REGULATORY COOPERATION: LESSONS & OPPORTUNITIES

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FINAL REPORT

Regulatory
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TABLE OF CONTENTS

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Unnecessary regulatory differences between countries persist as lingering barriers to trade even as traditional barriers are declining.

The George Washington University Regulatory Studies Center prepared this report as part of a grant from the European Union to analyze opportunities to improve regulatory cooperation between the EU and U.S. The first chapter presents an overview of the research. The case studies in chapters three through five examine how regulatory cooperation has worked in practice between three U.S. regulatory agencies and their EU counterparts. The fifth chapter analyzes regulatory activity in the U.S. likely to have significant effects on international trade and investment. These analyses identify areas of opportunity that can help reduce incompatible approaches and unnecessary costs while indicating areas where regulatory divergences could persist due to jurisdictional judgements of national sovereignty and structural differences between countries.

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WASHINGTON, DC

1

Experiences in International Regulatory Cooperation:

Benefits, Limitations, and Best Practices[1]

Daniel R. Pérez[2] *& Susan E. Dudley*[3]

Introduction

Unnecessary regulatory differences between countries persist as lingering barriers to trade even as traditional barriers are declining.[4] A study commissioned by the Commission of the European Communities finds that reducing non-tariff barriers to trade between the European Union and the United States by 50% in 2018 could lead to a 0.7% annual increase in gross domestic product (GDP) in the EU and a 0.3% increase for the U.S. The study estimates that compared to a base case of no action, this translates to an annual potential gain of €122 billion ($158 billion) in the EU and €41 billion ($53 billion) in the U.S.[5]

According to the study, these economic gains derive from 1) consumer welfare increases due to lower prices for imported products, 2) increases in exports and production for competitive

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[4] Thomas J. Bollyky, "Better Regulation for Freer Trade," Center on Foreign Relations, Policy Innovation Memorandum No. 22, June 2012. http://www.cfr.org/trade/better-regulation-freer-trade/p28508

[5] ECORYS, "Non-Tariff Measures in EU-US Trade and Investment – An Economic Analysis" December 2009. Available at trade.ec.europa.eu/doclib/html/145613.htm

sectors, 3) lower "production costs…for companies due to more aligned regulation and lower levels of [non-tariff measures] NTMs," and 4) increased investment flows "due to more harmonised investment regimes." The study concludes that "NTMs and regulatory divergences are clearly more important and economically relevant than the remaining tariff levels."[6]

Recognizing this, the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the U.S. aims to be "an ambitious and comprehensive trade agreement that significantly expands trade and investment between the United States and the EU, increases economic growth, jobs, and international competitiveness, and addresses global issues of common concern."[7] While recognizing that Europe and the U.S. have an "immensely successful economic relationship," officials on both sides of the Atlantic hope to "do more to strengthen the contribution of trade and investment in fostering jobs, growth, and competitiveness in both economies."[8]

One of the goals of the TTIP negotiations is to agree upon:

> Cross-cutting disciplines on regulatory coherence and transparency for the development and implementation of efficient, cost-effective, and more compatible regulations for goods and services, including early consultations on significant regulations, use of impact assessments, periodic review of existing regulatory measures, and application of good regulatory practices.[9]

In 2014, under a grant from the EU, the George Washington University Regulatory Studies Center prepared a report describing and comparing regulatory procedures and policies in the EU and the U.S. and analyzing regulatory challenges and opportunities for transatlantic trade. A conference held at the George Washington University and on Capitol Hill in November 2014 explored these themes with experts and practitioners on both sides of the Atlantic.[10] This current report continues to examine opportunities to improve regulatory cooperation between the EU and U.S. It includes four sections. The first three sections are case studies examining how regulatory cooperation has worked in practice between three U.S. regulatory agencies and their EU counterparts. The authors of these case studies are former senior regulatory officials at the

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[6] Ibid.

[7] Office of the U.S. Trade Representative, "U.S. Objectives, U.S. Benefits In the Transatlantic Trade and Investment Partnership: A Detailed View" March 2014. http://www.ustr.gov/about-us/press-office/press-releases/2014/March/US-Objectives-US-Benefits-In-the-TTIP-a-Detailed-View

[8] Final Report of the EU-US High Level Working Group on Jobs and Growth, February 11, 2013. Available at http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf .

[9] Final Report of the EU-US High Level Working Group on Jobs and Growth, February 11, 2013. This objective is reiterated in the Initial EU Position Paper "Trade Cross-cutting disciplines and Institutional Provisions," July 2013. Available at http://trade.ec.europa.eu/doclib/html/151622.htm

[10] Conference agenda and remarks are available at the GW Regulatory Studies Center website: https://regulatorystudies.columbian.gwu.edu/transatlantic-regulatory-issues

Department of Transportation (DOT), the Food and Drug Administration (FDA), and the Consumer Product Safety Commission (CPSC). The fourth chapter, authored by Daniel Pérez, is an analysis of regulatory activity in the U.S., with a focus on the number of significant regulations issued each year that are likely to affect international trade and investment and U.S. agency performance in providing advanced notice of these regulations.

These agencies all regulate a range of products that are widely traded internationally, and they have each developed strategies for improving cooperation with their European regulatory counterparts. DOT and FDA are both executive branch agencies, and thus subject to oversight and guidance from the president, while the CPSC is an independent regulatory agency subject to multimember, bipartisan leadership. Their experiences and practices not only offer models for other agencies interested in enhancing regulatory cooperation but also highlight opportunities for improvement.

The Department of Transportation: Former DOT Assistant General Counsel for Regulation and Enforcement, Neil Eisner, reviews DOT's communication and cooperation with the EU. His case study primarily covers three agencies within DOT whose responsibilities appear to have the greatest impact on the EU: the Federal Aviation Administration (FAA), the National Highway Traffic Safety Administration (NHTSA), and the Pipeline and Hazardous Material Safety Administration (PHMSA). These agencies have been heavily involved in international regulatory cooperation efforts and offer "significant information about what is being done, what works well, what does not, and what problems to anticipate."

The Food and Drug Administration: Two economists and former FDA officials examine that agency's practices. Randall Lutter served as Deputy Commissioner for Policy and David Zorn as Director, Division of Social Sciences, Center for Food Safety & Applied Nutrition. Their case study reviews FDA's "track record of engaging in dialogue with both multilateral regulatory organizations and foreign regulatory agencies." They find the agency has worked with counterparts in Europe and elsewhere to share information on potential food-borne hazards, and developed a range of memoranda of understanding to facilitate cooperation. In recent years, it has opened foreign offices in countries around the world aimed at sharing information with counterpart regulatory authorities and ensuring the safety and quality of medical and food products exported to the U.S.

The Consumer Product Safety Commission: Nancy Nord, former commissioner and acting chairman of the CPSC, examines the development of the CPSC's program to communicate and collaborate with safety regulators from foreign jurisdictions over the past 12 years. She finds that, particularly for a small agency with limited resources, "it has a good track record working with its foreign counterparts to enhance consumer safety." She offers recommendations for fostering communication and collaboration to protect consumer safety given "the growing complexity of both consumer products and the global marketplace."

In addition to illustrative cooperation with direct counterparts, the cases studies also include examples of successful cooperation via multilateral organizations, such as the United Nations (UN) and the Organization for Economic Cooperation and Development (OECD).

The next sections highlight what the case studies identified as benefits of international regulatory cooperation, some limitations and barriers, and some best practices.

Potential Benefits of Regulatory Cooperation

Eisner suggests that for international regulatory cooperation to be successful, regulatory staff—who are ultimately responsible for coordinating with their counterparts—must appreciate its benefits. The case studies indicate that successful regulatory cooperation can not only benefit regulated entities and the public, but can also result in cost savings and better regulatory outcomes for agencies themselves. These case studies are particularly valuable in demonstrating these effects since, as Lutter and Zorn point out, "there is very little publicly available information to evaluate the accomplishments and outcomes associated with [agencies'] international programs." Although agencies are transparent about listing particular agreements they negotiate with foreign regulators, the FDA and DOT case studies indicate that efforts to engage in international regulatory cooperation might be broadened if agencies collected and published data that quantified the benefits gained as a result of engagements with foreign regulators.

Data Sharing

Sharing data across borders can decrease costs for data collection and product testing due to the elimination of duplicative efforts. Additionally, data from counterpart agencies can also improve regulatory outcomes since such sharing expands the information on which agency decisions are based. Thus, it is not surprising that each of the case studies highlights the importance of sharing information for regulatory cooperation.

The CPSC has worked with its counterparts in other jurisdictions to identify potentially hazardous toys and even worked with Canada and Mexico to issue joint recalls of unsafe products. Nord illustrates how early efforts at data sharing can serve to provide advanced consultation prior to international meetings between regulators to improve the outcomes of these forums. The CPSC, for example, forms "joint project teams" which serve as an early point of contact for information sharing between regulators prior to their meetings during the North American Safety Summits.

Early sharing of data also helps agencies identify opportunities for recognizing foreign regulators' existing approaches to oversight and inspection of products that are likely to be imported into their countries—often eliminating the need to redundantly inspect products at

home and abroad or providing timely information regarding public health risks. For example, the FDA and the European Safety Authority shared data in 2007 that led to the successful identification of a contaminant in animal food products that was causing the deaths of animals. The data also helped the FDA develop a test for the contaminant and share it with the EU and other trade partners—increasing the effectiveness of monitoring regimes internationally.

Compliance and Enforcement

Regulatory agencies and the public stand to benefit from cooperative efforts to bridge disparate approaches to regulatory compliance and enforcement. Reducing the number of different compliance regimes under which companies operate can not only lower costs for businesses but also provide substantial benefits for the public. Better cooperation in this area also helps agencies and their foreign counterparts coordinate their efforts to engage companies in issuing joint product recalls across jurisdictions. Nord details CPSC's engagement with counterpart product safety agencies, first with Canada, and then with both Mexico and Canada via the North America Consumer Product Safety Summit in 2011. These cooperative efforts help agencies coordinate joint product recalls, increase market surveillance, expand consumer awareness, and provide training and outreach to agency staff across agencies.

U.S. and the EU regulatory agencies have also worked successfully to expand compliance and enforcement in aviation. In 2008, both countries signed the Agreement between the United States and the European Union on Cooperation in the Regulation of Civil Aviation Safety. Eisner describes the various benefits of the agreement's "broad scope" including the "reciprocal acceptance of approvals and findings of compliance with agreed upon standards …and assistance in any investigation or enforcement proceeding of any alleged violation of any laws."

Working with third countries

The CPSC experience shows that cooperation between the U.S. and EU can also help improve relationships with third countries. Starting in 2008 and continuing thereafter, the CPSC and representatives from the European Commission conducted a series of safety seminars in China to educate Chinese product manufacturers about EU and U.S. safety requirements for clothing, toys and electrical products.

Limits and Barriers to Regulatory Cooperation

The case studies also illustrate several areas that may constrain the ability of U.S. agencies to engage successfully in regulatory cooperation. These include:

- Limits on regulators' ability to keep business trade secrets confidential as part of the process of data sharing;

- Important differences in the exercise of political control over U.S. executive and independent regulatory agencies;
- The need for more effective performance in notifying trade partners and the public, in advance, of upcoming regulations likely to have significant effects on international trade and investment.

The scope of cooperation might also be limited by issues of risk management and political accountability. U.S. agencies, for example, might indeed cut costs by relying on inspections conducted by foreign counterparts, but may see this cost savings as a tradeoff because they will be held politically accountable by the public in the event of a domestic incident such as the presence of unsafe chemicals or pathogens in consumer products. Additionally, many aspects of international regulatory cooperation require up-front investments for which agencies might not get a return until sometime in the future.

Policy Limitations May Constrain U.S. Agencies

Lutter and Zorn point out that the FDA currently has policy limitations preventing it from expanding its use of mutual recognition agreements with foreign counterparts. The FDA is currently unable to recognize the EU food safety system as "comparable" due to an FDA policy determination that doing so requires recognition that a foreign government's *entire* domestic and export food safety system for *all* FDA regulated food products be comparable. The case study indicates that differing approaches between the EU and the U.S. regarding their respective regulations covering cheese from unpasteurized milk, for instance, act as a barrier to realizing the benefits of declaring mutual recognition for other products for which regulatory approaches are similar.

EU Member State Structure

U.S. regulatory agencies often perceive that there is a limit to the success they can expect to achieve via efforts to engage their EU counterparts due to structural differences between the U.S. and EU Member State system. Although our case studies illustrate many examples of U.S. and EU agencies successfully working together, there are instances where cooperation requires greater effort—particularly where agencies have to coordinate with different jurisdictions within the EU.

For example, Nord points out that the CPSC finds it more difficult to coordinate an EU-wide product recall than to issue a joint recall with Mexico and Canada. Although EU market surveillance currently requires Member States to inform each other of a recall issued within any jurisdiction, there is no mechanism that forces other states to follow suit (triggering an EU-wide recall.) Additionally, CPSC regulators might be concerned about the likelihood that confidential business information can be kept private. Although CPSC statutes do allow it to negotiate agreements to share confidential business information with foreign counterparts, EU countries

have not entered into such agreements since they depend on an assurance of confidentiality that would include a commitment to withhold information from parliamentary or judicial inquiry.

Best Practices

Despite these constraints, the case studies demonstrate that U.S. and EU agencies have successfully worked together bilaterally and multilaterally, and have a record of successes and "lessons learned" that can be applied to future efforts to improve international regulatory cooperation.

Agencies Should Be Shown the Value

Instead of merely exercising top-down political direction to cooperate with counterparts internationally, agencies should be shown the value—both in monetary terms and in the increased efficacy of regulatory outcomes— that can be gained via efforts to bridge incompatible regulatory approaches. To this end, better quantitative data collection and analysis could help overcome political barriers and demonstrate that efforts at international regulatory engagement do not constitute a "race to the bottom" in regulatory outcomes.

Eisner states that NHTSA successfully worked with both Japan and the EU through its 1998 Global Agreement in part because the regulatory agencies involved experienced the benefits to be gained by international regulatory cooperation through repeated interactions. Previous efforts working with foreign counterparts prior to rulemaking with the intention of avoiding divergent and less effective outcomes allowed DOT to internalize the value of international regulatory cooperation as a tool that can lead to harmonized standards and increases in consumer protections relative to unilateral action.

Leadership at the Agency Level

Many of the successes in these case studies detail initiatives launched by heads of agencies with the proactive intention to engage with foreign counterparts by: creating forums for regulators to meet and exchange ideas and concerns, establishing international offices for better coordination with trade partners, participating in foreign exchanges of executives and other personnel, leveraging technology to maintain regular communication between agencies, and working with counterparts to provide capacity building and training in regulatory compliance for foreign exporters—particularly for developing countries. The CPSC, for instance, changed its model from employing a "single staff member who ostensibly had responsibility for international activities" to establishing its Office of International Programs and Intergovernmental Affairs (IPIA) under the leadership of Chairman Hal Stratton. This change, enacted in 2004, shifted CPSC's approach to international cooperation from *ad hoc* and understaffed towards a more comprehensive and coordinated plan.

Memoranda of Understanding

Memoranda of Understanding (MOU) have proven valuable, in part, because they provide an agreed-upon structure for specific interactions between regulators. Their absence does not preclude the ability for regulators to engage in international cooperation, but the case studies detail instances where their use has facilitated dialogue and improved outcomes.

The Lutter-Zorn case study demonstrates both of these points. The FDA negotiated an MOU with the European Commission's Health and Consumer Protection Directorate General in 2005. This agreement affords protection of confidential commercial information shared with the EU at the same level afforded to U.S. companies submitting information to the FDA. However, the FDA has also successfully engaged in international regulatory cooperation without an MOU. The FDA participates in the Codex Alimentarius Commission (CODEX), the International Conference on Harmonization of Pharmaceutical Regulation (ICH), and the International Medical Device Regulators Forum (IMDRD)—none of which is the result of an MOU. Although the FDA is not bound to accept the results of any particular meeting, it seriously considers the results during its rulemaking processes.

International regulatory cooperation between the U.S. and the EU also has the added benefit of expanding the number of countries considering entering into a MOU. The CPSC signed an MOU with its Chinese counterpart agency, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) which led to a U.S./China Safety Summit in 2005. Nord observes that "the CPSC's very visible engagement with the EC [European Commission] in the safety arena could not help but be noticed in Beijing, since the U.S. and the EU were China's two biggest markets" and, hence, arguably, provided incentive for the Chinese to enter into the agreement with the U.S.

Mutual Recognition

Though often harder to achieve, mutual recognition agreements (MRA) can allow domestic regulatory agencies to save considerable time and resources by recognizing a foreign counterpart's methods as equivalent. This can reduce the amount of testing, certification, inspections, etc. that agencies need to engage in to allow goods to be traded between countries.

Nord is concerned that the CPSC has been reluctant to mutually recognize other jurisdictions' standards, which she thinks is unfortunate because "it could be an effective way to assure consumer safety while still promoting free flow of safe goods between jurisdictions." Eisner's research suggests that differing data requirements can hinder willingness to recognize each other's standards, although he notes that PHMSA may approve an application from a foreign-based company to perform cylinder inspections and verifications based on an approval by a competent authority of the country where the cylinder is manufactured. Lutter and Zorn point to

an agreement between the U.S. and UK on medical devices that ensures the countries "will exchange such information as is necessary for the mutual recognition of inspections related to medical devices manufactured in one country and intended for import into the other."

Jointly Developed Actions

The shared border between the U.S. and Canada provides incentives for mutual recognition and collaborative approaches to railroad and pipeline regulation. Eisner describes how U.S. and Canadian officials are jointly analyzing, inspecting, and sharing accident and enforcement data on cross-border pipeline operations. U.S. and Canadian regulators recently issued harmonized rules addressing hazardous material and rail safety. The CPSC has worked jointly with other jurisdictions to recall unsafe products.

Third Parties can Facilitate Multilateral Dialogue

Certain agencies find that multilateral organizations, such as the OECD, can serve as helpful intermediaries to facilitate the negotiation of "confidence building" measures and bring together international regulators. This may also provide cost-savings if agencies can participate in these international events rather than bearing the costs associated with hosting bilateral discussions.

The Organisation for Economic Cooperation and Development (OECD), the World Health Organization (WHO) and the United Nations (UN) have successfully served as forums for multilateral regulatory cooperation. As early as 1963, the Food and Agricultural Organization of the United Nations and the WHO jointly established the CODEX to develop harmonized international food standards. Lutter and Zorn estimate that over 300 standards, guidelines, and codes of practice have been developed to date. The FDA and the EU Directorate for Health and Food Safety are major participants in CODEX, FDA considers CODEX standards when they consider issuing regulations, and both agencies successfully employ the results to ensure they are complying with their World Trade Organization (WTO) obligations while safeguarding the health of their respective citizens.

Advanced Notice

Providing advanced notice of upcoming regulations likely to affect international trade and investment expands public participation in rulemaking and allows stakeholders to be aware of upcoming rules that might affect them. In addition to its potential to improve regulatory outcomes, effective tracking of these regulations helps identify opportunities for significant gains via regulator-to-regulator cooperation at relatively small cost.

Pérez tracks the number of rules that U.S. regulatory agencies issue each year that have a significant effect on international trade. He also identifies areas of opportunity for the U.S. to improve its current system of notifying trade partners and the public of regulations currently

under consideration by agencies. The earlier that the pubic, businesses, and trade partners are made aware of upcoming rules that might affect them, the more time they all have to participate in efforts to avoid unnecessary differences in standards, provide public comment to improve the outcomes of rulemaking, and—ultimately—avoid incompatible, costly, and less effective regulatory regimes between countries.

Foreign Offices and Foreign Exchange Programs

Regulatory agencies have also found it beneficial to exchange executives and technical staff between countries in addition to establishing foreign offices to better coordinate with trade partners. The case studies highlight instances where agencies have engaged in these foreign exchanges, which often facilitate other forms of international regulatory cooperation.

Lutter and Zorn detail FDA's 2011 announcement of a new effort to improve cooperation by setting up international offices and posts. "It has since opened several overseas offices, including one in Brussels, substantially increasing its international program." The activities of this office include work to negotiate MOUs, efforts to facilitate the Transatlantic Economic Cooperation (TEC) high level regulatory forum, and work to expand the effectiveness of confidentiality commitments. In addition to its foreign offices, the FDA also places many of its senior technical experts in counterpart agencies across the EU such as the European Medicines Agency (EMA) in London, UK, and the European Safety Authority (EFSA) in Parma, Italy. Technical experts from these agencies are also currently housed within the FDA.

The CPSC also established a foreign exchange program in 2012 "that hosted safety executives from Health Canada and the Australian Consumer Commission at CPSC headquarters for a 3 month period… as budgets and staffing resources were available." CPSC staff has also been hosted by foreign jurisdictions.

Conclusion

Increasingly complex trade patterns and higher levels of global market integration make successful international regulatory cooperation necessary to avoid technical barriers to trade and increase the effectiveness of regulatory outcomes. This research illustrates instances of successful international regulatory cooperation while identifying several limits and barriers that may cause regulatory divergences to persist.

These case studies in U.S.-EU regulatory cooperation highlight many of the tools and methods that U.S. agencies and their EU counterparts have employed in the last decade to reduce unnecessary regulatory differences. DOT, FDA and the CPSC have successfully collaborated with foreign partners to coordinate research and data gathering and sharing, establish an international presence via international offices or exchanges of executives and other staff

between counterpart agencies, create forums to increase dialogue regarding the harmonization of standards, provide advanced notice of upcoming regulations likely to affect international trade and investment, and coordinate enforcement of regulations across jurisdictions.

The four analyses also identify areas of opportunity (including convergence on testing and standards, expanded sharing of data, expanded participation through advance notice of rules, consideration of unnecessary differences when retrospectively evaluating domestic regulation, etc.) that can help reduce incompatible regulatory approaches and unnecessary costs. They also show where regulatory divergences are likely to remain due to jurisdictional judgments of national sovereignty and structural differences between countries.

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Facilitating Earlier Information Sharing and Cooperation Between the U.S. Department of Transportation and the EU

Neil Eisner[1]

The Department of Transportation consists of nine operating administrations and the Office of the Secretary (OST), each of which has statutory responsibility for a wide range of regulations. DOT regulates safety in the aviation, motor carrier, railroad, motor vehicle, commercial space, public transportation, and pipeline transportation areas. DOT also regulates aviation consumer and economic issues and provides financial assistance for programs involving highways, airports, public transportation, the maritime industry, railroads, and motor vehicle safety. In addition, the Department issues regulations to carry out a variety of statutes ranging from the Americans With Disabilities Act to the Uniform Time Act. Finally, DOT develops and implements a wide range of regulations that govern internal DOT programs such as acquisitions and grants, access for the disabled, environmental protection, energy conservation, information technology, occupational safety and health, property asset management, seismic safety, and the use of aircraft and vehicles.

One of the reasons DOT was created was to bring the various operating administrations together under one Department to allow better coordination of the interrelated responsibilities. For example, the Federal Aviation Administration and the National Highway Traffic Safety Administration coordinate on the development of rules for child safety seats so that the seats used in cars can also be used in aircraft; and all of the operating administrations regulating safety-sensitive employees coordinated on the development of drug and alcohol rules to share data, cover the same types of employees, and use the same testing procedures.

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OST's and DOT Operating Administrations' Substantive Regulatory Responsibilities

- Federal Aviation Administration (FAA)
  - Aviation safety and operations
  - Certification of airmen, aircraft, and airports
  - Commercial space transportation
  - Airport and airway fees and charges
  - Foreign air carriers operating in the U.S. and U.S.-owned aircraft outside the U.S.
- Federal Highway Administration (FHWA)
  - Highways and roads
- Federal Motor Carrier Safety Administration (FMCSA)
  - Motor carrier safety, operations, and equipment
  - Bus safety
  - Commercial drivers' licenses
  - Hours of service
- Federal Railroad Administration (FRA)
  - Railroad equipment, operations, and workplace safety
  - Engineer qualifications and certification
- Federal Transit Administration (FTA)
  - Mass transit safety
- Maritime Administration (MARAD)
  - Cargo preference
- National Highway Traffic Safety Administration (NHTSA)
  - Motor vehicle safety and fuel economy
  - Highway safety programs
  - Consumer information
- Pipeline and Hazardous Material Safety Administration (PHMSA)
  - Hazardous materials
  - Pipeline safety
- Saint Lawrence Seaway Development Corporation (SLSDC)
  - Tolls
  - Seaway operations
- Office of the Secretary (OST)
  - Transportation of Americans with disabilities
  - Aviation consumer protection and civil rights
  - Aviation passenger manifests

Coverage of this Paper

This paper primarily covers FAA, NHTSA, and PHMSA hazardous materials responsibilities. Their responsibilities appear to have the greatest impact on the EU. They are also agencies that

have been heavily involved in international regulatory cooperation efforts with other countries, particularly the EU, and international organizations. As a result, one can gain significant information about what is being done, what works well, what does not, and what problems to anticipate. This, in turn, will help identify policy recommendations. The paper also offers some excellent examples of international regulatory cooperation by other DOT agencies that help provide insight and support for the recommendations.

DOT and the Regulatory Process

Authority to Act

In the U.S. federal government, executive branch agencies can only act when they are given authority to do so by the Constitution or the Congress through a statute. The statutes can range from requiring specific action (e.g., require air bags in all motor vehicles) to providing very broad discretion (e.g., establish minimum standards for motor vehicle safety).

The Administrative Procedure Act

The basic statute governing the rulemaking process in the U.S. is the Administrative Procedure Act (APA).[2] The APA requires that decisions be made through informal or formal rulemaking or informal or formal adjudicatory orders. The authorizing statute may provide the agency discretion to choose the approach or mandate a particular process.

Generally, DOT and other U.S. agencies use informal rulemaking to adopt standards. This process requires the agency to issue a notice of proposed rulemaking (NPRM) that explains the need and authority for the rule and the subjects and issues involved and asks for public comment. (This process is often simply referred to as the "notice-and-comment" process.) The APA does not require a public hearing, but agencies have the discretion to hold them. After the comment period closes, the agency may adopt a final rule, which must respond to public comment and provide a statement of basis and purpose for the rule. There are some exceptions or exemptions from these requirements (e.g., if there is "good cause" the agency can issue a final rule without following the "notice-and-comment" process).

Other Rulemaking Processes

DOT and other agencies may also be subject to statutes that impose "hybrid rulemaking" standards; i.e., additional or different standards required in particular situations. For example, they may require that the agency hold a public hearing on a rulemaking proposal if one person requests it or they may require that the agency issue an interim final rule (IFR) to address a particular matter and ask for comment on the IFR rather than a proposed rule. In addition, DOT and other agencies also generally have the discretion to take extra steps when they think they

[2] 5 U. S. C. §§ 551 – 559 and §§ 701- 706.

would be helpful. For example, they may issue an advance notice of proposed rulemaking (ANPRM) before an NPRM to help gather data or to get suggestions for alternatives to address a problem.

Additional Procedural Requirements =

DOT and other agencies are also subject to numerous statutes and executive orders primarily requiring multiple analytical requirements and directing the consideration of specific effects on their rulemakings. For example, agencies must assess the costs and benefits of their rules and must submit significant rulemakings to the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) for interagency review.[3] They must also consider the effects of those rules on small businesses.[4]

Of particular importance to the EU and other countries are statutes and an executive order imposing: (1) a prohibition on setting standards that create "unnecessary obstacles to the foreign commerce" of the U.S.; a requirement to use performance standards, where appropriate; and a requirement to consider international standards and, where appropriate, use them as the basis for U.S. standards;[5] (2) a requirement to "use technical standards that are developed or adopted by voluntary consensus standards bodies" unless they are "inconsistent with applicable law or otherwise impractical;"[6] (3) requirements to encourage and support international regulatory cooperation and to consider reforming existing significant rules to address "unnecessary differences in regulatory requirements between the United States and its major trading partners."[7]

Types of Rules

There are four types of rules that are issued under the APA. It is important to understand the difference in their effects.

