse approaches (the EU uses an *ex ante* gate-keeper type approval, while the U.S. uses self-certification and *ex post* enforcement through recall and full liability). Although the U.S. and EU use different standard-setting organizations (the U.S. uses the Federal Motor Vehicle Safety Standards (FMVSS) developed by NHSTA, while the EU uses those developed by UN-ECE from the United Nation's Economic Commission for Europe (which has become a global harmonization effort know as WP-29)), the actual safety standards are generally functionally equivalent and produce similar levels of safety.

The ECORYS study, using elasticity calculations from its gravity trade flow model, estimates that about 26% of trade costs both ways across the Atlantic are due to NTMs, but only a fraction of those costs represent potential cost savings to society, because not all are considered politically feasible and some savings would come at the expense of others. Bilateral trade was $53 billion in 2007. Taking that into account, the potential transatlantic welfare gain is placed at $15 billion.[52]

A case study by Wilber and Eichenbrecht in 2008 points out the growing importance of economies of scale in the auto industry and how this will impact consumer welfare. Because economies of scale have become critical in the auto industry, auto producers must limit the number of locations where any one model is produced, and must rely on cross-shipping to the markets where there is demand. They conclude: "[t]his approach has the advantage of reducing production costs — therefore improving vehicle affordability — and increasing product choice across more regions/countries. Unfortunately, this strategy can be seriously impeded by divergent national and regional regulatory requirements and test procedures."[53]

Wilber and Eichenbrecht point out several non-safety related divergences, such as the use of different crash dummies in the U.S. and EU for certain tests (such as side impact) but not for

[52] *Ibid*. table 6.3.
[53] Vann H Wilber and Paul T. Eichbrecht, "Transatlantic Trade, the Automotive Sector: The Role of Regulation in a Global Industry Where We Have Been and Where We Need to Go, How Far Can EU-U.S. Cooperation Go Toward Achieving Regulatory Harmonization" paper presented at the German Marshall Fund Academic Policy Research Conference, May 8-9, 2008 at the University of Michigan.

others. They also summarize the efforts since 1958 to harmonize standards and testing procedures in general, as well as focusing on efforts for six standards. They present some principles and lessons learned for use in future cooperation efforts that provide guidance for ongoing regulator-to-regulator dialogue and support the use of autos as a key TARIA pilot. Efforts were more successful in developing *new* standards, where neither the U.S. or EU had current standards to defend, but neither country was ready to abandon efforts harmonizing existing standards. They concluded with a call for a more objective and evidenced-based analysis by individual governments, while keeping in mind the international perspective. Specifically, they stated:

> *Recommendation: Governments, therefore, should carefully analyze existing and proposed vehicle regulations to determine if the national objectives for which they are intended justify the added cost, and provide appropriate benefits while not encumbering the most efficient scale of production, which will allow their manufacturers to compete effectively in the global motor vehicle market. Conflicting and overlapping regulations impede that ability of manufacturers to export to other countries by adding cost and complexity and, in so doing; they hurt consumers by increasing price levels and limiting choice.*[54]

The TARIA approach is consistent with this recommendation and goes one step father by formalizing and institutionalizing the transatlantic perspective.

2. Chemical Safety Regulation

According to ECORYS, the EU and the U.S., along with Mexico and Canada, supply over 50% of world chemicals sales. Over 2 million people are employed in the chemical industry in the U.S. and EU, and this sector is a major exporter for both partners. Bilateral trade in chemicals reached about $60 billion in 2007.

As in autos, the two economies have approached the regulation of toxic chemicals in different ways. Under REACH, Evaluation, and Authorization of Chemicals (REACH) which came into effect in 2007, the European Chemical Agency (ECHA) is a gatekeeper that places the burden on manufacturers or importers of more than a ton of a chemical to provide evidence that the chemical poses "acceptable risks" to human health and the environment. ECHA can require restrictions on how the chemical is produced, sold, or used. The U.S.'s primary approach under

[54] *Ibid*.

the Toxic Substances Control Act (TSCA) places the burden on the EPA to go through rulemaking to show that an existing chemical (before 1979) does not pose an unreasonable risk.[55] Under TSCA, there is a greater burden of proof on manufacturers or importers to show acceptable risks for new chemicals. Other U.S. statutes and regulators also play an important part in regulating and classifying chemicals. For example, OSHA, under its hazard communications standard first issued in 1983, requires manufactures to classify, label and transmit material safety data sheets with product shipments. As mentioned above, OSHA is about to finalize a plan to harmonize these standards with the UN Globally Harmonized System of the Classification and Labeling of Chemicals, already used by the EU.

