

International Regulatory Cooperation, 20 Years Later: Updating ACUS Recommendation 91-1

Michael T. McCarthy*

Summary

In 1991, the Administrative Conference adopted Recommendation 91-1, Federal Agency Cooperation with Foreign Government Regulators, which set out principles for how U.S. regulators should engage with their foreign counterparts. As trade in goods, services, and information has expanded in the past decades, the need for U.S. regulatory agencies to work together with foreign counterparts has grown. In April 2011, the Administrative Conference and the U.S. Chamber of Commerce co-sponsored a discussion of global regulatory cooperation, its challenges, and potential solutions. Following up on this meeting, ACUS commissioned this study to review international regulatory cooperation in federal agencies and consider updates to Recommendation 91-1.

This study reviews how U.S. regulators interact with their foreign counterparts to better accomplish their domestic regulatory missions and eliminate unnecessary non-tariff barriers to trade. The study examines developments in global trade; U.S. participation in international regulatory partnerships; how global regulatory cooperation is pursued by the Executive Office of the President and several regulatory agencies; and the perspectives of business, regulated entities, and other stakeholders.

Based on interviews with government and non-government officials and review of studies and documents, this report identifies key issues that hinder regulatory cooperation, and the legal and practical obstacles to resolving these difficulties. These include lack of legal authority to account for international trade implications of regulatory decisions; the challenge of ensuring accountability when relying on foreign regulators; hesitation of agency leaders to pursue international cooperation due to resource constraints, high risks, and uncertain rewards; potential conflicts between regulatory goals and international cooperation; and coordination issues within the U.S. government.

The study analyzes Recommendation 91-1 and identifies portions that have been implemented or have become obsolete and other portions that might be restated or expanded. The study proposes a new recommendation for consideration by the Administrative Conference on the following topics:

* Executive Director, Administrative Conference of the United States. The author prepared this report in his capacity as a Conference staff member, but the views expressed are those of the author and do not necessarily reflect those of the members of the Conference or its committees. Thank you to Roland Frye, Andrea Green, Porscha Winston, Reeve Bull, Jonathan Siegel, and Paul Verkuil, who provided research and comments for this report.

International Regulatory Cooperation

- Promotion of U.S. regulatory principles to foreign counterparts
- Review of legal authority for international cooperation
- Mutual reliance between U.S. agencies and foreign regulators, as appropriate, to reduce costs and duplication while still achieving U.S. regulatory goals
- Exchanges of information, training, and employees between U.S. and foreign regulators
- Transparency and public input in U.S. engagements with foreign regulators
- Coordination and leadership on international cooperation within the U.S. government

I. Introduction

“If American administrative agencies could ever afford to engage in regulatory activities without regard to the policies and practices of administrative agencies abroad, the character and pace of world developments suggest that that era has come to a close.” This was the introduction to a recommendation of the Administrative Conference of the United States titled “Federal Agency Cooperation with Foreign Government Regulators.” What is notable is that this recommendation was adopted more than 20 years ago, in June 1991. While many of the issues identified in this recommendation remain relevant today, the pace of globalization in the past two decades has created new challenges and dynamics since then. A review of the background materials on the 1991 recommendation shows concern about how United States regulators engage with their counterparts in the Soviet Union and a partnership among European nations that was just beginning to develop strong centralized institutions, and contain little mention of U.S. trade or other engagement in Asia. Today’s dynamics are quite different. Not only are there much more robust institutions, such as the European Commission and World Trade Organization, but the volume of trade in goods, services, and information across borders has increased dramatically.¹

This report prepared for the Administrative Conference’s consideration reviews international regulatory cooperation at U.S. government agencies today, assessing how the 1991 recommendation has been implemented (or not), new challenges that have emerged in the past 20 years, and how the 1991 recommendation might be updated to guide agencies in improving international coordination today, to benefit U.S. regulatory goals and U.S. competitiveness. In April 2011, the Conference joined with the U.S. Chamber of Commerce to co-host a discussion of global regulatory cooperation, its challenges, and potential solutions. The panel discussions featured Presidential appointees from the current and prior Administrations, international affairs officials from regulatory agencies, and

¹ Between 1995 and 2010, international trade in merchandise has increased from \$1.324 billion to \$3.021 billion, and international trade in services has risen from \$355 billion to \$884 billion. *Compare* U.S. Int’l Trade Comm’n, *The Year in Trade: Operation of the Trade Agreements During 1995* (Aug. 1996) at 8, 10 *with* U.S. Int’l Trade Comm’n, *The Year in Trade 2010: Operation of the Trade Agreements Program* (July 2011) at pp. 1-8, 1-9, 1-12. These increases, though significant, are dwarfed by the increase in data transfer via the internet during the same period.

International Regulatory Cooperation

representatives of business interests.² This report draws on that forum and additional interviews of officials from U.S. government agencies, representatives of U.S. trade and industry groups, and former senior government officials. ACUS staff also reviewed U.S. government reports from the U.S. Trade Representative and Office of Information and Regulatory Affairs, requests for comment on international issues published in the Federal Register and the comments that were submitted, and academic studies.

Based on this research, the report finds that international regulatory cooperation is desirable for two reasons. First, it helps U.S. regulatory agencies accomplish their statutory regulatory missions domestically. Indeed, in some areas like regulating the safety of food and drugs, a large proportion of which are imported to the U.S., awareness and participation in foreign regulatory processes may be essential to ensure the safety of products reaching U.S. markets. Second, international regulatory cooperation can remove non-tariff barriers to trade and exports, promoting global commerce and U.S. competitiveness. Moreover, these benefits of international regulatory cooperation are not inconsistent; they often can be pursued in unison.

Although desirable, global regulatory cooperation can be difficult to accomplish. This report identifies key barriers, both legal and practical, to international regulatory cooperation for U.S. government agencies. Some agencies claim that they lack statutory authority to account for international effects when making regulatory decisions. Several agency officials, as well as high-level leaders, indicated that international regulatory cooperation was a low priority for agency leaders, as it is an issue with little visibility when accomplished successfully. Agencies indicated that legal restrictions on information sharing can hinder international cooperation. Finally, coordination among agencies within the U.S. government is a challenge, particularly for independent regulatory agencies, so that agencies focused on trade and competitiveness are not always aware of the activities of other federal regulators.

Despite these challenges, many agencies are effectively engaging in international cooperation, and the report reviews these success stories. Notably, there is evidence that better international cooperation can help agencies better accomplish their regulatory missions with fewer resources by dividing work with foreign counterparts and, where appropriate, mutually recognizing each others' inspections and other tests. These approaches, which show potential for cost savings without diminishing regulatory effectiveness, might be expanded for further cost-saving effects.

² The participants were Paul R. Verkuil, Chairman, Administrative Conference of the United States; C. Boyden Gray, Founding Partner, Gray & Schmitz, Former Ambassador to the EU, Former White House Counsel; Michael Fitzpatrick, Associate Administrator, OIRA, OMB; Dan Price, Senior Partner, Sidley Austin, Former Assistant to the President and Deputy National Security Advisor for International Economic Affairs; Mindel De La Torre, Chief, International Bureau, FCC; Steve Wood, Assistant Chief Counsel for Vehicle Rulemaking & Harmonization, NHTSA; Elizabeth Jacobs, Deputy Director, Office of International Affairs, SEC; Jeff Weiss, Senior Director, Technical Barriers to Trade, USTR; Ralph Carter, Managing Director, Legal, Trade & International Affairs, FedEx; and Michael Walls, Vice President Regulatory & Technical Affairs, American Chemistry Council.

International Regulatory Cooperation

Many of the issues identified were addressed in the 1991 recommendation. The report assesses that 1991 recommendation and proposes a new recommendation to be considered by the Administrative Conference. This new recommendation restates the parts of the 1991 recommendation that remain valid and relevant, expands on some elements of the 1991 recommendation, and adds new elements based on the current issues identified in this report.

II. Background

A. The 1991 Recommendation

In 1991, ACUS studied FAA cooperation with its counterpart agencies abroad related to aircraft certification, and the issues that such cooperation entailed. Based on that case study, ACUS developed a recommendation for all U.S. regulatory agencies on working with their international counterparts. ACUS recommendation 91-1 included the following:

- Each agency should be familiar with its foreign counterparts and weigh whether regulatory cooperation is appropriate, considering whether the agencies share common objectives, the importance of coordination in a given field, and whether the agencies can rely on common technical resources, tests, and inspections.
- When an agency concludes that it has a pronounced interest in cooperation with foreign regulatory bodies, it should consider adopting various modes of cooperation with those agencies, including establishment of common regulatory agendas; systematic exchange of information; alignment of rules; joint research and development; mutual recognition of certifications; and regularly scheduled meetings.
- Agencies must proceed in coordination with other U.S. interests and should consider that foreign regulators may have their own agendas, particularly when foreign industries are government-controlled. To this end, agencies should form interagency advisory groups with representatives from State, Commerce, Defense, and USTR.
- Agencies should provide notice to the public and regulated industries of cooperation with foreign regulators and an opportunity to participate in the proceedings. Agencies should be transparent about the effect of foreign negotiations in their own rulemakings.
- Coordination efforts should be pursued within the overall framework of the agency's statutory mandate and with due regard for the interests that Congress intended the agency to promote. Accordingly, agencies should ensure that any accord informally reached through international regulatory cooperation is genuinely subject to reexamination and reconsideration in the course of the rulemaking process.

When the Administrative Conference was revived in 2010, one of the key considerations in developing the Conference's agenda was thinking about how the world had changed during the 15-year dormancy of the Conference, from 1995-2010. The widespread adoption of the Internet and its transformation of global information sharing and transparency have transformed global economies and cultures. Similarly, global political realignments, such as increasing unification of Europe, terrorism and

International Regulatory Cooperation

armed conflicts, and the rapid development of economies in Asia, Latin America, and the Middle East, have influenced economic and political policy in the United States. Given these developments, when the Conference considered which previous recommendations to reexamine, the 1991 recommendation on global regulatory cooperation emerged as a prime candidate.

B. Developments in Global Trade

In the 20 years since the Administrative Conference adopted its recommendation on global regulatory cooperation, the United States has entered into a number of trade agreements intended to remove barriers to trade, such as tariffs, subsidies, and inconsistent technical standards or regulations. The Uruguay Round of the General Agreement of Trade and Tariffs was conducted from 1986 to 1994 and resulted in the creation of the World Trade Organization.³ This round also addressed the concern that, as free-trade agreements reduced measures such as tariffs, non-tariff barriers such as mandatory product standards and conformity assessment procedures could also disrupt trade.⁴ The Agreement on Technical Barriers to Trade (TBT Agreement), an outcome of the Uruguay Round and an elaboration of the Tokyo Round Standards Code, sets out procedures that countries must follow in developing, adopting and implementing mandatory product standards and conformity assessment procedures to protect the countries' legitimate regulatory interests such as protecting health, safety, and the environment, while avoiding the creation of unnecessary obstacles to trade in goods.⁵

The TBT Agreement acts as an analogue to the Administrative Procedure Act in the United States by setting out principles and procedures for countries to develop their regulatory standards to comply with WTO rules. Among the key obligations of the TBT Agreement are non-discrimination; ensuring that mandatory product standards are no more trade restrictive than necessary to fulfill a legitimate objective; enhanced transparency in the development of mandatory product standards and conformity assessment procedures; the use of relevant international standards as a basis for mandatory product standards and conformity assessment procedures (unless ineffective or inappropriate to fulfill a legitimate objective); and, where appropriate, basing product requirements on performance or outcomes instead of specific designs or descriptions. The Agreement also strongly encourages the acceptance of foreign regulations as equivalents, mutual recognition of tests and certifications, permitting foreign conformity assessment bodies to participate in domestic conformity assessment

³ Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 31874 (1994).

⁴ See David Lifshiz, *Updating American Administrative Law; WTO, International Standards, Domestic Implementation and Public Participation*, 24 Wis. INT'L L.J. 961, 961 (2007).

⁵ Agreement on Technical Barriers to Trade, Annex to the Marrakesh Agreement Establishing the World Trade Organization, 1868 U.N.T.S. 120 (1994). Another agreement, the Sanitary and Phytosanitary Measures Agreement (SPS Agreement), specifically addressed the alignment of international and domestic standards in food and agricultural products. Agreement on the Application of Sanitary and Phytosanitary Measures, Annex to the Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 493 (1994).