Legislative/substantive rules

These may only be issued following the notice-and-comment procedures, unless they meet one of the exceptions. They impose binding requirements on those to whom they apply; they have the same force and effect of a statute.

[3] Executive Order (EO) 12866 (Regulatory Planning and Review).
[4] Regulatory Flexibility Act, 5 U.S.C. §§ 601 – 612.
[5] Trade Agreements Act, 19 U.S.C. §§ 2531 – 2533.
[6] National Technology Transfer and Advancement Act, 15 U.S.C. § 272, Note.
[7] EO 13609 (Promoting International Regulatory Cooperation).

Interpretive rules

These interpret existing statutes or rules; they tell the public what the agency thinks a statute or rule means. Although agencies may ask for public comment on them, the APA does not require the agency to do so.[8] Interpretive rules are not binding, but the courts may give some deference to an agency's interpretation. Moreover, although not legally binding, an interpretation may have a "practical" binding effect.[9]

Policy Statements

These tell the public how the agency intends to exercise a discretionary power; for example, because of a reduction in appropriations, an agency may state that it will not enforce a speed limit until it is exceeded by at least 10 mph. As with interpretive rules, agencies are not required to seek public comment before issuing policy statements, but they may do so.[10] The agency is not bound by the statement.

Management, personnel, organization, procedure, and practice rules

These involve agency business and either do not affect the public or only provide information on the agency's structures, functions, and processes.

Public Rulemaking Record

The U.S. has a government-wide database for rulemaking files on each agency's rulemaking actions; it is referred to as regulations.gov.[11] The files are commonly called "dockets." The public dockets for DOT include all of the agency-issued rulemaking documents (e.g., a notice of proposed rulemaking or a notice of a public hearing), rulemaking supporting documents (e.g., an economic or environmental analysis), public comments, and other related material. Interested persons can sign up on the website for an email notification when particular documents are placed in that docket.

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[8] Pursuant to OMB Bulletin M-07-07, all executive branch agencies must seek public comment on drafts of "economically significant" interpretive rules. https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-07.pdf.

[9] Robert A. Anthony, "Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like – Should Federal Agencies Use Them To Bind the Public?" 41 Duke Law Journal 1311, 1329 (1992). See, also, later section on "Guidance Material."

[10] Pursuant to OMB Bulletin M-07-07, all executive branch agencies seek public comment on drafts of "economically significant" policy statements. https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-07.pdf.

[11] http://www.regulations.gov/#!home.

"Ex Parte" Comments

In accordance with DOT policy,[12] the agencies discourage oral communications from the public from the time an NPRM is issued until the end of the comment period and strongly discourage them between that time and the time a final decision is issued. If such comments occur, they must be summarized in writing and placed in the public dockets. If contacts occur after the close of the comment period, they must be closely scrutinized to determine whether it will be necessary to re-open the comment period. If oral communications occur before the NPRM is issued and contain information the agency wants to rely on, the information should be placed in the docket. This DOT policy is neither required nor prohibited by the APA. Some other agencies have similar policies. However, a 1995 Presidential Memorandum directed all agencies to "eliminate any [administrative ex parte rules] that restrict communication prior to the publication of a proposed rule."[13]

It is important to note that oral communications with foreign governments may be permissible, if they are government-to-government. If the foreign government is presenting information concerning issues about such things as a potential conflict between a proposal a DOT agency is considering (e.g., a requirement to test pilots operating in the U.S. for certain drugs) and the other country's privacy law, the informal contacts should be permissible (and the U.S. agency may want to consider adding the information about the conflict to its public docket). If, however, the foreign government wants to advocate on behalf of its citizens (e.g., the drug testing requirements will be too costly for its airlines), it would not be permissible. The foreign government and its citizens can still submit written comments to the docket or speak at any public hearings.

DOT Regulatory Website

DOT provides a significant amount of information about the regulatory proceedings of the Department and its operating administrations on its regulatory website[14] and references will be made to it throughout this paper. However, there are two "pages" concerning the rulemaking process in general that might be especially valuable for EU officials and others in the EU affected by the Department's rulemakings who are not familiar with the process. First, DOT provides a simple, question-and-answer description of the rulemaking process and how to effectively participate in it.[15] In addition, the Department provides a summary description of the

[12] DOT Order 2100.2, "Public Contacts in Rulemaking" (1970).

[13] Memorandum for Heads of Departments and Agencies, "Regulatory Reinvention Initiative" (March 4, 1995). http://govinfo.library.unt.edu/npr/library/direct/memos/reinvent.html.

[14] http://www.transportation.gov/regulations/.

[15] http://www.transportation.gov/regulations/rulemaking-process.

requirements imposed on the rulemaking process by statutes, executive orders, and other documents, such as those noted in the preceding paragraphs.[16]

Guidance Material

Interpretive rules and policy statements are often referred to as guidance. Many agencies provide substantial amounts of guidance. Some of it may be oral (in response to telephone calls, in meetings, etc.); much of it is in writing (letters responding to written requests, web sites with answers to frequently asked questions, agency published documents, etc.). While much of it is in response to requests for guidance from affected interests, some guidance is initiated by the agencies, because they see a need for general guidance or clarification or to address particular problems.

There are three significant problems the public can have with guidance.[17] First, some agencies treat guidance as if it were binding. It is easier and quicker to issue than a binding legislative rule, so they use it to address problems where a legislative rule should be used. Second, even when used to provide help, such as identifying a "safe harbor" (if you do X, you will be in compliance with the rule), some see that as equivalent to having a "practical" binding effect (because, if you cannot or do not want to do X and you need agency approval, you must find another alternative acceptable to the agency, and that may take time you cannot afford).[18] The third problem is that some affected by the guidance have trouble finding agency guidance or do not know how to get help that they need. To address some of the problems with guidance, DOT agencies seek public comment on some draft guidance, establish easy methods for getting help, and provide information on how their process works and how to find existing guidance.

DOT's regulatory website has a section devoted to guidance.[19] That section explains the types of guidance DOT issues and states that guidance is not binding on the public but explains the extent to which the public can rely on it. The site provides links to agency/OST lists of significant guidance documents, although it is not clear if these lists are being kept up-to-date. DOT also notes on this website that it has created a subcategory for "Guidance" in regulations.gov that the public may use to provide feedback or comments on any DOT guidance that is currently in effect and provides instructions on how to do that. Finally, the website also provides information on how to submit complaints about DOT's compliance with OMB Bulletin on guidance, M-07-07, or whether the Department is treating a significant guidance document as binding.

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[16] http://www.transportation.gov/regulations/rulemaking-requirement. This report has not been updated to include EO 13609.

[17] See, e.g., Administrative Conference of the United States (ACUS) "Guidance in the Rulemaking Process," Recommendation 2014-3 (2014). https://www.acus.gov/recommendation/guidance-rulemaking-process.

[18] See fn. 12.

[19] http://www.transportation.gov/regulations/guidance.

The individual agencies may also maintain lists with links to all of their guidance documents, including training materials. For example, the FAA has a very well-organized and thorough webpage broken into categories;[20] NHTSA has a webpage that contains its responses to public requests for interpretations based on specific factual circumstances;[21] and PHMSA has a webpage for its hazardous material guidance and related documents, including letters responding to specific factual circumstances.[22]

U.S.–EU Regulatory Cooperation Benefits and Concerns

For U.S.–EU regulatory cooperation to be most effective, the agencies must be willing participants in the process; they should not participate solely because they are directed to do so by what, in the U.S., are referred to as agency "political appointees" in senior leadership positions. This is especially important because effective initiatives may have to stretch over successive appointees and Presidential Administrations. It is also important for effective cooperation to understand the perspectives of the interests affected by the agencies' regulations. Those interests could include such groups as consumers, manufacturers, transportation companies, and employees who are directly regulated or affected by DOT regulations. It could also include State, local, and foreign government officials. Finally, the perspectives of Members of the U.S. Congress, especially members of the agencies' authorization and appropriations committees (those developing and overseeing the authority of, and budgetary resources for, the agencies) may be important. Without their support, the agencies may have problems effectively participating in regulatory cooperation efforts. The perspectives of these interests and recommendations for addressing their concerns will be noted as appropriate. In general, the best approach for gaining support from the agencies and those who are affected by or interested in their regulations is to stress the benefits of U.S.–EU regulatory cooperation.

It is also noteworthy that many of those interested in DOT rulemaking efforts are also members of organizations that very effectively represent their interests. Many employees are members of unions; companies have formed organizations; State or local governments have organizations representing state legislatures, city mayors, governors of States, State agencies, police, etc.; and the general public may be members of groups that are concerned about the safety of motor vehicles, drunken drivers, aviation accidents, etc. There are also organizations representing insurance company interests in the manufacture and operation of transportation vehicles. DOT agencies receive relatively small numbers of public comments on their rulemaking proposals. That may be because the groups can speak very well for large numbers of members. It also may indicate the ease with which the agency can communicate with the organizations.

[20] http://www.faa.gov/regulations_policies/.
[21] http://isearch.nhtsa.gov/.
[22] http://www.phmsa.dot.gov/hazmat/guidance.

Benefits of International Regulatory Cooperation

To the extent agencies or their affected interests do not fully appreciate the benefits of international regulatory cooperation described below, the respective governments should share examples of the good results of the steps taken.

Data Sharing

Under the U.S. rulemaking processes, agencies are required to have a reasonable basis for the actions they take. It is important that they have data identifying the problem that warrants the issuance of a rule and to help determine effective solutions, evaluate their costs and benefits, and periodically conduct retrospective reviews of the rules that agencies issue to determine how effective the rules are.

There are situations where U.S. agencies need to turn to other countries for such data, especially when they are dealing with new issues or equipment. For example, NHTSA lacked data on the effectiveness of mandatory motor vehicle seat belt usage programs and needed to obtain data from other countries in the late 1970's and early 1980's. The agency also has worked with its European counterparts for decades on the effectiveness of different types of dummies used for crash testing.

FAA and PHMSA and other transportation agencies have been continuously engaged with their counterparts around the world to gather data on the safe transportation of lithium batteries. Moreover, the agencies recognize the importance of sharing data. In a May 23, 2011 speech to the Association for Safer International Road Travel, then NHTSA Administrator David Strickland noted the work of researchers around the world studying electronic stability control (ESC) used by their different populations in their different driving environments and noted that they "all came to remarkably similar conclusions about the effectiveness of ESC in real world driving conditions."[23] It can be especially valuable to have access to this type of information when considering requirements for very expensive equipment. Those who seek to increase opportunities for regulatory cooperation need to stress the significant benefits to be gained by sharing data.

Easier and Less Costly Development

Regulatory cooperation can also ease the process and decrease the costs of developing a rule and the necessary supporting documents. Cooperating countries may be able to share the costs of research on alternative approaches, whether it is through gathering focus groups, performing technical analyses, or identifying research that has already been done. Furthermore, the exchange

[23] http://search.usa.gov/search?utf8=%E2%9C%93&affiliate=dot-nhtsa&query=international+regulatory+cooperation&commit=Search.

of ideas with experts in other countries may help refine approaches. All of these steps may help agencies develop solutions to safety or environmental issues more quickly.

More Effective Rules

If agencies in the EU and the U.S. cooperate in the development of their rules or take it further and harmonize or jointly develop them, the resulting rules may be more effective because they should be easier to comply with or enforce and less costly for regulated entities. As the world becomes one marketplace, a manufacturer or operator will find it easier to meet one standard or a harmonized standard; assembly lines will not have to be changed, and training courses will be simpler. Emergency responders will only have to learn one standard; e.g., one label for hazardous materials. Some fear that harmonization or joint development leads to less effective public participation and an increased likelihood of the adoption or a lower standard to get agreement. That is not necessarily true. Moreover, even if it results in a "lower" standard, that standard could be more effective, because a common standard may achieve better compliance.

More Acceptable Rules

Cooperation, harmonization, or joint development should lessen or eliminate overlapping or conflicting standards and, as noted above, lower costs of compliance. This should make the resulting rules more acceptable to the regulated entities, and they should be less likely to sue or otherwise challenge the agency and more likely to comply fully, easing the agency's litigation and enforcement burdens.

Concerns

Regardless of whether the following concerns expressed by some of the staff interviewed in the U.S. DOT, its agencies, other involved agencies, and the affected interests are fair or legitimate, the U.S. and the EU need either to refute them or address them.

Loss of Control

Some agencies[24] may fear they will lose control over the rulemaking process if they engage in international regulatory cooperation. This could be the case if they were to be pressured to work with their EU counterparts when they do not believe it will be worthwhile, especially when it involves harmonization or joint development. Where they are willing to work on a project, they may think they will be pressured to accept compromises that will not be effective; some are very concerned that there will be too much emphasis on agreeing to "a" rule rather than "a good" rule.

[24] The generic term "agencies" is used throughout the "Concerns" section of this paper. In some instances it may be a position of senior agency political appointees, senior agency career staff, or lower-level career staff. Whether it is the position of one, two, or all three of those, it can be an impediment to progress. Where it is necessary to distinguish for a clearer understanding of the concern, the paper will be more specific.

They also may be concerned about the need to clear their documents and decisions with multiple other U.S. agencies, in addition to OIRA; these may include the United States Trade Representative (USTR), the Department of Commerce (DOC), the Department of State (DOS), and some third agency or office that may be designated to resolve disputes. Even though other agencies may review another agency's rulemaking documents under existing requirements, an agency may avoid engaging in a regulatory cooperation activity if it believes that agencies that did not normally have an interest in its rules would want to review any resulting rulemaking documents.

Negotiation Balancing

Related to the concern about loss of control is a concern about the proper balance between developing rules to achieve agency statutory responsibilities for such things as safety or environmental protection and free trade objectives. There is some concern inside and outside the government that trade objectives—where they dominate—may lead to lower levels of protection than are appropriate. In this regard, it is important to note that taking into account trade-related objectives of regulatory cooperation can also lead to more effective regulations. Moreover, some have noted that the TTIP negotiations are leading to changes that are addressing regulators' concerns about protecting their statutory responsibilities. In addition, to address its concerns, one U.S. agency took a positive approach: the Food and Drug Administration (FDA) hired a person with trade experience as well as regulatory expertise to head an Office of Public Health and Trade. The agency believes he is a very effective negotiator and has helped significantly improve perspectives within FDA, as agency staff observed how well he represented their safety interests in the negotiations.

Necessary Data

Although U.S. agencies have received some very helpful data from their counterparts in other countries, there is significant concern in the U.S. about the lack of sufficient, quality data in many instances—data that the U.S. needs to meet its analytical or justification requirements. The concern appears to vary by agency and by country. Moreover, other countries, and also supranational organizations such as the EU, due to the specific features of their regulatory systems and instruments used, apply a different approach when it comes to data than the U.S. It is particularly problematic when the U.S. and the other countries are trying to agree on mutual recognition of each other's certifications or equivalency of standards.

From the U.S. perspective, its problem is compounded in the EU by both the lack of data and the difficulty in obtaining what data there are, in some cases where a lot of the data are held by individual Member States, there is no focal point for gathering the data at the EU level. Despite these concerns, there was some thought that the EU is trying to do a better job. Interestingly, when they cannot get data from their counterparts, some U.S. agencies can get the data from companies that have an incentive to provide it.

Inability to Protect Confidential and Related Information

When the U.S. cooperates with other countries and there is a need to share data, drafts of rulemaking documents, supporting analyses, and other documents that should be protected from public release during the pre-decisional stage, there is some concern on the U.S. side that the other country will "leak" the document to affected interests. Because this has happened, it is already hampering closer coordination through the sharing of such documents. For example, some agencies will not share drafts of their rulemaking documents with EU agencies that have provided them to non-governmental entities (e.g., a manufacturer). Again, the problems vary by country.

There is also a related concern in the U.S. that not all U.S. agencies can protect confidential data that other countries may be willing to share with them from release under the Freedom of Information Act.[25] The =FDA does have authority to protect such documents as law enforcement investigatory records, trade secrets, and confidential business information received from other countries as part of cooperative law enforcement and regulatory activities; it also has authority to provide such documents that it has gathered as part of its domestic activities to countries with whom it has such cooperative activities.[26]

FDA's program might serve as a model for similar grants of statutory authority for other agencies that could benefit from being able to receive and share more information with other governments as part of international regulatory cooperation efforts. This is not a problem for all agencies in all their programs, because they do not need confidential data to support their decisions; for example, PHMSA may only need to know the chemical in a product, not the specific percent used under the company's formula for its specific products.

Differences in Supporting Analyses

Some agencies also believe that differences in the analytical support necessary to inform/justify a rule in the EU and the U.S. hamper effective cooperation, particularly harmonization efforts. Agency staff who were interviewed for this paper raised the following concerns:

- The U.S. has a higher analytical burden.
- EU analyses are not as thoroughly prepared and objectively reviewed as the U.S. agencies' analyses.
- The EU only provides a basis for the action it wants to take.
- Scientific analysis and risk assessment is conducted separately by some decentralized agencies while risk management decisions are left to the EU Commission.

[25] 5 U.S.C. § 552.
[26] 21 CFR 20.89.

- Some U.S. agencies may try to avoid thorough analyses by contending that an international or multi-lateral agreement obviates the need for one. They will contend that, for example, harmonized standards decrease costs and are, therefore, cost-beneficial. In some cases, they may encourage an international or multi-lateral standard that they could not otherwise justify under U.S. requirements and then contend they "must" adopt that standard.

Although some believe that the EU is taking steps to improve the quality of its analyses, it may take some time to overcome some of these concerns. Moreover, on the U.S. side, despite the recent issuance of guidance on Executive Order 13609, there does not appear to be a good understanding of what is required for a well-done assessment of the international impacts of a rule.

Inconsistent Implementation

The desire to increase U.S.–EU regulatory cooperation does not clearly or specifically address the concerns that implementation can be different. For example, as pointed out by Dudley and Wegrich in their article = comparing U.S. and EU regulatory systems, "the EU in its capacity as a regulatory state has to rely on its member states for implementation and enforcement." [27] By contrast, in the U.S. enforcement is generally assumed by the same agencies who draft and issue the rule. In addition, there are differences in the role of judicial review and the approach to ex-post evaluation/restrospective review.

There are concerns in the U.S. that EU agencies do not enforce their rules as effectively as U.S. agencies do and they have different ways of using voluntary consensus standards to support regulation. Some commenters fear that different levels of stringency may exist between EU Member States' bodies; but any of them can certify products for the whole EU market, and companies may abuse this situation.

U.S. agencies also have to respond to recommendations from independent investigative agencies, such as the National Transportation Safety Board (NTSB), the Government Accountability Office (GAO), and Offices of Inspector General (OIG), which may recommend changes to regulations.[28] The EU may have similar entities examining their agencies. These responsibilities need to be addressed for any coordination to be effective, but the EU and the U.S. also need to consider the significant resources that would be required to coordinate these activities.

[27] Susan E. Dudley and Kai Wegrich. "The role of transparency in regulatory governance: comparing U.S. and EU regulatory systems." Journal of Risk Research, Vol. 18, 2015.

[28] See p. 16, under "NTSB, DOT IG, or GAO Recommendations," for more information about those entities affecting DOT.

Reliance on Consensus Standards Bodies

U.S. agencies are subject to a statutory requirement to "use technical standards that are developed or adopted by voluntary consensus standards bodies" unless they are "inconsistent with applicable law or otherwise impractical."[29] DOT is one of many U.S. agencies that significantly relies on such standards in its regulations. In any cooperation between the U.S. and the EU that relies on consensus standards bodies, the U.S. agency must meet the U.S. requirements for use of consensus standards bodies; among other things, the voluntary consensus standards body must have openness, a balance of interests, due process, and an appeals process.[30] These issues are currently being discussed in the TTIP negotiations.

Inadequate Resources

Agencies are concerned that regulatory cooperation may increase costs, such as for travel to meetings, technology for on-line meetings or to provide early notice of regulatory actions, or sharing data. It also may take extra time, which may cause problems for a short-handed agency or one facing a short-term statutory or judicial deadline to complete a rulemaking.

Limits on Transparency and Public Participation

U.S. agencies and, to a greater extent, those outside the government—especially individuals and small businesses—express concern that international regulatory cooperation decreases the opportunity for effective public participation in the rulemaking process as required under the APA. They fear that decisions between EU and U.S. agencies would be made in non-public meetings, often before the public has an opportunity to express its views or provide important data. Moreover, even though the agreements the U.S. reaches in negotiations may be subject to the APA requirements before they can be implemented through rules, the public may fear that it will be difficult to convince the agency to change the proposal after the time and effort the agency put into the international negotiations. However, there are some excellent examples of steps that agencies have taken to alleviate these concerns.

While increasing opportunities for public participation may address U.S. concerns, the EU may be frustrated when the U.S. notice-and-comment process leads to a need for the U.S. to make a change to what it agreed to do. This may be exacerbated if the U.S. takes extra time to obtain public comments before and during the negotiations with the EU.

[29] National Technology Transfer and Advancement Act, 15 U.S.C. § 272, Note.

[30] OMB Circular A-119 Revised, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (1998). https://www.whitehouse.gov/omb/circulars_a119/#4.

"Lowest Common Denominator" Syndrome

Some agencies and some public interest groups are concerned that international regulatory cooperation, especially efforts to attain harmonized or jointly developed standards, results in the lowest standard being considered by those in the negotiations group. Whether or not this is a legitimate concern, it needs to be addressed. Especially with respect to the public interest groups, it compounds their concerns about the potential lack of transparency and limited opportunities for effective public participation.

Limitations on Likelihood of Success

There are two separate concerns here. First, there is some strong concern that the differences between the U.S. and the EU systems of government make it very difficult to adopt equivalent or common standards. These differences are significant from a rulemaking perspective. The important role of the Member States in implementing EU directives and enforcing EU regulations also exacerbates the concern in the U.S. about whether there can be actual equivalence. The second concern is that U.S. Presidents change every four to eight years and political leadership within an agency generally changes more frequently. Those changes can lead to loss of support for international cooperation efforts. There could also be changes in either House of Congress that could lessen support. For these reasons, especially when close to an election, agency staff may be reluctant to enter into cooperation agreements, as they may believe it would be a waste of time and resources.

Existing U.S. DOT International Regulatory Cooperation Activities

Although the U.S. has required certain actions by executive branch agencies to enhance practices for communicating and cooperating on regulatory matters with other countries and international bodies, DOT took many initiatives on its own many years before they were required. This is noteworthy, because it indicates that the Department and its agencies, on their own, identified the benefits of doing so. The actions range from efforts to provide detailed information on the status of DOT rulemakings that may affect other countries, to engaging in harmonization or joint development of rules. They do not need to be convinced of the benefits, but they will need help in addressing the concerns they and those affected by their rules have.

This section is divided into two parts. The first covers steps that DOT and others take that provide early notice and information about actions that may lead to rulemaking that could affect other countries. The second section discusses cooperation activities in which DOT already engages; they may provide "lessons learned" or models to further enhance regulatory cooperation between the EU and the U.S.

Early Notice

In general, there are two stages to early communication about U.S. rulemaking. The first is information about actions that could lead an agency to initiate rulemaking; the second is information about rulemakings that have been initiated. The first could be actions by the agency or other entities, such as the Congress, the courts, investigatory agencies or offices, or even public petitioners. The second would be by the agency, and the first step would usually be when the agency publicly announces it has initiated action via the semi-annual Regulatory Agenda or some other agency public status report on its rulemaking activity. Sometimes the agency will first announce a new rulemaking through such steps as speeches or Congressional testimony and then add it to the Regulatory Agenda or status report. Some of these reports or other actions will provide information about potential rulemakings many months or even years before the agency issues a proposed rule. This early notice can provide opportunities for earlier and more enhanced regulatory cooperation before alternative approaches to the problem are even identified.

Regulatory Agenda

Agencies are required by statute, executive order, and, in some agencies, by internal agency orders to prepare agendas of their pending and recently completed regulatory actions. In response to these requirements, OIRA has established a uniform report, the Unified Agenda of Federal Regulatory and Deregulatory Actions, and publishes all of the agencies' Regulatory Agenda's semi-annually; they are supposed to be published in October and April of each year, but are often late. The Agenda provides an abstract and timetable for each rulemaking along with other helpful information. Pursuant to E.O. 13609, the agency is required to designate those rulemakings in the Agenda that may have significant international impacts.

The public can find the government-wide Agenda, including DOT's portion, on the OIRA regulatory website.[31] It also can be accessed from other sites, such as DOT's Regulatory site. When a docket has been opened for a rulemaking, its number is included in the Agenda and other DOT reports; by using that number, the public can locate the docket for that rulemaking in regulations.gov. Once entered into the Agenda data base, rulemakings are assigned a Regulation Identifier Number (RIN); that number may be used to help find a docket when it is created. The RIN can also be used to identify a specific rulemaking in other reports.

Regulatory Plan

Pursuant to E.O. 12866, a Regulatory Plan is published annually with the Fall Regulatory Agenda. The Plan describes the Department's regulatory priorities for the next year, its retrospective reviews of existing regulations; and expanded Agenda entries (providing more details on such matters as costs and benefits) for those pending rulemakings "that the Department

[31] http://www.reginfo.gov/public/.

believes will merit special attention in the upcoming year." E.O. 13609 added a requirement that agencies summarize their international regulatory cooperation activities, including a list of their significant rulemakings that are expected to have international effects. The Plans can be accessed at the same internet site as the Agenda.

Status Reports

At the beginning of each month, DOT provides an updated status report on each of its pending or recently issued significant rulemakings.[32] The reports contain abstracts of the rulemakings, the effects (such as effects on the EU) of the rulemaking, current schedules, and other information about the rulemakings. Because they are updated monthly, new rulemakings or actions on existing rulemakings may appear in this report before appearing in the Agenda.

Effects Reports

DOT also provides a separate, monthly-updated report on each of 21 different effects of all of its rulemakings.[33] The different effects include such categories as information collection, privacy, economically significant, EU, NAFTA, and foreign. A glossary defines the terms. For example, an EU effect means: "A rulemaking that would have an effect on the European Union or one of its member countries or the countries' business entities, citizens, etc." The report for each effect lists all of the rules with that effect, their current stage, and their RIN and docket number (if available).

Legislation

One of the earliest signs that an agency may undertake a new rulemaking is legislative action that may require or authorize the agency to issue new rules or take other action to explore the need for new rules. Congress may also require an agency to report to it on the need for new rules or hold hearings to gather information on whether rulemaking action is warranted. Agency websites may contain information on pending legislation or a Congressional hearing, but the best way to find this information is through the Congressional website.[34] At this website, for example, typing "Federal Aviation Administration" in the search box will pull up a list of pending legislation (called "bills") Congress is considering concerning the FAA, including the current status of the bills. A link to lists of pending committee hearings in each House can also be found on the home page.

[32] http://www.transportation.gov/regulations/report-on-significant-rulemakings.
[33] http://www.transportation.gov/regulations/reports-on-effects-DOT-rulemakings.
[34] www.Congress.gov.

NTSB, DOT IG, or GAO Recommendations

These entities have the authority to conduct investigations or studies that could result in recommendations to an agency to issue new rules or amend existing rules. For example, the NTSB issued a recommendation on January 15, 2015, that the FAA

> require that all newly manufactured aircraft used in extended overwater operations and operating under Title 14 Code of Federal Regulations (1) Part 121 or (2) Part 135 that are required to have a cockpit voice recorder and a flight data recorder, be equipped with a means to recover, at a minimum, mandatory flight data parameters; the means of recovery should not require underwater retrieval. Data should be captured from a triggering event until the end of the flight and for as long a time period before the triggering event as possible.[35]

Although not binding on the agency, the recommendations of these entities carry substantial weight, and the agency must respond to each recommendation.