Using elasticity calculations derived from its gravity trade flow model, the ECORYS study estimates that about 22% of trade costs both ways across the Atlantic are due to NTMs, but only a small portion of these costs represent potential savings to the public, because few are politically feasible, and savings to some might harm others. With that taken into consideration, the potential transatlantic welfare gain is placed at $6.5 billion.

The U.S. Administration has presented proposals for modernizing the TSCA, which would give the EPA more authority to require information of the safety standards and to regulate existing chemicals.[56] These signs of convergence in regulatory approaches also make this sector a good candidate for a TARIA pilot where transatlantic benefits and cost savings are evaluated. Moreover, since there would be duplication of effort, and significant economies of scale in testing and evaluating 15,000 high-use identical chemicals for unreasonable risk for sale and use on both sides of the Atlantic, it is likely that the result of the analysis of this pilot will be a determination of regulatory compatibility.

3. Pharmaceutical Safety Regulation

According to the European Federation of Pharmaceutical Industries and Associations (EFPIA), the world pharmaceutical market was $808 billion in 2009, with the U.S. and Canada

[55] For a comparison of the two approaches, *see* GAO's June 2007 report to requesters: CHEMICAL REGULATION Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals, http://www.gao.gov/new.items/d07825.pdf.

[56] *See* Statement of Lisa P. Jackson Administrator, U.S. Environmental Protection Agency Legislative Hearing on the Toxic Substances Control Act (TSCA) Senate Committee on Environment and Public Works, December 2, 2009. The Safe Chemical Act of 2011, recently introduced in the U.S., also moves more toward a REACH-type regulatory regime.

producing 40% and the EU 31%. Moreover, the U.S. has been the leading innovator. Since the mid-1990s, U.S. research-based companies have significantly increased their share in the world's top-selling medicines. According to data from IMS Health, 61% of sales of new medicines launched during the period 2005-2009 originated from the U.S. market, compared with 29% on the European market. North America launched 46% of the new chemical and biological entities during the period 2003-2007 versus 33% from EU companies.[57]

The ECORYS study, based on elasticity calculations from the gravity trade flow model estimates that about 15% of pharmaceutical trade costs are due to EU non-tariff measures, and about 10% result from U.S. regulatory issues. Bilateral trade between the U.S. and EU hit $55 billion in 2007; however, as was the case above, only a small amount of trade costs represent potential savings to society. Even with this reality, the potential transatlantic welfare gain from successful regulatory cooperation according to the ECORYS modeling is $3 billion.[58]

According to DiMasi and Grabowski, approval of a new pharmaceutical or biopharmaceutical takes from ten to thirteen years from patent to market authorization, and on average costs $1.3 billion, given the cost of the drugs that never make it through phase III clinical trials and the time costs of expenditures.[59] Although the new drug approval process with the preclinical and then three phases of clinical trials is similar in the U.S. and EU, outcomes can vary and the EU has added steps of cost-effectiveness assessments and member state pricing.

The ECORYS study suggests that the most important issues for U.S. companies exporting to the EU relate in particular to EU pricing policies: the EU Health Technology Assessment methods, divergent national authorization systems, data exclusivity, parallel trading (the reimportation issue), and international and therapeutic reference pricing. These policies are currently under consideration in the U.S.

The Food and Drug Administration and the European Medicines Agency appear to be compatible regulatory regimes especially when compared to third country regulators. A 2010 study that examined 400 new drugs approved in the U.S., EU and/or Japan from 1999 to 2007

[57] *See* EFPIA, The Pharmaceutical Industry in Figures (2010) at: http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=9158.
[58] ECORYS, Chapter 12.
[59] Joseph A. DiMasia, and Henry G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" MANAGERIAL AND DECISION ECONOMICS 28: 469–479 (2007).

found that 82% were approved by the U.S., 79% by the EU and only 55% by Japan. On average, the EU lagged the U.S. by only 2.7 months, while Japan lagged by 41.0 months.[60]

5. Conclusion

The experience of the last 20 years of data sharing and information exchange aimed at establishing mutual recognition agreements has shown that a bottom-up approach alone produces, at best, incremental results. It is time for the second step, promised in 2008. Three sectors with compatible product safety regulatory regimes have the potential to provide $25 billion in real savings to the transatlantic community, according to an EU sponsored study, and these three sectors present excellent candidates for a pilot program.