International Regulatory Cooperation

procedures on no less favorable terms as those accorded to domestic conformity assessment bodies, and use of international systems of conformity assessment.⁶

Because access to information is important in coordinating regulation, the TBT agreement requires that each member publish certain proposed measures at an early stage so that other members may have an opportunity to comment and have comments considered, and to promptly publish final measures.⁷ Each country is required to establish a National Inquiry Point to facilitate access to this information. The National Institute of Science and Technology (NIST) within the Department of Commerce plays this role for the United States. NIST operates a database, Notify U.S., containing proposed mandatory product standards and conformity assessment procedures from other countries that may significantly affect trade.⁸ The Notify U.S. database compiles summary information on foreign measures, allows users to request complete texts, guides U.S. entities in preparing comments, and forwards these comments to foreign regulators. NIST is also responsible for notifying foreign countries of proposed U.S. federal and state measures that may have significant trade effects.⁹

As one route to greater alignment, the TBT agreement encourages the adoption of voluntary international standards as national technical regulations.¹⁰ The agreement requires Members to use relevant international standards as a basis for their mandatory product standards and conformity assessment procedures, provided that such standards are not ineffective or inappropriate to achieve the legitimate policy objective pursued.¹¹ Such measures can be afforded a rebuttable presumption that they are not unnecessary technical barriers to trade.

⁶ Office of the United States Trade Representative, 2011 Report on Technical Barriers to Trade 9 (2011), *available at*

<http://www.ustr.gov/sites/default/files/TBT%20Report%20Mar%2025%20Master%20Draft%20Final%20pdf%20-%20Adobe%20Acrobat%20Pro.pdf>.

⁷ *Id.*

⁸ See Notify U.S., <https://tsapps.nist.gov/notifyus/data/index/index.cfm>.

⁹ U.S. Dep't of Commerce, U.S. TBT Inquiry Point: What We Do, <http://gsi.nist.gov/global/index.cfm/L1-4/L2-12/A-219>

¹⁰ Office of the United States Trade Representative, 2011 Report on Technical Barriers to Trade 21 (2011), *available at*

<http://www.ustr.gov/sites/default/files/TBT%20Report%20Mar%2025%20Master%20Draft%20Final%20pdf%20-%20Adobe%20Acrobat%20Pro.pdf>

¹¹ Office of the United States Trade Representative, 2011 Report on Technical Barriers to Trade 21 (2011), *available at*

<http://www.ustr.gov/sites/default/files/TBT%20Report%20Mar%2025%20Master%20Draft%20Final%20pdf%20-%20Adobe%20Acrobat%20Pro.pdf>

International Regulatory Cooperation

The United States has undertaken other efforts to align its regulations with those of other nations, adopting a law encouraging the use of voluntary consensus standards instead of government-unique standards. The National Technology Transfer and Advancement Act of 1995 (NTTAA)¹² directs U.S. regulatory agencies to adopt voluntary consensus standards, instead of creating standards unique to the government, whenever possible. OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, provides guidance to agencies on implementing the NTTAA. “This Circular instructs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. It also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. The aim of the Circular is to reduce to a minimum the reliance by agencies on government-unique standards.”¹³

In addition to participation in the WTO, including the TBT agreement, the United States has also entered into free trade agreements with a number of countries that include obligations for regulatory cooperation beyond the framework of the TBT Agreement.¹⁴ For example, these free trade agreements require trade partners to recognize U.S. conformity assessment bodies, including testing and certification bodies, on no less favorable terms than they accord to their own testing and certification bodies, and vice versa.¹⁵

To facilitate greater levels of international regulatory cooperation, the United States created high-level, bilateral regulatory cooperation forums with the European Union, Mexico, and Canada.¹⁶ In addition, the United States has offered proposals in various fora, such as the WTO’s Doha Round, Asia-Pacific Economic Cooperation, and the Trans-Pacific Partnership negotiations to promote transparency and the use of good regulatory practices, as well as to better align regulatory approaches (including labeling and packaging requirements) in specific product areas such as textiles, apparel, footwear, and travel goods; electronic goods; goods with cryptographic capabilities; automotive goods; wine and distilled spirits; medical devices, pharmaceuticals, and cosmetics.¹⁷

¹² Pub. L. No. 104-113, 110 Stat. 775 (1996).

¹³ EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, October 15, 2008, at 4, *available at* http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_october_2008.pdf.

¹⁴ *Id.* at 14 n.10. The U.S. has entered into Free Trade Agreements with regulatory cooperation provisions with Australia, Bahrain, Central America and the Dominican Republic, Chile, Morocco, Oman, and Peru.

¹⁵ *Id.* at 15.

¹⁶ *Id.* at 40.

¹⁷ *Id.* at 44.

III. The Rationale for Increased International Regulatory Cooperation

Both the United States government and business groups such as the U.S. Chamber of Commerce agree that, even as international regulatory cooperation has improved over the past 20 years, there are still shortcomings in cooperation that hinder regulatory effectiveness and commerce. While the international efforts of U.S. agencies have greatly expanded, the need for international coordination has also greatly expanded due to increased trade in goods, services, and information.

Incompatible regulatory requirements in different countries persist. Sometimes regulations are different for non-substantive reasons – regulators share common goals and methods of regulation, but for historical or other reasons, regulations remain inconsistent. Sometimes regulations differ because regulators in different countries do not agree on important substantive issues, such as how to weigh scientific evidence or balance competing priorities. When differences are substantive, the differences can sometimes be ascribed to countries asserting legitimate national goals such as protecting health, safety or the environment at the levels that they consider appropriate. Other substantive differences, however, disrupt trade and serve no legitimate objective, or otherwise operate as de facto protectionist measures. Moreover, even when regulations themselves are aligned, different national requirements for conformity assessment, such as testing, certification, inspection, or accreditation, frequently impose their own costs and delays.

Past and current informal regulatory barriers include (i) uncertainty about foreign regulations, which could force U.S. manufacturers to “make practical design, production, and commercial decisions without adequate information”;¹⁸ (ii) uncertainty caused by excessive time to process appeals from regulatory decisions;¹⁹ (iii) ineffective, inconsistent or overly lengthy enforcement efforts;²⁰ and (iv) reimbursable advances (loans) and direct subsidies for companies;²¹ and (v) lack of regulatory transparency of foreign markets.

Because of the global nature of the economy, the domestic regulatory mission of U.S. agencies is affected by what happens overseas. For example, imports of food and pharmaceutical products to the U.S. have greatly increased over the past 20 years, so that the FDA’s mission of ensuring food, drug, and device safety in the United States is necessarily intertwined with how these products are regulated in their country of origin. The Consumer Products Safety Commission (CPSC) faces a similar challenge.

¹⁸ Office of the United States Trade Representative, “European Union” at 180, *available at* http://www.ustr.gov/sites/default/files/uploads/reports/2009/NTE/asset_upload_file348_15473.pdf.

¹⁹ *Id.* at 193.

²⁰ *Id.* at 191-92.

²¹ *Id.* at 206-08.

International Regulatory Cooperation

Pollutants do not respect political boundaries and carbon emissions have global effects, so that the Environmental Protection Agency's missions of ensuring clean air and clean water in the United States are reliant on environmental regulations in other countries. Financial institutions in the United States participate in the global banking system and are exposed to risks in economies all over the world, which requires financial regulators to coordinate globally in their missions of ensuring safety and soundness of United States institutions.²² And trade in data flows across national boundaries, requiring the Federal Trade Commission to cooperate with other global regulators in policing Internet fraud. A CPSC report outlined reasons that disparate safety standards could have negative consequences, including:

- A potential for production errors due to periodic changes of components or procedures to meet different regulations. Such mistakes may result in an otherwise safe product meeting the "wrong regulation" or, worse, the accidental absence of, or even the intentional deletion of, a required safety element.
- Higher costs for consumers where production must be modified to meet different safety requirements.
- Confusion and concern by consumers who do not understand why a foreign safety requirement is not applied to the same products sold in their own market.
- Purchase abroad of an otherwise identical product that does not meet safety requirements in the consumer's own market.
- Unavailability of a useful and safe product in a given market because the manufacturer finds it cost-prohibitive to meet different safety standards in multiple markets.²³

In addition to the impact on regulatory goals such as health, safety, and environmental and consumer protection in the United States, inconsistent regulatory regimes can act as barriers to trade. For example, different food labeling requirements between the United States and Europe require producers who distribute food in both markets to produce the same goods in different packaging, depending on the market, which hinders economies of scale and adds cost and delay. Another example is that the United States and Europe have different approaches to regulating the length of tractor-trailers. While the U.S. regulations address the length of the trailers, the European regulations address

²² Coordination with foreign financial regulators often occurs through a variety of means, which affords flexibility in addressing cross-border issues. Examples include membership in international standard setting bodies, such as the International Organization of Securities Commissions (IOSCO); bilateral and multilateral engagements; and the Financial Stability Board.

²³ CPSC Office of International Programs and Intergovernmental Affairs, Toy Safety Regulatory and Standards Coordination and Alignment: A Roadmap, April 25, 2011, at p. 5.

the combined length of the tractor and trailer.²⁴ The result of this disparity is that European trucks typically place the driver's cab over the engine compartment so that the truck is shorter, while American trucks place the driver's cab behind the engine compartment, resulting in a longer truck with a more aerodynamic profile. This disparity has both regulatory and trade effects: the American design has better fuel economy, and American manufacturers cannot export their trucks which comply with U.S. requirements into European markets without significant redesign.

Disparities between regulatory regimes hinder the regulatory effectiveness of the U.S. government and have costs to the U.S. economy. Regulatory differences between the U.S. and foreign governments can require U.S. 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."²⁵ A 2009 European Commission study found that the elimination of 50 percent of non-tariff barriers between the U.S. and the EU would result in a \$150 billion increase in gross domestic product (GDP), yielding 0.7-percent and 0.3-percent in permanent increases to the EU's and the U.S.'s GDP, respectively.²⁶ In addition to the financial savings, an increase in GDP could also result in lives saved²⁷ and would yield other non-market benefits to public health, safety and the environment.²⁸

A challenge for U.S. regulators is the increased ability of other countries and economic partnerships to influence regulations globally. While the United States was by far the global economic leader after the fall of the Soviet Union, the past 20 years has seen the rise of the European Union as a common market rivaling the United States. Several government and private sector officials interviewed for this project indicated that the European Union is actively marketing its approach to standards, regulation, and conformity assessment to developing countries. For example, an FCC official discussed how even though the U.S. was first in setting a digital television standard, the European Union did a

²⁴ Comment of Navistar, Inc. in response to Request for Public Comments Concerning Regulatory Cooperation Between the United States and the European Union That Would Help Eliminate or Reduce Unnecessary Divergences in Regulation and in Standards Used in Regulation That Impede U.S. Exports, 76 Fed. Reg. 24860 (May 3, 2011), available at <http://www.regulations.gov>, Docket No. ITA-2011-0006-0046.

²⁵ John F. Morrall III, Determining Compatible Regulatory Regimes between the U.S. and the EU (U.S. Chamber of Commerce White Paper) (2011) at p. 23, available at http://www.uschamber.com/sites/default/files/grc/Determining%20Compatible%20Regulatory%20Regimes%20-%20Final_0.pdf

²⁶ Judith M. Dean, et al., Estimating the Price Effects of Non-Tariff Barriers (U.S. International Trade Commission Working Paper) (2009) at p. 2, available at http://www.usitc.gov/publications/332/working_papers/EC200606Ar.pdf

²⁷ Morrall, *supra* note 25, at 2 n.6 (a \$150 billion increase in GDP would result in 6,000 lives saved).

²⁸ *Id.* at 32.

better job of selling their standard in other countries. Now most of South America uses either a European or Japanese standard for digital television, and an opportunity was lost. Another example is that EU vehicle safety and emissions standards have been or are in the process of being adopted in a number of markets, including Chile, Columbia, and Taiwan. Although Taiwan has been a major export market for U.S. truck manufacturers, the adoption of EU standards that diverge from U.S. standards will add costs and hinder U.S. exports to that market.²⁹ As their economies grow, member states of the EU and other countries will enjoy more influence in multilateral forums. When new markets import a regulatory structure, it is to the advantage of businesses already subject to that regulation, as they are less likely to incur new compliance costs in exporting to the new market.