National Transportation Safety Board

The National Transportation Safety Board has the authority to investigate transportation accidents or perform safety studies and make recommendations to improve safety. NTSB recommendations can be found on its website.[36] An interested user may search the data base in a variety of ways, including by the mode of transportation or a specific accident. Agency responses may also be available on the internet.[37]

Department of Transportation Inspector General

The DOT Office of the Inspector General has the autonomy to do its work without interference. The OIG has the general responsibility to stop fraud, waste, and abuse in departmental programs through audits and investigations. The OIG may act on its own initiative or be asked to conduct an audit at the request of a Member of Congress or the Secretary of Transportation. The DOT OIG lists its audits on its website.[38]

Government Accountability Office

The Government Accountability Office is an independent, nonpartisan agency that works for Congress. GAO is headed by the Comptroller General, who is appointed by the President from a list of candidates proposed by Congress and confirmed by the Senate. It investigates how the Federal government spends its money. GAO performs its work at the request of Congressional

[35] http://www.ntsb.gov/safety/safety-recs/recletters/A-15-001-008.pdf. Recommendation A-15-3.
[36] http://www.ntsb.gov/layouts/ntsb.recsearch/RecTabs.aspx
[37] See, e.g., http://www.phmsa.dot.gov/ntsb.
[38] http://www.oig.dot.gov/audits.

committees or subcommittees, as mandated by Congressional legislation or committee reports, or pursuant to the general authority of the Comptroller General. Its reports can be found on its website.[39]

Petitions for Rulemaking

Under the informal rulemaking procedures in the APA, the public has the right to petition an agency for the issuance, amendment, or repeal of a rule.[40] DOT agencies generally post these petitions in their public rulemaking docket at regulations.gov and may publish the petitions in the *Federal Register* and/or post them on the internet. They may also seek public comment on the petitions before making a decision. The decision on a petition is usually a response to the requestor, but if the agency places the petition in the docket, it should also place the response in the docket. A full or partial grant of the petition would only be a commitment to initiate a rulemaking and seek public comment.

DOT agencies generally note in the DOT Regulatory Agenda and monthly status reports which rulemakings were initiated in response to a petition. Some agencies have publicly available lists of pending petitions for rulemaking.[41] For others, it may be necessary to search the agency website for "petitions for rulemaking" to obtain information.[42]

Retrospective Reviews of Existing Rules

Agencies are required by statute, executive order, and, for some, their own internal requirements to periodically review their existing rules to determine whether they need to be revised or revoked. These reviews, obviously, could result in new rulemaking initiatives. DOT has performed such reviews for decades, and in 1998, the Department began a more organized approach by creating a formal plan for the review of all of its rules over a 10-year period, with a new plan created every 10 years; the plans may have to be modified if others, such as the President, require specific reviews and deadlines for action.

DOT's regulatory website has a section on its retrospective review plan that describes its 10-year plan and also provides information about any special reviews it is required to conduct.[43] The Department also provides information and brief status reports on each of its reviews in the Regulatory Agenda. The public may submit comments or information about the plan and the specific, individual reviews. This information can provide a very early opportunity for getting a DOT agency to focus on unnecessary differences in the regulatory standards of the U.S. and the

[39] http://www.gao.gov/browse/date/week.
[40] 5 U.S.C. §553 (c).
[41] See, e.g., http://www.phmsa.dot.gov/hazmat/standards-rulemaking/petitions.
[42] See, e.g., http://search.usa.gov/search?utf8=%E2%9C%93&affiliate=dot-nhtsa&query=petitions+for+rulemaking&searchCommit=Search.
[43] http://www.transportation.gov/regulations/dot-retrospective-reviews-rules.

EU, and E.O. 13609 specifically directs agencies to consider such unnecessary differences when selecting rules for retrospective review.

Agency Studies or Reports

Agencies may identify the need to consider changing existing rules or issuing new ones through a wide variety of factors. For example, after an aviation accident, FAA may identify a problem with an existing rule that should have prevented the accident. As a result of a review of general data, NHTSA may note increasing deaths and injuries in side collisions. An excellent example of this is the June 2015 report on "Overview of NHTSA Priority Plan for Vehicle Safety and Fuel Economy, 2015 to 2017."[44] Indeed, NHTSA notes in the report that it is "a means to communicate to the public and regulators in other countries NHTSA's highest priorities." NHTSA hopes the report will "encourag[e] regulatory cooperation."[45] In the second part of the report, the agency describes its priority projects and includes milestone dates for activities such as completing research or participating "in automotive industry's sharing forum to ensure timely exchange of information concerning cybersecurity threats."[46] There does not appear to be a consistent manner for finding these kinds of reports other than periodic searches of agency websites.

Federal Register

Agencies subject to the APA are required to publish their proposed and final rules in the *Federal Register*, unless those subject to the rule are personally served or otherwise have actual notice. It is relatively rare for a rule not to be published. Even if the agency uses personal service, if the agency wants the rule to remain in effect for more than a short-term event or emergency, it needs to publish the rule in the *Federal Register* for it to be codified in the Code of Federal Regulations (CFR).

If interested persons want to receive notice about a particular rulemaking, a general category of rulemakings, or all of a particular agency's rulemakings, the Office of the Federal Register (OFR) provides for email notification subscriptions or RSS feeds. OFR provides a number of options; for example, users can subscribe to a particular agency's documents, a particular topic, or create a customized subscription. Users could also limit the rulemakings to those identified as "significant." OFR provides instructions for this service on its website.[47]

[44] www.nhtsa.gov/staticfiles/nvs/pdf/NVS_priority-plan-June2015_final.pdf.
[45] Id. at p. 4.
[46] Id. at p. 11.
[47] www.federalregister.gov/learn/user-information//.

Litigation Reports

After a U.S. agency issues a final rule, it can be challenged in court. The court may uphold the rule, remand it to the agency for further review, or overturn it in whole or in part. Anyone who is interested in the progress of any litigation because of its potential impact on a rule can follow its status via a DOT-wide, semi-annual "Litigation News" report and a list of, and links to, court decisions in a DOT-wide report on "Recent Judicial Decisions." Both reports can be accessed at a DOT website.[48]

Notices of Opportunities for Public Participation in International Regulatory Cooperation

DOT agencies generally advise the public of their international regulatory cooperation activities and opportunities to comment on any issues. Below are some examples of this.

PHMSA issued a notice on November 19, 2013, that it was participating in a public meeting of the U.S. Interagency Globally Harmonized System (GHS) coordinating Group in preparation for a meeting with the United Nations (UN) Subcommittee of Experts on the GHS of Classification of Labelling of Chemicals. The notice said the Group would provide the public "an update on GHS-related issues and an opportunity to express their views orally and in writing for consideration in developing U.S. Government positions for the upcoming UNSCEGHS [United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals] meeting."[49]

NHTSA issued a similar notice in 1998 to announce that it was seeking public comment and holding a public workshop on a draft statement of policy concerning its priorities in implementing the UN/Economic Commission for Europe 1998 Agreement on Global Technical Regulations for Wheeled Vehicles, Equipment and Parts and its activities and practices for facilitating public participation in the implementation of that agreement. It also announced it was exploring other means of effective public participation, such as "the possibility of including members of the public as advisers in the NHTSA delegation."[50]

The FAA has a Regulatory Cooperation Council Work Plan with Canada covering their collaboration on unmanned aircraft systems that includes combined "efforts on bilateral webinar discussions with stake holders" during 2015–2020. It lists possible topics and notes events for stakeholder engagements. The Work Plan is available on a Department of Commerce website.[51]

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[48] http://www.transportation.gov/administrations/office-general-counsel/office-litigation.

[49] http://www.phmsa.dot.gov/portal/site/PHMSA/menuitem.6f23687cf7b00b0f22e4c6962d9c8789/?vgnextoid=1e12894e08c12410VgnVCM100000d2c97898RCRD&vgnextchannel=597583b287227110VgnVCM1000009ed07898RCRD.

[50] http://www.nhtsa.gov/cars/rules/rulings/RIN2127-AH29/RIN2127-AH29.html.

[51] http://trade.gov/RCC/documents/f5-tc-dot-wp-aviation-regs.pdf.

Cooperation Activities

DOT has engaged in regulatory cooperation activities that run the full gamut of possibilities from exchanging information to jointly developed standards. They have used negotiated rulemakings and joint public meetings; they have provided opportunities for public participation before and during negotiations on international or bilateral agreements; they have done joint research and investigations; and they have agreed to mutual recognition/acceptance and common standards. Many of these activities have been with the EU or its members states, but this paper also notes actions with other countries, particularly Canada, or international bodies; there is no apparent reason those approaches could not be used with the EU also. Moreover, the extent to which the DOT agencies have engaged, and the variety of the methods they have used, in regulatory cooperation activities clearly illustrates their willingness to participate, their appreciation of the benefits, and importantly, the wide range of very effective approaches available.

International Organizations

DOT agencies work with a number of international organizations. FAA primarily deals with the International Civil Aviation Organization (ICAO); NHTSA works with the United Nations/Economic Commission for Europe (UN/ECE) and the World Forum For Harmonization Of Vehicle Regulations, and the World Trade Organization (WTO). Because of the multi-modal aspects of hazardous material transportation regulations, PHMSA deals with a number of organizations, including the UN and its Committee on Transportation of Dangerous Goods, ICAO, and the International Maritime Organization (IMO). All three also work with international voluntary consensus standards organizations, such as the International Standards Organization (ISO) and the Society of Automotive Engineers. All three also engage in international regulatory cooperation efforts with other countries pursuant to bilateral or multi-lateral agreements such as the North American Free Trade Agreement.

EU Bodies

FAA

The most noteworthy agreement in the aviation area is "The Agreement between the United States and the European Union on Cooperation in the Regulation of Civil Aviation Safety" signed in 2008. [52] The broad scope of this agreement is significant. Its purpose is to enable reciprocal acceptance, promote a high degree of safety, and "ensure the continuation of the high level of regulatory cooperation and harmonization between the" U.S. and the European Community.

[52] http://www.faa.gov/aircraft/air_cert/international/bilateral_agreements/baa_basa_listing/media/EU-US-agreement-R0A5.pdf.

This agreement created an oversight board to ensure effective functioning; its responsibilities included discussions of common approaches to safety and environmental issues, sharing of information, consultation on proposals for new or changed safety measures; early warning of draft regulations and legislation. It requires acceptance of findings of compliance and approvals made by the other party and agreement that the other party's standards, etc. are "sufficiently compatible to permit reciprocal acceptance of approvals and findings of compliance with agreed upon standards." It also requires the parties to adopt procedures for regulatory cooperation in safety and environmental testing and approvals, including, where possible, an opportunity for experts from one party to consult and participate in the early drafting stages of "aviation regulatory materials" by the other party. It allows the participation of one party in the other's "internal quality assurance and standardization inspection functions related to accreditation and monitoring." The parties also agreed to provide "appropriate mutual cooperation and assistance in any investigation or enforcement proceeding of any alleged violation of any laws or regulations under the scope of this Agreement." It provides for the exchange of safety information and notice of "all applicable requirements, procedures and guidance material." Finally, it provides for the protection of proprietary data and requests for information.

The Agreement, in turn, resulted in another very important step. On June 13, 2013, FAA and the European Aviation Safety Agency (EASA) signed "Rulemaking Cooperation Guidelines."[53] The Agreement documented what EASA and FAA had already been doing for a long time. They agreed "that harmonization can best be achieved through effective communication during the definition and early stages of implementation of the respective rulemaking programmes." Their stated objectives include exchanging "intentions and priorities" to align their programs, identifying initiatives of common interest to "avoid unnecessary divergence and duplication," and defining "working methods."

Finally, they provided three different methods that could be used to execute rulemaking tasks they have identified as "tasks of common interest" and set out procedures for ensuring appropriate communication. The three methods were: (1) EASA takes the lead and gives the FAA "sufficient involvement in the EASA rulemaking project to understand the content of the draft rule and to be able to contribute to this process as necessary to allow it, where appropriate, to launch an equivalent" NPRM or take other equivalent action; (2) FAA takes the lead giving EASA the same sufficient involvement; and (3) the FAA and EASA "develop their rulemaking projects separately, but concurrently (to the extent practicable)."

EASA and FAA expect to develop work plans for each project. Among other things, these plans will include a description of technical documents, which may include "jointly developed issue papers, analyses, research results, and other technical documents;" participation in work groups

[53] http://easa.europa.eu/system/files/dfu/FAA-EASA%20Rulemaking%20Cooperation%20Guidelines_signed%20text_13%20June%202013_Paris.pdf.

that might include advisory committees; and other cooperative activities deemed mutually beneficial. The work plans for identified projects and the current status of the rulemakings are publicly available on an EASA website.[54]

With respect to the provision above for participation in advisory committees, U.S. agencies have authority to establish advisory committees pursuant to the Federal Advisory Committee Act (FACA).[55] These committees can provide the agency with advice and recommendations on rulemaking activities, but they are subject to requirements such as representational balance and openness. In addition, foreign governmental agencies, businesses, or individuals can be appointed to membership in the committees but are not allowed to vote (with some special exceptions). Although they cannot vote, their views can be clearly heard and accommodated by the voting members. FAA has a large, standing committee for rulemaking issues referred to as the Aviation Rulemaking Advisory Committee (ARAC), and it has foreign members. FAA also has some committees that are created under different statutory authority that are not subject to FACA limitations.[56] Committees established under the latter authority are referred to as Aviation Rulemaking Committees (ARC).

Under FAA's Aviation Rulemaking Advisory Committee (ARAC) Order,[57] a committee charter can include the assignment of specific rulemaking actions for which the committee may be asked to develop a draft proposed rule. Section 12. d. specifically provides that civil aviation authority representatives from other governments can request non-voting status, and many have been made members. The FAA has also established ad hoc advisory committees under its non-FACA authority for specific rulemaking issues.[58] Foreign governments may participate but not vote in the ARCs.

NHTSA

Although NHTSA's cooperation efforts are primarily done through the UN, the EU or its Member States have traditionally been the key players in the UN process under what is referred to as the 1998 Global Agreement.[59] The Agreement is administered by the UN Economic Commission for Europe's World Forum for the Harmonization of Vehicle Regulations (WP.29).

An example of the benefits of this Agreement is a final rule issued by NHTSA in 2007 on "Federal Motor Vehicle Safety Standards; Door Locks and Door Retention Components."[60]

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[54] http://easa.europa.eu/system/files/dfu/EASA-FAA%20pilot%20projects%20status%20report%20revision%20-%20V.6%202%202%202015.pdf.

[55] 5 U. S. C. App. II.

[56] 49 U.S.C. § 106(p)(5).

[57] http://www.faa.gov/documentLibrary/media/Order/1110.119P.pdf.

[58] http://www.faa.gov/regulations_policies/rulemaking/committees/documents/index.cfm/committee/definitions.

[59] http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29glob.html.

[60] 72 Fed. Reg. 5385 (2/6/07).

NHTSA noted in the final rule that its efforts to improve its rules to better address door ejections coincided with the adoption of a work program under the 1998 Global Agreement. The agency "sought to work collaboratively on door ejections with other contracting parties," particularly Canada, the EU, and Japan. The four governments exchanged information on ongoing research and testing and leveraged resources for testing and evaluation, leading to the first global technical regulation (GTR) under the 1998 Agreement.[61] In the final rule, NHTSA noted that

> This first GTR demonstrated that U.S./EU regulatory cooperation can achieve increased safety and harmonized standards that are science-based and free of unjustified requirements. If adopted into domestic law by the U.S. and EU, the GTR on door locks and door retention systems would essentially eliminate the differences between the U.S. and EU standards… Adopting the amendments based on the GTR will not only result in improvements to the U.S. standard, but also to the EU standard. This will also benefit other countries since the EU standard is the United Nations' Economic Commission for Europe regulation (ECE R.11), which is used by the majority of the world community.[62]

Unlike the earlier 1958 Global Agreement (to which the U.S. was not a signatory), the 1998 Agreement requires consensus and addresses many of the other problems the U.S. had with the earlier agreement. The U.S. may feel more comfortable with the 1998 Agreement, and it might provide a forum for a significant strengthening of cooperation under TTIP and work on developing consensus positions.

NHTSA also has a variety of programs for joint research. For example, they are involved in an Experimental Safety Vehicles (ESVs) Program originated four decades ago under the North Atlantic Treaty Organization (NATO) Committee on the Challenges of Modern Society. It was implemented through bilateral agreements between the Governments of the U.S., France, Germany, Italy, Great Britain, Japan, and Sweden. They agreed to develop ESVs to advance the state-of-the-art technology in automotive engineering and to meet periodically to exchange information. The group has grown to include a number of others, including the European Commission.[63] Another example is a study with France that covered a vehicle's compartment strength and occupant protection systems.[64]

[61] Id at 5386.
[62] Id.
[63] See, http://www-nrd.nhtsa.dot.gov/pdf/esv/esv22/introduction.pdf.
[64] http://www-nrd.nhtsa.dot.gov/pdf/esv/esv21/09-0329.pdf.

PHMSA

Although PHMSA primarily works through international bodies on its hazardous materials rulemaking, when it does this, it often will work with another country, such as the Netherlands,[65] Germany,[66] or Belgium[67] to develop a joint proposal for the international body to consider.

DOT Regulatory Cooperation with Other Countries

FAA

FAA has agreed to promote cooperation in the early stages of a rulemaking with its Canadian counterpart, Transport Canada (TC). This was intended to help the U.S. and Canada align their Unmanned Aircraft Systems (UAS) programs as they prepare new UAS regulations. The FAA provided and discussed with TC the release of its UAS Roadmap and a Comprehensive Plan on the UAS Path Forward. TC and FAA also have coordinated their efforts addressing illegal UAS operations.[68]

NHTSA

NHTSA has been involved in many regulatory cooperation efforts with Canada. For example, it has done several collaborative research projects with Transport Canada; these include one on quiet vehicles and child restraints and another on fuel vehicle safety and clean technologies (e.g., low rolling resistance tires). Finally, they are taking steps to ease collaboration on enhanced standards development.[69]

PHMSA

PHMSA also has taken various regulatory cooperation actions with other countries. For example, it may approve an application from a foreign-based company to perform cylinder inspections and verifications based on an approval by a competent authority of the country where the cylinder is manufactured.[70] In addition, PHMSA and its Canadian counterpart, the National Energy Board, have agreed to improve their cooperation and coordination to improve the safety of their pipelines. There is a growing number of cross border pipelines being built, and they are jointly inspecting and sharing accident and enforcement data on these operations as well as conducting joint technical analyses. PHMSA is also working with its Canadian and Mexican counterparts to develop consistent guidelines for use by firefighters, police, and other emergency services

[65] See, e.g., http://www.unece.org/fileadmin/DAM/trans/doc/2008/ac10c3/ST-SG-AC10-C3-2008-87e.pdf.
[66] See, e.g., http://www.unece.org/fileadmin/DAM/trans/doc/2012/dgac10c3/ST-SG-AC10-C3-2012-56e-ST-SG-AC10-C4-2012-4e.pdf.
[67] See, e.g., http://www.unece.org/fileadmin/DAM/trans/doc/2014/dgac10c3/ST-SG-AC.10-C.3-2014-74e.pdf.
[68] See, https://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-canada-rcc-joint-forward-plan.pdf, p.37.
[69] See, id. at 35
[70] 49 CFR 107.803(c)(8).

personnel for hazardous material transportation incidents.[71] PHMSA and some of its bilateral partners jointly chair some public meetings.

In May of 2015, PHMSA also issued a final rule jointly developed with FRA partly in response to an accident in Canada involving a U.S. railroad.[72] Before the accident, PHMSA had also received petitions from the railroad industry to address problems that played a role in the accident. The rulemaking is important in the context of international regulatory cooperation because PHMSA and FRA worked with their Canadian counterpart in developing the rule as a result of common concerns. In addition, other countries also had an interest because their businesses manufacture railroad train cars, and there was close cooperation with them also. FRA and PHMSA used FRA's Railroad Safety Advisory Committee (RSAC), which is similar to the FAA ARAC described above, and Canada and the other interested governments participated in that process. The final rule notes the many steps taken to effectively cooperate and illustrates the importance placed on those steps. For example, the final rule notes that, in an effort to harmonize their rules, PHMSA and FRA met with their Canadian counterpart, Transport Canada, for informal staff discussions; they held formal discussions through a Regulatory Cooperation Council; the leadership of DOT and TC met frequently; and the DOT Secretary and Canadian Transport Minister held multiple meetings to specifically discuss the rulemaking issues.

Multiple DOT Agencies

After a railroad accident in the 1980's involving a crash between two trains, where the crew of one had been using marijuana, the DOT Secretary decided it was necessary for the Department to impose drug testing on safety-sensitive employees working in six modes of transportation (at the time, the U.S. Coast Guard was part of DOT). Subsequent to the successful completion of those rulemakings, the Secretary decided to create alcohol testing requirements for the same employees.[73] Some of the rules had international effects, particularly the FAA's, which affected every airline that operated into the U.S. The most significant effects were on Canada. Canada's airlines, commercial motor vehicles, and maritime vessels operated into U.S. territory, its trains and pipelines crossed over U.S. borders in some locations.

When Transport Canada learned of DOT's decision to initiate the drug testing rulemaking, it informally asked to meet with DOT officials to discuss how this would impact their operators under their privacy laws. Recognizing the need to address these significant governmental concerns as well as DOT's concerns that any rules needed to be effectively implemented, the

[71] http://www.phmsa.dot.gov/international.

[72] 80 Fed. Reg. 26643.

[73] Final rules for both drug and alcohol testing were issued by each of the six DOT agencies regulating such things as who was covered. Separate rules covering the testing procedures to be used by each of the agencies were issued by OST. The rules have been amended many times. The current version of the testing procedures are in 49 CFR Part 40.

Department agreed to meet and continued to meet regularly throughout the drug and alcohol rulemakings, successfully addressing Canada's concerns and issuing effective rules.

FHWA

Another example involved the use of negotiated rulemaking. This is a process in which an agency is required to use, or identifies regulatory issues that it believes can be best addressed by, an advisory committee that has representatives of all interests potentially affected by the rulemaking. The committee attempts to develop a consensus proposal with the help of a neutral facilitator, and after notice and comment proceedings under the APA, a final rule. Although the rule has to be approved by the head of the agency and comply with APA requirements, the agency is represented on the committee and any negotiated rule would generally satisfy the agency head. The proposal should also result in shorter comment periods and less adverse comment. The Negotiated Rulemaking Act[74] establishes a "framework" for negotiating a rulemaking but makes it clear that agencies are permitted to innovate and experiment with the process.[75] Although not appropriate for many rulemakings, it can be valuable for some contentious ones.

This FHWA rulemaking arose from the concern of the U.S. Congress that the States had diverse laws covering parking permits for people with disabilities and that the permit of one state was not always accepted by another state, causing problems for permit holders. So Congress passed legislation directing DOT (which did not otherwise regulate parking permits) to convene a negotiated rulemaking advisory committee to develop a uniform system for the States to use for such permits.

Again, Transport Canada asked to be involved. The Canadians thought that it would be better for both countries to have one uniform system since U.S. and Canadian citizens routinely drive through each other's country. DOT invited TC to be a member of the advisory committee that it was establishing. Although as a foreign entity it could not vote, it was heard, and a final standard was successfully adopted by FHWA, which represented DOT in the negotiations. The preamble to the 1991 final rule describes the rulemaking.[76]

[74] 5 U. S. C. §§ 561 – 570a.

[75] Id. at § 561.

[76] 56 FR 10329, March 11, 1991.

FMCSA

Another noteworthy program involves FMCSA's commercial drivers licenses (CDLs). The U.S. and Canada agreed in 1989 that the testing and issuance of CDLs in the two countries was similar and would be mutually recognized.[77]

Recommendations

The Department of Transportation is generally at the forefront of international regulatory cooperation. It has effectively worked with international organizations, individual countries, and regional bodies through formal treaties or agreements and very informal decisions to work together to address common problems or just assist the other with information and data. Nevertheless, as noted earlier in the paper, cooperation efforts may face some obstacles. At some or all levels—career staff, career senior officials, and politically-appointed officials—DOT agencies may harbor concerns about international regulatory cooperation that could cause them to oppose or reluctantly and ineffectively participate, particularly with the steps necessary to develop harmonized or common standards or mutual recognition.

To make the process easier, there are a number of steps that could be taken—individually or in concert with other recommendations—to address the possible concerns. Generally, as noted earlier, to the extent agencies do not appreciate the benefits of cooperation, the EU and the U.S. need to present them with the data or examples illustrating the benefits. The concerns may be unfair or legitimate, but the EU and the U.S. should either refute them or address them; they should not ignore them.

Encouraging Regulatory Agency Participation in Regulatory Cooperation

If the U.S. President and the Commission President want agencies to engage in regulatory cooperation, it is very likely to happen. In the long run, it may achieve significant benefits. However, in the short term, to get effective cooperation from reluctant agenies it is not sufficient to merely issue a mandate. Senior Executive Branch and Commission officials need to be involved in ensuring effective implementation by, and support from, the regulatory agencies.

Positive steps have already been taken during the TTIP negotiations, but more may be necessary to address agency concerns. The concerns may be more of a perceived than an actual problem, but efforts to ensure that all participants in the agency process are aware of what is being done could help either way. Informal roundtable discussions where staff can be asked for input or can ask what is being done or what they can do if they do not think there is a proper balance might help, especially if there are actual problems. Other alternatives would be to provide an

[77] http://www.fmcsa.dot.gov/international-programs/reciprocity-and-recognition-united-states-and-canadian-commercial-drivers

anonymous process for concerns to be raised or for an independent ombudsman to be available to review the concerns. Additionally, U.S. agencies could consider following the FDA approach by hiring officials who have both a trade and a regulatory background.

For some, encouragement may have to include discussions about the benefits of regulatory cooperation. For example, that may mean illustrating for staff how uniformity may result in higher safety at lower cost than a more demanding U.S. standard that may conflict with an EU standard; the conflict may result in implementation problems causing confusion and raising costs. Alternatively, raising a U.S. standard to achieve consistency may be objectionable to a U.S. agency that thinks it may impose unnecessary costs. Extensive, good quality data and thorough analyses of the alternative approaches should help with the necessary balancing. Most importantly, it may be necessary to agree to support the agency if it has a clear case for not agreeing. Agreement for agreement's sake can be helpful to get a program going, but it may do more damage in the long run. It helps to have agency regulatory staff involved in the discussions.

It is also valuable to accent for the agency that its early participation in increased cooperation efforts can help it shape the process.. For example, getting in on the "ground floor" by volunteering to work on initial cooperation projects might mean the agency will have opportunities to play a significant role in setting up effective procedures that address its concerns (e.g., clear procedures for when and how USTR or OIRA participate or standards for trade impact analyses). DOT has recognized the advantages of ground floor participation via its active participation in the development and use of digital technology to enhance its rulemaking work. Other steps could include informal meetings, such as those noted above, to hear and address staff concerns.

Resources

When considering cooperation projects, it is also necessary to consider alternatives for the extra resources that an agency may need to participate effectively. For example, increased cooperation should not have to result in fewer opportunities for public participation. The EU and the U.S. might need to focus on areas where additional resources may be available. As an example, it may be possible that an agency could get additional appropriations for some projects and not others, because of interest in those projects in Congress. Alternatively, an agency may be able to move funds from a lower-priority project to some cooperation projects. New technology may be able to decrease the costs of cooperation. For example, certain projects may be easier to work on together because necessary meetings could be held effectively with digital technology.