This paper proposes a new approach to transatlantic regulatory cooperation aimed at improving regulator efficiency and effectiveness through mutual recognition of "compatible regulatory regimes." It proposes to more tightly intertwine the promising regulator-to-regulator dialogues with the successful OMB-EC dialogue infused with a transatlantic approach and building on the principles of smart regulation recently articulated by both Administrations. That approach emphasizes greater public protections through efficient and effective rulemaking. As pointed out above, the citizens of the United States and the European Union seek the same protections and performance from their regulatory regimes. By eliminating unnecessary regulatory divergences between us, we can also reduce existing — and head off new — non-tariff barriers to transatlantic trade and investment, generating growth, jobs and greater public protection in the world's largest economic partnership.

[60] Tsuji K, Tsutani K. "Approval of New Drugs 1999-2007: Comparison of the U.S., the EU and Japan Situations." *Journal of Clinical Pharmacy and Therapeutics*. 2010 June; 35(3):289-301.

ANNEX A

U.S.-EU Regulatory Cooperation:

A New Approach to

Mutual Recognition of Compatible Product Safety Regulatory Regimes

As democratic developed societies, the U.S. and EU strive for similar levels of protection for consumers, the environment and investors. Previous attempts to benefit from this through mutual recognition agreements floundered as they were seen as driven by trade policy concerns, were product-specific and technical "bottom-up" approaches, and pre-dated the extensive regulatory cooperation built up over the past decade. With that experience and sharp increases in imported products from poorly regulated markets, many U.S. and EU regulators are concerned that limited enforcement resources are misdirected toward policing relatively low-risk transatlantic products.

This initiative would create a 2-3 year process to allow related transatlantic regulators to determine where they have "comparable regulatory regimes" and use this to seek legislative authority to accept product/service/supplier approvals from the other jurisdiction unless they have reason not to (retaining a right to intervene). The initiative could be launched as a series of pilot sectors (motor vehicles, chemicals, and pharmaceuticals) or could nominally cover all regulated sectors, although the work would have to be staggered and would surely take at least a decade to complete. In some cases regulators may end up choosing not to pursue this "comparable regulatory regime" determination.

Under this approach, regulatory agencies would work with transatlantic peers toward a determination of "comparable regulatory regime;" this would be used to pursue legislative authority to accept decisions made by their counterparts, while retaining a right to disregard those approvals when necessary (safeguard).

Properly constructed, the process would:

- be regulator driven and controlled, based on an agency's determination self-interest;
- focus scarce enforcement resources from relatively low-risk but immense volume markets to policing growing import flows from poorly-regulated areas;
- establish an operational role for the High Level Regulatory Cooperation Forum, a body where a wide range of senior U.S. and EU regulators exchange best practices on risk analysis, impact assessments, cost-benefit analysis, etc.

In brief, the process could be:

- Inventory regulated product/service sectors and their U.S. and EU regulators (e.g., for toys, CPSC and SANCO; for pharmaceuticals, FDA and DG ENT; for motor vehicles, NHTSA and DG ENT; for securities, the SEC and DG MARKT);

- Identify all or some (pilots) to go through the comparable regimes process;
- Ask independent body (academic/consultant/think-tank) to conduct in-depth study on whether the regulators strive to achieve broadly similar regulatory outcomes *(three months);*
- Allow respective regulators to comment on the reports, and then have them comment on one another's comments *(three months);*
- Publish the report and comments for public comment *(three months);*
- Agencies review comments, and consult and present conclusions and recommendations to the U.S.-EU High Level Regulatory Cooperation Forum (HLRCF) *(by following HLRCF);*
- HLRCF advises whether agencies should proceed to determine whether they have "comparable regulatory regimes;"
- If so, they each undertake to obtain legislative authority to recognize/accept the other agency's decisions within a certain period;
- If obtained, they conclude an agreement on Mutual Recognition of Comparable Regulatory Regimes which, *inter alia*, obliges them to accept approval decisions of the other authority but allows them to retain a right not to do so with reason, consultation (presumably the other authority would share the concerns) and potentially mediation.