IV. Perspectives of U.S. Government Agencies and Regulated Industries

To assess how the 1991 recommendation had been implemented and identify best practices and potential improvements to international regulatory cooperation, I conducted interviews at U.S. government agencies and with representatives of several industry groups. I also reviewed websites and other documents, such as Federal Register notices, for these agencies and industry groups. Overall, every agency reviewed engages with its foreign counterparts and international organizations to coordinate regulatory and enforcement activity. This engagement can take the form of formal and informal information sharing; mutual recognition of standards, certification, and testing; or consultation in advance of rulemaking to align regulations. Despite the extensive nature of international cooperation, the agencies also believed that more coordination is necessary, and they identified both legal and practical obstacles to regulatory convergence.

A. Executive Office of the President

Improving international regulatory cooperation has been a focus of the Executive Office of the President across Administrations, with substantial participation from several components – the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB), the Office of the U.S. Trade Representative (USTR), the National Security Council, and the National Economic Council. Much of the work in this field has been establishment of high-level regulatory cooperation partnerships with the European Union and, more recently, Canada and Mexico. Leadership and responsibility rests in the Executive Office of the President, cutting across its components.

The most robust high-level regulatory cooperation partnership has been with the European Union. In 2002, the United States and European Union agreed on Guidelines for Regulatory Cooperation and Transparency, negotiated as part of the Transatlantic Economic Partnership launched at the London

²⁹ *Id.*

International Regulatory Cooperation

Summit of May 1998.³⁰ The objectives of the agreement were to “improve cooperation between regulators and to promote transparency to the public in establishing and amending regulations.”³¹

In implementing these guidelines, the U.S. and EU have issued regularly updated “roadmaps” that outline specific sectors for cooperation, such as pharmaceuticals, auto safety, information and communications technology standards, cosmetics, consumer product safety, nutritional labeling, energy

³⁰ See TEP Guidelines on Regulatory Cooperation and Transparency Implementation Roadmap (2002), available at http://www.ustraderep.gov/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/TEP_Guidelines_on_Regulatory_Cooperation_Transparency_Implementation_Roadmap.html.

³¹ *Id.* Specifically, the guidelines proposed to:

(a) Improve the planning and development of regulatory proposals; leverage resources for regulations development; improve the quality and level of technical regulations; pursue, as appropriate, harmonized, equivalent or compatible solutions; and take appropriate steps to minimize or, where appropriate, eliminate unnecessary divergence in regulations through a more systematic dialogue between regulators, involving increased cooperation at all phases of the regulations development process;

(b) Obtain an increased predictability in the development and establishment of regulations by identifying and exchanging regulatory objectives, instruments and timetables;

(c) Grant the opportunity for regulators of each side to provide the other with meaningful input on regulatory matters, and the possibility to obtain reasonable consideration of such input;

(d) Promote public participation through disclosure of and access to supporting documents, particularly the timely release of the supporting rationales, analyses and data for regulatory proposals, and a timely opportunity for all interested parties, both domestic and non-domestic, to provide meaningful comments concerning regulatory proposals, including supporting materials;

(e) Obtain from each other and interested parties the benefit of the expertise, perspectives and ideas for alternative approaches, and of a fuller identification of unintended effects and practical problems associated with regulatory proposals, thereby promoting the adoption of technical regulations that are more performance-oriented and cost-effective and have fewer adverse effects;

(f) Provide public explanations for technical regulations, including the technical information and major regulatory alternatives considered, the analyses performed, the potential impacts on consumers, regulated parties, and others identified, the criteria applied to guide decision-making, and the consideration given to the public comments; and

(g) Create greater public understanding of the purpose and effect of regulatory proposals, greater public confidence in the fairness and openness of the regulations development process, and greater public acceptance of the technical regulations adopted, thereby enhancing the development and implementation of regulations, and contributing to a stable and sustainable foundation for long-term economic and social growth and development.

International Regulatory Cooperation

efficiency, and nanotechnology.³² To provide additional formal mechanisms for regulatory cooperation, in 2005 the U.S. and EU agreed to a regular meeting schedule known as the EU-US High-Level Regulatory Cooperation Forum, which brings together senior officials semiannually in Brussels or Washington to exchange views on cooperative best practices (including how to cooperate in specific sectors) and regulatory workplans.³³ These meetings have identified issues that hinder effective regulatory cooperation, including:

- information exchange suffers from a lack of legal authority that allows sharing and appropriate protections for confidential business information;³⁴

³² See 2004 Roadmap for EU-U.S. Regulatory Cooperation and Transparency (2004), available at http://www.ustraderep.gov/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/2004_Roadmap_for_EU-US_Regulatory_Cooperation_Transparency.html; 2005 Roadmap for EU-U.S. Regulatory Cooperation and Transparency (2005), available at http://www.ustraderep.gov/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/2005_Roadmap_for_EU-US_Regulatory_Cooperation_Transparency.html; Joint Report on the Roadmap for EU-US Regulatory Cooperation (2006), available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/joint_report_on_the_roadmap_for_eu-us_regulatory_cooperation_june_2006.pdf; Joint Report of the Roadmap for EU-U.S. Regulatory Cooperation (2007), available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/joint_report_on_the_roadmap_for_us-eu_regulatory_cooperation_april_2007.pdf; EU-US High-Level Regulatory Cooperation Forum, Report on the Sixth Meeting of the EC-U.S. High-Level Regulatory Cooperation Forum (2009), available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_july_2009.pdf.

³³ See EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, April 25, 2008, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_april_2008.pdf; EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, October 15, 2008, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_october_2008.pdf; EU-US High-Level Regulatory Cooperation Forum, Report on the Sixth Meeting of the EC-U.S. High-Level Regulatory Cooperation Forum, July 24, 2009, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_july_2009.pdf; European Commission-United States High-Level Regulatory Cooperation Forum, Report of the 8th Meeting, June 29-30, 2010, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_june_2010.pdf; European Commission-United States High-Level Regulatory Cooperation Forum, Report of the 9th Meeting, Dec. 16, 2010, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_december_2010.pdf.

³⁴ See EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, April 25, 2008, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_april_2008.pdf; see also Office of the United States Trade Representative, "European Union" at 179 (the U.S. chemical industry is

International Regulatory Cooperation

- differences between how the U.S. and EU measure and analyze risk;³⁵
- differences in the standards system between the U.S. and EU, including divergent views in what constitutes an international standard.³⁶

In June 2011, the Forum issued a Common Understanding on Regulatory Principles and Best Practices which reaffirmed the commitment of the U.S. and EU to the following regulatory principles:

(1) evidence-based policy-making for all regulatory measures likely to have significant impacts, with consideration of all relevant benefits and costs;

(2) transparency and openness, allowing participation by citizens and stakeholders;

(3) analysis of relevant alternatives;

(4) monitoring and evaluation of the effectiveness of existing regulatory measures; and

(5) use of approaches that minimize burden and aim for simplicity.³⁷

Following the model of extensive high-level partnership with the European Union on regulatory issues, the White House has recently entered into similar arrangements with Canada and Mexico. In February 2011, President Obama and Prime Minister Harper of Canada directed the creation of the United States-Canada Regulatory Cooperation Council, with the mission of increasing regulatory transparency and coordination.³⁸ In March 2011, terms of reference were adopted by the United States and Mexico for the U.S.-Mexico High-Level Regulatory Cooperation Council. While these coordination mechanisms are in their early stages, it is notable that they adopt the same high-level model as the U.S.-

concerned that its polymer manufacturers may be forced to disclose confidential business information), *available at* http://www.ustr.gov/sites/default/files/uploads/reports/2009/NTE/asset_upload_file348_15473.pdf.

³⁵ See EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, October 15, 2008, *available at* http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_october_2008.pdf.

³⁶ See EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, October 15, 2008, *available at* http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_october_2008.pdf.

³⁷ See United States – European Commission High-Level Regulatory Cooperation Forum, Common Understanding on Regulatory Principles and Best Practices, June 2011, *available at* <http://www.whitehouse.gov/sites/default/files/omb/oira/irc/common-understanding-on-regulatory-principles-and-best-practices.pdf>.

³⁸ The White House, Joint Statement by President Obama and Prime Minister Harper of Canada on Regulatory Cooperation, February 4, 2011, *available at* <http://www.whitehouse.gov/the-press-office/2011/02/04/joint-statement-president-obama-and-prime-minister-harper-canada-regul-0>.

International Regulatory Cooperation

EU partnership – participation of high level officials who have the authority to reach agreements and the clout to implement them within their respective governments’ regulatory agencies. Bob Hamilton, a Senior Associate Secretary for Canada’s Treasury Board who is a leader of the U.S.-Canada Council, emphasized the importance of attention to the issue of regulatory cooperation at the highest levels of the national government, and said that he had a specific mandate directly from Prime Minister Harper, which bolstered his authority and credibility with Canadian regulatory agencies.³⁹

In May 2011, the Office of the United States Trade Representative and the Office of Information and Regulatory Affairs issued a memorandum to the heads of executive departments and agencies and independent regulatory agencies titled “Export and Trade Promotion, Public Participation, and Rulemaking.” This memo recommended steps that agencies can take to reduce unnecessary regulatory barriers to exports and trade.

The memo stated that cost-benefit analysis required by Executive Orders 13563 and 12866 should consider “productivity, employment, the ability of small and medium-sized enterprises (SMEs) to participate in the global economy, and competitiveness.”⁴⁰ The memo also noted provisions of OMB Circular A-4 that “[t]he role of Federal regulation in facilitating U.S. participation in global markets should also be considered” and that “[c]oncerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.”⁴¹ In addition, the memo points out that the Trade Agreements Act prohibits Federal agencies from engaging in “any standards-related activity that creates unnecessary obstacles to the foreign commerce of the United States.”⁴² The memo notes that openness and the opportunity for the public to participate in the regulatory process is required by Executive Order 13563, and providing public access over the Internet to proposed rules, analyses, and supporting documents pursuant to the Executive Order and the requirements of the Technical Barriers to Trade Agreement makes them available to both domestic and foreign stakeholders, so that impacts to export and trade may be considered.⁴³

Finally, the memo encourages international collaboration, to include “information exchanges, dialogues, or meetings with other governments; information exchanges, dialogues, or meetings with

³⁹ Meeting with Bob Hamilton, Senior Associate Secretary, Treasury Board of Canada, at Embassy of Canada to the United States, June 9, 2011.

⁴⁰ Office of the U.S. Trade Representative and Office of Information and Regulatory Affairs, Export and Trade Promotion, Public Participation, and Rulemaking, M-11-23, May 19, 2011, *available at* <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-23.pdf>

⁴¹ *Id.* at 2.

⁴² *Id.* at 2-3. See Trade Agreements Act of 1979, Pub. L. No. 96-39, as amended by the Uruguay Round Agreements Act, Pub. L. No. 103-465 (codified at 19 U.S.C. § 2532).

⁴³ *Id.* at 3.

interested stakeholders, including SMEs, in other countries; coordination of regulatory activities with other governments; participation in efforts to share best practices and to harmonize relevant regulatory approaches, standards, and related procedures, as well as consideration of such efforts in the development of regulatory measures; and consideration of regulatory schedules that allow for sufficient time to consider regulatory approaches in other countries, as well as relevant developments in international, regional, and other fora.”⁴⁴ The memo argued that “such practices can help reduce regulatory costs, making it easier to do business, and also promote U.S. exports and trade by removing unnecessary regulatory divergences, which impose costs on U.S. exporters, especially SMEs.”⁴⁵ These practices “could have many domestic benefits, including increasing the safety and quality of other countries’ exports to the United States and thus helping to protect U.S. consumers.”⁴⁶

Similarly, in its 2011 Report to Congress on the Costs and Benefits of Regulation, OMB recommended that “in order to promote trade and exports, and thus to increase job creation, agencies should promote regulatory cooperation initiatives with key trading partners.”⁴⁷

There is a consensus among Presidential appointees from the current and prior Administrations that high-level attention from the White House is necessary to make international cooperation a priority for the agencies. They emphasized that for agency leaders to take the issue seriously, it must be something that they know senior officials at the White House are monitoring. A senior official perceives widespread support for international cooperation in the career ranks in agencies, but it is hard for these officials to feel empowered to change regulations or pursue alignment unless there is someone at the policy level pushing change.

