



Report to the Chairman, Committee on
Oversight and Government Reform,
House of Representatives

August 2013

INTERNATIONAL REGULATORY COOPERATION

Agency Efforts Could
Benefit from
Increased
Collaboration and
Interagency Guidance

GAO Highlights

Highlights of [GAO-13-588](#), a report to the Chairman, Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Trade has increased as a share of the economy for several years, but U.S. companies can face difficulties competing in foreign markets when countries apply different regulatory requirements to address similar health, safety, or other issues. GAO was asked to examine what U.S. agencies are doing to engage in international regulatory cooperation. This report (1) provides an overview of U.S. regulatory agencies' international cooperation activities; (2) examines ways that U.S. agencies incorporate outcomes from international regulatory cooperation activities and consider competitiveness during rulemaking; and (3) examines factors identified by U.S. agencies and stakeholders that act as facilitators or barriers to international regulatory cooperation. GAO analyzed documents and interviewed officials from seven U.S. agencies that regulate products traded internationally and four U.S. agencies with government-wide roles and responsibilities. GAO also interviewed officials from 11 organizations representing business and consumer advocacy perspectives that reported or publicly commented on international regulatory cooperation. The scope of this study is not intended to be a complete catalog of agencies' activities and is not generalizable to all entities that have interests in this area.

What GAO Recommends

GAO recommends the RWG include in forthcoming guidance on Executive Order 13609 tools to enhance collaboration, such as mechanisms to facilitate staff level dialogues. The Office of Management and Budget (OMB) did not have comments on the recommendation.

View [GAO-13-588](#). For more information, contact Michelle Sager at (202) 512-6806 or sagem@gao.gov.

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Agency Efforts Could Benefit from Increased Collaboration and Interagency Guidance

What GAO Found

All seven U.S. regulatory agencies that GAO contacted reported engaging in a range of international regulatory cooperation activities to fulfill their missions. These activities include the United States and its trading partners developing and using international standards, recognizing each other's regulations as equivalent, and sharing scientific data. U.S. agency officials GAO interviewed said they cooperate with foreign counterparts because many products they regulate originate overseas and because they may gain efficiencies—for example, by sharing resources or avoiding duplicative work. Cooperation can address both existing and avoid future regulatory differences. Officials also explained how cooperative efforts enhance public health and safety, facilitate trade, and support competitiveness of U.S. businesses. Several U.S. interagency processes require or enable interagency collaboration on international cooperation activities. The Regulatory Working Group (RWG), chaired by OMB and the Trade Policy Staff Committee (TPSC) are forums that have different responsibilities related to the regulatory and trade aspects of international regulatory cooperation. U.S. regulatory agency officials said the current processes could benefit from better information sharing among agencies on the implementation of international cooperation activities and lessons learned. Without enhancements to current forums, opportunities to share practices and improve outcomes could be missed. Executive Order 13609, issued in May 2012, tasked the RWG with enhancing coordination and issuing guidance on international regulatory cooperation, which the RWG is developing. Nonfederal stakeholders GAO interviewed reported challenges to providing input on U.S. agencies' international regulatory cooperation activities, in particular that they are not always aware of many of these activities and participation can be resource intensive.

Officials GAO interviewed said the outcomes from international regulatory cooperation inform all phases of the rulemaking process, from helping an agency decide whether to regulate to implementing and enforcing regulations. U.S. agencies are not required to conduct a separate analysis on the competitiveness impacts on U.S. businesses when developing regulations. However, five of the seven U.S. agencies told GAO they do consider competitiveness. Officials we interviewed also pointed out that any analysis of impacts may not rise to the level of inclusion in the rulemaking record. In addition, U.S. agencies' use of international standards in regulations can lower costs for U.S. businesses and reduce barriers to trade. Officials from all of the U.S. agencies GAO interviewed said they consider international standards during rulemaking partly in response to requirements in trade agreements, U.S. statutes, and executive orders.

Officials from all of the U.S. agencies GAO interviewed identified seven key factors that affect the success of international regulatory cooperation activities: (1) dedicated resources, (2) established processes, (3) high-level leadership, (4) scientific and technical exchanges, (5) stakeholder involvement, (6) statutory authority, and (7) early and ongoing coordination. When present, these factors can facilitate U.S. agencies' efforts, but they can also act as barriers when absent. GAO found that these factors also reflect the seven key features for implementing collaborative mechanisms previously identified in its September 2012 report on interagency collaboration.