Rulemaking Processes

The EU and the U.S. need to help both agency staff and the public better understand their respective rulemaking processes and their differences. This is important because the agencies and the public need to be able to effectively participate in the cooperation process. More

importantly, the agencies and the public may be able to identify better approaches that will address their concerns if they have a better understanding of the processes. The steps that the two governments could take include the following:

- **Guidance on cooperation**: The U.S. and the EU should include in TTIP or another document provisions enabling and guiding regulatory cooperation (including the commitment to offer to each other early opportunities for information and cooperation and to take into account each other's approaches).
- **Educational material**: The EU and the U.S. should provide information on, or easy access to, studies that have been done on the two processes, such as the American Bar Association study of "Administrative Law of the European Union" (2008) and the recent EU comparative studies of EU and U.S. law by Parker and Alemanno (2014) and Dudley and Wegrich (2015).
- **Joint training courses**: Although this may be difficult without extra resources, it might be possible to conduct joint training courses when officials from the EU or the U.S. are visiting the other on business. Joint training could be especially valuable since the "students" may be especially helpful to each other when questions arise or confusion reigns.
- **Employee exchange programs**: Again, resources may make this unlikely, but even if a small number of employees could work in their counterpart's offices for 3–6 months, the learning experience could be very valuable for both the visiting employee and the visited agency but also for what the employee brings back to her office to help others at home.
- **Agency rulemaking websites**: More agencies on both sides of the Atlantic should be encouraged to put more information on the web about their rulemaking processes—not just about how they develop and issue binding rules, but also other things such as how they grant waivers and exemptions, how they work on international regulatory cooperation, and how the public can participate in the process.
- **Best practices**: After training on how the respective rulemaking processes work, it is important for the EU and the U.S. to begin providing regular training opportunities on best practices for EU/U.S. regulatory cooperation.
- **Lessons learned**: Training in best practices should also include developing and continually updating joint guidance documents for regulatory cooperation drawing on input from the regulators, on their experiences with what works best, and what could be a model for othe agencies facing similar problems.
- **Addressing particular problems**: The EU and the U.S. should also develop guidance on such cross-cutting issues as how to resolve issues relating to exchange and use of confidential information between agencies, bridging differences in regulatory processes, and how to fund joint cooperation initiatives.

In order to be effective in the educational steps as well as the work on individual rulemaking projects, it is important that the U.S. and the EU assess their own processes for appropriate consistency in implementation. For example, the EU and U.S. agencies should be able to have informal, oral communications any time before or after a proposed rule is issued as long as they are not doing so to raise concerns of their regulated entities or affected interests with the proposal. Although the APA and agency policies do not prohibit it, some think it is not permitted. Pre- and post-NPRM informal meetings can be very valuable for effective negotiations.

Another area for emphasis in any educational efforts is the practical effect of U.S. agency guidance, including potential judicial deference to the guidance.

Initial Projects

The EU and the U.S. should focus initially on identifying projects for which success should be relatively easy but that will allay concerns and clearly illustrate the advantages of cooperation. For example, on the process side, they might look for early, easily and automatically provided notifications to each other about studies, recommendations, or rulemaking status. For a substantive rulemaking, even if only one side is currently considering a rule, they might agree to jointly chair a public meeting on the issues held via the internet. Moreover, selecting easy-to-accomplish rulemakings may also quickly generate best practices or lessons learned that will help when the agencies move to more complex matters.

Another area to focus on for initial regulatory cooperation efforts is currently unregulated matters—areas where an agency is not yet "locked into" an approach or existing scheme. Essentially, for an emerging risk, the goal might be for the EU and the U.S. to jointly gather the data, analyze the risks, and develop alternative solutions. One subject might be driverless motor vehicles. Another could be unmanned aircraft systems; as noted above, the U.S. and Canada are working together on this issue. A third might be transportation of lithium batteries.

The agencies may already have moved too far on these matters, but if they have not developed a reasonable solution yet, a cooperative approach may be worth considering. A generic area might be where agencies are moving from rules that impose risk control (e.g., no driver may drive more than eight hours without a rest) to risk management (e.g., a driver must operate under a system, approved by the agency, that is tailored to the driver's specific operations by assessing and managing risks by monitoring and evaluating performance; presumably, the use of technology in the vehicle that measures fatigue symptoms would suffice).[78] This approach to regulatory requirements might also lessen concerns about enforcement differences between the EU and the U.S.

[78] See, e.g., 14 CFR 117.7. See, also, the FAA's "Risk Management Handbook" at http://www.faa.gov/regulations_policies/handbooks_manuals/aviation/risk_management_handbook/.

Public Participation

Both governments must emphasize the value of public participation to their agencies and not allow the use of regulatory cooperation to avoid it. The EU has announced the extra steps it intends to take to ensure more effective participation in its "Better regulation for better results – An EU agenda."[79] The U.S. objective should be to provide as much opportunity for participation as possible before and during negotiations with the EU to try to lessen the likelihood that changes will be necessary after the NPRM is issued. The governments should encourage early planning to ensure time is available for the participation, help identify and encourage the use of effective technology to enhance it and perhaps lower its cost, help obtain necessary resources to support it, and encourage the use of joint efforts by the counterpart agencies, such as joint public hearings or meetings, to increase is effectiveness.

Joint Public Meetings

EU and U.S. agencies should consider jointly chairing public meetings with interest groups, regulated entities and others who wish to attend to (1) discuss the benefits of, and objections to, regulatory cooperation; (2) discuss EU and U.S. proposals for addressing concerns or objections; and (3) receive and respond to public questions and suggestions. In addition, after identifying initial projects on which the EU and the U.S. agree to proceed with cooperation, the first steps should be to hold a public meeting to hear comments and discuss suggestions. Joint public meetings could also be held to obtain public comment during the comment period.

Early Notice

DOT and its EU counterparts should jointly explore whether they are taking sufficient steps to provide early notice of legislative and interpretative rules and policy statements. Both sides should discuss what they need and why they need it, rather than simply requesting or demanding specific action; that should enable them to identify the best and easiest way to provide it. The emphasis should be on getting notice of potential rulemakings early enough so that the agencies can lessen or eliminate possible conflicts or problems. Examples such as the DOT drug and alcohol and parking permits rulemakings illustrate the value to both sides of early notice.

Both sides should also discuss whether better access to U.S. information about petitions for rulemaking, exemptions, and waivers; litigation; draft legislation; NTSB, OIG, and GAO recommendations; retrospective reviews; agency reports or studies; and other similar information and the comparable EU information would be valuable. If so, the agencies should explore best practices for providing better access and take appropriate steps. For example, if helpful, U.S. agencies should be able to create separate files for petitions for rulemaking, waivers, or

[79] "Better regulation for better results – An EU agenda," Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (2015).

exemptions in regulations.gov and "code" them with effects such as "EU" to help searches or generate reports.

Regular Meetings

Regular meetings (or video-conferencing or phone-calls) between counterpart agencies can ensure momentum is established and maintained. DOT agencies hold regular meetings currently with some of their counterparts. They could require extra time and expenses, especially if the meetings require travel, but that could be mitigated by taking advantage of internet meeting tools. Among other things, the discussions could cover research priorities, identification of new safety or environmental problems, new rulemaking initiatives, and lessons learned in cooperation efforts.

Rulemaking Data

The EU and the U.S. need to address the data the U.S. needs from the EU to support its rulemaking development as well as subsequent compliance and enforcement activities. This is an important issue for the U.S. agencies. The EU may believe it has a better alternative, but the U.S. rulemaking process demands that the U.S. have adequate data to support that conclusion. This is a problem that has to be resolved with the involvement of regulatory and analytical staff. The EU appears to be trying to address the problem and discussions could start off with the steps taken so far.

Confidential and Related Information

The fear of internal or draft documents being leaked and the inability of some agencies to protect confidential information are having an adverse effect on current cooperation efforts. There is a cost in time and money to obtain needed information from other sources. If it is not available elsewhere, it may mean an alternative cannot be justified. The inability or reluctance to share information may make it more difficult to reach the level of cooperation desired. Both sides have to address these problems.

The U.S. needs to explore the possibility of getting legislative authority, for those agencies that do not already have it, to protect confidential data in regulatory cooperation efforts – authority to share data they have and to protect data they receive from another government. The FDA authority noted above could be a model.

As to the leaking of documents or information, it can be very difficult to prevent that. Even some U.S. agencies complain of problems when, during interagency coordination, another U.S. agency may leak their documents. Regardless, the EU and the U.S. should try to address the problem. For example, if the leaks result primarily because of a difference in the way the EU and the U.S. deal in general with their public under their respective processes, educational efforts may help.

Agency personnel who want more cooperation may not realize that leaks may make it harder to get the consensus that both sides want.

Rulemaking Supporting Analyses

One of the most significant concerns expressed by U.S. agencies and their affected interests involves the economic and other analyses supporting rulemaking. The EU is already taking steps to address this. However, the depth of the concerns may mean that more is expected than is promised. Both sides should consider creating a joint committee of regulators and economists to develop a consensus plan of action. Because it may be difficult to achieve consensus, the governments should consider using neutral facilitators and/or peer reviewers to assist in the decision making. To the extent the parties cannot reach agreement on what is necessary for a satisfactory analysis, they should be encouraged to identify ways to maximize cooperation and narrow differences without that agreement. There are a variety of approaches that might help address disparities. For example:

- The EU and the U.S. agencies could each prepare their own analysis and seek peer review of both and address the reviewer's comments.
- The agencies could jointly prepare one analysis and update it together as they go through the various stages of any internal and public review of the rulemaking; that may mean extra steps for both when the stages do not overlap closely. If necessary, they could note any areas where they disagree (e.g., on the need for better data) and seek any required public comment, and try to resolving the differences. A peer review also may help resolve disagreements.

Implementation of Rules

Implementation issues range from guidance to rule amendments to forum shopping. For comparable standard setting or reciprocal recognition approvals to be effective, the EU and the U.S. must ensure that the implementation of the rule does not defeat its intended objectives – essentially eliminating the harmonization or comparability. Again, there is some agreement that the EU is already taking steps to make implementation consistent among the Member States, but more may be necessary to achieve the promise of full regulatory cooperation. From the EU perspective, it might be beneficial for the U.S. to discuss the likelihood of judicial review or Congressional action affecting implementation of an agreed-to action.

Advisory Committees

The EU and the U.S. should explore expanded use of advisory committees for regulatory cooperation. The ability of U.S. agencies to invite their counterpart agencies to be non-voting members has been very helpful. It brings in early, joint participation by both sides in addressing problems and alternative solutions, includes important public participation, and may make consensus solutions more attainable. The EU and the U.S. should also consider using the

advisory committees to conduct negotiated rulemakings in appropriate situations. Among other things, the use of a neutral facilitator or mediator in the negotiations should increase the likelihood of achieving consensus. If EU participation in U.S. advisory committees is found to be workable and valuable, the U.S. could seek waivers or legislation to permit Europeans to have voting membership on U.S. advisory committees.

Neutral Facilitators

For discussions of contentious issues, both sides should consider the use of neutral facilitators who are skilled at helping participants in meetings reach agreement by getting them to focus on their interests rather than their positions. (E. g., both parties may want the one available apple and will not settle for half; asking why they want the apple may result in one party saying she is hungry and the other saying he needs the core for an art project.) Focusing on interests can result in the development of better resolutions and could be useful in government-to-government talks as well as public meetings. They could be especially valuable in the early stages of regulatory cooperation to help everyone learn to work well with each other. They would add to the up-front cost to of the process, but they could be well worth it, saving much more in the long-run. Moreover, their use need not be limited to individual rulemakings; they could also be used effectively to help resolve process issues (e.g., use of voluntary consensus standards setting bodies).

Digital Technology

The EU and the U.S. should consider expanding the use of different digital tools to enhance regulatory cooperation. The tools also can decrease costs, increase transparency, and address public concerns. They can be used for a range of matters, such as early notice, joint drafting, public participation, and coordination. For example, DOT agencies and their EU counterparts should consider whether social media tools could be valuable in providing information and education in addition to or in lieu of existing tools. For example, it might provide easier notification when a DOT agency places a document in regulation.gov. Another example is FAA's use, with Canada, of a bi-lateral webinar discussion with stakeholders in the FAA-Canadian cooperative efforts involving unmanned aircraft systems.

Reviews of Existing Rules or Legislation

As noted earlier, the U.S. has requirements for retrospective reviews of rules, including a requirement that they specifically consider rules with "unnecessary differences" with the requirements of other countries. The EU has a Regulatory Fitness and Performance Programme (REFIT) to ensure "that EU legislation remains fit for purpose and delivers the results intended."[80] With this emphasis in mind, the EU and the U.S. should consider establishing a

[80] Id. at 10.

special, joint review of their respective rules that focusses on "unnecessary differences." The counterpart agencies could jointly identify the problem areas. Alternatively, if resources are a problem, the focus could be on particular agencies with good, established relationships and/or the reviews could focus on one major area (e. g., commercial aircraft certification).

Data Collection

The EU and the U.S. should ensure that their agencies keep good data on the costs and benefits of their regulatory cooperation. This should include data on the process (e.g., more or less time needed to do research or analyses) as well as the substance (e.g., more alternatives identified, better data collected, or more or less cost-beneficial rules). The data collected should objectively evaluate the effects on the process and the rules; if positive, it should help address the concerns described in this paper and encourage more cooperation from the participating agencies and other agencies and develop more support from the public. To the extent there are negative findings, it should help identify improvements to the process. The data collected should cover such things as:

- Any savings from joint research.
- Dates for completing key steps in the rulemaking process and explanations for any delays; this information can help determine whether regulatory cooperation is delaying rulemaking and help identify areas where improvements may be possible.
- Data on costs and benefits of rules adopted through cooperative efforts; this could help determine the merits of the underlying rule as well as how those costs and benefits compare to such things as estimates for rules that would have resulted from individual rulemakings.
- The effects of any mutual recognition on costs and benefits of the underlying rules. Any enforcement problems for rules that are jointly developed and any differences in safety benefits in the EU and the U.S.

This need not be overly burdensome. For example, if new software programs are necessary for enhancing the cooperation, every benefit may not have to be analyzed if one or two are sufficient to justify the costs.

Independent Studies of Regulatory Cooperation

The Administrative Conference of the United States (ACUS) is a small U.S. agency that works with a large advisory committee made up of government and public members. Its mission is "to promote improvements in the efficiency, adequacy, and fairness of the procedures by which federal agencies conduct regulatory programs, administer grants and benefits, and perform related governmental functions."[81] It develops recommendations primarily directed to U.S.

[81] https://www.acus.gov/

agencies and Congress that are generally based on scholarly research projects. It also prepares publications and seminars on best procedural practices.

If the EU has an agency such as ACUS or could create a temporary body that could work with ACUS, the EU and the U.S. should recommend that ACUS and the EU body jointly study EU-US initial regulatory cooperation efforts, identify best practices, areas for improvement, and other ideas for joint recommendations. Alternatively, the EU and the U.S. could jointly solicit such studies by non-governmental researchers, such as academics or "think tanks" in the EU and the U.S. Third-party studies rather than reviews by the involved governments might produce more objective analyses. A neutral study might also be more effective in allaying any remaining public concerns.

Conclusion

The significant achievements of the U.S. DOT suggest there has been some, if not significant, reciprocity by its EU counterpart agencies. DOT is also a Department that has not been afraid to be innovative. There are many things that could be done to enhance the processes of cooperation, and transportation regulations may be an area where it is likely to get done.

3

Improving Regulatory Cooperation Between the U.S. Food and Drug Administration and the EU

Randall Lutter[1] and David Zorn[2]

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety of a very broad class of products, and enjoys substantial authority, including an ability to ban medical products for which it has not granted marketing approval. A large part of FDA's activities goes beyond simply sending warning letters that threaten or initiate the closure of facilities or the recall of products. Rather it involves collecting information about risks of certain products or classes of products, organizing and analyzing this information to reach conclusions about risk, and then disseminating these conclusions to manufacturers or distributors of FDA-regulated products, as well as to members of the public, health care professionals and staff at other U.S. and non-U.S. government entities. Seen in this way, FDA's activities offer ample opportunities for sharing information, i.e., cooperating with other government entities to collect, organize, analyze and evaluate information and to disseminate information about the risks associated with certain products.

Seeing FDA in part as an information management organization suggests that there may be opportunities for more meaningful cooperation between the FDA and entities around the world with similar responsibilities. Such cooperation could in principle help focus regulatory efforts on areas of greatest risk and thereby reduce both risk and regulatory burdens on lower risk activities around the globe. It could improve efficiency by allowing for more coordinated activities among major trading partners such as the U.S. and the EU and its member countries.

The EU does not have any single government entity with the same responsibilities and authorities as FDA. We endeavor to distinguish among the different EU entities, as necessary. Within the EU Commission, for example, the Directorate General for Health and

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Food Safety (DG SANTE) has health and food safety responsibilities.[3] As a regulatory authority it drafts laws, and its proposals become official only once the College of Commissioners adopts them.[4] The European Food Safety Agency is a decentralized agency with responsibilities for risk assessment and communications, but not for risk management; thus it does not issue or enforce regulations.[5] The European Medicines Agency is also a decentralized agency, and its evaluations of marketing-authorization applications submitted through the centralized procedure provide the basis for the authorization of medicines in Europe.[6]

In this report we analyze the scope and effectiveness of FDA's efforts to cooperate with entities in the EU, using publicly available information. We find that FDA provides ample information about its agreements with foreign regulators but no meaningful information about its progress in implementing such agreements. We recommend a high-level agreement and commitment for periodic disclosure of information regarding implementation of international agreements for regulatory cooperation. The development of performance plans and goals and of quantitative measures of progress to achieve those goals is routine for many of FDA's programs, despite the existence of some goals that are not easily quantifiable. The FDA's Office of International Programs should follow the practice of other FDA offices in adopting such planning and reporting procedures.

This report begins by summarizing the scope of FDA's regulatory activities. We then turn to a description and analysis of FDA's multilateral and bilateral efforts at international cooperation, including a careful consideration of various memoranda of understanding and confidentiality commitments. We then provide a critical review of the effectiveness of FDA's management of its program of international cooperation. We provide a description of opportunities for better cooperation, based on our analysis, and then conclude with some policy recommendations.

Background

A Summary of FDA's Regulatory Activities

The U.S. Food and Drug Administration has very broad regulatory authority, covering most products sold in supermarkets, and many products sold to hospitals. FDA has estimated that the

[3] See, e.g., European Commission, D G Health and Food Safety, *About Us, http://ec.europa.eu/dgs/health_food-safety/about_us/who_we_are_en.htm*

[4] See, e.g., European Commission, About the European Commission, http://ec.europa.eu/about/index_en.htm#directorates

[5] See, e.g., European Food Safety Agency, *About EFSA,* http://www.efsa.europa.eu/en/aboutefsa .

[6] See, e.g., European Medicines Agency, *What We Do,* http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp

products that it regulates represent between twenty and twenty-five percent of all consumer spending.[7]

Regulatory Scope

In addition to food and drugs, FDA regulates cosmetics, food additives, food contact substances, dietary supplements, animal feed, veterinary medicines, and biologics—a category of medical products that includes vaccines and 21st century biotech innovations. It also regulates tobacco and vaping products, products that emit radiation such as microwave ovens, as well as medical devices—a category that spans products from X-ray machines to tongue depressors, and includes sonograms and pregnancy tests. We elaborate briefly on its program to regulate two major classes of products.

Medical Products

With respect to medical products, FDA regulates all aspects of clinical testing, manufacturing, and marketing of drugs and biologic products and medical devices, from the first trial with human subjects to production, labeling and post-marketing surveillance of safety concerns. It also approves and regulates products that do not need clinical trials, that is, generic drugs approved because they are shown to be bioequivalent to innovator products[8] and medical devices that are substantially equivalent to devices already legally marketed in the U.S.[9] Beyond regulating products, FDA oversees the research of principal investigators involved in trials of the medical products that it regulates.[10] FDA also regulates Institutional Review Boards that oversee trials of medical products regulated by FDA.[11] FDA can put a hold on such clinical trials if it believes they cannot be conducted without unreasonable risks to subjects/patients.[12]

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[7] See, e.g., U.S. Food and Drug Administration. *Global Engagement*. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM298578.pdf

[8] U.S. Food and Drug Administration. "Drugs: Abbreviated New Drug Application (ANDA): Generics." http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm

[9] U.S. Food and Drug Administration. "Medical Devices: Overview of Device Regulation." http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ .

[10] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, & Center for Devices and Radiological Health. *Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects*. October 2009. http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf

[11] See, e.g., U.S. Food and Drug Administration. "Science & Research: Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors." http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm .

[12] U.S. Food and Drug Administration. "Drugs: Drug Development and Review Definitions." http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm176522.htm

Food

FDA regulates foods for humans and animals (with the major exception of meat, poultry, and egg products which are the responsibility of the U.S. Department of Agriculture) in a manner that is only slightly less comprehensive than the way that it regulates medical products. Any food offered for sale in the U.S. must meet the content, processing, packaging, labeling and storage requirements specified by FDA in Title 21 of the United States Code of Federal Regulations. All facilities that produce, store and handle the food must be registered with the United States according to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The registrant of a facility agrees that FDA will be permitted to inspect the facility at times and in the manner authorized by the United States Food Drug and Cosmetic Act even if that facility is located outside the borders of the United States.

If FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may suspend the registration of a facility that:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

Importers of food must notify U.S. officials of pending shipments prior to their arrival in the United States. FDA may inspect imported foods at the point of entry. Once a food has been allowed to enter the U.S., it is subject to inspection at any time by federal, state or local officials. Additionally, FDA's Reportable Food Registry is open for industry and regulators to report situations in which they believe that there is reasonable probability that an article of food will cause serious adverse health consequences. The Registry is intended to help the FDA better protect public health by tracking patterns and targeting inspections.

Outbreaks of foodborne illness or the discovery of food that is adulterated or mislabeled by U.S. standards prompts investigations. FDA uses transaction records required of industry to trace the implicated food back to the cause of the contamination at the manufacturer, repacker or warehouse, even if it is located overseas.

Administrative Procedures

The scope of these routine enforcement activities comports not only with multiple statutes, but also with FDA's regulations interpreting statutory requirements. As required by the Administrative Procedure Act, FDA must publish proposed rules in the *Federal Register* and solicit public comment on them, before publishing them in the *Federal Register* in final form.[13]

[13] 5 U.S.C. §552: Public information; agency rules, opinions, orders, records, and proceedings

The Administrative Procedure Act also requires FDA to respond to public comments at the time it issues final rules. FDA typically treats all public comments equally, without regard to citizenship, place of legal residence, or whether the author is a private or government entity.

FDA issues economically significant regulations at a relatively slow pace, compared with the scope of its regulatory oversight. For the 10 years between October 1, 2004 and September 30, 2014, the U.S. Office of Management and Budget identifies only 5 economically significant regulations issued by the FDA.[14] It also reports that the annual benefits and costs of these regulations are between $0.4 billion and $14 billion for benefits and $0.2 billion and $0.5 billion for costs, in 2010 dollars. These regulations do not include recent rules that FDA has issued to implement the Food Safety Modernization Act (FSMA), such as the Preventive Controls for Human Food and the Preventive Controls for Animal Food. Also excluded are the Foreign Supplier Verification Rule and the Produce Rule, two economically significant rules for which OMB completed review on October 30th, 2015. OMB's list of economically significant final rules also does not include additional rules implementing FSMA, which FDA has proposed and is expected to issue soon in final form.[15]

In addition, FDA issues a large number of regulations that are not economically significant. The entry for FDA in the *Unified Agenda* provides information on all final and proposed regulations expected through the end of 2016.[16] For proposed rules, as of November 11, 2015, FDA lists 28 separate regulatory actions, of which 22 had no statutory deadline. In addition, FDA reports that it plans to issue 29 final rules by the end of 2016, 18 of which have no statutory deadline. The list of those final rules includes some economically significant regulations as well as some with "projected" publication dates that are prior to when the list was most recently updates in July of 2015.

Regulatory Guidance

FDA also issues many guidance documents that describe to FDA staff, applicants and sponsors of medical products, and to the public generally, its interpretation of regulations or its policy on specific regulatory issues. These guidance documents cover a very broad range of topics, from purely procedural requirements to outlining safe harbors in regulatory areas where technology is rapidly changing.

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[14] Office of Management and Budget. *2015 Draft Report to Congress on the Benefits and Costs of Federal Regulations*. Table 1-2. https://www.whitehouse.gov/sites/default/files/omb/inforeg/2015_cb/draft_2015_cost_benefit_report.pdf

[15] For a reasonably up to date list, please see FDA's list at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm.

[16] See http://www.fda.gov/AboutFDA/Transparency/track/ucm351742.htm We note that some of these rules have release dates in the past. We have not ascertained whether these are rules that in fact have been issued, or are ones still to be issued in the future.

In issuing guidance, FDA follows a regulation that it issued in 2000 setting forth Good Guidance Practices—FDA's policies and procedures for developing, issuing, and using guidance documents.[17] This regulation, which we believe to be unique among federal regulatory agencies, essentially guarantees an opportunity for the public to comment on all FDA guidance documents that are "Level 1." Level 1 guidance documents are those that present initial interpretations of statutory or regulatory requirements, set forth changes in interpretation or policy that are of more than a minor nature, include complex scientific issues, or cover highly controversial issues. As with proposed regulations, this opportunity to comment is open to all entities, regardless of residency or citizenship.

Guidance documents include, but are not limited to, documents that relate to the design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies. FDA has issued more than 260 proposed (draft) and final guidance documents since January 1, 2015.[18] FDA specifically identifies 15 of these guidance documents as being related to imported products, but given the large percentage of FDA regulated products that are imported, almost all of these guidance documents are likely to have indirect international impacts.

International Regulatory Cooperation

FDA has cooperated with foreign regulators for many years, but in 2011 it announced a new effort to improve international cooperation and outlined a collection of strategies for global engagement:[19]

- International offices and posts
- Strengthening regulatory capacity
- Harmonizing science-based standards
- Leveraging knowledge and resources
- Risk-based monitoring and inspection
- Global Surveillance, Preparedness and Emergency Response
- Advancing Regulatory Science

FDA's international regulatory program may be in seen in light of Kingsbury, Krisch and Stewart's work describing "global administrative law."[20] They recognize the growth of trans-governmental regulation in an increasingly global economy.

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[17] 21 C.F.R. 1, §10.115. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.115

[18] See, e.g., U.S. Food and Drug Administration. "Regulatory Information: Search for FDA Guidance Documents." http://www.fda.gov/RegulatoryInformation/Guidances/default.htm .

[19] See, e.g., See, e.g., U.S. Food and Drug Administration. *Global Engagement*. 2011. p. 8.http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM298578.pdf

> "[V]arious transnational systems of regulation or regulatory cooperation have been established through international treaties and more informal intergovernmental networks of cooperation, shifting many regulatory decisions from the national to the global level. Further, much of the detail and implementation of such regulation is determined by transnational administrative bodies—including international organizations and informal groups of officials—that perform administrative functions but are not directly subject to control by national governments or domestic legal systems or, in the case of treaty-based regimes, the states party to the treaty."[21]

Kingsbury, et al. note that these networks and coordination arrangements need transparency.[22] Their observations are consistent with our recommendations for improved reporting on the activities of FDA's international programs.

FDA's activities to promote international cooperation can be divided into multilateral and bilateral efforts. We briefly review FDA's multilateral cooperation before turning to bilateral cooperation between the FDA and entities of the EU.