(1) Office of Information and Regulatory Affairs (OIRA)

In addition to its participation in the international high-level regulatory cooperation groups, OIRA manages international regulatory cooperation policy in its oversight role over U.S. regulatory and information collection activities, especially regulatory review.

In 2008, OIRA provided guidance to U.S. agencies on analyzing the international effects of regulation, stating that agencies should consider effects on international trade and investment as part of the Regulatory Impact Analysis required by OMB Circular A-4.⁴⁸ In preparing their analyses, agencies

⁴⁴ *Id.* at 3-4.

⁴⁵ *Id.* at 4.

⁴⁶ *Id.* at 4.

⁴⁷ Office of Management and Budget, 2011 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, *available at*: http://www.whitehouse.gov/sites/default/files/omb/inforeg/2011_cb/2011_cba_report.pdf

⁴⁸ Office of Management and Budget, 2008 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, *available at*:

International Regulatory Cooperation

should consider international trade as a “private market where economic exchange takes place across national boundaries.”⁴⁹ Therefore, regulations that hinder international trade have costs that should be measured against the benefits that the regulations provide, focusing on “benefits and costs that accrue to citizens and residents of the United States.”⁵⁰ In measuring costs and benefits related to international trade effects, agencies should “distinguish a regulation affecting trade which benefits the producers in their country at the expense of the consumers in their country, from a regulation that retains welfare-enhancing trade where possible and only restricts trade, either indirectly or directly, in cases where the benefits outweigh the costs.”⁵¹

OIRA has added a data element on international impacts to <http://www.reginfo.gov>, the online system that provides information and status updates on the unified regulatory agenda, regulatory review process, and information collection review process. Proposed rules submitted to OIRA for review are categorized by whether they have international impact, and users of the reginfo website can check a box to search for rules that have international impact, to facilitate transparency and comments from foreign regulators and stakeholders.

While OIRA plays a major role in international regulatory cooperation and issuing policy guidance, resource issues at OIRA limit its involvement in international issues at the agency level. OIRA does not have any full-time staff devoted to international work, and the international portfolio is handled unofficially by one branch chief, who estimates that he spends about half of his time on international issues, and by other OIRA staff on an as-needed, collateral duty basis.

OIRA staff emphasized that agencies should involve OIRA, trade officials, and national security staff early in the process. To this end, OIRA staff noted a State Department regulation “that nobody knows about,” which requires federal agencies to coordinate with OIRA before entering into an international agreement with potential regulatory impacts.⁵²

http://www.whitehouse.gov/sites/default/files/omb/assets/information_and_regulatory_affairs/2008_cb_final.pdf.

⁴⁹ *Id.* at 71.

⁵⁰ *Id.* at 71 (citing OMB Circular A-4).

⁵¹ *Id.* at 72.

⁵² “The Secretary of State is responsible, on behalf of the President, for ensuring that all proposed international agreements of the United States are fully consistent with United States foreign policy objectives. ... [N]o agency of the U.S. Government may conclude an international agreement, whether entered into in the name of the U.S. Government or in the name of the agency, without prior consultation with the Secretary of State or his designee.” 22 C.F.R. § 181.4(a); “If a proposed agreement embodies a commitment that could reasonably be expected to require (for its implementation) the issuance of a significant regulatory action (as defined in section 3 of Executive Order 12866), the agency proposing the arrangement shall state what arrangements have been planned or carried out concerning timely consultation with the Office of Management and Budget (OMB) for such commitment. The

International Regulatory Cooperation

As befitting their role within OMB, OIRA staff sees potential resource savings through international regulatory cooperation. Mutual trust between regulators is an opportunity for worksharing – if agencies don't have to duplicate tests or science, they can share their workload with foreign counterparts and shift limited inspection and other resources to areas of greater need.

OIRA staff also expressed the view held by others that high level political leadership, in both the executive and legislative branches, is needed to spur agencies to make international cooperation a priority.

(2) U.S. Trade Representative

To promote international regulatory coordination, USTR staff regularly review proposed foreign regulations that stakeholders bring to their attention to determine if they might have an impact on trade. If so, USTR staff must engage with the appropriate U.S. regulators and other key agencies through the Trade Policy Staff Committee to develop a U.S. position that balances the goal of trade facilitation with regulatory goals.

USTR staff noted that the trade and regulatory authorities are much more closely aligned in the European Commission than in the U.S., which has an effect on bilateral negotiations on regulatory issues. The European Commission's Directorate General - Enterprise, which looks at standards development through a competitiveness lens as well as a regulatory one, can take the lead in representing the EU position, while for the U.S., regulatory agencies take the lead instead of trade-focused agencies like USTR.

USTR staff stated that U.S. trade and regulatory goals would be advanced by better, earlier coordination between regulatory agencies and USTR. Agencies should consult with USTR at the outset of developing regulations, to learn of potential impacts on trade and commerce. USTR would also benefit from regulatory agencies reporting back on what they learn about other national regulatory agendas through their formal and informal interactions with their foreign counterparts, since it is easier to prevent the creation of unnecessary obstacles to trade and unnecessary regulatory divergences than it is to eliminate problematic measures once they are in place.

USTR staff sees a correlation between the attention that agency leadership pays to international issues and agencies' effectiveness in pursuing international cooperation. The Consumer Product Safety Commission was held out as a model agency in this regard. The agency conducts a planned and goal-oriented international program with close interagency coordination. The Chair personally engages with her foreign counterparts, and as a result, the CPSC has made considerable progress in aligning global standards and improving compliance in the area of toy safety.

Department of State should receive confirmation that OMB has been consulted in a timely manner concerning the proposed commitment." 22 C.F.R. § 181.4(e)(2)

B. U.S. Executive and Independent Regulatory Agencies

Review of high-level focus on international regulatory cooperation in the Executive Office of the President provides one perspective on challenges and potential solutions, but international coordination takes place on a day-to-day level in the various regulatory agencies, in both Cabinet departments and in independent agencies. To research how these agencies engage with their international counterparts and the difficulties they encounter, I reviewed documents and conducted interviews at several agencies. Agency officials from the Federal Communications Commission, National Highway Traffic Safety Administration, and the Securities and Exchange Commission participated in the March 2011 forum convened by ACUS and the U.S. Chamber of Commerce. In addition, I interviewed officials at the Food and Drug Administration, Consumer Product Safety Commission, and Federal Trade Commission. A fuller discussion of the international activities of each agency is attached as an Appendix to this report. This section highlights themes that emerged from reviewing these agencies – areas where agencies face common problems, and areas where the different experiences of agencies highlight what works and what doesn't.

One such issue is the question of statutory authorization for international regulatory cooperation. Differences in the degree to which agencies can engage in such activities depend on the agency's specific statutory authorization. Some agencies have clear authorization and a mandate to engage in international activities. For example, the FCC has statutory mandates to pursue international cooperation for international communications topics, including international long distance, submarine cables, and satellites. The U.S. SAFE WEB Act of 2006⁵³ gave the FTC new authorities to share information and provide investigative assistance to foreign law enforcement agencies. The SEC also has statutory authority to provide enforcement assistance to its foreign counterparts.⁵⁴ Yet other agencies state that their authorizing statutes do not grant them legal authority to consider international impacts when making regulatory decisions. The CPSC emphasized that all of its international work takes place in pursuit of the mission of promoting product safety.⁵⁵ While alignment of standards may be beneficial from a trade perspective, the CPSC will only pursue alignment if it would increase safety, and will not support efforts toward alignment where safety is not improved.⁵⁶ NHTSA staff emphasized that the authorizing statute makes safety the overriding priority of the agency, and there is no mention of coordination in the authorizing statute. The SEC's primary mission is to protect investors; maintain fair,

⁵³ Pub. L. 109-455, 120 Stat. 3372 (2006).

⁵⁴ 15 U.S.C. § 78u(a)(2)

⁵⁵ See also CPSC Office of International Programs and Intergovernmental Affairs, Toy Safety Regulatory and Standards Coordination and Alignment: A Roadmap, April 25, 2011.

⁵⁶ CPSC Office of International Programs and Intergovernmental Affairs, Toy Safety Regulatory and Standards Coordination and Alignment: A Roadmap, April 25, 2011.

International Regulatory Cooperation

orderly, and efficient markets; and facilitate capital formation. The SEC will only pursue alignment if it would further that mission.

Another common theme was the extent to which agencies engage in both formal and informal collaboration with their foreign counterparts. Agencies emphasized that extensive informal contacts and information sharing were key to regulatory cooperation. The FDA has extensive formal and informal exchange programs with foreign counterparts, especially the European medicine and food safety agencies. There is an employee exchange program in place between the FDA and its EU counterparts, and the FDA's Deputy Commissioner for International Affairs reported that he communicates with foreign counterparts on a daily basis. The CPSC has informal relationships with European counterparts, with multiple phone calls and emails every week. CPSC staff also have close informal working relationships with counterparts in Canada, Mexico, Australia, Japan, and Korea. The FTC provides training and technical assistance to other countries in developing their regulatory policies. For example, the FTC helped Eastern European countries write their competition laws and establish their competition agencies. The FCC maintains an international visitors program which hosted more than 500 visitors from overseas in 2010, and it hosts Web forums to discuss current issues with foreign counterparts. The SEC's international office also has a very active program to provide training and technical assistance to foreign regulators. It conducts formal training and exchange programs attended by more than 1,000 regulators per year.

When these types of relationships with foreign counterparts are well-developed, it facilitates formal cooperation and possible mutual recognition, which have the potential for cost savings as U.S. agencies can divide and share workloads with foreign counterparts. The FDA believes there is great potential for cost savings and improved health and safety in mutual reliance on the data from clinical trials and manufacturing quality inspection regimes in other countries. For example, the FDA recently concluded a pilot project with European and Australian regulators to inspect manufacturing plants in China and other countries that manufacture active pharmaceutical ingredients.⁵⁷ The agencies compared their lists of plants subject to inspection and the resources that each country had available, and where two or more agencies were scheduled to visit the same plant, the agencies agreed on one agency to inspect that plant or to do a joint inspection, and reallocated resources so that they could cover more plants. Building on the success of that pilot, the FDA is now pursuing a similar project with European regulators for site inspections of clinical trials. Despite these successes, there is some hesitance in relying upon inspectional data from foreign regulators, as it is unclear where accountability would lie if there were a failure in the system. Although U.S. officials have views of which foreign country regulators are reliable, it is difficult to identify data or outcome measures to support those perceptions. The CPSC is conducting an experiment with four jurisdictions – the U.S., EU, Canada, and Australia – to review standards for three products – corded window coverings, chairtop booster seats,

⁵⁷ EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, October 15, 2008, *available at*

http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_october_2008.pdf.

and baby slings. The goal of the initiative is for the four agencies to review safety requirements for the three products together, reach consensus on how requirements can be improved to remove serious hazards, and then shepherd a consensus through either rulemaking or voluntary standards procedures, as each jurisdiction chooses. A fully successful outcome would include an International Standards Organization standard that closely reflects that consensus approach taken in each of the four jurisdictions.

Some agencies noted that legal restrictions on sharing of information and data can be a barrier to international cooperation. For example, the FDA engaged in more than 3000 confidential exchanges with the European Medicines Agency in 2010. Data sharing with foreign regulators is critical to the FDA's regulatory cooperation efforts, and the FDA has a robust program of confidential exchanges with trusted foreign regulators. However, the legal requirements to develop information sharing protocols are burdensome. The FDA has regulations in place that allow it to share information with foreign agencies that can protect confidential business information to the same extent as it is protected in the United States, although under no circumstances can the FDA share trade secrets.⁵⁸ So information exchanges are possible, but require investment of time and resources to review materials to determine what can and cannot be shared and redact materials. This can be particularly wasteful when companies are submitting the same information to the FDA and foreign regulators, but the agencies are limited in how they can exchange it. The CPSC faces similar restrictions. Although the agency received statutory authority to exchange sensitive information, the legislation limits the ability of CPSC to make such exchanges fully reciprocal. Foreign partners have rejected non-reciprocal terms, so no agreements have been reached. The FTC has encountered similar difficulties in reaching information exchange agreements when foreign governments insist on restricting how U.S. agencies share such information within the U.S. government, terms which the U.S. government will not accept.