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Abbreviations

(Q)SARs	Quantitative Structure-Activity Relationships
4E	Efficient Electrical End-Use Equipment
AMS	Agricultural Marketing Service
APA	Administrative Procedure Act
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
Commerce	Department of Commerce
CPSC	Consumer Product Safety Commission
DOE	Department of Energy
DOJ	Department of Justice
DOT	Department of Transportation
EMA	European Medicines Agency
EPA	Environmental Protection Agency
EU	European Union
FAS	Foreign Agricultural Service
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FSMA	Food Safety Modernization Act
FTA	Free Trade Agreement
FTC	Federal Trade Commission
GDP	Gross Domestic Product
HC	Health Canada
HHS	Department of Health and Human Services
ICN	International Competition Network
IEA	International Energy Agency
ISO	International Organization for Standardization
ITA	International Trade Administration
NAFTA	North American Free Trade Agreement

NHTSA	National Highway Traffic Safety Administration
NIST	National Institute of Standards and Technology
NOP	National Organic Program
OAR	Office of Air and Radiation
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OIE	World Organization for Animal Health
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
PAI	Pilot Alignment Initiative
PHMSA	Pipeline and Hazardous Materials Safety Administration
RCC	U.S.-Canada Regulatory Cooperation Council
RWG	Regulatory Working Group
SPS	Sanitary and Phytosanitary
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
State	Department of State
TBT	Technical Barriers to Trade
TBT Agreement	WTO Agreement on Technical Barriers to Trade
TDG Subcommittee	Transport of Dangerous Goods Subcommittee
TPSC	Trade Policy Staff Committee
UN	United Nations
Unified Agenda	Unified Agenda of Federal Regulatory and Deregulatory Actions
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USTR	Office of the United States Trade Representative
WHO	World Health Organization
WP.29	World Forum for Harmonization of Vehicle Regulations
WTO	World Trade Organization

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August 1, 2013

The Honorable Darrell E. Issa
Chairman
Committee on Oversight and Government Reform
House of Representatives

Dear Mr. Chairman:

U.S. exports and imports grew from 22.8 percent of gross domestic product (GDP) in 2002 to 31.4 percent of GDP in 2012, or a total of \$4.9 trillion. Doubling U.S. exports by 2014 is a goal of the President's National Export Initiative.¹ Nonetheless, U.S. companies can find it difficult to compete in foreign markets when countries have different requirements for addressing similar health, safety, or other regulatory issues. International regulatory cooperation—agencies' engagement with foreign counterparts on issues related to their regulatory missions, such as international standards development, scientific collaboration, and information sharing—can help lower costs for businesses, increase U.S. exports, and further economic growth and job creation.² International regulatory cooperation can also have other benefits, including increasing the safety and quality of other countries' exports to the United States, thus helping to protect U.S. consumers. Some of our recent reports have shown that U.S. regulatory agencies have been struggling to adequately protect the public in the face of rising imports and increasingly complex supply chains.³ For example, in September 2009, we reported that the Food and Drug Administration (FDA) needed to address gaps in

¹Exec. Order No. 13534, National Export Initiative, 75 Fed. Reg. 12,433 (Mar. 16, 2010).

²Commerce officials pointed out that the term standard can have different meanings. For example, the term standard may be used to define a technical requirement or a technical standard, or refer to a regulatory requirement in the context of a model regulation, or refer to a commonly used general requirement. For simplicity, we use the term international standard throughout the remainder of this report.

³See GAO, *Consumer Product Safety Commission: Agency Faces Challenges in Responding to New Product Risks*, [GAO-13-150](#) (Washington, D.C.: Dec. 20, 2012); *Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources*, [GAO-12-933](#) (Washington, D.C.: Sept. 28, 2012); and *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, [GAO-09-873](#) (Washington, D.C.: Sept. 15, 2009).

enforcement and collaboration domestically and abroad to enhance the oversight of food imports.⁴

In May 2012, the President issued Executive Order 13609 on promoting international regulatory cooperation to provide high-level support and direction for U.S. agencies' international regulatory cooperation efforts. The executive order directed agencies to consider addressing unnecessary differences in existing regulations and describes processes to help avoid regulatory divergence in the future. Recent reports show that nonfederal stakeholders have mixed views regarding international regulatory cooperation. Some industry stakeholders are generally supportive of international regulatory cooperation efforts, especially in the context of reducing unnecessary barriers to trade,⁵ while some consumer advocacy stakeholders expressed concerns that efforts to align U.S. regulations with trading partners could lower the protection of safety and health in U.S. regulations.