Multilateral Efforts

FDA's Activities to Promote International Cooperation

In 1963 the Food and Agriculture Organization of the United Nations and the World Health Organization jointly established the Codex Alimentarius Commission (CODEX) to develop harmonized international food standards to protect public health and promote fair trade practices for foods. Over 300 standards, guidelines, and codes of practice have been developed.[23] The issues addressed by CODEX cover a broad range of topics from seafood to vegetables, organic to biotech products, and sanitation to labeling.[24]

Both FDA and the EU Directorate General for Health and Food Safety are major participants in the CODEX processes. FDA reports that CODEX is "the major international mechanism for encouraging fair international trade in food while promoting the health and economic interest of

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[20] Kingsbury, Benedict, Nico Krisch, and Richard B. Stewart, "The Emergence of Global Administrative Law," *Law and Contemporary Problems*. Vol 68. pp. 15-61. 2005.
[21] Ibid, p. 16.
[22] Ibid, p. 38.
[23] See http://www.codexalimentarius.org/standards/en/.
[24] CODEX Alimentarius International Food Standards. "Thematic Compilations."http://www.codexalimentarius.org/standards/thematic-publications/.

consumers."[25] Nations are not bound to adopt CODEX standards. However, FDA considers CODEX standards when making regulatory decisions to meet World Trade Organization obligations while at the same time protecting the health of U.S. consumers.

In 1990 the European Community initiated the International Conference on Harmonization (ICH) of pharmaceutical regulation.[26] The ICH (now the International Council on Harmonization) involves a number of developed countries in an endeavor that seeks to make recommendations towards achieving greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines.[27] FDA implements these ICH recommendations in the form of guidance documents, which fall under four categories: ICH Efficacy, ICH Joint Safety and Efficacy, ICH Quality and ICH Safety.[28] Each of these is an area of major activity. For example, the ICH Efficacy recommendations alone have led to 30 different FDA guidance documents made public between March 1995 and July 2015. FDA has issued three of these in draft (proposed) form, and 27 as final documents.

Examples of Multilateral Cooperation

On several occasions, FDA has endeavored to cooperate with foreign entities on an *ad hoc* basis, because of the exigencies of particular circumstances. These cases illustrate active behind the scenes cooperation.

In early spring of 2007, FDA became aware of deaths of cats subjected to taste tests for different varieties of pet food. FDA, working with independent researchers eventually identified melamine as the responsible contaminant, especially when it was present along with cyanuric acid, another industrial contaminant.[29] FDA is credited with developing and disseminating a test for melamine, which apparently had been fraudulently added in China so as to make flour from wheat and rice appear higher in protein than it actually was.[30] The European Food Safety Authority ("EFSA")

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[25] U.S. Food and Drug Administration. "Food: International Cooperation." http://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalCooperation/default.htm

[26] See e.g., ICH. "History." http://www.ich.org/about/history.html.

[27] ICH. "Vision." http://www.ich.org/about/vision.html.

[28] U.S. Food and Drug Administration. "Drugs: International Council on Harmonisation – Efficacy" http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065004.htm.

[29] U.S. Food and Drug Administration. "Animal & Veterinary: Melamine Pet Food Recall - Frequently Asked Questions" http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm129932.htm

[30] See, e.g., FDA's April 2007 public notice at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048192.htm and also a scientific presentation of its scientists at http://acs.confex.com/acs/mwrm07/techprogram/P51682.HTM

acknowledged, if indirectly, prior work by FDA identifying the contaminant in animal food products originating from China.[31]

As a second example, in January of 2008, FDA relaxed a voluntary moratorium on the sale of food products from animal clones because it had completed a scientific risk assessment that concluded that such foods were as safe as foods from traditional animals.[32] The issue of safety of food from animal clones had been controversial, because such foods were not labeled and many people reacted emotionally to news reports that the meat they were bringing home from the supermarket came from animal clones. Months after the FDA decision, which was issued only after public notice and extensive comment, the EFSA released a complementary finding.[33] The FDA officials responsible for coordinating the January 2008 announcement were aware of the status of the EFSA work because of unofficial communications with EFSA, and anticipated correctly that EFSA would likely reach a similar conclusion. Back-channel communications of the pending EFSA work helped reassure U.S. government officials that the FDA finding was trustworthy.

The International Medical Device Regulators Forum ("IMDRF") began in 2011 to discuss the harmonization of medical device regulations. The current members are: Australia, Brazil, Canada, China, Europe, Japan, Russia, and the U.S. IMDRF has developed a number of guidances and standards to harmonize regulatory activities such as definitions for software that acts as a medical device, processes and standards for recognizing auditing organizations, unique identifiers for devices, and standards for reports of device manufacturer audits.[34] An example of progress in harmonization related to the IMDRF is a pilot program on applying a common standard for medical device manufacturer audits in order to most efficiently allocate inspection resources.[35]

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[31] See e.g., European Food Safety Authority. *Scientific Opinion on Melamine in Food and Feed: EFSA Panel on Contaminants in the Food Chain (CONTAM) and EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF).* April 2010. http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1573.pdf

[32] U.S. Food and Drug Administration. "FDA News Release: FDA Issues Documents on the Safety of Food from Animal Clones. Agency Concludes that Meat and Milk from Clones of Cattle, Swine, and Goats, and the Offspring of All Clones, are as Safe to Eat as Food from Conventionally Bred Animals." January 15, 2008. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116836.htm

[33] European Food Safety Authority. "Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals." July 2008. http://www.efsa.europa.eu/en/efsajournal/pub/767

[34] International Medical Device Regulators Forum. "IMDRF and GHTF documents." http://www.imdrf.org/documents/documents.asp

[35] U.S. Food and Drug Administration. "Training and Continuing Education: International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP) Pilot." http://www.fda.gov/Training/CDRHLearn/ucm372921.htm

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ("VICH") is an international industry/government effort that was launched in April 1996. The founders were the World Organization for Animal Health, the International Federation of Animal Health, Japan, the U.S., and the EU. They wanted the VICH to develop consensus guidelines that describe the study protocols and designs for the testing required to demonstrate product safety, quality and efficacy for the purpose of licensing or registering veterinary medicines.[36] In addition to preapproval study requirements, VICH has also developed guidance for post-marketing monitoring and reporting of adverse drug events.

Bilateral Regulatory Cooperation

FDA's Activities Promoting Cooperation with the EU

Regulatory cooperation between the FDA and EU organizations can be seen both in terms of high-level efforts at cooperation and efforts initiated by FDA. We consider each in turn.

High-level efforts to promote regulatory cooperation between the U.S. and the EU date to at least 2007, when the White House and the European Commission created the Transatlantic Economic Council ("TEC"). The current workplan of the TEC includes only a few topics related (somewhat indirectly) to FDA. Moreover, these differ substantially in terms of the attention they have received in recent years. For example, among all the topics related at least indirectly to FDA, since 2011, e-Health received seven updates, the Innovation Action Partnership received two, Limiting Regulatory Divergence received two but both were prior to December 2011, and Nanotechnology received one in November 2011.[37] We could not find up to date information on the current status of these initiatives at the FDA or USTR websites.

Past cooperation topics of the Transatlantic Economic Council include six items, of which five, (all but "Finance") are fairly directly related to FDA:

- Finance[38]
- Innovation and Technology[39]
- Intellectual Property Rights[40]
- Pharmaceuticals[41]

[36] See http://www.vichsec.org/what-is-vich.html

[37] U.S. Department of State. "Current Workplan of the Transatlantic Economic Council." http://www.state.gov/p/eur/rt/eu/tec/c33533.htm.

[38] U.S. Department of State. "Transatlantic Economic Council: Specific Cooperation Topics--Finance." http://www.state.gov/p/eur/rt/eu/tec/c33621.htm

[39] U.S. Department of State. "Transatlantic Economic Council: Specific Cooperation Topics--Innovation and Technology." http://www.state.gov/p/eur/rt/eu/tec/c33625.htm

[40] U.S. Department of State. "Transatlantic Economic Council: Specific Cooperation Topics--Intellectual Property Rights." http://www.state.gov/p/eur/rt/eu/tec/c33624.htm

- Safety and Regulations[42]
- Use of Standards[43]

The State Department website, however, provides no information on any activity in any of these six topics in the last four years. The topic "Safety and Regulations" itself includes eight subtopics, and five of these involve FDA, but this report of the TEC provides no information on the status of these cooperation topics since March 2010, more than five years ago.[44] For two of these items, the links to additional information, in the form of a final report or an annual activities report, lead to defunct website addresses.[45] The lack of a single annual report on implementation of these agreements contributes to an impression of relative inattention to implementation.

FDA Memoranda of Understanding with Foreign Government Entities

Turning to FDA-level cooperation with foreign government entities, we find that FDA provides to the public substantial information on its website about the nature of its interactions with foreign entities.[46] Specifically, it lists and provides MOUs and confidentiality commitments with foreign entities. Before analyzing the MOUs that FDA has finalized with EU entities, however, it is worth reviewing FDA's criteria for entering into an MOU with a foreign government entity. On its website, FDA describes the process for developing MOUs with entities in foreign governments or with international organizations. The description was last modified in 1995, but appears on a website that was updated in 2015, and thus appears to have withstood the test of time.[47] Interestingly, it represents part of the FDA's Compliance Policy Guides, which predate its 2000 Good Guidance Practice regulation, requiring public notice and comment for guidance documents.

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[41] U.S. Department of State. "Transatlantic Economic Council: Specific Cooperation Topics--Pharmaceuticals." http://www.state.gov/p/eur/rt/eu/tec/c47302.htm

[42] U.S. Department of State. "Transatlantic Economic Council: Specific Cooperation Topics--Safety and Regulations." http://www.state.gov/p/eur/rt/eu/tec/c33620.htm

[43] U.S. Department of State. "Framework for Promoting Transatlantic Economic Integration, Annex I: Fostering Cooperation and Reducing Regulatory Barriers, A. Horizontal--Standards." http://www.state.gov/p/eur/rt/eu/tec/131810.htm

[44] See http://www.state.gov/p/eur/rt/eu/tec/c33620.htm

[45] See 07/27/11 Transatlantic Administrative Simplification Action Plan - Final Report on implementation, and 06/01/11 Interactions Between the European Medicines Agency and U.S. Food and Drug Administration September 2009-September 2010 (2011 FDA/EU Annual Activities Report)

[46] U.S. Food and Drug Administration. "About FDA: FDA Memoranda of Understanding." http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm

[47] U.S. Food and Drug Administration. "Inspections, Compliance, Enforcement, and Criminal Investigations: CPG Sec. 100.900 International Memoranda of Understanding." http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073828.htm

The criteria for a new MOU include:

- Health Benefits (Including Risk Reduction) Associated with Products or Programs: FDA should consider the benefits to public health (particularly for the United States population) when it sets priorities for its international activities.
- Products Imported into the United States: FDA should place a higher priority on international activities that are directed toward improving the quality, safety, or efficacy of products offered to consumers in the United States. For example, FDA should give a low priority to investing resources in developing a memorandum of understanding with a foreign country that covers a product where there is little likelihood of significant exports to the United States or significant risk to the public.
- History of Compliance Problems: FDA should place a higher priority on international activities directed toward remedying product defects that have been demonstrated to be previous compliance problems or where there is a demonstrated scientific basis for increased surveillance.
- Comparative Costs of Alternative Programs: FDA should pursue international programs and activities that provide the greatest benefit in relation to the resources required to administer them. For example, the costs of developing, implementing, and monitoring an agreement should be weighed against the costs of higher sampling levels to obtain the same degree of confidence in rates of compliance in the absence of an agreement.
- Regulatory Burden on Industry: FDA should consider the regulatory burden on industry that could be diminished by harmonization efforts. However, these activities need to be compatible with FDA's primary public health mission, the act, and other laws and regulations that FDA enforces.
- U.S. Foreign Policy Objectives and Priorities of Other U.S. Government Agencies: FDA should be knowledgeable of U.S. foreign policy objectives and international programs and policies of other U.S. Government agencies and appropriately balance these interests with those of FDA’s primary mission.

These criteria have an understandable focus on FDA’s mission to protect and promote public health in the United States. The list also includes, however, reducing the regulatory burden on industry and balancing interests of other U.S. government agencies with those of FDA’s primary mission. FDA’s approval of drugs for the U.S. President’s Emergency Plan for AIDS Relief

program to provide low-cost anti-retrovirals to fight AIDS in very low-income countries may be seen as an example of such balancing.[48]

FDA lists on its website one MOU, and four different confidentiality commitments with entities of the EU. Table 1 below summarizes key characteristics of these documents.

The memoranda of understanding and confidentiality commitments between FDA and the EU primarily serve to set forth the standards of the U.S. Freedom of Information Act ("FOIA") and the U.S. Administrative Procedure Act ("APA"), as well as FDA regulations for sharing information between the parties. Specifically, FDA commits to sharing with the EU certain information, and FDA is open to receiving information from the EU. FDA also commits to respecting the protections from disclosure under FOIA to confidential commercial information, trade secret information and personal privacy information. The confidentiality commitments also extend to information that the EU shares with FDA on law enforcement and internal, pre-decisional matters — the same protections that would be afforded to parts of the U.S. federal government beyond the FDA.

[48] U.S. Food and Drug Administration. "International Programs: Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan." http://www.fda.gov/InternationalPrograms/PEPFAR/ucm119231.htm

Table 1: Memoranda of Understanding and Confidential Commitments Between the U.S. Food and Drug Administration and Entities in the European Union					
Type of Document	Memorandum of Understanding	Confidentiality Commitment			
Date	2005	2005	2007	2009	2010
Products Covered	Foods	Foods, Drugs, Biologics, Medical Devices, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, Tobacco Products	Foods	Drugs, Biologics, Animal & Veterinary Drugs	Drugs, Biologics, and Animal and Veterinary Drugs
EU Entity	European Commission's Health and Consumer Protection Directorate General[49]	European Commission's Health and Consumer Protection Directorate General[47]	European Food Safety Authority	European Directorate for the Quality of Medicines & HealthCare[50]	European Medicines Agency
Selected Issues Addressed	Documents required to be made public under the APA	Non-public documents and/or information related to products that are regulated by both entities.			
	Documents relating to controls to ensure effective inspections ("verification") enforcing the 1999 Agreement on foods of animal origin	Bilateral commitment on confidentiality of FOIA exempt information--confidential commercial information; trade secret information; personal privacy information; law enforcement information; and internal, pre-decisional information			
	Information relating to outbreaks of foodborne illness	FDA commits to inform the foreign party if it receives requests for information that would otherwise be protected by FOIA through mechanisms such as subpoenas or Congressional document requests.			

[49] This Directorate General was reorganized in 2015 to the Health and Food Safety Directorate General.

[50] A directorate of the Council of Europe, the European Directorate for the Quality of Medicines and Health Care facilitates the development, implementation, and application of quality standards, such as the European Pharmacopeia, for safe medicines and their safe use. The European Pharmacopeia is legally binding in the 37 states and the EU which have signed the Convention on the Elaboration of a European Pharmacopoeia.

Underlying these provisions is an FDA regulation that strengthens its ability to protect information provided to it by foreign governments and information that it provides to foreign governments.[51] Specifically, under limitations on exemptions, it states "communications with foreign government officials shall have the same status as communications with any member of the public, except that":

> Investigatory records compiled for law enforcement purposes by foreign government officials who perform counterpart functions shall be exempt from public disclosure to the same extent to which the records would be so exempt (pursuant to other provisions on equal access by all members of the public), as if they had been prepared by or submitted directly to FDA employees.
>
> Disclosure of investigatory records compiled for law enforcement purposes by the FDA to foreign government officials who perform counterpart functions to the FDA in a foreign country as part of cooperative law enforcement efforts does not invoke the provision that such records shall be made available for disclosure to all members of the public.

This same FDA regulation allows designated FDA officials to "authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic, predecisional documents concerning the FDA's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements."[52] This authority may be noteworthy.

The confidentiality commitments between FDA and the various EU organizations are very similar.

The MOU between the FDA and the EU does not address medicines or medical devices, although these products are the subject of MOUs between the FDA and decentralized agencies of individual European countries, both within and outside the EU. Table 2 provides some selected information about such MOUs.

[51] See 21 CFR 20.89.
[52] Ibid.

Table 2: Selected Memoranda of Understanding Between the U.S. Food and Drug Administration and Foreign Government Entities				
Type of Document	Memorandum of Understanding			
Date	1972	1986	1988	2010
Country	Sweden	United Kingdom (UK)	The Netherlands	Russian Federation
Products Covered	Inspection of Drug Manufacturing Plants	Medical Device	Good Laboratory Practices	Drugs
Foreign Government Entity	Swedish National Board of Health and Welfare	Department of Health and Social Security of the UK and Northern Ireland	Ministry of Welfare, Health and Cultural Affairs	Federal Service on Surveillance in Health Care and Social Development
Selected Issues Addressed	Provides for joint inspections and annual or periodic review.	"will exchange such information as is necessary for the mutual recognition of inspections related to medical devices manufactured in one country and intended for import into the other"	- Provide the other party, regularly, with the names and addresses of nonclinical laboratories operating within their country, the dates the laboratories were inspected, and their compliance designation; - Provide upon request of the other party, further information regarding whether or not a specific laboratory or study is in compliance with the good laboratory practice standards; - Honor a request by the other party to conduct a GLP inspection or data audit at a specified nonclinical laboratory	Simplification of information exchange and emergency notification procedures to be followed in case of contamination or counterfeit, whether occasional or deliberate, of drug products and their ingredients.

Table 2 and the single MOU in Table 1 represent only an illustrative selection of the 20 MOUs that FDA reports having with other nations and international organizations. The focus on information sharing in each MOU emphasizes that information sharing is one of the primary activities and values that FDA has in its international interactions. However, the lack of uniformity in the MOUs is also notable. Without more information on the background of the MOUs it is impossible to know whether the differences in MOUs or the lack thereof is because of barriers on the FDA side of the negotiations or on the side of the other parties. It may also be the result of a lack of interest or lack of perceived need by both potential parties.

Additionally, the existence of international cooperation in the absence of specific MOUs indicates that MOUs are not required for FDA and the EU to have productive working relationships. However, without reports on international accomplishments, it is impossible to judge whether refinement of existing MOUs or the establishment of additional MOUs would improve cooperation and information sharing between FDA and the EU.

Program Management

Since 2008 the FDA has taken a variety of steps to strengthen its international program. It has created an Office of Public Health and Trade and an Office of Strategy, Partnerships and Analytics within its Office of International Programs.[53] It has opened several offices overseas, including one in Brussels, substantially increasing its international program. Regarding its Brussels office, the FDA states

> The mission of FDA's Europe Office is to strengthen the safety, quality, and effectiveness of medical products and food produced in Europe for export to the United States. The objective of the Europe Office is to foster collaboration and to share knowledge and information with FDA's counterpart regulatory authorities throughout the region.[54]

The FDA lists five activities of its Europe Office:[55]

1. Transatlantic Economic Council High Level Regulatory Cooperation Forum
2. Memoranda of Understanding and Other Cooperative Arrangements

[53] U.S. Food and Drug Administration. "About FDA: IOP Offices." http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm245229.htm

[54] U.S. Food and Drug Administration. "About FDA: Europe Office."http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm243678.htm (downloaded November, 2015)

[55] U.S. Food and Drug Administration. "About FDA: Europe Office." http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm243678.htm

3. European Medicines Agency
4. Confidentiality Commitments
5. Transatlantic Task Force on Antimicrobial Resistance

Four of these five items, although described as activities, are in fact documents (items 2 and 4), foreign government agencies (item 3), or a new transnational bureaucratic entity (item 5). The exception, the TEC High Level Forum ("TECHLRCF") is a process of ongoing U.S.-EU consultation involving a series of meetings among designated officials. FDA's website provides a description of the TECHLRCF, and lists 14 separate projects with the EMA and the European Commission. (See Appendix A.) It does not, however, provide any information about the status of these projects, e.g., whether they have been initiated, are on schedule, or have ended or already been completed. A recent State Department report on the TECHLRCF is also silent on these projects and indeed on the FDA, although these projects may be encompassed by the ongoing Transatlantic Trade and Investment Partnership talks.[56] The USTR website, however, provides no additional information about FDA's implementation of those measures.[57]

FDA does not appear to provide information about the accomplishments or performance of its international programs, and specifically its Brussels office. At least, we were unable to find information about the results or accomplishments of the activities of its international program or its Brussels office.

International Activities in the FDA Budget Justification

FDA's most recent budget justification provides additional information about its international activities, which involve two different offices: FDA's Office of Regulatory Affairs ("ORA"), which is responsible for enforcement, and the much smaller FDA Office of International Programs. However, FDA provided little information on the expected public health achievements (outcomes) of its international programs in the budget justification.

The ORA's FY2016 budget request listed "Extending FDA's Global Presence" among its most significant accomplishments. In particular, it stated:

> The foreign inspection program is critical to FDA's mission to protect public health. The global supply of FDA regulated products continues to grow in volume

[56] U.S. Department of State, Bureau of European and Eurasian Affairs. *Transatlantic Economic Council (TEC) Facilitators Report to Stakeholders*. March 27, 2015. http://www.state.gov/p/eur/rls/or/2015/240826.htm
For TTIP, see Executive Office of the President, Office of the United States Trade Representative. "Transatlantic Trade and Investment Partnership (T-TIP)." https://ustr.gov/ttip

[57] Executive Office of the President, Office of the United States Trade Representative. "T-TIP Issue-by-Issue Information Center."https://ustr.gov/trade-agreements/free-trade-agreements/transatlantic-trade-and-investment-partnership-t-tip/t-tip.

> and complexity. In response to the growing trend, ORA conducted 3,000 inspections in 2014, a 300 percent increase from ten years ago. In addition to using its domestic staff, FDA is increasing the number of personnel stationed in its foreign offices.[58]

In another section, entitled "Analyzing and Utilizing Global Data to Manage Risk," FDA ORA states "FDA performs routine surveillance inspections both within the U.S. and globally to assess regulated industry compliance with appropriate regulations and conducts for-cause inspections when violations are discovered or outbreaks occur."[59] It does not elaborate, however, how FDA will use new technologies or new institutional arrangements with foreign government regulators to facilitate such work.

FDA's most recent budget justification includes an additional $20.5 million for Import Safety, the Foreign Supplier Verification Program Implementation.[60] FDA describes this program, which is primarily directed at facilitating imports of food product, as follows: [61]

> One of FDA's best opportunities for return on investment is helping foreign governments ensure the safety of food and feed before it is even shipped to the U.S. FDA continues to invest in this effort in three ways by:
>
> - placing staff in foreign offices
> - increasing the number of foreign inspections
> - developing partnerships with its counterparts overseas.
>
> Some of those efforts are focused more on technical assistance, such as helping other nations strengthen their regulatory systems and upgrading their public health laboratory methods and training.

FDA's budget justification for FY2016 includes some information about the activities of its foreign offices, but this activity is primarily in terms of outputs not outcomes that matter to policy makers and the public. Outputs represent FDA activities, e.g., inspections completed, but not accomplishments that matter more directly to people's welfare, such as reductions in the occurrence of pathogens on food or reductions in incidence of foodborne illness or reduced harm from medical products with poorly understood risks.

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[58] U.S. Food and Drug Administration, Office of Regulatory Affairs. *Narrative by Activity: Office of Regulatory Affairs - Field Activities*. p. 142. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM438022.pdf p. 142.

[59] Ibid, p. 146.

[60] Ibid, p. 151.

[61] Ibid, p. 152.

Regarding international inspections, FDA reports:

> In FY 2014, FDA implemented six new Confidentiality Commitments to promote information sharing with foreign counterpart agencies and international organizations; these include agencies in Denmark, Italy, Estonia, Spain, the United Kingdom, and one Confidentiality Commitment with the World Health Organization in support of information sharing related to Ebola.[62]

FDA goes on to describe collaboration and communication in India, and overseas offices in India, China, Mexico, and Chile, and inspections and short-term assignments of FDA inspectors to various countries.

These budget justifications fail to describe quantitatively the performance of FDA's foreign offices in terms of outcomes or accomplishments that ought to matter directly to the public's health and welfare. They do not provide quantitative descriptions of cooperation in responding to outbreaks of foodborne illness, tainted or mislabeled drugs, or even sharing of news about positive or negative inspection results, technical cooperation developing risk assessments to address novel threats like melamine, etc.

FDA Offices in Foreign Countries

FDA issued a report to Congress in 2012, as required by the FSMA, on the offices that FDA has established in foreign countries.[63] The report describes the progress of those foreign posts in working with foreign government counterpart regulatory authorities and others in the countries. FDA has a senior technical expert embedded in the European Medicines Agency in London.. The foreign posts enable FDA and border officials to make better-informed decisions about product entry into the United States by activities such as inspecting facilities in the EU, obtaining information about products to be exported to the U.S., reporting on adverse events in Europe that could affect products destined for the U.S., and speeding bilateral information flows and enhancing working relationships. However, even with all of these activities, the report to Congress does not provide quantitative measures of accomplishments (outcomes) of the FDA's foreign offices.

FDA in other contexts has accepted a collection of quantitative performance goals, in terms of outputs and outcomes. FDA's user fee programs, for example, have expanded over the years to cover new drug review, generic drug review, new animal drug review, generic animal drug

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[62] U.S. Food and Drug Administration, FDA Headquarters. *Narrative by Activity: FDA Headquarters*.http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM438025.pdf

[63] U.S. Food and Drug Administration. "Food: Report to Congress on the FDA Foreign Offices." http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm291803.htm

review, medical device review, and others. In these programs FDA receives additional resources in the form of user fees collected from all firms covered by a given regulatory program, e.g., all innovative drug manufacturers, in exchange for committing to meet certain performance goals. For example, the performance goals for the Prescription Drug User Fee Act have FDA reviewing 90 percent of all standard new drug applications (for marketing approval) within 6 months.[64]

The U.S. Department of Health and Human Services, of which FDA is a part, has developed a set of quantitative performance goals, Health People 2020, which FDA uses outside of the user fee context. These goals include reductions in incidence of illness from foodborne pathogens to prescribed levels, and improvements in use of safe food handling practices.[65] FDA does post information on inspections completed by type of product and by region or foreign country.[66] But it provides no quantitative information about the effectiveness of its international program and efforts at cooperation. We are unaware of the existence of quantitative goals or performance measures focusing on the outcomes of FDA's international programs.[67]

Cooperation Under Existing Statutes

Opportunities for Greater Efficiencies

If we step back from the details of international agreements and program management, it is easy to see that there are substantial opportunities for greater cooperation between FDA and the EU to yield more efficient risk management. These opportunities are most obvious regarding food because millions of Americans travel to the EU and enjoy food regulated by the EU standards without any special interventions by the FDA or any adverse consequences. The Centers for Disease Control and Prevention offers no warnings to travelers for eating in the EU that are different from eating in the U.S. We know of no evidence that there is a higher incidence of foodborne illness among U.S. travelers to the EU than for the U.S. population in general (or EU travelers to the U.S.). If U.S. travelers are able to treat the regulatory food standards of the U.S. and the EU as essentially equivalent, then there are no clear reasons why FDA and the EU cannot recognize this fact. Doing so would allow regulators on both sides of the Atlantic to more efficiently target resources on areas of greatest risk.