C. Stakeholder Views

To identify issues of regulatory divergence that hinder U.S. exports, the Commerce Department issued two requests for comment on areas in which regulatory cooperation could be improved with the European Union, and, separately, with Canada and Mexico.⁵⁹ The EU request yielded 53 comments and 46 comments were submitted for the North America request.

I reviewed each comment submitted in response to the ITA requests. Overall, the comments submitted identify technical divergences in regulations between the U.S. and the EU, Canada, and

⁵⁸ 21 C.F.R. § 2089.

⁵⁹ Request for Public Comments Concerning Regulatory Cooperation Between the United States and the European Union That Would Help Eliminate or Reduce Unnecessary Divergences in Regulation and in Standards Used in Regulation That Impede U.S. Exports, 76 Fed. Reg. 24860 (May 3, 2011); Request for Public Comments Concerning Regulatory Cooperation Activities That Would Help Eliminate or Reduce Unnecessary Regulatory Divergences in North America That Disrupt U.S. Exports, 76 Fed. Reg. 11760 (Mar. 3, 2011).

International Regulatory Cooperation

Mexico that the submitters believe are unjustified by any policy consideration such as health, safety, or environmental concerns, but act as de facto barriers to trade. Most of the comments are highly specific to regulations in a particular industry or product, but my review identified several themes that appeared in multiple comments as issues across a number of sectors:

- Because EU standards are frequently adopted in other markets, divergences between the U.S. and EU do not just hinder U.S. exports to the EU, but to other countries as well.⁶⁰
- EU regulations are developed in a top-down approach, and therefore are perceived as being less evidence-based than U.S. regulations.⁶¹
- Timeframes should be sufficient to allow comment and allow transition and implementation of new rules.⁶²

⁶⁰ Comment of Navistar, Inc. in response to Request for Public Comments Concerning Regulatory Cooperation Between the United States and the European Union That Would Help Eliminate or Reduce Unnecessary Divergences in Regulation and in Standards Used in Regulation That Impede U.S. Exports, 76 Fed. Reg. 24860 (May 3, 2011), *available at* <http://www.regulations.gov>, Docket No. ITA-2011-0006-0046.

⁶¹ Comment of National Confectioners Association in response to Request for Public Comments Concerning Regulatory Cooperation Between the United States and the European Union That Would Help Eliminate or Reduce Unnecessary Divergences in Regulation and in Standards Used in Regulation That Impede U.S. Exports, 76 Fed. Reg. 24860 (May 3, 2011), *available at* <http://www.regulations.gov>, Docket No. ITA-2011-0006-0052; Comment of National Pork Producers Council (NPPC) and the American Meat Institute (AMI) in response to Request for Public Comments Concerning Regulatory Cooperation Between the United States and the European Union That Would Help Eliminate or Reduce Unnecessary Divergences in Regulation and in Standards Used in Regulation That Impede U.S. Exports, 76 Fed. Reg. 24860 (May 3, 2011), *available at* <http://www.regulations.gov>, Docket No. ITA-2011-0006-0025. This view is shared by USTR. See Office of the United States Trade Representative, “European Union,” *available at* <http://www.ustr.gov/countries-regions/europe-middle-east/eurpoe/european-union> (“the EU has restricted or excluded altogether U.S. [agricultural] exports . . . through nontariff barriers or regulatory approaches that do not reflect science-based decision-making or a sound assessment of actual risks to consumers or the environment”); Office of the United States Trade Representative, Ambassador Ron Kirk, “Overly Restrictive Regulations Effectively Shut Out Producers,” *available at* <http://www.ustr.gov/about-us/press-office/blog/2011/july/overly-restrictive-regulations-effectively-shut-down-producers> (“U.S. companies still face significant ‘behind the border’ barriers, which typically take the form of complex, burdensome regulations and standards”); Office of the United States Trade Representative, “Key Technical Barriers to American Exports,” *available at* <http://www.ustr.gov/about-us/press-office/fact-sheets/2010/march/key-technical-barriers-american-exports> (some of the EU’s regional standards “are lacking a sufficient scientific or technical basis and [their] adoption would favor EU producers and firms”).

⁶² Comment of TechAmerica in response to Request for Public Comments Concerning Regulatory Cooperation Between the United States and the European Union That Would Help Eliminate or Reduce Unnecessary

International Regulatory Cooperation

- While the U.S. allows adoption of voluntary consensus standards from a range of organizations, the EU only allows adoption of standards from a small number of standards organizations headquartered in Europe.⁶³

In addition to reviewing comments submitted in response to the Commerce Department request, I also met with representatives from a range of business groups to solicit their views on shortcomings in international regulatory cooperation and areas for improvement.⁶⁴ Several themes emerged from these discussions. First, business groups are wary of the term “harmonization” and its implication that single, uniform, global standards should be established. Instead, business groups would like to see compatibility and convergence between regulatory regimes, using similar testing and evaluation methods. This would tend to reduce the burdens placed on business by regulations that are divergent although directed toward the same goals, without locking in a single standard that business may disfavor. Second, business groups do not believe that regulatory analysis and impact assessments properly account for effects on trade. Third, business groups believe that agreements by global regulators to use common data standards and scientific principles, and mutually recognize each others’ inspection regimes, would save money for governments and reduce burden on industry.⁶⁵ Finally, businesses would like to receive more advance notice from U.S. agencies that are entering into discussions with their overseas counterparts, so business can provide comments that the agencies may consider, rather than learning about regulatory dialogues after they have been completed.

Divergences in Regulation and in Standards Used in Regulation That Impede U.S. Exports, 76 Fed. Reg. 24860 (May 3, 2011), *available at* <http://www.regulations.gov>, Docket No. ITA-2011-0006-0031.

⁶³ Comment of Air-Conditioning, Heating, and Refrigeration Institute in response to Request for Public Comments Concerning Regulatory Cooperation Between the United States and the European Union That Would Help Eliminate or Reduce Unnecessary Divergences in Regulation and in Standards Used in Regulation That Impede U.S. Exports, 76 Fed. Reg. 24860 (May 3, 2011), *available at* <http://www.regulations.gov>, Docket No. ITA-2011-0006-0018.

⁶⁴ On August 16, 2011, I met with representatives from the U.S. Chamber of Commerce Global Regulatory Cooperation Project, Business Roundtable, American Chemistry Council, National Association of Manufacturers, American Bankers Association, and BAFT-IFSA (Bankers’ Association for Finance and Trade-International Financial Services Association).

⁶⁵ “Some governments do not permit U.S. suppliers to use competent conformity assessment bodies . . . located in the United States to demonstrate that their products comply with their technological regulations. Rather, U.S. exporters are required to use conformity assessment services provided by bodies in the destination market, which can impose additional costs and burdens on U.S. exporters These costs and burdens can be compounded by significant delays when the foreign market lacks sufficient domestic testing, inspection, or certification capacity.” Office of the United States Trade Representative, “Key Technical Barriers to American Exports,” *available at* <http://www.ustr.gov/about-us/press-office/fact-sheets/2010/march/key-technical-barriers-american-exports>.

International Regulatory Cooperation

A working paper prepared for the U.S. Chamber of Commerce proposed ten questions to be considered during regulatory impact analysis in assessing the costs and benefits of regulatory alignment between the United States and European Union:

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?
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?⁶⁶

The comments received in response to the Commerce Department request were mainly from industry groups; consumer groups did not submit comments. However, in the past, consumer groups have expressed concern that regulatory alignment efforts had the potential to sacrifice regulatory effectiveness in favor of trade promotion.⁶⁷ The concern has been that alignment entails a race to the

⁶⁶ Morrall, *supra* note 29, at 12-13.

⁶⁷ See David Lifshiz, *Updating American Administrative Law; WTO, International Standards, Domestic Implementation and Public Participation*, 24 WIS. INT'L L.J. 961, 977 (2007); Lori M. Wallach, *Accountable*

bottom. (This is the opposite of the business concern that alignment would lead to overly rigid standards.) I did not identify evidence that the concerns of consumer groups that alignment would lead to lower standards have been realized, and U.S. government officials do not believe that such a problem exists. In fact, several U.S. officials stated that their international activities were intended to raise and improve standards. However, such views should be accounted for in the Conference recommendation if they emerge in the consideration process.

V. Analysis of Challenges in International Regulatory Cooperation and Potential Solutions

Barriers to effective international coordination for U.S. regulators can arise from legal authorities governing agencies, agency incentives and resources, and the relatively decentralized structure of federal administrative agencies.

A threshold question for U.S. administrative agencies in pursuing international convergence in their regulatory activities is whether they have the statutory authorization to do so. It is a tenet of American administrative law that agencies may exercise only the powers assigned to them by Congress in statute, and interviews revealed that agencies take this restriction quite seriously in limiting the extent to which they can consider international implications of their work. Many agencies were established by statute in the first half of the 20th century, when today's global economy was not even contemplated. While some agencies have clear statutory authority to coordinate regulatory activities with overseas counterparts, other agencies stated that they were limited in their ability to do so, as it was not part of their agency's statutory mission. The CPSC has a statutory mission of ensuring product safety, and the agency's position is that product safety can be the only factor in issuing regulations and setting its enforcement agenda. Similarly, NHTSA has a statutory mission of promoting vehicle safety; international convergence is not provided as a factor that may be considered. These agencies state that they work with international counterparts on developing regulations and on enforcement issues, but can do so only to the extent that these activities clearly further the agency's goal of promoting safety. For example, even if minor compromises on a safety regulation would allow regulatory alignment that would greatly facilitate business and trade, these agencies do not believe that they have the statutory authority to make such a compromise.

To address this problem, several officials suggested that ACUS might recommend to Congress a statute that would explicitly permit agencies to pursue international coordination and consider the effects of regulations on trade and U.S. competitiveness. While this solution may solve one problem, it creates other problems of its own. First, the Administrative Conference's authorizing statute states that the administrative procedure that ACUS is to consider "does not include the scope of agency

Governance in the Era of Globalization: The WTO, NAFTA, and International Harmonization of Standards, 50 U. KAN. L. REV. 823, 831 (2002).

responsibility as established by law.”⁶⁸ Second, such a change could create conflicts of interest for the regulator, creating a potential for regulatory capture if the same regulator is trying to both regulate and promote a particular industry. Collaboration may also create perceptions that a regulator is acting on behalf of U.S. industry rather than pursuing regulatory goals, diminishing the credibility of the regulator in the eyes of its foreign counterparts.⁶⁹ Such a perception can also hinder the effectiveness of the U.S. Trade Representative in persuading other countries to abandon regulations that act as protectionist barriers to trade. Finally, many agencies believe they already have ample authority under their statutes, so a one-size solution is not necessary. The better approach for an ACUS recommendation may be to encourage each agency to conduct its own analysis of legal authorities and, if authority for international cooperation is insufficient, to seek new authority through OMB and the legislative process.

Another challenge that agencies face is that agency leadership and resources are not focused on international coordination. While all agencies reviewed have international affairs offices, several stated that the amount of work necessary to achieve effective international cooperation outstripped the personnel and budgetary resources available. Agencies and their leaders focus on priorities of key constituencies, Congress, and high-profile issues. International regulatory cooperation seldom garners such attention. As one agency official put it, there are a lot of issues that could land an agency leader in hot water, but no political appointee is ever going to get in trouble with Congress or the press because of obscure technical differences between their agency regulations and those of foreign regulators. However, if an agency relied on a foreign counterpart to regulate or inspect and a problem arose which threatened health or safety in the U.S., the U.S. agency would be exposed to criticism. Another former official pointed out that for regulatory agencies, their impact is global, but political accountability is local. Because of this, several senior officials emphasized that high-level attention and leadership on international regulatory cooperation is essential to its success, to push officials to pursue international cooperation and give them cover from criticism if such cooperation creates complications.

A factor that can hinder international efforts is the relative independence of U.S. regulatory agencies from central, executive branch control. The degree of independence of regulatory agencies is one of the great questions of American administrative law, but the principle that certain regulators enjoy a measure of independence vis-à-vis other agencies is widely accepted. These issues of institutional structure can present obstacles to international coordination, as U.S. regulators may be pursuing policy goals and priorities that are not necessarily integrated with other U.S. national priorities pursued by other agencies. These potential conflicts can arise most prominently in the context of trade,

⁶⁸ 5 U.S.C. § 592(3).

