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Experiences in International Regulatory Cooperation: Benefits, Limitations, and Best Practices¹

Daniel R. Pérez² & Susan E. Dudley³

The George Washington University Regulatory Studies Center

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

¹ The contents of this introduction are the sole responsibility of authors and can in no way be taken to reflect the views of the European Union. This introduction does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.

² Daniel R. Pérez, Policy Analyst, the George Washington University Regulatory Studies Center. danielperez@gwu.edu.

³ Susan E. Dudley, Director, the George Washington University Regulatory Studies Center and Distinguished Professor of Practice, Trachtenberg School of Public Policy and Public Administration, the George Washington University. sdudley@gwu.edu.

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

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 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

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>

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 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 public, 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.