Our point is not that regulations need to be made uniform but that the regulatory systems for foods can be recognized as already providing essentially equivalent levels of public health

[64] See http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.
[65] U.S. Department of Health and Human Resources, Office of Disease Prevention and Health Promotion. "Food Safety." https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives.
[66] U.S. Food and Drug Administration. "Data Dashboard: Global Inspections." http://govdashboard.fda.gov/public/dashboards?id=140.
[67] FDA's 2014 strategic priorities report includes a strategic plan but few specific quantitative performance goals. See http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM416602.pdf .

protection. In 1999 the U.S and the EU concluded an agreement on sanitary standards for live animals and foods of animal origin. Under that agreement the U.S. Department of Agriculture has acknowledged the equivalence of sanitary standards for meat and poultry produced in numerous EU countries. FDA has not acknowledged equivalent standards for any EU countries on any of the products that it regulates.

Case Study: Foreign Food Safety Controls for Shellfish

The case of shellfish illustrates how difficult it has been for FDA to recognize foreign food safety controls as equivalent. In 2010, during bilateral discussions with the European Commission, FDA considered the role of the CODEX Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems[68] in making equivalence determinations of each other's food safety controls for shellfish. FDA determined that systems recognition assessments would provide FDA with an objective basis for applying the CODEX concept of relying on FDA's knowledge, experience, and confidence in the EU system to support this equivalence determination.

In 2011, FDA began work with the EU regarding an equivalence determination on molluscan shellfish, including a systems recognition assessment. To date FDA has not reported on the progress toward either recognition of systems or equivalence even for this narrow category of products. By contrast, after only two years FDA and New Zealand were able to establish a bilateral agreement recognizing that the food safety systems of each other's countries provide a comparable level of safety for the food regulated by FDA.[69] This recognition will allow FDA to use data from New Zealand to make decisions about imports and as a factor in prioritizing resources dedicated to foreign facility inspections, import field exams, and import sampling.

Identifying the Low-Hanging Fruit

A 2012 GAO report indicates a significant barrier to recognition between the US and the EU.[70] FDA's approach to comparability of international food safety systems with the U.S. domestic system requires comparability with a foreign government's *entire* domestic and export food safety systems for *all* FDA regulated food products. Given the very different approaches to cheese between the FDA and the EU, this prevents the FDA from leveraging the resources of

[68] See *Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53/2003). http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/

[69] See *FDA - New Zealand MPI, Food Safety Systems Recognition Arrangement*. http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm331907.htm

[70] U.S. Government Accountability Office. *FOOD SAFETY: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources.* (GAO-12-933). September 2012. http://www.gao.gov/assets/650/649010.pdf

countries with comparable systems for anything less than the entire food supply. In the GAO's assessment, "FDA can only take full advantage of comparability assessments if it modifies its approach for selecting comparable foreign countries and uses comparability assessments to identify countries that have similar food safety systems for targeted food products." In 2013 FDA indicated a willingness to entertain suggestions on how systems comparability could be pursued on a commodity-specific basis.[71]

Given some fundamental differences within both the U.S. and the EU regarding some products (cheese from unpasteurized milk, for example), that will preclude overall systems recognition, and the long-lasting stalemate over molluscan shellfish, FDA and the EU should try a different approach. They should identify opportunities for easy success. In 2012, FDA issued its draft Qualitative Risk Assessment Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm.[72] FDA was concerned about food processes occurring on farms because of the proximity to animal waste and the potential for contamination of the food. However, the qualitative risk assessment identified many products that FDA considers low risk, including:

- Hard candy, fudge, taffy, toffee;
- Cocoa products from roasted cocoa beans;
- Honey;
- Jams, jellies and preserves from acid foods;
- Maple syrup;
- Soft drinks and carbonated water;
- Sugar from sugarcane and sugar beets;
- Intact fruits and vegetables, grains and grain products, peanuts and tree nuts, coffee beans, and cocoa beans;
- Mixed intact fruits and vegetables, grain and grain products, peanuts, tree nuts, honey, maple sap and maple syrup, coffee beans, and cocoa beans;
- Coated or seasoned intact fruits, vegetables, peanuts and tree nuts;
- Shelled/hulled intact fruits and vegetables, peanuts, tree nuts, and cocoa beans;
- Chopped peanuts and tree nuts;
- Ground/milled/cracked/crushed grains (e.g., corn meal), coffee beans, cocoa beans, and peanuts and tree nuts;

[71] U.S. Food and Drug Administration. "Information for Foreign Governments: Frequently Asked Questions on Systems Recognition." September 5, 2013. See the answer to question 19: http://www.fda.gov/Food/InternationalInteragencyCoordination/ucm367400.htm#QAs

[72] U.S. Center for Food Safety and Applied Nutrition, Food and Drug Administration, & U.S. Department of Health and Human Services. *DRAFT Qualitative Risk Assessment Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm*. August 2012. http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM334110.pdf

- Dried/dehydrated intact fruits and vegetables (without sulfiting), grains and grain products, peanuts and tree nuts, coffee beans, and cocoa beans;
- Oils from grains; and
- Fermented cocoa beans and coffee beans.

These products represent an opportunity for FDA and the EU to come to an agreement on comparability for selected products and in the process to develop trust and cooperation upon which to build future agreements. Also, FDA and the EU may be able to develop a streamlined or simplified approach to agreeing on equivalent standards for public health protection. As suggested here, risk assessment and epidemiology should play a greater role in the identification of products for agreement and in the judgment of equivalence of effect. The standard for equivalence should be an equivalent level of public health protection as seen in epidemiological estimates of effects associated with regulated products (i.e., cases of foodborne illness) and not solely through the testing standards of the different entities.

Recommendations

FDA has a track record of engaging in dialogue with both multilateral regulatory organizations and foreign entities. Recent years have seen both high-level regulatory initiatives involving the Executive Office of the President and the European Commission and FDA-level initiatives, such as opening new offices in countries around the world. The effects of this cooperation on outcomes that matter to people's welfare, such as fewer or shorter outbreaks of foodborne illness, reduced risks associated with medical products or a greater variety of products available at lower cost, is not at all clear.

Although FDA has long provided information on its performance in reports mandated by user fee statutes or statutes such as the Government Performance and Results Act, we are unable to find any publicly available information about the effectiveness of FDA's international program at improving outcomes related to safety of products that it regulates. FDA has developed its international program without developing a plan with quantitative milestones to denote progress toward clear programmatic goals, and thus has not reported progress in achieving those milestones in a manner that allows systematic evaluation. This should change.

We recommend that FDA leadership prepare a draft plan with quantitative milestones regarding outputs and outcomes for its international program and all international cooperation activities, in the same way that FDA regularly prepares quantitative performance plans for many of its other programs. We believe that this plan should include quantitative measures for international sharing of information about risk, recognizing differences in completeness and timeliness of information.

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Appendix A

FDA Projects to Implement

The Transatlantic Economic Council High Level Regulatory Cooperation Forum[73]

FDA has reported under the TEC umbrella for several areas of EU-US cooperation. It states "The most robust of these concern FDA activities with the European Medicines Agency and the European Commission. Those projects include the following:"

1. Collaboration on inspections
2. Collaboration on third country inspections
3. Dedicated facilities for high risk products
4. Biomarkers
5. Regulatory collaboration on the outputs of the Critical Path and Innovative Medicines Initiatives
6. Combating counterfeit medicines
7. Collaboration on product specific risk management activities
8. Convergence of risk management formats
9. Parallel scientific advice
10. Exchange of information on herbal medicines
11. Collaboration on biosimilar medicinal products / follow-on biologics
12. Collaboration on development of medicinal products for children
13. Advanced therapy medicinal products
14. Safety reporting from clinical trials

[73] See http://www.fda.gov/InternationalPrograms/Partnerships/ucm389495.htm. Downloaded November 6th, 2015.

4

Regulator-to-Regulator Communication and Collaboration at the U.S. Consumer Product Safety Commission

Nancy Nord[1]

The Consumer Product Safety Commission (CPSC) presents a good case study of cooperation between regulators internationally because, even though it is a small agency, it developed a robust program of outreach to its counterpart regulators around the world in a relatively short period of time. As discussed below, this program developed because of the growing need for regulatory scrutiny beyond U.S. borders brought about by safety issues arising in connection with imports into the U.S.

In addition, it is a good case study because the CPSC is an independent regulatory agency, unlike the Department of Transportation and the Food and Drug Administration, both of which are under executive control. Independent agencies function outside the direct control of the President and are distinguished by three statutory characteristics: a bipartisan process for appointing members, fixed term appointments for those members with terms usually extending beyond that of the President, and a requirement that removal from office be for cause. In addition, their organizational form as multimember bodies also can mark a difference between independent agencies and executive branch departments (although there are executive branch multimember agencies).[2] The result of a multimember body made up of members of both political parties serving fixed terms and who can be removed only for cause is, at least in theory, to insure collegial and considered decision making.

Unlike executive branch departments and agencies, regulations of independent regulatory agencies like the CPSC are not subject to review and interagency coordination by the Office of

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[2] For a good description of the characteristics of independent agencies, see Verkuil, Paul R., "Purpose and Limits of Independent Agencies", Duke Law Journal, 1988.

Information and Regulatory Affairs in the White House Office of Management and Budget.[3] With more and more policy being made by independent regulatory agencies, insulation from presidential control can lead to more fractured and less consistent government-wide positions on important policy issues. As independent agencies see the global economy impacting the scope of their responsibilities and consequently need to reach out to their counterparts around the world to carry out these responsibilities, the need for government-wide coordination and control may increase as an issue. This dynamic is important to understand when discussing how regulators from different countries interact with each other.

Regulator-to-Regulator Collaboration at the CPSC

CPSC's International Activities

The international activities of the CPSC were shaped by the rapid development of the global marketplace. The vast expansion of international trade, the sourcing of consumer products and components throughout the world and the growing sophistication and safety expectations of U.S. consumers about the products they purchase necessarily required a closer level of communication and coordination between regulators in the U.S. and other jurisdictions. The rest of this case study examines how the CPSC, through its leadership and its international program, developed and facilitated regulator-to-regulator communication and cooperation, the lessons learned from those efforts and recommendations for moving forward.

Early Efforts (2004-2006)

For many years the CPSC had a staff member who ostensibly had responsibility for international activities but any outreach between U.S. and EU safety regulators was of an *ad hoc* nature. This changed in 2004, when the CPSC Office of International Programs and Intergovernmental Affairs (IPIA) was established under the leadership of then-CPSC Chairman Hal Stratton.[4] Among the stated purposes of the office was to "provide a more comprehensive and coordinated effort in the international… arena versus the ad hoc approach of the past decade" and to provide "liaison activities [with] international counterparts."[5] Outreach to foreign regulators was the responsibility of this office and it took several different forms. A discussion of the major activities of the office and agency that involved regulator-to-regulator communication and cooperation follows.

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[3] There are legislative efforts to establish greater executive oversight over the activities of independent agencies, such as the CPSC. For example, legislation has been introduced that would subject major rules issued by independent agencies to review by the Office of Information and Regulatory Affairs (OIRA).

[4] The CPSC was certainly neither the first nor the last independent agency to establish an international programs office. The Securities and Exchange Commission established such an office in 1988. The Federal Trade Commission consolidated its global activities into one office in 2007.

[5] Joseph P. Mohorovic. *IPIA White Paper*. Office of International Programs and Intergovernmental Affairs (IPIA), U.S. Consumer Product Safety Commission. July 11, 2006.

Standards Harmonization

The ability of standards to facilitate access to markets and the significance of divergent standards as a drag on trade was recognized and the IPIA office was specifically tasked as one of its goals to address harmonization of standards.[6] While the Commission stated its support for harmonizing standards, it recognized that it was "an arduous and ambitious undertaking."[7] It also recognized that the level of safety enjoyed by U.S. consumers could not be compromised by harmonization efforts. The office's activities to achieve harmonization focused on working with consensus standards groups rather than with foreign regulators, and, as predicted, accomplishing demonstrable results proved to be arduous.

Memoranda of Understanding

The CPSC negotiated memoranda of understanding (MOUs) with a number of countries beginning in 2004.[8] The MOUs were typically negotiated between the CPSC and the foreign country's counterpart safety agency and indicated the parties' intention to share information and cooperate on relevant safety issues. In early 2005, the CPSC and the Directorate-General Health and Consumer Protection of the European Commission[9] negotiated an MOU setting out a framework for the exchange of information on such matters as emerging health and safety issues, standardization activities, and market surveillance and recall activities, among other things. The MOU with the European Commission (EC), while necessarily cast in general terms, represented an important commitment for engagement on safety issues, and, as will be discussed below, that bi-lateral engagement used the MOU and subsequent agreements as a framework.

Bilateral U.S./China Safety Summit

Negotiating an MOU with the Chinese counterpart safety agency, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), in 2004 was a watershed achievement with respect to regulator-to-regulator cooperation. The MOU led to the first U.S./China Safety Summit in 2005.This was the first example of Chinese participation in such an agreement and meeting of product safety regulators. The parties agreed to set up working groups of U.S. and Chinese government experts to meet periodically to address safety issues for certain product classes (toys, fireworks, lighters and electrical products). The willingness of the Chinese to engage the CPSC was influenced by the growing concern in the U.S. and the rest of the world

[6] See IPIA White Paper, July 11, 2006, for a discussion of the Commission's goals for the office with respect to standards harmonization.

[7] IPIA White Paper.

[8] The fact that these agreements were MOUs underlines the nature of the CPSC as an independent regulatory agency. The agreements were not negotiated through the Department of State (although State and the U.S. Trade Representative were typically consulted) and did not commit the U.S. Government to any kind of formal action.

[9] The MOU was signed for the EC by Robert Madelin, Director General, and for the CPSC by Harold Stratton, Chairman.

over the safety of Chinese products. In addition, the CPSC's very visible engagement with the EC in the safety arena could not help but be noticed in Beijing, since the U.S. and the EU were China's two biggest markets. The CPSC's outreach to the EC helped get AQSIQ to the table to discuss safety issues.

International Consumer Product Safety Caucus

The International Consumer Product Safety Caucus (the Caucus) was established in 2006 to provide an organizational platform for enhanced cooperation among product safety regulators and market surveillance authorities from around the globe. The objectives of the Caucus were enunciated in the Bethesda Declaration[10] of May 2006 and included an exchange of information on government policy, legislation and market surveillance. The U.S. representative agreed to act as the first chairman of the Caucus and the group agreed to meet twice a year, often meeting in conjunction with the meetings of the International Consumer Product Health and Safety Organization (ICPHSO).[11]

Import "Crisis" Drives Increased Cooperation (2006-2009)

The growing number of recalls of products imported from China as well as several high-profile recalls of popular consumer products that received wide-spread media attention resulted in a heightened public concern about the safety of imported products. That public outcry drove legislative action in the United States.[12] However, safety regulators in both the U.S. and in Europe recognized the need to increase efforts to address import safety both individually and collectively. Those efforts built on the foundation that had been established earlier and took several forms, including enhanced cooperation among regulators.

Second Bilateral U.S./China Safety Summit

The second meeting of U.S. and Chinese safety officials, in September 2007, in Washington, DC, took place at the height of the "recall crisis." Unlike the first summit, here the Chinese made specific promises with respect to safety, agreeing to ban lead paint in children's products, to conduct monthly meetings with their U.S. counterparts to try to resolve problems that led to each recall, and to other procedures addressing recurring safety issues.

[10] "Bethesda Declaration." *International Consumer Product Safety Caucus.* Accessed November 2016. http://www.icpsc.org/Bethesda_Declaration.html

[11] ICPHSO is a non-profit organization made up of government and private sector professionals working in the product safety sector and seeks to provide a neutral forum for discussing safety issues.

[12] The Consumer Product Safety Improvement Act of 2008, Public Law 110-314, 122 Stat. 3016 (August 14, 2008).

U.S. - EU Toy Safety Working Group

This group was established in 2007 to provide a focal point for discussions between the CPSC and the EC on toy import safety issues. Initially the group met quarterly and explored closer collaboration on toy safety standards, areas for potential convergence of standards or test methods and possible joint outreach activities.

U.S. - EC Joint Safety Outreach to China

Immediately following the passage of new safety legislation in the United States, representatives of the CPSC, including the acting chairman of the agency, and representatives of the European Commission conducted a series of safety seminars in China in September 2008. The purpose of the seminars was to educate Chinese product manufacturers about the EU and U.S. safety requirements for clothing, toys and electrical products, including the new statutory requirements. The seminars had the visible support of Chinese officials from AQSIQ. This joint outreach effort by representatives of the two largest markets for Chinese products speaking with one voice about the importance of safety, with the Chinese government looking on in support, was designed to make a loud statement about the serious need to promote respect for, and compliance with, safety requirements.

Trilateral U.S.-EU-China Product Safety Summit

The safety outreach effort described above was immediately followed, in November 2008, by a high-level trilateral meeting in Brussels attended by the EU Consumer Affairs Commissioner, the CPSC Acting Chairman and the Chinese Vice Minister of AQSIQ. The purpose was to signal the importance of product safety as an international political issue. The parties agreed to cooperate on safety standards for toys and children's products, strengthen information and expertise exchange and address product traceability. The parties agreed to similar meetings on a biannual basis.

2010 to 2014

Among other things, legislation passed in 2008 directed the CPSC to issue specific regulations addressing the safety of imported products. As the agency rolled out those regulations, the focus of the CPSC's interaction with other regulators shifted to explaining those regulations and their implications on the global supply chain. In addition, as a further recognition of the nature of the global marketplace, the agency reached out to its North American neighbors to establish a more collaborative relationship. The maturation of the CPSC outreach program manifested itself in several different ways.

U.S. - China Safety Summits

While the CPSC and AQSIQ did hold a 3rd and 4th safety summit, the summit decreased in importance as a device for formal regulator-to-regulator communication on a going forward basis after 2011. While summits were scheduled for both 2013 and 2015, both were cancelled for budgetary reasons. It should be noted that at this time, the agency opened an office in Beijing, concluding an effort that was started in 2008. This office provided a means for more accessible information exchange and interaction with product manufacturers in China and other points in Asia.

Trilateral Summits

Trilateral product safety summits among the U.S., the EC and China were held in 2010, 2012 and in 2014.[13] Future plans for continuing this effort have not been announced as yet.

Organisation for Economic Cooperation and Development

Beginning in 2008 and moving forward, the Organisation for Economic Cooperation and Development (OECD), through its Committee on Consumer Policy, began to play a bigger role in facilitating discussion of product safety issues among governments, including the CPSC, businesses and NGO stakeholders. This activity focused first on making recommendations for enhancing information sharing among jurisdictions. Later, the Committee focused its efforts on establishing a Global Recalls Portal, which was launched in 2012.[14] CPSC staff participated in both of these activities.

North American Safety Summits

Recognizing that products imported from outside North America can easily cross into each other's jurisdictions because of extensive shared borders, in 2011, the CPSC and its sister product safety agencies from Mexico and Canada held their first product safety summit in Bethesda, Maryland.[15] At this meeting, under a Cooperative Engagement Framework, the parties agreed, among other things, to consult on proposed regulations and voluntary standards, consult and cooperate on potential joint recalls as well as import and market surveillance activities, undertake coordinated consumer awareness campaigns, and cooperate on training and outreach.

[13] www.cpsc.gov/en/Business--Manufacturing/International/International-Activities

[14] The Global Recalls portal includes automobiles and other products outside the jurisdiction of the CPSC.

[15] www.cpsc.gov/en/Business--Manufacturing/international/International-Activities/First North America Consumer Product Safety Summit Joint Statement

In 2013, in Ottawa, Canada, the parties met for the second summit and revised the Cooperative Engagement Framework to set out a four year work plan.[16] Very importantly, the parties recognized the concrete cooperative achievements that had been undertaken through this effort. These achievements included several safety campaigns, the first coordinated trilateral recall,[17] and ongoing information exchanges among the technical staffs of the three safety agencies.

The third North American Summit took place in November 2015 in Mexico City. Well prior to the meeting, the three agencies established "joint project teams" to examine various issues including outreach campaigns and joint customs exercises. The need for increased consultation prior to standards development and increased information sharing was recognized. Like the earlier summits, the most recent also included public seminars by regulators and stakeholders on safety issues that relate to all three jurisdictions.[18]

Major Coordination Projects

Safety Summits

As described above, the U.S./China bilateral and the U.S./EC/China trilateral safety summits provided an effective means for establishing the CPSC's cooperative outreach to other safety agencies. This was important as the program was being developed and when the parties were wrestling with solving the immediate import safety problem. The summits allowed for interaction between technical agency staff and provided a means for senior agency leadership to establish a relationship with peers. That cooperation was enhanced by the fact that the bilateral and trilateral summits both involved the same parties, although addressing somewhat different issues, so that there was ample opportunity for engagement.

The second bilateral summit with China and the North American Summits show the benefits of identifying specific areas for engagement. In addition, to the extent that desired outcomes can be identified and addressed in a specific manner or on a timeline rather than in aspirational terms the parties have a more realistic chance of pushing forward desired action.

The summits also laid the groundwork for more specific cooperative activities between the CPSC and the EC with respect to outreach to Chinese product manufacturers. As noted above, the first of such ventures occurred in 2008, shortly after Congress mandated new U.S. safety

[16] www.cpsc.gov/en/Business--Manufacturing/International/International-Activities/Second North America Consumer Product Safety Summit Joint Statement.

[17] http://www.cpsc.gov/en/Recalls/2013/Teavana-Recalls-Glass-Tea-Tumblers/ and www.cpsc.gov/en/Recalls/2015/Graco-Recalls-11-Models-of-Strollers.

[18] See Product Safety Letter, November 23, 2015. See also http://www.cpsc.gov/en/Newsroom/News-Releases/2016/Collaborating-Across-Borders-North-American-Regulators-Working-Together-to-Protect-Children-from-Harmful-Toys/

requirements, when the staffs of the CPSC and the European Commission conducted joint safety seminars in China for product manufacturers. These joint educational activities have continued with the most recent occurring in September 2015 and included product safety training for sourcing professionals dealing in electrical products, apparel and toys from China.[19]

Caucus/OECD Activities

CPSC staff has participated both in the Caucus and in the product safety activities of the OECD. The Caucus provided an important opportunity for market surveillance authorities to informally meet for consultation and information exchange. One of the early projects undertaken by the Caucus was to develop enhanced product tracking and traceability tools. Even as the Caucus was engaged in this work, the OECD Product Safety Working Party initiated a project in 2010 to undertake very similar activity. It became clear that many of the same parties were participating in both efforts and that both were competing for the same scarce resources. Even though the Caucus was seen as a more flexible forum for informal discussion, the OECD was considered the more appropriate forum for pushing forward the issues identified by the Caucus and it had the administrative infrastructure to support the work. In February 2014, a decision was made to transfer the substantive work items of the Caucus to the OECD Working Party and the Caucus was, for all intents and purposes, disbanded.

Whether initiated by the Caucus and then taken on by the OECD or whether initiated by the OECD, several important cooperative projects are now underway. With respect to product tracking, after a period of public comment and consultation, a proposed product identification system is being developed that will be detailed in a report, soon to be published, with the thought that businesses will adopt the recommendations and governments will endorse them. The Working Party is also undertaking a forecasting project to identify emerging issues, including a matrix of issues of interest to multiple jurisdictions. The Global Recalls Portal is seen as a key informational tool for accomplishing the objective of identifying safety issues at an early point.[20]

One especially effective example of regulator collaboration in the international safety arena dealt with consumer education about the dangers of button batteries. In June 2014, the OECD member safety agencies participated in an *International Awareness Week on Button Battery Safety* aimed at raising the awareness worldwide of the dangers of children swallowing button batteries. The program included coordinated media, social media, online and on-site initiatives in over 26 jurisdictions around the world, culminating in an international safety conference in Brussels,

[19] See http://www.cpsc.gov/en/Newsroom/Public-Calendar/

[20] Presentation by Peter Avery, Consumer Policy Unit, OECD, Global Product Safety Meeting, Review of Ongoing International Collaboration Projects, Orlando, FL, February 23, 2015.

Belgium.[21] The program was a well-coordinated effort and provides a roadmap for similar efforts in the future.

Foreign Executive Exchange Program

In 2012 the CPSC established a foreign exchange program. This program hosted safety executives from Health Canada and from the Australian Competition and Consumer Commission at the CPSC headquarters for a three-month period. Other jurisdictions have also sent executives for training sessions at the CPSC. As budgets and staffing resources are available, CPSC staff has also been hosted by foreign jurisdictions. The program provides a means of developing expertise with the regulatory systems of other jurisdictions and has fostered greater collaboration with other safety regulators.

Joint Recalls with Other Jurisdictions

From time to time, products sold in several different countries may present hazards dictating that those products be recalled in multiple jurisdictions. Until 2009, the CPSC's practice was to announce the U.S. recall, request that the recalling company contact other jurisdictions where the product was sold and, in some cases, notify foreign safety regulators of the recall after it had been announced in the U.S. The Consumer Product Safety Act constrains the ability of the agency to share product-specific information with other jurisdictions without agreement of the product seller before a recall is publicly announced.[22]

In February 2009, the CPSC conducted its first joint recall with Health Canada and since that time, has conducted several hundred more joint recalls with Health Canada. It is important to remember that these are all voluntary recalls and are done with the cooperation of the recalling company. The first joint recall with both Canada and Mexico occurred in May 2013.[23] In this case, the U.S. and Canada announced the recall on the same day and Mexico made a recall announcement shortly thereafter. In November 2014, the three jurisdictions announced a trilateral joint recall on the same day using the same press release.[24]

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[21] See http://www.cpsc.gov/en/newsroom/news-releases/2014/cpsc-joins-international-effort-to-prevent-button-battery-related-injuries-and-deaths/

[22] See 15 U.S.C. §2055(b) (1) which requires that the agency give the submitter 15 days' prior notice before releasing product specific information without the agreement of the manufacturer and directs the agency to make every effort to assure that the information released is fair and accurate. The manufacturer may appeal commission decisions with respect to information release under this provision. In addition, 15, U.S.C. §2055 (b)(5) prohibits the public disclosure of information submitted by a manufacturer pursuant to 15 U.S.C. §2064 relating to corrective actions of substantial product hazards unless the submitter agrees to the release or the Commission determines that public health and safety require disclosure prior to the 15 day period referenced above.

[23] See http://www.cpsc.gov/en/Recalls/2013/Teavana-Recalls-Glass-Tea-Tumblers/

[24] See http://www.cpsc.gov/en/Recalls/2015/Graco-Recalls-11-Models-of-Strollers/

The agency has not undertaken a joint recall with the European Commission. Conducting a joint recall in the EU would present problems since the CPSC would need to work with each member country individually because each member country has responsibility for enforcing its safety laws.[25] Instead, the agency collects information on other jurisdictions where the product has been sold and urges the recalling company to report to those other countries or allow the agency to contact them. In these instances it is important that the regulators and the company coordinate closely since a premature recall announcement in another jurisdiction could impact the timing and substance of the recall in the U.S. In most instances where a recall is needed in multiple jurisdictions, the company does not object to the agency working with other regulators since this advances the common goal of reducing duplication and enhancing efficiencies for both the government and the company.

Standards Alignment

From the beginning, standards alignment (or harmonization) has been a consistent but elusive goal of the CPSC's work with other foreign jurisdictions. In addition, Congress has expressed an interest in the agency working to reduce regulatory burdens through standards alignment.[26] The agency has undertaken several efforts to explore the feasibility of harmonizing or otherwise aligning U.S. safety standards with those throughout the world.

In 2011, the agency unveiled its pilot alignment initiative (PAI) with the EC, Australia and Canada to seek alignment of safety standards for three product classes: corded window coverings, infant slings and chair-top booster seats for children. The PAI work attempted to reach consensus among the jurisdictions about preferred substantive requirements for standards for the three products under review with the notion that these consensus requirements would be adopted by each jurisdiction when it undertook a review of existing standards for those products. However, with respect to window coverings, consensus could not be reached on a preferred regulatory approach and instead included options for regulatory requirements for these products.[27] The consensus agreement for booster seats did include specific recommendations for standards alignment.[28] As yet, this effort has not resulted in the alignment of the standards for any of the products under discussion.