ANNEX B

Regulatory Impact Analysis of TARIA

Before the current regulatory impact assessment programs can play a larger role in transatlantic regulatory cooperation, a review of the current programs' effectiveness and efficiency and projection of the potential effectiveness of TARIAs is in order.

The potential benefits to the transatlantic community of a successful TARIA program appear to be quite large. An indication of the magnitude and effectiveness of TARIA may be estimated by using data from the current U.S. regulatory impact assessment program, managed by OMB's Office of Information and Regulatory Affairs (ORIA), now predominately focused on domestic impacts. Over the ten fiscal years ending September 30, 2010, OMB reviewed 3,325 "significant" regulations, 540 of which were "major" regulations, each with an impact on the U.S. economy of at least $100 million. Based on the 106 "major" regulations where OMB was able to estimate both the benefits and costs from the impact assessments required by Executive Order, the total of the estimated costs and benefits of the identified regulations was about $540 billion, or about four percent of GDP.[61]

If the requirement that agencies prepare RIAs, submit them to OMB for quality control, and subject them to notice and comment from outside interested parties results in regulations that either reduce costs or increase benefits by merely one percent, that would represent a benefit of approximately $5.4 billion. Thus, the net benefit to society of improved regulations would exceed the budget for regulatory review over the ten years by over 270-fold.[62] This is an underestimate because it does not count improvements that are likely to occur from reviewing the impact assessments of the remaining 434 "major" rules that are not in the above sample of 106 rules.[63] Moreover, quality controls and enforcement programs often produce "sentinel"

[61] Calculated from Table1.1, p. 13 of the 2011 Draft Report to Congress on the Benefits and Costs of Federal Regulations. OMB (March 2011) (midpoints of cost and benefit estimates were used and converted to 2010 dollars). Compliance costs are about 0.5 % of GDP.

[62] OIRA's budget for FY 2011 is $8 million. About half of the staff works on regulation and about half of their time is spent on reviewing "major" regulations, with the other half spent reviewing about 275 non-major regulations and 3,000 information collection requests per year. The $5.4 billion estimate is 270-fold greater than the $20 million budget estimate ($2 million of OIRA costs over ten years). This budget estimate implies that OMB spent on average a little over one person year reviewing (proposal and final stages) these major regulations. (These estimates are based on my experience managing OIRA's budget as Acting Deputy Administer during part of this ten year period).

[63] These rules are likely to have lower impacts on average than the 106 rules and many are budget or transfer rules which do not produce social benefits or compliance costs of the $100 million magnitude. Nevertheless, many of these regulations have significant costs but are not included because their benefits (homeland security, ecologic, civil rights) are difficult to monetize. Moreover, many budget or transfer regulations produce hard to measure social costs because of rent-seeking lobbying and harmful work, investment, and innovation effects.

benefits because agencies are discouraged from proposing regulations that would not "pass the muster" of OMB and outside public review.[64]

These estimates do not include agency costs to produce regulatory impact assessments and respond to OIRA quality control concerns. A reasonable estimate is that ten times as much time is spent by OMB and the agencies producing a major RIA as OIRA spends reviewing it.[65] Using these conservative assumptions, a one percent improvement in the cost-effectiveness of regulations due to the RIA program implies a benefit to cost ratio for the ten year program of 27 to 1 and net benefits of $5.2 billion.[66]

Costs and Benefits of TARIA

The next step is to estimate what this might imply for a proposed TARIA program. Based on findings and data from a study by the Dutch think-tank ECORYS commissioned by the European Commission, a reduction of 50% in the non-tariff barriers between the EU and U.S. over a ten year period ending in 2018 could lead to a half of a percent increase in combined EU and U.S. GDP ($240 billion per year in 2018).[67] Based on business survey results and expert opinion, the study concluded that the 50% reduction on average across different sectors was possible although "ambitious." They also provided estimates for a less optimistic success of 25% reduction in non-tariff barriers, which could lead to a $106 billion increase in combined EU and U.S. GDP. Clearly the potential welfare gains to the citizens and consumers of the U.S. and EU in pursuing transatlantic regulatory cooperation are large.[68]