⁶⁹ Likewise, fears of the domestic industries that foreign regulators have been captured by their own regulated industry could diminish the foreign regulator in the eyes of U.S. regulators. See, e.g., Office of the United States Trade Representative, “Key Technical Barriers to American Exports,” available at <http://www.ustr.gov/about-us/press-office/fact-sheets/2010/march/key-technical-barriers-american-exports> (some of the EU’s regional standards “are lacking a sufficient scientific or technical basis and whose adoption would favor EU producers and firms”).

as U.S. government agencies such as the U.S. Trade Representative and Department of Commerce work to open markets and reduce trade barriers, but regulatory agencies may pursue their own regulatory goals that are not coordinated with, or are even in conflict with, the trade promotion agenda. This contrasts with the European Union, where both regulatory and trade policy are coordinated in the European Commission. To address this problem, regulatory agencies might consider whether they can work more closely with the White House and executive branch agencies when their actions implicate international issues.

Several officials recommended improved international coordination as a resource-saving measure. As the federal government seems to be entering an extended period of constraints on the discretionary budgets that fund most federal agencies, agencies facing budget constraints are exploring improved alliances with foreign counterparts to eliminate duplicate efforts and share burdens of inspection and enforcement. For example, the FDA recently concluded a pilot project with European and Australian regulators to inspect manufacturing plants in China and India that manufacture pharmaceutical components.⁷⁰ The agencies compared their lists of plants subject to inspection and the resources that each country had available, and where two or more agencies were scheduled to visit the same plant, the agencies agreed on one agency to inspect that plant, and reallocated resources so that they could cover more plants. Building on the success of that pilot, the FDA is now pursuing a similar project with European regulators for site inspections of clinical trials.

Another constraint on international regulatory cooperation is legal restrictions on the extent to which U.S. agencies can share data with their international counterparts. Although agencies are subject to different restrictions, it is common for agencies to receive trade secret and confidential business information in the course of their regulatory activities, for which there are restrictions on disclosure. Before sharing information with foreign counterparts, agencies must consider whether they can do so consistent with law and regulation. While protection of trade secrets is important so that agencies can receive accurate information from regulated industries, regulated industries frequently submit the same data to foreign regulators, and foreign regulators have their own legal restrictions on how they may disclose trade secret information that they receive.

VI. Recommendations

A. Analysis of the 1991 ACUS Recommendation

Based on the research and analysis presented above, this section reviews the 1991 recommendation (printed in italics) to assess which portions remain relevant and can be restated and which should be modified.

⁷⁰ EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, October 15, 2008, available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_october_2008.pdf.

International Regulatory Cooperation

1. Each agency should inform itself of the existence of foreign (including regional and international) regulatory bodies [FN1] whose activities may relate to the mission of that agency.

[FN1] Throughout this recommendation, the term "foreign regulatory bodies" includes, where appropriate, also regional and international regulatory bodies.

As discussed in the introduction, the past 20 years have seen the development of multiple new and varied institutions for regulatory cooperation, and every U.S. regulatory agency reviewed has established an active international affairs office. However, this paragraph remains relevant and can be restated in a new recommendation.

2. Each agency should determine whether and to what extent regulatory cooperation with one or more foreign regulatory bodies is appropriate. Desirable forms of cooperation may include the simple exchange of information, coordination of regulatory objectives, consultation in advance of rulemaking, and reciprocal participation in rulemaking processes. Apart from general considerations of cost and staffing, factors to be considered in deciding the importance and intensity of the cooperative effort to be made, the forms of cooperation to adopt, and the geographic range of foreign regulatory bodies with which to cooperate, include:

- a. The extent to which the participating regulatory agencies share common regulatory objectives;*
- b. The importance of commonality, and therefore international harmonization, [FN2] in the development of regulatory policy in the particular field;*

[FN2] Harmonization does not necessarily imply regulatory uniformity. It implies a reduction in the differences (including but not limited to inconsistencies) among the regulatory standards of different jurisdictions.

- c. The extent to which the capabilities of foreign regulatory bodies justify the agency's reliance on their technical, regulatory and administrative resources;*
- d. The opportunities that international regulatory cooperation presents for improvement in the enforcement and administration of the agency's program (as, for example, through mutual recognition of tests, inspections and certifications or through mutual assistance in information gathering and other forms of assistance);*
- e. The presence of existing bilateral or multilateral international frameworks for addressing common regulatory concerns;*
- f. The receptivity of a given foreign regulatory body to meaningful participation by American regulatory and private interests in its policymaking processes; and*
- g. In appropriate consultation with the Department of State, the foreign policy of the United States.*

International Regulatory Cooperation

This paragraph addresses how agencies should determine whether and to what extent they engage with foreign counterparts, and factors to be considered. Although in 1991 there may have been some agencies for which engagement with international affairs was not necessary, in today's interconnected world, the Conference might consider restating this paragraph in stronger terms – that agencies should engage with foreign counterparts, not just that they should consider whether to do so.

The factors to be weighed in determining the extent of cooperation cover a range of topics, and might be most usefully considered separately. Subparts c and d address mutual recognition and reliance on other agencies, which was a point of emphasis for officials interviewed for this report, and can form the basis for a separate paragraph in the new recommendation. Similarly, subpart g addresses an aspect of how an agency's international cooperation might fit in with the larger agenda of the U.S. government, which is a critical issue discussed above, and can form the basis for a separate paragraph.

3. Even when an agency concludes that the factors set out in paragraph 2 do not counsel substantial regulatory cooperation with foreign governments, it should nevertheless explore the possibilities of international cooperation in enforcement, including mutual assistance in information gathering and, where appropriate, reliance upon foreign tests, inspections, and certifications.

The 1991 recommendation draws a distinction between international cooperation in developing regulations and cooperation in enforcement, and addresses itself only to the former. Although there may be formal distinctions between the two, this study found that most agencies with international programs are engaged in cooperation in both regulations and enforcement. Some of the issues identified, such as the need for reliable mechanisms to share common data, apply equally to cooperation in both regulation and enforcement. The new ACUS recommendation on international regulatory cooperation could expand the focus beyond development of regulations and identify principles that apply both to development of regulations and enforcement practices, as relationships between agencies and their foreign counterparts produce a continuum of cooperation that crosses both areas.

4. When an agency concludes that it has a pronounced interest in cooperation with foreign regulatory bodies, it should consider adopting various modes of cooperation with those agencies, including:

a. The establishment of common regulatory agendas;

b. The systematic exchange of information about present and proposed foreign regulation;

c. Concerted efforts to reduce differences between the agency's rules and those adopted by foreign government regulators where those differences are not justified;

d. The creation of joint technical or working groups to conduct joint research and development and to identify common solutions to regulatory problems (for example, through parallel notices of proposed rulemaking);

International Regulatory Cooperation

e. The establishment of joint administrative teams to draft common procedures and enforcement policies;

f. The mutual recognition of foreign agency tests, inspections and certifications, to the extent that the American agency is satisfied that foreign regulatory bodies have sufficient expertise and employ comparable standards; and

g. The holding of periodic bilateral or multilateral meetings to assess the effectiveness of past cooperative efforts and to chart future ones.

The description of potential methods of collaboration between agencies and their foreign counterparts from the 1991 recommendation remains relevant today; the listed range of techniques that agencies may use in pursuing regulatory cooperation are consistent with the types of activities that agencies interviewed for this report have employed. Subpart f, recommending mutual recognition of foreign agency tests, is worthy of added emphasis, since several officials recommended worksharing with foreign agencies as having potential for expanding capacity while reducing costs. This potential for cost savings is important in the current budget climate and might be addressed more prominently as a separate paragraph.

5. a. When engaging in international regulatory cooperation, an agency should ensure that it does so in a manner consistent with national statutes and international engagements.

b. An agency engaging in international regulatory cooperation should also be alert to the possibility that foreign regulatory bodies may have different regulatory objectives, particularly where a government-owned or controlled enterprise is involved.

This section of the 1991 recommendation briefly touches on some of the most significant issues identified in this report – how U.S. agencies balance consideration of regulatory alignment against their statutory missions and U.S. treaty obligations, and the implications of cooperation for business and trade interests. These issues should receive more thorough consideration in any new recommendation, as discussed above and proposed below.

6. To promote acceptance of and compliance with the measures that result from its cooperation with foreign regulatory bodies, an agency should enlist the support and participation of other affected agencies, regulated interests, public interest groups, and other affected domestic interests, as follows:

a. Where appropriate, agencies should, so far as considerations of time and international relations permit, afford affected private and public interests timely notice of any formal system of collaboration with foreign regulatory bodies that exists and an opportunity where reasonable to participate and comment on decisionmaking under such system.

b. The agency should, where appropriate, also encourage the establishment of working relations between domestic interests and their foreign counterparts, including manufacturers, other trade and industry interests, and consumer and other public interest groups.

c. The agency should assemble an interagency advisory group, consisting of the Department of State and other affected agencies such as the Departments of Commerce and Defense and the U.S. Trade Representative's Office, if one does not exist. Each member agency of an advisory group should, without prejudice to its independent decisionmaking, both inform that group about the nature and extent of its concerted activities with foreign regulatory bodies relevant to the purposes of the group and seek that group's advice. In addition, the Chairman of the Administrative Conference should convene a meeting of the heads of interested agencies to discuss the need for establishing a permanent, government-wide mechanism for organizing, promoting, and monitoring international regulatory cooperation on the part of American agencies.

This part of the 1991 recommendation, on outreach by U.S. regulatory agencies, deals with three different aspects of outreach that may better be considered separately. Subpart a, providing for public notice of proposed regulatory cooperation, can be restated and possibly emphasized and expanded. Improved information technology and treaty obligations have greatly increased transparency, and there is a consensus among stakeholders interviewed for this report that transparency is essential to effective international regulatory cooperation. Subpart b, suggesting that federal agencies encourage connections between U.S. and foreign interest groups, might be abandoned. The rise of the Internet has reduced barriers to communication between U.S. and overseas groups, such that the encouragement of U.S. agencies to form such connections does not appear to be necessary.⁷¹ In preparing this report, I did not encounter any information suggesting that absence of links between U.S. and foreign interest groups was a problem. Subpart c, addressing how U.S. agencies coordinate interests within the United States government, is a major issue identified in this report. The specific solutions recommended in this subpart do not seem to have been implemented. Although agencies participate to varying degrees in interagency working groups, the interagency advisory groups within each U.S. regulatory agency contemplated by this recommendation do not exist in any formal or consistent way. And while access to records from 20 years ago is incomplete, I have not found any record that the meeting to discuss establishing a permanent, government-wide mechanism for organizing U.S. international regulatory cooperation ever took place. The results of the current study suggest that the need and desire for such a coordinating mechanism remains. A new ACUS recommendation should address the need for better mechanisms for coordination within the U.S. government, and I present options for the form that mechanism should take in the proposed recommendation below.

⁷¹ Indeed, there may be some agencies, such as the Nuclear Regulatory Commission, for whom an express promotion of communication between the US and foreign industries might be construed as a violation of its statutory charter. When Congress abolished the Atomic Energy Commission (AEC) and created the NRC in 1975, it assigned to the NRC the AEC's regulatory responsibilities, and it assigned to the Energy Research and Development Administration (now part of the DOE) the AEC's responsibilities involving industry promotion. See 42 U.S.C. §§ 5814(a), (c), 5841(a), (f).

International Regulatory Cooperation

7. Agencies should, consistent with their statutory mandate and the public interest, give sympathetic consideration to petitions by private and public interest groups for proposed rulemaking that contemplate the reduction of differences between agency rules and the rules adopted by foreign government regulators, where those differences are not justified.

This paragraph, stating that agencies should consider petitions to eliminate unnecessary divergences between their regulations and foreign regulations, can be restated in the parts of the new recommendation addressing transparency and participation.

8. a. Once an agency has a program of international regulatory cooperation with a foreign regulatory body, it should routinely advise that body before initiating proposed rulemaking, and should seek to engage that body's participation in the rulemaking process.

b. Conversely, the agency should see to it that it is informed of initiatives by those foreign regulatory bodies and ensure that its views are considered by those bodies early in the conduct of their rulemaking procedures.

c. Where, following joint rule development efforts, an agency ultimately proposes a rule that differs from the rule proposed by the foreign counterpart, it should specify the difference in its notice of proposed rulemaking and request that it be specified in any corresponding foreign notice.