In contrast, the agency has taken a somewhat different approach to activities seeking alignment of toy standards. In 2010, the Commission directed staff to draft a plan to address the agency's

[25] EU rules of market surveillance usually foresee that if one member state recalls a product it informs the other member states- so at least they are aware and will in all likelihood follow. Nevertheless, there is no mechanism for doing a EU wide recall.

[26] 15 U.S.C. §2063(i) (3) (A) (v).

[27] See GAO, International Regulatory Cooperation, GAO-13-588, p 41. The consensus report for window coverings is at http://ec.europa.eu/consumers/archive/safety/int_coop/docs/pai_window_blinds_and_coverings_en.pdf

[28] See http://ec.europa.eu/consumers/archive/safety/int_coop/docs/booster_seats_consensus_en.pdf.

role in aligning toy safety requirements in various international jurisdictions and how the elements of that plan could be applied to alignments of requirements for other products. The resulting "Roadmap for Toy Safety Regulation and Standards Coordination and Alignment" sets out a fairly detailed analysis of the history and issues surrounding alignment of toy standards.[29] While the Roadmap does acknowledge that the existence of differing standards can lead to market confusion and adversely impact safety, it recommends that any standards alignment activity must result in improved safety. It also recognizes that the bulk of the work with respect to toy standards alignment must be done by industry since the CPSC mandatory toy standards are based on voluntary industry consensus standards. The plan acknowledges that the U.S. Government could and should play a role in encouraging its counterpart safety regulators to work for greater alignment of standards and does include recommendations to this point, but those recommendations are very general and nonspecific in nature.

In 2014, the agency chairman undertook a project, in response to Congressional pressure to reduce testing costs, to look at toy standards in jurisdictions around the globe to try to determine whether a unified standard incorporating the most stringent tests could be developed. The conclusion was that such a standard would not result in reducing testing burdens and so was not pursued. [30]

The toy industry has been working over the years in various ways to seek greater harmonization of global toy standards. Some of those efforts are detailed in the Roadmap. Most recently, the Toy Industry Association has been working with its counterpart association in Canada to develop recommendations for aligning the standards between the two countries. The parties have set up a steering committee made up of all relevant stakeholders to set out the process for moving forward as well as specialized groups to deal with technical issues. The group is working to identify "low hanging fruit" where consensus on alignment can be reached more easily while the group works to identify options for resolving more challenging issues.

This is very significant since, should a U.S./Canadian aligned standard be adopted by ASTM (the voluntary standards development organization), this could become the basis for the mandatory U.S. toy safety standard and the mandatory Canadian standard. In addition, both Hong Kong and Israel recognize the ASTM standard (as well as the European and ISO toy standards). Therefore these efforts, if successful, provide a stronger position for those who are seeking to achieve greater alignment of toy safety standards on a global basis, or alternatively, mutual recognition of standards from other jurisdictions.

[29] See http http://www.cpsc.gov/pagefiles/90341/toyplan.pdf.

[30] http://www.cpsc.gov/global/about-cpsc/reports/miscellaneous/staff-report-burden-reduction-while-assuring-compliance-march2015.pdf. See also Senate Commerce Committee, CPSC QFR Responses Aug 8, 2015, Response to question 3.

Recommendations

Given the challenges of delivering safe products to consumers when those products are sourced and manufactured throughout the world, it is apparent that greater collaboration among safety regulators can only aid in meeting that challenge. That collaboration can take many forms including (1) greater engagement with foreign counterparts on both a technical and policy level; (2) greater cooperation on market surveillance and enforcement matters; and (3) regulatory cooperation efforts, including efforts to align or harmonize standards.

Greater Engagement

The agency's experience with safety summits is that they served to focus attention as an issue is developing. In addition it is important to clearly define expectations and deliverables going into such meetings for them to be of real value.

The agency's work with its European safety counterparts in educating suppliers and manufacturers about the safety requirements of the two jurisdictions offers a template for others to follow. To the extent that the agency has complex requirements (and the CPSC does), educating suppliers about how to comply with those requirements will help lessen chances that product will be out of compliance and either be refused entry into the U.S. or be recalled. That many of these educational sessions are being conducted with officials of the European Commission amplifies the safety message. It also offers the opportunity to emphasize where regulations differ between the jurisdictions. That is important since many factories are producing goods for both jurisdictions. These educational efforts should be continued and, if available resources allow, expanded. The agency's work here could probably be leveraged through greater use of association and other private resources.

The button battery safety campaign conducted with the OECD and discussed above is another example of an engagement effort that offers opportunity for greater collaboration. Working through the OECD to identify an emerging hazard and collaborating on a safety campaign to educate consumers about the hazard could provide real safety benefits to consumers worldwide.

Compliance and Enforcement

Capacity Building

Given the global nature of the consumer products marketplace, consumers in one country are not isolated from the regulatory shortcomings of other countries. Certainly this was abundantly apparent during the recalls from China during the 2007-2008 period, and safety issues from imported counterfeit products show that this is an ongoing issue. Therefore U.S. and European consumers benefit from building the regulatory capacity of supplier countries in Asia and in other developing countries that are building export markets, since stronger internal safety

regulations will work to improve the safety of exported products.[31] Executive exchange programs and supplier training can work to support capacity building efforts. A focused effort (1) to examine regulatory practices of developing countries that seek to become export markets, (2) to provide technical and other assistance in developing appropriate regulatory and legal frameworks, and (3) to support the complimentary structures needed to assure successful implementation of those systems could result in regulatory systems that complement those in the U.S. and Europe.

Joint Recalls

The practice of conducting joint recalls with Canada and, to a lesser extent, Mexico, emphasizes the importance of the North American trading region. There is no reason to think that such recalls will not increase, given how closely aligned the laws and safety practices of the trading partners are. When appropriate, such recalls offer a way to effectively address a regional safety issue, generate more publicity for a safety issue and reach more consumers across a greater area.

However, one observation that is made with increasing frequency is that Canada is more efficient in managing the details surrounding publicizing the recall than is the U.S., which is a surprising development given the relative size of the organizations.[32] The CPSC staff explains this by pointing to internal time deadlines imposed by Health Canada in dealing with recalls depending on risk while CPSC staff scrutinizes very closely language proposed for every press release, regardless of risk, which can be a time-consuming process.[33] Nevertheless the growing concern of practitioners before the agency about delays at the CPSC in announcing recalls that are also being conducted in Canada points to a problem that should be addressed by the agency if the joint recall program is to fulfill its potential as a trans-border consumer protection device.

Regulatory Collaboration

Compliance with Executive Order 13609

Like many independent regulatory agencies, the CPSC takes every effort to make clear that it is not required to follow presidential executive orders. However, it also strives to minimize executive conflict by noting its compliance with those orders, such as Executive Order 13609,[34]

[31] GAO-13-588 International Regulatory Cooperation, p 46.

[32] Contrast Canadian press release for Franklin Corp Power Reclining Furniture Switch recall: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/52493r-eng.php issued March 12, 2015, with CPSC release issued May 7, 2015: http://www.cpsc.gov/en/recalls/2015/power-reclining-furniture-recalled-by-franklin/. It took the CPSC two additional months to notify the public of the same hazard.

[33] Email from Scott Wolfson, CPSC Director of Communications, to author, September 23, 2015.

[34] See https://www.whitehouse.gov/sites/default/files/omb/inforeg/eo_13609/eo13609_05012012.pdf. The order, issued on May 1, 2012, recognizes that differing regulatory approaches among jurisdictions addressing similar

when such happens. With respect to recent regulations, the CPSC has not methodically addressed differences between its standards and those of other jurisdictions, and such an analysis is not systematically integrated into the rulemaking process of the agency. While such analysis is relevant to the cost benefit analysis that the agency must do for some of its regulations, and should do for all its regulations, tight Congressionally-mandated deadlines for certain rules make such analysis difficult to do in a thorough and meaningful manner.[35]

Standards Alignment

Not all standards can and should be harmonized. Product differences, cultural differences, available power supplies, government regulations and many other factors inhibit harmonization. However, divergent standards and redundant testing for compliance with those standards can increase costs to consumers and make regulatory compliance more complex, and so standards alignment, when appropriate, is a goal worth pursuing.

The Commission has acknowledged that differing standards can lead to market confusion and adversely impact safety. Yet, for the CPSC, this is apparently not a sufficient reason in itself to engage in standards alignment activity. That may be a reaction to concerns that alignment may devolve to adopting the least stringent standard and result in a "dumbing down" of standards. To assure against that result the agency requires that any aligned standards (at least with respect to toys, where there has been the most activity) must result in a net increase in safety. While this requirement is not formalized in statute or guidance, it appears to have the support of the majority of commissioners and thus is expressed in CPSC policy.

However, as recent activity has shown, that requirement has not led to productive results and so should be reconsidered. In rethinking how to approach alignment, certainly the current level of safety that U.S. consumers enjoy should be maintained. However, that goal should also recognize the value of facilitating the entry of new and safe products into the U.S. market, especially if those products are being safely enjoyed by consumers in other jurisdictions. As an example, with respect to plastic toys, the European standard EN-71 and the U.S. standard ASTM 963 arguably provide the same level of protection but have somewhat different requirements. The agency should explore the concept of determining the two to be substantially equivalent for the purposes of recognizing the validity of testing to either of the two standards.

A corollary to the issue of standards alignment is that of mutual recognition of standards of other jurisdictions. There has been strong reluctance on the part of the agency to aggressively explore the concept of mutual recognition of standards, which is unfortunate since this could be an

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issues can hinder open trade and directs federal agencies to take steps to reduce unnecessary requirements between the U.S. and its trading partners.

[35] Passage of legislation clarifying that independent agencies are subject to presidential executive orders would help rectify this situation.

effective way to assure consumer safety while still promoting free flow of safe goods between jurisdictions. Mutual recognition would be especially relevant when different test results are mandated for a standard with generally the same regulatory objective or where the differences in the standards are relatively minor and the regulatory policy objectives of the jurisdictions are aligned. In addition, as the agency reviews existing standards under any regulatory review activity, alignment or mutual recognition should be part of the analysis. The agency needs to rethink its position on that issue.

The agency has a number of new rulemakings now underway. The Commission should direct the staff to investigate standards in other jurisdictions as a part of its work in developing a proposed rule and provide an explanation of what efforts were made to align the proposed rule with any existing rule. That would be consistent with Executive Order 13609. In addition, the agency should continue to provide positive support to the ongoing efforts of the U.S. toy industry in its work with the Canadian industry to develop an aligned standard and then encourage work with stakeholders to promote any aligned standard to other jurisdictions.

Information Exchange

Robust exchanges of information among jurisdictions can only serve to promote efforts to align standards or, alternatively, provide justification for maintaining differences. The agency does not have a mechanism to share information as it develops mandatory standards and as it works with those developing consensus standards. While there are no statutory prohibitions for this result, there are also no statutory requirements either.

As an independent agency, the CPSC is not required to follow the dictates of Executive Order 13609 (as noted above) which could arguably result in more information sharing. While the Commissioners have authority to set overall direction on such matters to the staff, that has not been done in any formal way and until that happens there is little incentive to engage in systematic information exchange when developing mandatory standards. The situation is sometimes exacerbated by the short statutory timeframes that apply to certain mandatory rule proceedings. The need for open information flows becomes more critical as products become more and more complex, technology dependent, and more interconnected.[36] Yet the agency's efforts here are *ad hoc* at best. The Commission should consider a direction to staff to make more robust efforts to share information as it engages in its rulemaking responsibilities.

Sharing information with other jurisdictions about specific recalls before those recalls are announced presents more problematic issues. The Consumer Product Safety Act gives competing direction to the agency with respect to information sharing. The Act directs product sellers to immediately report to the agency if a product it sells "could" present a substantial product

[36] See http://www.natlawreview.com/article/internet-things-and-inevitable-collision-product-liability-part-4-government for a discussion of the security and safety implications presented by the Internet of Things.

hazard.[37] While this standard is somewhat vague, it is designed to encourage early reporting of potential hazards to the agency.[38] Since such reporting necessarily demands that confidential business information be given to the agency, the statute also encourages reporting by providing strong protections against the release of such information while the agency is investigating the nature of the hazard and considering whether a recall is required.[39] Finally, the statute allows the agency to negotiate agreements to share product specific information with other jurisdictions before a recall is announced if those jurisdictions have comparable procedures for protecting confidential business information.[40] No agreements with foreign jurisdictions have been negotiated to date.[41]

Under this statutory construct, there is a low threshold for reporting potential hazards to the agency, but the agency takes what time it needs to determine whether a hazard requiring a recall actually exists. And it should be noted that it is not unusual for the agency, after investigation, to determine that no recall is warranted. The resulting question is whether sharing information about *potential hazards* with other jurisdictions before the agency has determined the existence of an *actual hazard*, especially if that information were made public, could both impede reporting and the ability of the agency to effectively investigate the need for a recall. Instead of unilaterally releasing information, including sensitive business information, to other jurisdictions before a decision to do a recall is made, the agency both collects information on where in the world the product under investigation has been sold, and encourages a product seller to reach out to those countries' safety authorities. Any efforts to change this balanced approach should be done only after a stronger case for change has been made and should be mindful of the potential negative impact the change may have on the ability of the agency to collect information from product sellers and to investigate potential hazards.

Conclusion

Over the past twelve years, the CPSC has built an impressive track record of outreach to and cooperation with safety regulators in foreign jurisdictions. This is especially true given its small size and constrained resources. Given the growing complexity of both consumer products and the global marketplace, there is every reason to expect that consumer safety will demand greater communication and collaboration among regulators.

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[37] 15 U.S.C. §2064(b) (3).

[38] Adverse event and defect reporting requirements in other statutes administered by other agencies are more precise in their requirements and do not result in the judgment differences that this provision has brought about. See, for example, the Food, Drug and Cosmetic Act, 21 U.S.C. §379aa.

[39] 15 U.S.C. §2055 (b).

[40] 15 U.S.C. §2078 (f).

[41] With respect to the EC, it would be difficult to structure an agreement that would meet the statutory requirements because of the differing jurisdictions and the need to withhold the information from a parliamentary or judicial inquiry.

The agency should continue to look for ways to educate foreign suppliers about U.S. standards and safety expectations, including leveraging the resources of non-governmental groups. On the enforcement side, the agency's efforts to reach out to its North American trading partners to engage in recalls provides an added level of safety to consumers in those jurisdictions. However, the agency's reluctance to more aggressively work to minimize regulatory burdens by supporting efforts to align standards and to embrace the related concepts of substantial equivalency and mutual recognition of standards represents a timid and unimaginative approach to regulation and, in the end, does not necessarily advance consumer protection.

5

Identifying Regulations Affecting International Trade and Investment:

Better Classification Could Improve Regulatory Cooperation

Daniel Pérez[1]

Technological and political innovations continue to reduce barriers to international trade. As a result, trade accounts for increasingly larger portions of economic output. During the ten years from 2002 to 2012, U.S. exports and imports grew a total of $4.9 trillion – a change from 22.8% of U.S. gross domestic product (GDP) to 31.4% of GDP.[2] Within jurisdictions such as the European Union and the United States nearly a quarter of the goods and services that are available are the direct results of international trade.[3] Additionally, as the level of global market integration increases, markets are now characterized by increasingly complex supply chains[4] which expand the number of countries able to participate in international trade.[5] Although this unbundling and disaggregation of trade is largely responsible for increased competition and lower prices,[6] it also means that country-specific regulations affecting internationally traded goods have the potential to create significant costs, reducing the economic benefits generated through trade.

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[2] Government Accountability Office. (2013). *International Regulatory Cooperation: Agency Efforts Could Benefit from Increased Collaboration and Interagency Guidance*. (GAO Publication No. 13-588). Washington, D.C.: U.S. Government Printing Office

[3] Morrall, John., III. "Determining Compatible Regulatory Regimes between the U.S. and the EU" *U.S. Chamber of Commerce. Advancing Transatlantic Business* (2011): 4

[4] Government Accountability Office (2013)

[5] For a further discussion of the international trade landscape, including the prevalence of intra-industry trade and multinational firms see: Melitz, Marc J., and Daniel Trefler. 2012. "Gains from Trade When Firms Matter." *Journal of Economic Perspectives*, 26(2): 91-118.

[6] Bollyky, Thomas J. "Better Regulation for Freer Trade" *Council on Foreign Relations. Renewing America. Policy Innovation Memorandum No. 22*. June 2012. http://www.cfr.org/trade/better-regulation-freer-trade/p28508 : "… global production models now dominate international commerce, with intermediate products comprising 56% of global goods trade and 73% of global services trade."

Innovations within financial markets are also responsible for sizeable gains in the efficient allocation of capital towards its most productive uses via foreign direct investment (FDI).[7] Although the United States Office of Management and Budget (OMB) points out that "…more attention has been paid to issues of international competitiveness and barriers to international trade than to… impacts on cross-border investment,"[8] regulations that (intentionally or not) restrict FDI can also generate significant costs to the global economy. Within the United States alone, the Department of Commerce (DOC) estimated that as of 2013 U.S. assets of foreign affiliates totaled $3.9 trillion with an estimated yearly inflow of FDI of $166 billion.[9] The greatest portion of these FDI flows are the result of cross-border investments between the U.S. and its largest trading partners – which account for about 80% of new FDI.[10]

International Regulatory Cooperation

As a result of the magnitude of the market for international trade, countries are bolstering their efforts to engage in international regulatory cooperation (IRC) in an effort to improve regulatory outcomes and avoid duplicative and, ultimately, costly and unnecessary differences in the treatment of goods across borders. IRC is also a central component of current U.S. efforts to negotiate international trade agreements, such as the Transatlantic Trade and Investment Partnership (TTIP) with the European Union and the Trans Pacific Partnership (TPP) with 11 countries throughout the Asia Pacific region.[11]

The Organization for Economic Co-operation and Development (OECD) published several estimates of the potential economic savings possible through IRC that indicate its importance in efforts to continue lowering barriers to international trade and investment. For example, it finds that an elimination of half the existing non-tariff barriers to trade between the EU and the U.S. could result in an annual gain of .7% of GDP for the EU and .3% of GDP for the U.S.[12] This amounts to an increase of $129.22 billion for the EU and $52.26 billion for the U.S., calculated in 2014 USD.[13] Similarly, the OECD finds that a decrease of 10% in a country's restrictions on FDI could result in a net increase of its exports by almost 2%.[14] Even relatively small

[7] José Guimón "Government Strategies to Attract R&D-intensive FDI" *The Journal of Technology Transfer*, 34(4): 364-379.

[8] U.S. Office of Management and Budget and Secretariat General of the European Commission. "*Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment: Final Report and Conclusions*". May 2008.

[9] U.S. Department of Commerce, President's Council of Economic Advisers. "*Foreign Direct Investment in the United States*". October 2013.

[10] Ibid.

[11] Pérez, Daniel. "Consistent Inconsistencies: Misclassification of Rules Could Hamper International Regulatory Cooperation" *Commentary, the George Washington University Regulatory Studies Center*. August 26, 2015.

[12] OECD (2013), *International Regulatory Co-operation: Addressing Global Challenges*, OECD Publishing. 178

[13] GDP calculated using 2014 World Bank estimates. http://data.worldbank.org/country/united-states

[14] OECD (2013): 178

improvements in international regulatory cooperation such as mutual recognition agreements (MRA) or harmonization of labeling requirements can reap significant economic gains; the White House "estimates that the divergence of safety labeling requirements internationally… cost the U.S. chemical industry $475 million annually."[15]

Importance of Stakeholder Participation in Notice-and-Comment Process

Countries have traditionally improved the quality of their regulations and facilitated regulatory cooperation with others by employing several complementary strategies and agreements. Some of these are very high level, top-down approaches – such as bilateral and multilateral trade deals or multi-country agreements including membership in formal institutions like the World Trade Organization (WTO) and its Technical Barriers to Trade (TBT) provisions.[16] Others may take the form of regulator-to-regulator dialogues that focus on particular economic sectors, e.g. the United States–Canada Regulatory Cooperation Council.[17]

However, as identified by OMB's Office of Information and Regulatory Affairs (OIRA), any efforts that "increase regulatory transparency and provide early warnings"[18] contribute to better outcomes in IRC. Accordingly, several U.S. initiatives focus on standardizing good regulatory practices (GRP[19]) by engaging its rulemaking agencies in the IRC process. A substantial portion of these efforts is targeted at improving transparency and increasing stakeholder participation via improvements in agencies' notice-and-comment rulemaking process. Public comment "has been a central element of U.S. regulatory procedure since it was required by the Administrative Procedure Act (APA) of 1946."[20]

In contrast to the high level, top-down approaches previously mentioned, accessible and widespread participation by stakeholders—both foreign and domestic—in agency notice-and-comment rulemaking before a rule is promulgated is a bottom-up strategy that can provide valuable information agencies can use to improve regulatory outcomes. Although agencies contain significant subject matter expertise concerning the markets they are responsible for

[15] Bollyky, Thomas J. (June 2012)

[16] https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

[17] http://www.trade.gov/rcc/documents/RCC_Joint_Forward_Plan.pdf

[18] Office of Information and Regulatory Affairs. "International Regulatory Cooperation and Multilateral Efforts" July 13, 2011. Briefing in Mexico City.

[19] Office of Management and Budget. Regulatory Working Group Guidelines, Executive Order 13609 "Promoting International Regulatory Cooperation" June 26, 2015. OIRA defines good regulatory practices as: "internationally recognized processes and procedures that can be used to improve the quality and cost-effectiveness of domestic regulations... practices aimed at (a) increasing regulatory transparency and accountability by promoting public participation to ensure that stakeholders can share their views, expertise, and data during the development of regulations."

[20] Dudley, Susan E., Wegrich, Kai. "The Role of Transparency in Regulatory Governance: Comparing US and EU Regulatory Systems" *Journal of Risk Research*. 2015. 1-17

regulating, it is unlikely that they have on-hand, complete information regarding the myriad of international standards and approaches pertinent to any specific rule currently under consideration.[21]

Additionally, the U.S. Government Accountability Office (GAO) identified that regulatory agencies themselves state that early and ongoing participation is a "key factor that affect[s] the success of international regulatory cooperation activities."[22] Regulatory Working Group (RWG) guidance published by OMB elaborates on the need for participation in transparent and inclusive notice-and-comment rulemaking:

> Making the text... available for public scrutiny and comment is necessary to enable... decision making. Transparency and public participation can also help regulators achieve common regulatory objectives in ways that minimize potentially unnecessary divergences and identify unintended consequences of regulation that may unnecessarily hamper international trade and investment.... domestic and foreign stakeholders can provide useful input on priorities and information about the practical realities of implementation.[23]

Finally, advanced warning of pertinent rules under consideration and increased stakeholder participation in notice-and-comment rulemaking helps identify and avoid international regulatory divergences. This is particularly important because multiple experts have observed that it is particularly difficult to align regulatory approaches once countries have already issued their own regulations.[24]

OIRA Guidance to Agencies in 2008

The United States OMB and General Services Administration (GSA) electronically publish a *Unified Agenda of Regulatory and Deregulatory Actions* twice a year that contains information concerning specific regulatory and deregulatory actions that agencies intend to implement via rulemaking. The fall version of the *Unified Agenda* also contains the Regulatory Plan which provides "additional detail about the most important significant regulatory actions that agencies

[21] For more on the importance of public comment see: Balla, Steven J., & Dudley, Susan E. "Stakeholder Participation and Regulatory Policymaking in the United States" Report for the OECD, *The George Washington University Regulatory Studies Center*. October 2014.

[22] Government Accountability Office (2013)

[23] OMB. "Regulatory Working Group Guidelines"

[24] Ambassador Miriam Sapiro. Deputy U.S. Trade Representative. Remarks at the European Policy Centre. "The Transatlantic Trade Relationship – Achieving its Full Potential" Brussels. Belgium. (2011). And: U.S. Office of Management and Budget, Office of Information and Regulatory Affairs. "Promoting Regulatory Cooperation in the Asia-Pacific Region" APEC 2011 Symposium. Also: U.S. Office of Management and Budget. "International Regulatory Cooperation: Recent Developments in the United States". United Nations Economic Commission for Europe. (2012)

expect to take in the coming year."[25] Pursuant to Executive Order (E.O.) 12866, both executive and independent regulatory agencies must list their upcoming regulations in the *Unified Agenda*. Accordingly, one of the most important aspects of the *Unified Agenda* is its role in providing "early warning" for anyone with an interest in participating in the rulemaking process.

OIRA issued guidance to agencies in 2008 to begin "flagging" rules in the 2008 *Unified Agenda* that were expected to have a significant impact on international trade and investment partly in response to public comments on its May 2008 report, jointly authored with the Secretariat General of the European Commission regarding IRC.[26] OIRA justified the requirements on the grounds that "an evaluation of the effect of regulation on trade may help to ensure that regulatory policy does not become a tool for establishing unnecessary barriers to trade."[27]

Executive Order 13609

On May 1, 2012, President Obama issued E.O. 13609: "Promoting International Regulatory Cooperation".[28] Through this Executive Order the President reinforced OMB's 2008 directive by formally directing agencies to "ensure that significant regulations… having significant international impacts are designated as such in the *Unified Agenda of Federal Regulatory and Deregulatory Actions*, on Reginfo.gov, and on Regulations.gov."[29] In addition, its definition of "international impact" reinforced the fact that effects on FDI were also important to consider when promulgating rules.[30] Although the executive branch has historically avoided attempting to increase its role to compel independent agencies to comply with executive orders, E.O. 13609 implicitly makes mention of the fact that "flagging" rules that will likely impact international trade and investment is a good regulatory practice and encourages independent agencies to comply.[31]

As of the 2008 Regulatory Plan, all executive agencies should be flagging rules in the *Unified Agenda* that are likely to have a significant impact on international trade and investment. In theory, this also creates an "early warning" system and a forum that foreign stakeholders can use to identify upcoming regulations that will likely affect them and participate in the notice-and-comment period.[32]

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[25] http://www.reginfo.gov/public/do/eAgendaMain

[26] OMB 2008: 27 "OMB agrees that the DOT database is a promising step in providing more timely notice of planned regulatory initiatives to our international trading partners, and intends to as that all U.S. agencies include such indications in the fall, 2008 Regulatory Agenda."

[27] Ibid. 14

[28] https://www.whitehouse.gov/sites/default/files/omb/inforeg/eo_13609/eo13609_05012012.pdf

[29] Executive Order No. 13609, 77 Federal Register 26413 (May 4, 2012).

[30] Ibid. Definitions. Sec 4(b)

[31] Ibid. Sec 5. *Independent Agencies*

[32] Dudley, Wegrich (2015)

Agency Performance in Identifying Rules with an International Impact

OMB succinctly states the expectations concerning early warning and stakeholders' ability to comment on pertinent rules in its Regulatory Working Group Guidelines of June 26, 2015 – concerning E.O. 13609:

> Given that regulations with "international impacts" are flagged in the *Unified Agenda*... U.S. trading partners have an opportunity to review upcoming regulatory actions and identify potential effects and areas of upstream regulatory cooperation. Foreign governments and stakeholders have the same ability to participate in the regulatory review process… that domestic U.S. entities have.[33]

However, this assumption may not be valid if agency performance is inconsistent in identifying rules that are likely to affect international trade and investment. If this is the case, then only stakeholders who are deeply involved in a particular issue (such as large multinational corporations with a presence in Washington) or neighboring countries involved in high-level regulatory cooperation with the United States—such as Mexico or Canada—are likely to be positioned to contribute to regulatory design and policy. It should also be noted that mechanisms for cooperation, e.g. the U.S.-Canada[34] or U.S.-Mexico[35] Regulatory Cooperation Councils (RCC) do not act as a true "early warning" system for stakeholders. The U.S.-Canada RCC, for example, focuses on discussing broad, forward-looking aspects of regulatory cooperation and shared standards in specific issue-areas such as pipeline safety and motor vehicle standards rather than serving as a forum for broadly alerting stakeholders of individual rules that agencies are in the process of promulgating.