The ECORYS study estimates are based on long run dynamic effects that are calculated using a general computable equilibrium model which attempts to take into account sectoral interactions — such as reduced insurance and transportation costs — that favorably reverberate through the economy. For our purposes, the direct non-dynamic estimates of the limited 25% reduction in non-tariff barriers is more conservative and seems more likely given the slowdown in transatlantic regulatory cooperation since 2008, when the survey upon which these results was

[64] To date, systematic empirical evidence for an OIRA effectiveness impact on costs and benefits has not been found. (Hahn, R. W. and P. C. Tetlock (2008). "Has Economic Analysis Improved Regulatory Decisions?" *Journal of Economic Perspectives* 22(1): 67-84, Morrall, J. F. (2003). "Saving Lives: A Review of the Record." *Journal of Risk and Uncertainty* 27(3): 221–237, Morrall and Shapiro, 2011.

[65] Over the ten year period, OMB took on average 88 days to review major rules, counting proposal and final review stages. Agencies spend about ten times as long (2½ years) developing an RIA. When they briefed OIRA on these major RIAs, they often outnumber the OMB staff economists ten to one. The ten to one estimate implies that on average about $1. 9 million was spent producing, revising and reviewing the RIA during the life of the rulemaking. To put this estimate in perspective, the average rule imposed compliance costs of about $600 million per year in 2010 dollars.

[66] $5.4 billion/$200 million is 27; $5.4 billion less $200 million is $5.2 billion.

[67] ECORYS Nederland B.V. Non-Tariff Measures in EU-U.S. Trade (December 2009). This is calculated by combining the estimates for both economies and using the April 29, 2011 exchange rate. For 23 sectors, ECORYS first estimates the tariff equivalence cost of NTBs and then determines the percentage of NTBs are "actionable." It estimates that on average about 50% of the cost of NTBs could be eliminated in ten years through transatlantic regulatory dialogues and cooperation assuming the political will exists. The estimates are based on business survey results and expert opinion by sectors which are plugged into a "gravity" model of trade and investment flows. For the longer run dynamic interactions that take into account expanded trade and investment flows these sectoral data are plugged into computable general equilibrium (CGE) model of world economies.

[68] It should be noted that some of these gains result from trade and investment divergence from the rest of the world making the rest of the world less well-off. These gains are also based on growth in GDPs to 2018.

conducted.[69] Using those parameters, the ECORYS study predicts that EU real income could increase by 0.11% and U.S. real income by 0.05%.

Since the ECORYS study does not take into account nonmarket benefits to public health, safety and the environment, as the OMB study does, to compare the gains from a domestic focus on regulations to a transatlantic focus, the OMB cost estimates are a better comparator of potential benefits. The cost of the 106 regulations issued over the last ten years as estimated by OMB is about 0.5% of GDP ($64 billion) which rises to 0.7% ($100 billion) if the higher rate of costs over the last two years is projected for ten years.[70] This suggests that a moderately successful program such as TARIA that increases U.S. incomes by 0.05% could potentially eliminate $7 billion (from 10% to 7%) of the unnecessary and divergent costs of U.S. regulation by providing information that leads to aligning compatible regulatory regimes.[71]

As estimated above, the OIRA ten year budget for reviewing the RIAs of major regulations is about $20 million and the overall agency costs cost about $200 million. Since adding a TARIA requirement to the existing RIA would certainly not double budgetary costs, the TARIA program is likely to be highly cost beneficial and comparable to the existing RIA program. To be as effective in reducing unnecessary costs, the existing OIRA program would have to have an effectiveness rate of more than 7% and program costs less than $200 million to be more effective than the TARIA proposal.[72]

Moreover, if the OMB benefit estimates and our analysis of its effectiveness are reasonable, additional and significant health, safety, and environmental benefits should follow from the TARIA program. The potential for both a reduction in costs with an increase in public benefits could align broad-based supporters with regulatory officials and interests who feel strongly about agency regulatory missions.

[69] Using the non-dynamic short run estimates also limits the gains from trade diversion which come at a cost to countries outside of the transatlantic partnership.

[70] The OMB estimate is that about $6.4 billion per year in costs has been added on average over the last ten years by these 106 regulations. These estimates also indicate that over the last two years, costs are being added at a rate of $10 billion per year based on 33 regulations for which both costs and benefits have been calculated. (OMB (2011) Table 1-3.

[71] Using 2010 U.S. GDP of $14 trillion. That is 0.05% /0.5% = 10% and .05%/7% =7%.