This paragraph, that agencies with cooperative relationships should provide notice of and comment in each others' proceedings, has been implemented through the Notify U.S. system, required by the WTO under the Technical Barriers to Trade agreement and administered by NIST.

9. An agency should adopt reasonable measures to facilitate communication of views by foreign regulatory bodies on proposed rules.

This paragraph has also been implemented through the Notify U.S. system, required by the WTO under the Technical Barriers to Trade agreement and administered by NIST.

10. While international consultations of the sort described in this recommendation do not appear to necessitate any radical departure from an agency's ordinary practices in compliance with applicable procedural statutes, [FN3] an agency engaged in such consultations should make reasonable efforts to ensure that affected interests are aware of them. For example, when an agency substantially relies on those consultations in its rulemaking (or where foreign government rules, practices or views have otherwise substantially influenced the agency's proposals), it should describe both the fact and the substance of those consultations in its notices of proposed rulemaking, rulemaking records and statements of basis and purpose under the Administrative Procedure Act. Where the objective of harmonizing American and foreign agency rules has had a significant influence on the shape of the rule, that fact also should be acknowledged.

[FN3] See, e.g., Federal Communications Commission v. ITT World Communications, Inc., 466 U.S. 463 (1984) (international consultative processes leading to informal policy understandings are not covered by

Government in the Sunshine Act); *Public Citizen v. United States Department of Justice*, 109 S. Ct. 2558 (1989); *Food Chemical News v. Young*, 900 F. 2d 328 (D.C. Cir. 1990); *Center for Auto Safety v. Federal Highway Administration*, No. C.A. 89-1045 (D.D.C. Oct. 12, 1990) (groups not formed by the Executive Branch are not "utilized" committees within the meaning of FACA).

This paragraph, that agencies publically acknowledge when international regulatory coordination has played a role in its process, comports with the accepted practice and OMB guidance. It can be restated in the context of new recommendations regarding transparency and participation.

11. An agency that engages in systematic exchanges of information and consultation with foreign regulatory bodies should seek to ensure that domestic interests do not suffer competitive disadvantage from the release of valuable information by those bodies to foreign private interests. This may require that the agency seek to reach agreement with its foreign counterparts concerning the conditions under which information will be disclosed.

This paragraph addresses the handling of confidential information exchanges, which stakeholders interviewed for this study identified as a major complication in international regulatory cooperation. It can be updated and restated in the new recommendation.

12. While harmonization of standards with foreign regulatory bodies may be a legitimate objective of any agency whose activities affect transnational interests or transactions (and therefore may appropriately influence the rulemaking outcome), it should be pursued within the overall framework of the agency's statutory mandate and with due regard for the interests that Congress intended the agency to promote. Accordingly, agencies should ensure that any accord informally reached through international regulatory cooperation is genuinely subject to reexamination and reconsideration in the course of the rulemaking process.

Whether and how agencies can pursue international regulatory cooperation within their statutory mandate is a key issue addressed by this study. As discussed in the analysis section above, the legal considerations for agencies in reconciling regulatory convergence with their statutory, domestic responsibilities can vary by agency, depending on authorizing statutes. The interests of this paragraph, that agency international cooperation should not conflict with its regulatory mission, can be incorporated in the new ACUS recommendation.

B. Proposed ACUS Recommendations

1. Each agency should inform itself of the existence of foreign (including regional and international) authorities whose activities may relate to the mission of that agency. Each agency should consider a strategy for regulatory cooperation with one or more foreign authorities, when appropriate to further the agency's regulatory mission or remove unjustified barriers to trade.

International Regulatory Cooperation

2. Agencies should review their legal authorities to cooperate with foreign authorities and international organizations under their authorizing statutes, the WTO Agreement on Technical Barriers to Trade and other relevant treaties adopted by the U.S., and OMB guidance. Agencies that determine their legal authorities do not sufficiently permit international cooperation that would benefit their regulatory mission and U.S. competitiveness should recommend appropriate amendments to OMB and Congress. Absent clear conflict with other legal authority, agencies should consider the international implications of regulatory activity, consistent with OMB guidance.
3. When an agency concludes that it has authority and interest in cooperation with foreign authorities, it should consider adopting various modes of cooperation with those authorities, including but not limited to:
 - a. The establishment of common regulatory agendas;
 - b. The exchange of information about present and proposed foreign regulation;
 - c. Concerted efforts to reduce differences between the agency's rules and those adopted by foreign government regulators where those differences are not justified;
 - d. The holding of periodic bilateral or multilateral meetings to assess the effectiveness of past cooperative efforts and to chart future ones.
 - e. Mutual recognition of tests, inspections, and certifications of foreign agencies
4. To deploy limited resources more effectively, agencies should identify foreign regulatory agencies that maintain high quality and appropriate standards; identify areas in which the tests, inspections, or certifications of U.S. agencies and such foreign agencies overlap; and, where appropriate, divide responsibility for necessary tests, inspections, and certifications and mutually recognize their results. When practicable, agencies should also create joint technical or working groups to conduct joint research and development and to identify common solutions to regulatory problems (for example, through parallel notices of proposed rulemaking) and establish joint administrative teams to draft common procedures and enforcement policies. U.S. agencies should document cost savings and regulatory benefits from such mutual arrangements.
5. To accurately assess whether foreign authorities maintain high quality and appropriate standards, U.S. agencies should develop and maintain relationships with foreign counterparts by methods such as providing training and technical assistance to foreign agencies and developing employee exchange programs, as resources permit. U.S. agencies should also consider whether foreign or international practices represent best practices that should be considered for adoption in the U.S.

International Regulatory Cooperation

6. U.S. agencies should engage in exchanges of information with their foreign counterparts to promote better data-driven decisionmaking. Types of information exchanges may include formal agreements to share data or informal dialogues among agency staff. To facilitate cooperation, information exchange should be mutually beneficial and reciprocal, to the extent practicable. Prior to exchanging information, agencies must reach arrangements with foreign counterparts that will protect sensitive information such as confidential information or trade secrets.
7. U.S. agency interactions with their foreign counterparts should be transparent, subject to appropriate exceptions to protect law enforcement, trade secrets, or similar sensitive information. When engaging in regulatory dialogues with foreign counterparts, U.S. agencies should seek input and participation from interested parties as appropriate, through either formal means such as Federal Register notices and requests for comments or informal means such as outreach to regulated industries, consumers, and other stakeholders. Agencies should, consistent with their statutory mandate and the public interest, consider petitions by private and public interest groups for proposed rulemaking that contemplate the reduction of differences between agency rules and the rules adopted by foreign government regulators, where those differences are not justified.
8. Agencies should promote to their overseas counterparts and to other standards-setting bodies the principles of transparency, openness and participation, evidence-based and risk-based regulation, cost-benefit analysis, consensus-based decisionmaking, and impartiality that undergird the U.S. administrative and regulatory process.
9. When engaging with foreign authorities, U.S. agencies should consult with other U.S. government agencies with interests that may be affected by the engagement, including but not limited to OIRA, USTR, Commerce, State, and Defense. In particular, agencies should adhere to the requirements of 22 C.F.R. § 181.4, requiring agencies to consult with OIRA before entering into international agreements that require significant regulatory action, and 19 U.S.C. § 2541, giving the U.S. Trade Representative responsibility for establishing mutual arrangements for standards-related activities. An agency engaging in international regulatory cooperation should also be alert to the possibility that foreign regulatory bodies may have different regulatory objectives, particularly where a government-owned or controlled enterprise is involved.
10. To provide high-level, government-wide leadership on international regulatory issues, the Executive Office of the President should create a permanent, high-level interagency working group of agency heads and other senior officials. The Chairman of the Administrative Conference should convene a meeting of the heads of interested agencies to consider the best form of organization for such a working group, including the appropriate organization, funding, and staffing of such a mechanism; existing efforts at interagency coordination and differences among agencies with respect to existing international cooperation agreements;

and whether an Office of International Affairs should be established within the Office of Information and Regulatory Affairs.

11. While international consultations of the sort described in this recommendation do not appear to necessitate any radical departure from an agency's ordinary practices in compliance with applicable procedural statutes, an agency engaged in such consultations should make reasonable efforts to ensure that affected interests are aware of them. For example, when an agency substantially relies on those consultations in its rulemaking (or where foreign government rules, practices or views have otherwise substantially influenced the agency's proposals), it should describe both the fact and the substance of those consultations in its notices of proposed rulemaking, rulemaking records and statements of basis and purpose under the Administrative Procedure Act. Where the objective of aligning American and foreign agency rules has had a significant influence on the shape of the rule, that fact also should be acknowledged.

VII. Conclusion

This study found that U.S. agencies engage in extensive international regulatory cooperation, which is a necessary component of their regulatory missions in today's globally integrated economy. While progress has been made in reducing unnecessary barriers to cooperation between countries, the scope of the problem leaves much more work to be done. There are some systemic barriers to coordination between U.S. agencies and their foreign counterparts, and ACUS recommendations can reduce those barriers by promoting best practices in mutual reliance, information sharing, and coordination within the U.S. government.

Appendix

Individual Agencies' Perspectives on International Regulatory Cooperation

Consumer Product Safety Commission

The Consumer Product Safety Commission has the mission of protecting the public against unreasonable risks of injury from consumer products through education, safety standards activities, regulation, and enforcement.⁷² Due to the large number of consumer products that enter the U.S. as imports, the CPSC has actively pursued international coordination of standards and enforcement. However, CPSC emphasized that all of its international work takes place in pursuit of the mission of promoting product safety.⁷³ While alignment of standards may be beneficial from a trade perspective, the CPSC will only pursue alignment if it would increase safety, and will not support efforts toward alignment where safety is not improved.⁷⁴ In addition to the statutory mandate to improve safety, the status of the CPSC as an independent regulatory agency also affects how it approaches international issues. Unlike the European Union, where trade and regulatory agencies are integrated, many U.S. regulators have unique and sole mandates. For example, although the CPSC actively participates in meetings of coordinating bodies such as the Transatlantic Economic Council and the U.S.-EC High Level Regulatory Cooperation Forum, its staff cannot agree to undertake specific deliverables since their work may not be directed apart from an agenda voted by the Commission. Moreover, its regulatory coordination activities must be focused on improving product safety.

CPSC has had success in aligning regulations because it relies mainly on voluntary standards organizations, rather than issuing government-developed regulations. CPSC staff expressed the view that it is the responsibility of industry to work through voluntary standards organizations toward regulatory alignment, not the job of national governments to make everything magically line up. However, the CPSC is conducting an experiment with four jurisdictions – the U.S., EU, Canada, and Australia – to review standards for three products – corded window coverings, chairtop booster seats, and baby slings. The goal of the initiative is for the four agencies to review safety requirements for the three products together, reach consensus on how requirements can be improved to remove serious hazards, and then shepherd a consensus through either rulemaking or voluntary standards procedures, as each jurisdiction chooses. A fully successful outcome would include an International Standards Organization standard that closely reflects that consensus approach taken in each of the four jurisdictions.

⁷² U.S. Consumer Product Safety Commission, 2011-2016 Strategic Plan.

⁷³ Interview with CPSC staff, July 18, 2011; see also CPSC Office of International Programs and Intergovernmental Affairs, Toy Safety Regulatory and Standards Coordination and Alignment: A Roadmap, April 25, 2011.

⁷⁴ CPSC Office of International Programs and Intergovernmental Affairs, Toy Safety Regulatory and Standards Coordination and Alignment: A Roadmap, April 25, 2011.

International Regulatory Cooperation

The CPSC is also a leader in the Working Party on Consumer Product Safety within the Committee on Consumer Policy at the Organization for Economic Cooperation and Development (OECD). In the Working Party, in which the CPSC serves in a vice chair role, the agency is spearheading the creation of a global web platform on which the world's product safety regulators (not just OECD members) will be able to have their product recall information displayed in a single global pool for anyone in the world to see. This is the first of a number of projects in the Working Party's work plan that will enhance international regulatory coordination. In addition to the OECD, the CPSC cooperates closely with USTR and USDOC in capacity building and regulatory coordination in APEC and it also works closely with the Organization of American States on capacity building for product safety regulators in the Western Hemisphere. The CPSC stresses that its international coordination and capacity building work must have a calculated benefit to U.S. consumers by helping to ensure the safety of consumer products manufactured abroad that may find their way into the United States.