A 2013 study conducted by GAO concerning IRC found that non-federal stakeholders continue to find it difficult to provide input to U.S. agencies, in particular because they are not always aware of agency actions that are likely to have a significant impact on their efforts to trade with the United States.[36] In addition, "there is no single source of public information on anticipated U.S… rulemakings with an international impact."[37] This suggests that despite the 2008 OIRA requirement for agencies to flag relevant upcoming actions in the semiannual *Unified Agenda*, and President Obama's 2012 executive order, agencies are still not consistently identifying upcoming regulatory actions with potential international trade and investment effects.

[33] OMB. "Regulatory Working Group Guidelines" 17
[34] http://www.trade.gov/rcc/
[35] http://trade.gov/hlrcc/
[36] Government Accountability Office (2013): 34
[37] Ibid. 18

To determine whether this continues to be a problem, we examine significant regulatory actions issued between 1997 and 2014, independently determine whether they are likely to have international effects, and compare our determination with the agencies'. The remainder of this paper describes the regulatory dataset and analyzes agency performance in flagging these rules by identifying the difference between rules flagged in the *Unified Agenda* as having "international impacts" and those flagged by our method.[38] The study also discusses any potential limitations in the dataset and suggests areas of opportunity to improve agency participation in the IRC process.

Data Collected

For this analysis, we primarily collected data on executive regulatory agencies but also include independent regulatory agencies. Although the latter are not required to comply with executive orders, their inclusion in the dataset helps inform the findings concerning how many rules the U.S. promulgates each year that are likely to affect international trade and investment. The dataset includes yearly information on major agency rules issued from 1997 through 2014. We chose this window because 1997 is the first full year that GAO began tracking independent agency rules.[39]

We relied on the Reginfo.gov website[40] maintained by OIRA and GSA for information pertaining to agency flagging of rules with a likely international impact in the *Unified Agenda of Regulatory and Deregulatory* actions. This site also provided the data for published rules finalized by executive regulatory agencies.[41] We also used the GAO database[42] for published rules issued by independent regulatory agencies. In order to keep the data collection process manageable and focus on rules that were likely to have the greatest impact and, therefore be of greatest interest to stakeholders, the analysis narrows its scope to focus primarily on rules with expected impacts of $100 million or more in a year, or "economically significant"[43] rules promulgated by executive regulatory agencies and "major"[44] rules promulgated by independent

[38] Rules concerning international trade in goods flagged by our method were also included in NIST submissions to the WTO as TBT notifications: http://tbtims.wto.org/web/pages/search/notification/BasicSearch.aspx

[39] Pursuant to the Congressional Review Act of 1996, all agencies must submit final regulations to GAO upon publication.

[40] http://www.reginfo.gov/public/do/eAgendaAdvancedSearch

[41] http://www.reginfo.gov/public/do/eoAdvancedSearchMain

[42] http://gao.gov/legal/congressional-review-act/about

[43] Executive Order No. 12866, 58 Federal Register 190 (Oct. 4, 1993): Sec. 3(f) (1): A rule is considered economically significant if it is likely to "have an annual effect on the economy of $100 million or more."

[44] 5 U.S.C § 801(a)(1)(A): The CRA defines a major rule as one "likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets."

agencies. Additionally, we categorized the rules in the dataset according to the industry being regulated; this includes eight categories: Agriculture, Transportation, Manufacturing, Energy, Finance, Oil & Gas, and "Other."

Our criteria for whether a rule should be considered as likely to have a "significant international impact" derives from E.O. 13609: "a direct effect that proposed or final regulation is expected to have on international trade and investment, or that otherwise may be of significant interest to the trading partners of the United States."[45] We identified three distinct types of rules that likely create such an impact: those with a direct effect on international trade, rules concerning international investment, and rules pertaining to direct U.S. government subsidies likely to distort specific industries engaged in international trade.

Although the analysis initially counts regulations affecting areas such as domestic agricultural subsidies because these are likely to "be of significant interest to trading partners," it also presents results with these excluded, particularly when considering agency performance in flagging rules. The logic here is that foreign trading partners may well be affected by U.S. domestic subsidies but IRC is unlikely to improve due to public comment inputs by foreign trade partners in this area as the decision to pass legislation subsidizing a domestic sector of the economy is largely a political issue involving U.S. sovereignty.

Limitations of the Data Collected

Although the analysis attempts to capture rules which are likely to have a *significant* impact on international trade and investment, it is worth noting that the parameters defining an "economically significant" rule and a "major" rule are similar but not identical.[46] This will affect the accuracy of any discussion of the total number of rules with a "significant international impact" issued by U.S. agencies since different search parameters must be used when identifying pertinent rules within the *Unified Agenda*. The data collected could also suffer from any omissions or inaccuracies in the databases of either OIRA or GAO. Furthermore, it is possible that this analysis actually understates the total number of rules that should have been flagged. This would be the case if rules were not correctly labeled as either "economically significant" or "major," even if *ex post* costs actually justified these designations.

[45] Executive Order 13609

[46] For a concise analysis of this difference see: http://www.regblog.org/2011/09/27/measuring-regulatory-activity-what-can-we-learn-from-the-unified-regulatory-agenda/

Finally, although the criteria used to define which rules will likely have a "significant international impact" is derived from E.O. 13609, there is an inherently qualitative aspect to the selection that includes reading through the text of rules and making judgements regarding which regulated sectors of the domestic U.S. economy involve considerable FDI. It is noteworthy, however, that the validity of our selection methodology is implicitly bolstered due to the fact that rules we identified with an impact on international trade in goods also appear on the list of the World Trade Organization's (WTO) Technical Barriers to Trade (TBT) notifications submitted by the United States' National Institute of Standards and Technology (NIST). NIST is the U.S. agency responsible for sending notifications to the WTO of rules that are likely to have significant impacts on international trade, as required by the Agreement of Technical Barriers to Trade, which was negotiated at the end of the Uruguay Round in 1994.[47]

How Many U.S. Regulations Affect International Trade and Investment?

Although the United States issues over 3,500 rules every year, many of these include routine matters such as posting the times when drawbridges may be operated.[48] Table 1 contains information on the number of rules that were published each year in the U.S. from 1997 through 2014, how many were "significant" and, therefore, reviewed by OIRA, how many of them were "economically significant" (executive branch agencies), "major" (independent agencies), and, among these, the total number of rules we identified as likely to have a significant international impact. The data indicate that over this period, according to our analysis, an average of 20% of the larger rules likely had a significant impact on international trade and investment.

[47] http://gsi.nist.gov/global/index.cfm/L1-4/L2-12/A-219

[48] Dudley, Wegrich (2015)

Table 1: Published Final Rules Classified by Category, from 1997 through 2014						
Year Published	Total Rules	Significant Rules	Economically Significant	Major	"ES/Major" Total	International Impact (GW Analysis)
2014	3,554	177	56	11	67	19
2013	3,659	191	57	23	80	11
2012	3,708	232	46	15	61	16
2011	3,807	293	53	22	75	17
2010	3,573	308	74	17	91	17
2009	3,503	260	56	16	72	17
2008	3,830	331	64	19	83	19
2007	3,595	285	44	11	55	13
2006	3,718	303	33	8	41	4
2005	3,943	285	42	8	50	9
2004	4,101	282	47	10	57	15
2003	4,148	369	43	11	54	12
2002	4,167	307	39	8	47	10
2001	4,132	298	56	10	66	8
2000	4,313	296	50	23	73	15
1999	4,684	271	36	13	49	8
1998	4,899	245	40	31	71	10
1997	4,584	229	36	26	62	10
Totals	**71,918**	**4,962**	**872**	**282**	**1,154**	**230**

Executive Regulatory Agency Data

Table 2 shows the data for executive regulatory agency rules reviewed by OIRA from 1997 through 2014. This dataset includes the number of rules concerning domestic subsidies but does not count them in the total rules affecting trade and FDI because, as previously mentioned, these are likely less pertinent to our efforts to improve IRC. Of the 872 economically significant rules reviewed by OIRA during this period 165, or 18% by our measure, likely have a significant impact on international trade and investment. Of these rules, 85% concerned international trade in goods while the remaining 15% affected FDI flows.

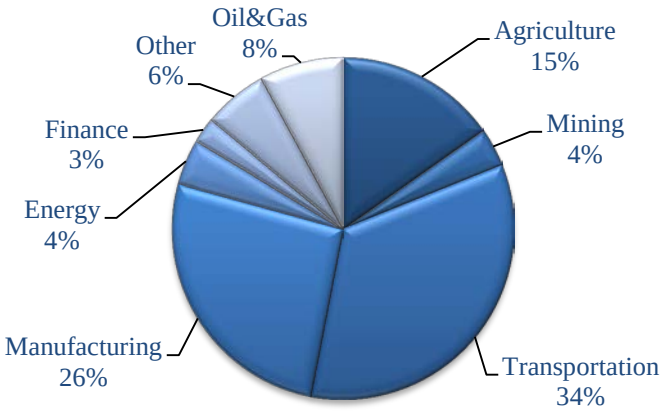
Table 2: Executive Regulatory Agency Data, from 1997 through 2014 (GW classifications regarding international impact)						
Year Published	**Total Rules Reviewed by OIRA**	**Economically Significant Rules**	**Rules With Domestic Subsidies**	**Rules With Significant Effect on Trade**	**Rules With Significant Effect on FDI**	**Total Rules Affecting Trade and FDI**
2014	177	56	3	9	2	11
2013	191	57	1	7	0	7
2012	232	46	0	7	4	11
2011	293	53	2	11	0	11
2010	308	74	3	12	1	13
2009	260	56	5	10	2	12
2008	331	64	0	12	5	17
2007	285	44	0	12	0	12
2006	303	33	1	2	1	3
2005	285	42	2	5	1	6
2004	282	47	2	10	3	13
2003	369	43	3	7	1	8
2002	307	39	4	5	0	5
2001	298	56	2	5	0	5
2000	296	50	4	9	1	10
1999	271	36	1	6	0	6
1998	245	40	0	3	3	6
1997	229	36	0	8	0	8
Totals	**4,962**	**872**	**33**	**140**	**24**	**164**

Figure 1 shows the industry breakdown of economically significant rules affecting international trade and investment. Thirty-four percent of rules with international impacts concerned transportation – which includes planes, trains, boats, and automobiles. Manufacturing was the second most prevalent category, with 26% of all rules. Agriculture, even with the exclusion of domestic subsidies, accounted for 15% while all other sectors accounted for less than 10% each. Table 3 highlights the affected sectors for each calendar year.

Table 3: Industries Affected by Economically Significant Rules with a Significant International Impact, Executive Regulatory Agency Final Rules Issued, from 1997 through 2014

Year	Transportation	Manufacturing	Ag	Oil & Gas	Mining	Energy	Finance	Other
2014	3	6	0	0	1	1	0	0
2013	1	3	1	0	0	0	0	2
2012	3	2	0	4	0	1	1	0
2011	3	8	0	0	0	0	0	0
2010	5	5	0	1	0	1	0	1
2009	4	3	2	1	0	1	0	1
2008	7	1	2	4	2	0	1	0
2007	5	2	3	0	0	0	2	0
2006	2	0	0	0	1	0	0	0
2005	2	1	2	0	0	1	0	0
2004	3	0	5	1	1	1	0	2
2003	1	0	3	1	0	0	0	3
2002	3	2	0	0	0	0	0	0
2001	2	3	0	0	0	0	0	0
2000	4	2	3	0	1	0	0	0
1999	4	1	1	0	0	0	0	0
1998	0	2	1	1	0	1	0	1
1997	4	2	2	0	0	0	0	0
Totals	**56**	**43**	**25**	**13**	**6**	**7**	**4**	**10**

Figure 1. Economically Significant Rules Affecting International Trade and Investment by Industry, From 1997 through 2014



Executive Agency Performance in Flagging Rules

OMB, GAO, and the heads of executive regulatory agencies themselves have all pointed out the importance to IRC of early notice to facilitate stakeholder participation during notice-and-comment.[49] It is, therefore, important to determine how well agencies have provided early notice since they began flagging these rules in the *Unified Agenda* per OMB guidance.[50] Even if agencies had not fully embraced the requirement to flag rules with international impacts in 2008, one would expect them to have done so under the direction of President Obama's E.O. 13609.

Table 4 compares the number of rules executive agencies flagged in the *Unified Agenda* as likely to have a significant impact on international trade and investment with the rules flagged by our review. The table is divided into two sections: "*Unified Agenda* – Notice for Stakeholders," which is the period of time we are most interesting in, where stakeholders can be informed with ample opportunity to participate in a rule's notice-and-comment period, and "Final Rules Published – OIRA Review Concluded." The latter is a count of final rules that agencies published following the conclusion of review by OIRA. For each period we identify the total number of economically significant rules, how many were flagged by executive regulatory agencies as likely to have an impact on international trade and investment, the number of rules that our criteria determined were likely to affect trade, FDI, and the total number of rules we identified—the combination of rules affecting trade in goods and FDI flows.

[49] Government Accountability Office (2013): 7, 18 Also**:** Office of Information and Regulatory Affairs. "International Regulatory Cooperation and Multilateral Efforts" July 13, 2011. Briefing in Mexico City. And: OMB. "Regulatory Working Group Guidelines"

[50] OMB 2008: 27

To summarize, the highest percentage of success in flagging rules with an international impact occurred in 2008 but was still only 43% of the total that, according to our analysis, should have been flagged for that year. Surprisingly, agencies' performance appears to have decreased after the issuance of E.O. 13609. Using our criteria, they flagged an average of 34% of total rules affecting international trade and FDI prior to E.O. 13609 and an average of 28% thereafter. These results are illustrated in Figure 2.

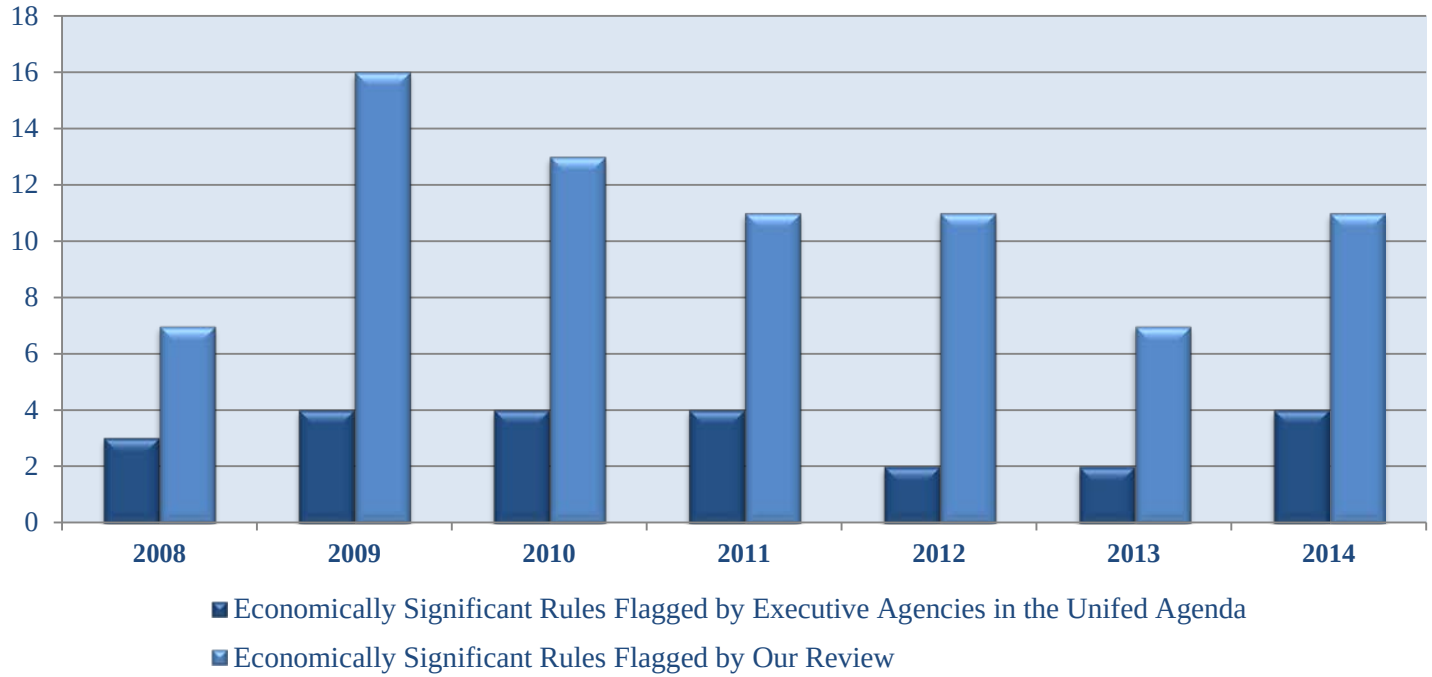
Interestingly, agencies did not flag a single rule that we identified as affecting FDI in any of these years. It is also noteworthy that even excluding the rules identified in Table 4 as having a significant effect on FDI, agencies' flags in the *Unified Agenda* have only identified an average of 38% of rules we identified as likely to have an effect on international trade in goods from 2008 through 2014. As previously mentioned, our selection of rules in this case is implicitly validated as being of likely interest to international trade partners because they are rules that were also flagged by NIST and submitted to the WTO as TBT notifications.

Our analysis of final rules published once OIRA review had concluded reinforces our assessment that agencies are missing opportunities to flag rules and expand stakeholder participation in notice-and-comment periods during rulemaking. Although the numbers cannot be compared directly for each year vis-à-vis the *Unified Agenda* entries—due to the fact that rules can either end up published in a different year or several rules can be combined into one, etc.—our analysis concluded that several rules that were not originally flagged in the *Unified Agenda* were flagged by the time they had completed OIRA review and were published.[51] Three mechanisms might be responsible for eventually identifying these missed opportunities to flag rules: OIRA review could have alerted agencies that a rule should have been flagged, public comment could have demonstrated significant interest by international trade partners in a rule's outcome, or research by agencies during the rule-development process might have alerted them to potential international consequences they had not originally considered.

[51] 4 rules; Regulation Identifier Numbers: 1904-AC00, 1904-AC19, 1904-AC22, and 2060-AR55

Table 4: Executive Regulatory Agency Performance in Flagging Economically Significant Rules with a Significant International Impact, from 2008 through 2014										
	Unified Agenda Proposed Rules – Notice for Stakeholders					Final Rules Published – OIRA Review Concluded				
Year	Economically Significant Rules in the *Unified Agenda*	Flagged "International Impacts" by Agencies in the *Unified Agenda*	Rules We Identified with an Impact on International Trade	Rules We Identified with an Impact on FDI	Total for Rules We Identified with a "Significant International Impact"	Economically Significant Rules Published	Flagged "International Impacts"	Rules We Identified with an Impact on International Trade	Rules We Identified with an Impact on FDI	Total for Rules We Identified with a "Significant International Impact"
2014	58	4	9	2	11	56	4	9	2	11
2013	35	2	5	2	7	57	4	7	0	7
2012	45	2	8	3	11	46	5	7	4	11
2011	68	4	10	1	11	53	3	11	0	11
2010	64	4	13	0	13	74	7	12	1	13
2009	57	4	11	5	16	56	6	10	2	12
2008	26	3	6	1	7	64	4	12	5	17
Totals	**353**	**23**	**62**	**14**	**76**	**406**	**33**	**68**	**14**	**82**

Figure 2. Economically Significant Rules in the *Unified Agenda* flagged with an International Impact, Executive Regulatory Agency Flags vs GW Flags, from 2008 through 2014



How Well did Each Executive Agency Perform?

Table 5 shows individual agency performance in flagging rules in the *Unified Agenda*. Our analysis demonstrates significant variation among agencies in their identification of rules likely to have an effect on international trade and investment. For example, from 2008 through 2014, the Department of Transportation (DOT) and the Department of Health and Human Services (HHS) each flagged around 80% of rules identified using our criteria while the Environmental Protection Agency (EPA) flagged 20% and the Department of Energy (DOE) flagged about 5%. Agencies initiating rules with a direct effect on FDI, such as the Department of the Treasury (Treasury), did not flag any of these rules in the *Unified Agenda*.

Table 5: Executive Regulatory Agency Performance in Flagging Rules with a Significant International Impact, Agency Breakdown, from 2008 through 2014

	Unified Agenda – Notice for Stakeholders			Final Rules Published – OIRA Review Concluded		
Agency	Economically Significant Rules in the *Unified Agenda*	Flagged "International Impacts" by Agencies in the *Unified Agenda*	Total Rules We Identified with a "Significant International Impact"	Economically Significant Rules Published	Flagged "International Impacts" by Agencies	Total Rules We Identified with a Significant International Impact
DOT	35	12	15	35	14	17
HHS	166	3	4	136	3	4
USDA	20	1	2	39	1	3
DOC	5	1	2	6	0	1
DHS	10	1	3	15	3	5
EPA	34	4	20	37	6	21
DOE	23	1	19	22	3	19
DOI	13	0	5	20	0	6
TREAS	10	0	4	8	1	2
DOL	20	0	4	40	1	4

Independent Regulatory Agency Data

Table 6 shows the data on independent regulatory agency rules listed in GAO's database from 1997 through 2014. Independent regulatory agencies issued 282 major rules during this period, but only 11%, by our measure, were likely to have a significant effect on international trade and investment. Twenty-nine of these rules affect FDI, while only three rules have a direct effect on

trade in goods. This makes sense considering that the majority of these rules were issued by agencies that regulate financial sectors such as: the Securities and Exchange Commission (SEC), the Federal Deposit Insurance Corporation (FDIC), the Commodities Futures Trading Commission (CFTC), and the Federal Reserve System (FRS).

Table 6: Independent Agency Data, from 1997 through 2014				
Year Published	**Major Rules**	**Rules With Significant Effect on Trade**	**Rules With Significant Effect on FDI**	**Total Rules Affecting Trade + FDI**
2014	11	0	5	5
2013	23	0	4	4
2012	15	2	3	5
2011	22	0	4	4
2010	17	1	0	1
2009	16	0	0	0
2008	19	0	2	2
2007	11	0	1	1
2006	8	0	0	0
2005	8	0	1	1
2004	10	0	0	0
2003	11	0	1	1
2002	8	0	1	1
2001	10	0	1	1
2000	23	0	1	1
1999	13	0	1	1
1998	31	0	2	2
1997	26	0	2	2
Totals	**282**	**3**	**29**	**32**

Independent Regulatory Agency Performance in Flagging Rules

Table 7 compares the number of rules independent regulatory agencies flagged in the *Unified Agenda* as likely to have a significant impact on international trade and investment with the rules flagged by our review. The table is divided into two sections similar to Table 4, although there is no comparison available between the rules these agencies flagged in the *Unified Agenda* and those flagged once published in final form since independent regulatory agencies are not subject to OMB review and there is no "international impacts" flag in the Federal Register.

The data show that independent regulatory agencies did not flag major rules in the *Unified Agenda* following OMB's 2008 guidance. Additionally, only the Federal Deposit Insurance Corporation (FDIC) has flagged major rules likely to have a significant impact on international

trade and investment after President Obama issued E.O. 13609. Independent regulatory agencies are not required to comply with executive orders; this might explain their lack of participation in flagging rules in the *Unified Agenda* but reduces our ability to measure agency efforts in notifying trading partners and stakeholders as to international impacts. However, since voluntary compliance with E.O. 13609 could be a relatively low-cost way for independent agencies to improve regulatory outcomes by expanding participation of international stakeholders in notice-and-comment rulemaking, information regarding independent agency rules likely to affect international trade and FDI is still informative.

In addition to showing major rules likely to affect international trade and investment by year, Table 7 quantifies the number of opportunities, by our estimate, which independent regulatory agencies had to provide advanced notice of major rules to international trade partners. Table 8 breaks down major rules issued by specific independent regulatory agencies. As previously noted, the FDIC is the only independent regulatory agency that flagged major rules in the *Unified Agenda*.

Table 7: Independent Regulatory Agency Performance in Flagging Major Rules with a Significant International Impact 2008 through 2014									
	Unified Agenda Proposed Rules – Notice For Stakeholders					Final Rules Published			
Year	Major Rules in the *Unified Agenda*	Flagged "International Impacts" by Agencies in the *Unified Agenda*	Rules we Identified with an Impact on International Trade	Rules we Identified with an Impact on FDI	Total Rules we Identified with a "Significant International Impact"	Major Rules Published	Rules we Identified with an Impact on International Trade	Rules we Identified with an Impact on FDI	Total Rules we Identified with a "Significant International Impact"
2014	7	1	0	4	4	11	0	5	5
2013	15	2	1	3	4	23	0	4	4
2012	31	1	2	9	11	15	2	3	5
2011	8	0	0	3	3	22	0	4	4
2010	8	0	0	1	1	17	1	0	1
2009	7	0	0	1	1	16	0	0	0
2008	7	0	0	2	2	19	0	2	2
Totals	83	4	3	23	26	123	3	18	21

Table 8: Independent Regulatory Agency Performance in Flagging Rules with a Significant International Impact, Agency Breakdown, from 2008 through 2014					
	Unified Agenda – Notice for Stakeholders			Federal Register – Final Rules Published	
Agency	Major Rules	Flagged "International Impacts"	Total Rules Identified with an Effect on International Trade and Investment	Major Rules	Total Identified Rules with a Significant International Impact
FDIC	7	4	6	2	2
CFTC	36	0	12	19	10
CPSC	2	0	2	2	2
SEC	34	0	6	45	5
FRS	1	0	1	19	3

Conclusions

Our analysis estimates that an average of 20% of the economically important rules published every year by U.S. regulatory agencies are likely to have a significant effect on international trade and investment. However, our analysis of agency performance in flagging these rules indicates that neither OMB guidance in 2008 nor E.O. 13609 have been sufficient to create a robust system of "early notice" for international stakeholders. Consequently, there are still areas of opportunity for improving regulatory outcomes through earlier notice that could engage domestic and international parties during notice-and-comment periods on rules with potential international impacts.

Perhaps the most telling example of the limits of President Obama's 2012 requirement is that, even for rules that agencies have correctly flagged as likely to have an international impact, preambles include no mention of E.O. 13609. Agencies include sections within the text of their rules—e.g., "Regulatory Assessment Under Executive Order 12866"—that disclose and elaborate on their efforts to comply with certain requirements as they consider rulemaking. Although agencies could very well be thinking seriously about avoiding the creation of technical barriers to trade by, for example, considering existing regulatory approaches used by foreign trade partners, they are not explaining this in the context of E.O. 13609 within their preambles.

Recommendations

Some agencies appear to be taking their responsibility to flag rules with significant international trade and investment effects more seriously than others. OIRA may need to provide some guidance to agencies for identifying relevant rules, and ensure that future *Unified Agenda* entries are accurately flagged.

Better identification of regulations that might have international trade and investment impacts could improve the quality of regulatory impact analysis and contribute to promoting GRP both domestically and internationally. In particular, an expansion of input from domestic and international stakeholders during notice-and-comment periods could aid agency efforts to better project costs, be more aware of additional international standards they might consider, and avoid duplicative or unnecessary regulations. Finally, better flagging could aid in efforts to improve the outcomes of IRC – where countries are focusing their efforts to eliminate unnecessary remaining barriers to international trade and investment flows.

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