[72] To reiterate, this calculation assumes a ten year TARIA program would produce the limited short term impact of the EC study (the lowest bound estimate) and that the last two years of costs reported by OIRA would extend for ten years.

ANNEX C

History of U.S.-EU Regulatory Dialogues

Following the conclusion of the 1995 U.S.-EU "New Transatlantic Agenda," the U.S. and EU made some progress on Mutual Recognition Agreements (MRAs) between 1995 to 1998, despite opposition from some regulators who thought trade policy concerns should have no place in domestic regulatory considerations.[73] At the end of that period, the two governments announced six conformity assessment MRAs in the areas of telecommunications equipment, electromagnetic compatibility, electrical safety, recreational crafts, pharmaceutical good manufacturing practices, and medical devices.[74] These initial MRAs, however, focused on mutual recognition of conformity testing procedures for specific products, which would merely allow U.S.-based companies to have products tested in the U.S. as conforming to EU requirements, and vice versa. In the end, they have not been used much, in part as the process of accrediting labs to do such testing is itself a hurdle.

From 1998 to 2004, U.S. and EU officials focused more on the principles of better regulation, such as transparency and cooperation, concluding "Roadmaps" for 10 and then 15 sectors in 2004 and 2005, respectively. Work under these roadmaps helped intensify regulator-to-regulator discussions and cooperation, but achieved little progress in actually removing regulatory differences. A 2009 Congressional Research Service report that reviewed transatlantic regulatory cooperation to 2008 suggested the two sides made modest progress,[75] especially in terms of information exchange among regulators, although the U.S. and EU did agree a full MRA on marine equipment in 2004.

To intensify cooperation and step up political oversight, European Commission President José Manuel Barroso, German Chancellor Angela Merkel (then President of the EU Council) and U.S. President George W. Bush in April 2007 signed the "Framework for Promoting Transatlantic Economic Integration," which established the Transatlantic Economic Council, or TEC. The TEC was initially co-chaired by White House National Economic Council Director Allan Hubbard and European Commission Vice President Günter Verheugen, who would hold monthly phone calls to discuss the road map issues and prepare for meetings of the TEC and for U.S.-EU Summits.

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[73] For an in-depth analysis of this period and the problems of implementation afterwards see Chapter 7, "The U.S.-EU Mutual Recognition Agreements," Charan Devereaux, Robert Lawrence and Michael Watkins, *Case Studies in U.S. Trade Negotiation: Making the Rules, Vol. 1*. Institute for International Economics (2006).

[74] The six conformity assessment MRAs may be found here: http://gsi.nist.gov/global/docs/mra/U.S.-EU_MRA_Final_Version_1998.pdf.

[75] Raymond J. Ahearn, "Transatlantic Regulatory Cooperation: Background and Analysis" Congressional Research Service, RL34717 August 24, 2009. For a more sanguine report on progress up to 2008 see the presentation of USTR at http://www.fordschool.umich.edu/news/event_details/reg_coop_and_comp_08/presentations/presentation_sanford.pdf.

Attempts to actually resolve unnecessary regulatory differences that resulted in trade barriers became highly controversial, however, even when the principals largely agreed on the science and merits.[76]

Divergent regulations in such areas as animal testing for cosmetics (banned by the EU for animal rights reasons but required by the U.S. for safety reasons), U.S. poultry imports (banned by the EU because U.S. poultry is treated with pathogen-reduction substances even though scientific regulatory bodies on both sides agree the U.S. process presents no food safety risk), and electrical equipment (the Occupational Health and Safety Administration refuses to allow regulated workplaces to use low voltage electrical equipment not certified in the laboratories it regulates even though there is no evidence that the EU supplier declaration of conformity is less safe) occupied much of the time. The problem was not that the safety provided by the divergent regulatory regimes was different or that the political leaders involved in the TEC were in disagreement; the problem was that the regulatory agency experts did not want to change the way they did business and knew that the issues were so complex that they could wait out the pressure from the executive branch while receiving support from legislative bodies.[77]