In addition to formal cooperation programs like this, the CPSC also engages in informal collaborations with foreign counterparts – in particular, the CPSC international office proactively notifies their foreign colleagues about proposed changes to regulations, instead of solely relying on Federal Register notices. The informal relationships with European counterparts are especially strong, with multiple phone calls and emails every week. CPSC staff also have close informal working relationships with counterparts in Canada, Mexico, Australia, Japan, and Korea.

Federal Trade Commission

The Federal Trade Commission engages in international activity across its functions of antitrust enforcement, consumer protection, and privacy. The FTC's Office of International Affairs has a staff of 25. Prior to 2007, international affairs staff were spread throughout the FTC's bureaus, but are now consolidated in one office of international affairs, with a director reporting directly to the FTC Chairman. FTC staff believe that this organizational structure gives the international functions greater stature in dealing with other U.S. government agencies and with foreign counterparts.

For enforcement on consumer protection and privacy matters, the FTC has a bilateral cooperation agreement in place with Canada and Memoranda of Understanding with other countries. The U.S. SAFE WEB Act of 2006⁷⁵ gave the FTC new authorities to share information and provide investigative assistance to foreign law enforcement agencies. FTC staff stated that clear legislative authority to share information with foreign counterparts is key to their consumer protection mission, since so much of the workload in areas such as Internet fraud crosses national boundaries.

The FTC is aware of business interests and tries not to disadvantage them, but the mission of the agency is consumer protection, not promotion of business. FTC staff believe that the agency would lose credibility if it were perceived by foreign counterparts as promoting U.S. business interests. For example, when U.S. business interests had concerns about a new consumer protection regime in

⁷⁵ Pub. L. 109-455, 120 Stat. 3372 (2006).

International Regulatory Cooperation

Australia, the FTC did not intervene with their counterparts in Australia. However, the FTC did informally advise the U.S. Trade Representative and Commerce Department on the issues involved.

The FTC participates in interagency working groups within the U.S. government on issues such as privacy protection, joining with the Commerce, State, and Justice Departments. FTC staff are not concerned that participation in such working groups compromises the FTC's status as an independent regulatory agency, because such cooperation is essential to effectively carry out the mission of the agency. On some issues, like rules for transfer of consumer data, the FTC and Commerce Department are approaching the issue with different goals, but have generally been able to accommodate each others' concerns.

Like other officials interviewed, FTC staff support convergence of regulatory policy in areas such as antitrust, but believe that total harmonization should not be the goal, since the U.S. and EU have reached different policy judgments in areas such as antitrust and privacy. FTC staff believes there is room to reduce the transaction costs for business by encouraging implementation of the non-binding recommendations of the International Competition Network, which provide for streamlined merger filing obligations. They also pursue convergence of substantive merger review standards, recognizing that it is ultimately up to each national enforcer to determine how to interpret and implement its national law.⁷⁶

The FTC provides training and technical assistance to other countries in developing their regulatory policies. For example, the FTC helped Eastern European countries write their competition laws and establish their competition agencies, and, more recently, has been training officials in China and India in connection with the design and implementation of competition laws and policies. **FTC staff sees the EU also actively working to export European-style regulations to new economies as they develop, in areas such as privacy protection. Because the EU regulatory system tends to adopt formal, rigid rules – as opposed to the flexible guidelines approach of the U.S. in this area⁷⁷ – they are easier for developing countries to adopt, since these countries tend to have limited institutional capacity and a civil law tradition.**

Federal Communications Commission

The Federal Communications Commission has an International Bureau with 40 staff. The Bureau is divided into three divisions: policy, satellite, and strategic analysis and negotiations. The FCC has statutory mandates to pursue international cooperation for international communications topics including international long distance, submarine cables, and satellites. In its role regulating radio waves,

⁷⁶ See John J. Parisi, *Cooperation Among Competition Authorities in Merger Regulation*, 45 CORNELL INT'L L. J. 55, 63 (2010).

⁷⁷ See Lawrence A. Kogan, *The Extra-WTO Precautionary Principle: One European "Fashion" Export the United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L. REV. 491, 521 (2008).

International Regulatory Cooperation

the FCC must coordinate with Canada and Mexico to coordinate allocation of these resources in border regions.

The FCC works very closely with operators when they have problems overseas. For example, when a Pacific island nation cut off access to U.S. telecom companies over a payment dispute, the FCC issued a stop payment order so that the island nation would not be paid through the settlement process until the dispute was resolved. The FCC also participates in multilateral organizations such as the International Telecommunications Union which allocates spectrum globally, and the FCC represents U.S. interests, including the interests of U.S. industry.

The FCC also tries to promote good regulatory practices overseas. FCC maintains an international visitors program which hosted more than 500 visitors from overseas in 2010. FCC hosts Web forums to discuss current issues with foreign counterparts.

National Highway Traffic Safety Administration

The National Highway Traffic Safety Administration participates in international negotiations regarding regulation of auto safety and fuel economy. In doing so, NHTSA has worked to promote a science-based and data-based process in developing these standards. NHTSA has an Office of International Policy, Fuel Economy and Consumer Programs, and also has an Assistant Chief Counsel for Vehicle Rulemaking and Harmonization within the Office of Chief Counsel.

NHTSA staff have participated in development of global standards for vehicle safety, including the 1998 Agreement for Global Technical Regulations for Auto Safety and Emissions. NHTSA has developed new standards on emerging technologies such as electronic vehicle stability that have then been adopted by international bodies.

NHTSA staff emphasized that the authorizing statute makes safety the overriding priority of the agency, and there is no mention of regulatory alignment in the authorizing statute. Because failures in vehicle safety are often immediately and gruesomely visible, the priority of the agency is to ensure the highest level of safety – it is faulted for safety lapses but is given no credit for cost savings, especially overseas.

Like others interviewed, NHTSA staff see a need for some mechanism for sustained involvement of senior staff to pursue international coordination.

Securities and Exchange Commission

Given the cross-border nature of financial products and services, the Securities and Exchange Commission Office of International Affairs is engaged with foreign counterparts in both regulation and enforcement. The SEC Office of International Affairs has about 40 staff. It is divided into four areas: international enforcement assistance, international regulatory policy, comparative law and regulation, and international technical assistance.

International Regulatory Cooperation

The SEC participates in international organizations including the International Organization of Securities Commissions (IOSCO), the Financial Stability Board (FSB), the Council of Securities Regulators of the Americas (COSRA) and the Financial Action Task Force (FATF). The SEC staff also has bilateral exchanges with the European Securities Market Authority, the Japan Financial Services Agency, the China Securities Regulatory Commission, the Korea Financial Supervisory Commission, the Securities and Exchange Board of India, and the Capital Markets Board of Turkey, as well as regular discussions with the UK Financial Services Authority and the Swiss Financial Market Supervisory Authority (FINMA).

Pursuant to Section 21(a)(2) of the Exchange Act, the SEC has the statutory authority to conduct investigations on behalf of foreign securities regulators, and has reciprocal arrangements with regulators in several countries. The enforcement assistance program processes approximately 1,000 requests for assistance annually, including approximately 600 requests to foreign agencies.

The SEC plays a leadership role in the International Organization of Securities Commission, participates in the Financial Stability Board, and engages with investors, the financial services industry, and other US financial regulators in connection with its work relating to IOSCO. To provide technical expertise, the SEC Office of International Affairs also provides comparative law research on standards to assist the Commission in developing domestic standards and provides technical advice to the US Treasury Department and the United States Trade Representative in their roles as lead negotiators for free trade agreements.

SEC's Office of International Affairs also has a very active program to provide training and technical assistance to foreign regulators. It conducts formal training and exchange programs and trains more than 1,000 regulators per year.

Food and Drug Administration

The statutory regulatory focus of the Food and Drug Administration is domestic – protection and promotion of public health in the United States. However, to accomplish this mission, the FDA has a significant international operation, because of the globalization of supply chains and large quantity of imports of food, drugs, cosmetics, and medical devices. While the FDA realizes that its actions have an impact on the larger trade picture, the FDA's authorizing statute states that its regulatory decisions must be based only on safety, efficacy, and manufacturing quality – not costs, country of origin, or other factors.⁷⁸ Although the FDA has some cognizance of trade issues, they believe it is important to keep an arms'-length relationship with trade promotion agencies, such as the U.S. Trade Representative, to maintain their credibility as an independent, science-based regulatory agency with foreign counterparts.

The FDA works extensively with foreign agencies on alignment of technical and administrative standards. In particular, the FDA and foreign counterparts collaborate on scientific and administrative procedures for preclinical, clinical, and manufacturing testing of products. The goal is to develop

⁷⁸ 21 U.S.C. § 393(b)(2). See generally *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

International Regulatory Cooperation

common data sets that will be accepted by most countries, from which each country can make its own benefit-risk assessments. This may not necessarily produce the same final outcome in each jurisdiction, since how to manage benefits and risks is often a cultural decision that must take into account tolerance to various risks and how they can be managed within that jurisdiction's legal and medical framework. This approach – finding convergence on testing and data, rather than final regulatory decisions – can help eliminate unnecessary regulatory divergences, while allowing divergences that result from different judgments of national sovereignty.

The FDA believes there is great potential for cost savings and improved health and safety in mutual reliance on the data from clinical trials and manufacturing quality inspection regimes in other countries. For example, the FDA recently concluded a pilot project with European and Australian regulators to inspect manufacturing plants in China and other countries that manufacture active pharmaceutical ingredients.⁷⁹ The agencies compared their lists of plants subject to inspection and the resources that each country had available, and where two or more agencies were scheduled to visit the same plant, the agencies agreed on one agency to inspect that plant or to do a joint inspection, and reallocated resources so that they could cover more plants. Building on the success of that pilot, the FDA is now pursuing a similar project with European regulators for site inspections of clinical trials. Despite these successes, there is some hesitance in relying upon inspectional data from foreign regulators, as it is unclear where accountability would lie if there were a failure in the system. Although U.S. officials have views of which foreign country regulators are reliable, it is difficult to identify data or outcome measures to support those perceptions.

Information sharing with foreign regulators is critical to the FDA's ability to successfully accomplish its domestic mandate, and the FDA has a robust program of confidential exchanges with trusted foreign regulators. The FDA has confidentiality arrangements with approximately 50 different foreign counterpart agencies (listed on the FDA Website). For example, the FDA engaged in several thousand formal confidential exchanges with the European Medicines Agency in 2010. However, the legal requirements regarding information sharing protocols are burdensome. The FDA has regulations in place that allow it to share certain information with foreign agencies that can protect confidential information to the same extent as it is protected in the United States, although under no circumstances can the FDA share trade secrets.⁸⁰ So information exchanges are possible, but require investment of time and resources to review materials to determine what can and cannot be shared and redact materials. This can be particularly wasteful when companies are submitting the same information to the FDA and foreign regulators, but the agencies are limited in how they can exchange it.

⁷⁹ EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, October 15, 2008, *available at* http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_october_2008.pdf.

⁸⁰ 21 C.F.R. § 2089.

International Regulatory Cooperation

The FDA has extensive formal and informal exchange programs with foreign counterparts, especially the European medicine and food safety agencies. There is an employee exchange program in place between the FDA and its EU counterparts. There are permanent liaison officials from the European Medicines Agency and the European Food Safety Authority who reside full time in the FDA, and there are permanent, full time FDA liaison staff who likewise reside in the European Medicines Agency and the European Food Safety Authority. The FDA's Deputy Commissioner for International Affairs reported that he communicates with one of his foreign counterparts on a daily basis. Until 2008, the FDA did not have staff permanently stationed overseas. Since then, the FDA has received statutory authorization and funding to establish permanent posts overseas in China, Europe, India, Latin America, the Middle East, and sub-Saharan Africa.⁸¹

⁸¹ EU-US High-Level Regulatory Cooperation Forum, Report to the Transatlantic Economic Council, October 15, 2008, *available at* http://www.whitehouse.gov/sites/default/files/omb/oira/irc/hlrcf_summary_report_october_2008.pdf.