A review of the regular progress reports on the roadmap sectors issued between 2005 and 2008 finds the reports mostly speaking in terms of the "enhanced" dialogue, "expanded" information exchanges and "deepening" collaboration. By 2008, despite monthly meetings held by the Office of the U.S. Trade Representative with the regulatory agencies with roadmap responsibilities, there was little to showcase, except in the financial and securities sectors, and both sides stopped reporting on progress on the roadmaps. Emphasis shifted back again to methodological and horizontal issues such as risk assessment, regulatory impact analysis, voluntary standards, and early warnings of new regulations – important issues, but more for the long run.[78]

The Congressional Research Service Report mentioned above politely concluded in 2009 that key stakeholders were not impressed by the 15 years of transatlantic regulatory cooperation (TRCs) efforts:

> *Since the establishment of the New Transatlantic Agenda (NTA) in 1995, there have been a number of new (transatlantic regulatory cooperation) initiatives, all aimed at removing or reducing regulatory barriers to trade. While each of these initiatives has made some progress towards reducing regulatory burdens, many U.S. and European companies heavily engaged in the transatlantic marketplace maintain that the results have not been materially significant*.[79]

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[76] I was a staff member on many of these calls and follow-up calls to U.S. regulatory officials. It is very difficult to pull on a string, especially when there are so many to choose from.

[77] These issues have a long history. Cosmetic testing was on the list in the roadmap in 2004 and appears to have been dropped from discussion. Workplace electrical equipment testing was one of the MRA issues negotiated in 1998. Below we discuss OSHA's denial of the EC request to consider the EU suppliers declaration of conformity approach in the *Federal Register* just before the December 17, 2010 TEC meeting in Washington. In January 2009, the Bush Administration brought the poultry dispute to the WTO where it still stands.

[78] The horizontal and methodology dialogues were touted as true successes by the TEC and certainly they are a prerequisite for the TARIA approach proposed here.

[79] Raymond J. Ahearn, "Transatlantic Regulatory Cooperation: Background and Analysis" Congressional Research Service, RL34717, August 24, 2009, p.1.

The Report also summarizes the "accomplishments" (mostly listed as gains in mutual understanding in various areas with promises of more to come) and "disappointments" (the fading of enthusiasm for significant mutual recognition agreements because of the resistance of regulators to implement them). [80]

The December 2010 High Level Regulatory Cooperation Forum (HLRCF) report illustrates why more ambition needs to be injected into the regulatory cooperation process. Specifically, although regulatory cooperation between EPA, DOE, and DG Energy on energy efficiency has been presented as a success by several HLRCFs, and eco-design and energy efficiency have been part of the roadmap and specific sectoral cooperative efforts since 2004, the 2010 HLRCF promises future "technical level" collaboration in three areas: commercial refrigerators, transformers, and solid state lighting. Even with the best of wills, such a bottom-up process will take years.

[80] *Ibid*, p. 14-16.

ANNEX D

EXISTING EC-OMB RIA GUIDELINES ON TRADE IMPACTS

OMB Circular A-4, Regulatory Analysis, issued in 2003, states:

> *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.*[81]

However, it offers little guidance other than advising that the regulatory impact assessment

> *…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.*[82]

The Commission's latest Impact Guidance, issued in 2009, offers similarly less concrete advice about considering an international perspective:

> *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.*[83]

Moreover, the Commission's guidelines, although asking for information on divergences, seem to focus on domestic competitiveness concerns:

> *In the context of likely impacts on trade and cross-border investments, will the proposal:*
> - *Increase or reduce differences between the regulatory regimes faced by EU companies and competitors in non-EU countries?*
> - *Place EU firms at an advantage or disadvantage compared to their international competitors?*[84]

The guidelines, however, do express concern about impacts on developing countries:

> *EU policies can also have unintended economic, social and environmental impacts. Often, the fact that an EU policy is changed may present a challenge for a developing*

[81] OMB Circular A-4, Regulatory Analysis (September 17, 2003) at http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf.
[82] *Ibid*.
[83] Commission Impact Assessment Guidelines (January 2009) at http://ec.europa.eu/governance/impact/key_docs/key_docs_en.htm.
[84] *Ibid*.

> *country when it needs to align its policy to comply with new standards. Many developing countries have weak administrations and find it difficult to adapt to changing regulations.*[85]

The TARIA proposal is designed to revise these guidelines to provide information not just on domestic competitiveness concerns but on the cost savings and safety benefits of regulatory actions accruing to the transatlantic community regardless of which side of the Atlantic firms and citizens are located.

[85] *Ibid*.

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