In this context, you asked us to examine what federal agencies are doing to engage in international regulatory cooperation. This report (1) provides an overview of regulatory agencies' international cooperation activities; (2) examines ways that agencies incorporate outcomes from international regulatory cooperation activities and consider competitiveness during rulemaking; and (3) examines factors identified by agencies and nonfederal stakeholders that act as facilitators or barriers to international regulatory cooperation and to considering competitiveness. For the purposes of this report, competitiveness refers to the ability of U.S. firms to sell into international markets.

To identify the U.S. regulatory agencies with a significant number of regulations related to international trade, we analyzed the 2010 and 2011 Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified

⁴[GAO-09-873](#). In this report, we made 12 recommendations to improve the coordination, collaboration, information sharing, and screening systems supporting U.S. food safety programs, 9 of which have been implemented.

⁵The World Trade Organization (WTO) Agreement on Technical Barriers to Trade obligates WTO members to ensure that technical regulations are not prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to international trade. See Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instrument - Results of the Uruguay Round, 1868 U.N.T.S. 120 (1994) [hereinafter referred to as the TBT Agreement].

Agenda),⁶ as well as data from the 2011 World Trade Organization (WTO) Technical Barriers to Trade (TBT) Information Management System. We applied criteria to select agencies that regulate products that are traded internationally and assure the inclusion of some independent regulatory agencies in our review. We analyzed documents and interviewed officials from seven U.S. regulatory agencies out of 60 U.S. agencies that are included in the Unified Agenda, including the Department of Energy (DOE), the Department of Health and Human Services' (HHS) FDA, the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the United States Department of Agriculture (USDA), the Consumer Product Safety Commission (CPSC), and the Federal Trade Commission (FTC). We selected these agencies because they regulate products that are traded internationally, such as medical devices, chemicals, toys, automobiles, and food. These views are not generalizable to all U.S. agencies. We reviewed documents and interviewed officials from the four agencies with government-wide regulatory and international coordination roles and responsibilities: the Office of Management and Budget (OMB), the Office of the United States Trade Representative (USTR), the Department of Commerce (Commerce), and the Department of State (State).⁷ To obtain a broader set of perspectives, including those of participants from outside government agencies, we interviewed officials from 11 academic and stakeholder organizations representing business and consumer advocacy perspectives, such as the U.S. Chamber of Commerce and Public Citizen. We selected these organizations based on published views on international regulatory cooperation and recommendations from agencies in our study. These views are not generalizable, but provided insights. Using criteria based on our September 2012 report on interagency collaborative efforts, we also compared agencies' documents and testimonial evidence about their international regulatory cooperation

⁶The Unified Agenda provides uniform reporting of data on regulatory and deregulatory activities under development throughout the U.S. federal government. All entries in the online Unified Agenda contain uniform data elements, including "international impacts" (whether the regulation is expected to have international trade and investment effects, or otherwise may be of interest to the nation's international trading partners).

⁷USDA, which is a regulatory agency, also has a coordinating role as the national enquiry point for the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

activities to the seven key features that we found agencies should consider when implementing collaborative mechanisms.⁸

We tested the reliability of the databases used to help select agencies to include in this review by reviewing related documentation, interviewing knowledgeable agency officials, and tracing a sample of entries to source documents. We concluded that the data were sufficiently reliable for the purposes of this report. Throughout this report, we use specific, selected examples to illustrate general agency processes and practices. The scope of our inquiry is neither a complete catalog of international regulatory activities nor generalizable to all individuals who have interests in international regulatory cooperation and global competitiveness. Appendix I provides a more detailed description of our objectives, scope, and methodology.

We conducted this performance audit from March 2012 to August 2013, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

U.S. Agency Roles and Responsibilities

U.S. agencies have different responsibilities related to international regulatory cooperation. For example, Commerce, State, USTR, OMB, and USDA have government-wide responsibilities. Their roles and responsibilities are determined primarily through statutes and executive orders. U.S. treaty obligations also influence their activities, as shown in table 1. To some extent these agencies bring structure and direction to activities that are in practice pursued in a decentralized manner by multiple agency participants.

⁸GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012). To identify the key features, we conducted a literature review of academic work, interviewed a number of experts in governmental collaboration, and analyzed a sample of our prior work.

Table 1: Government-wide Roles and Responsibilities Related to International Regulatory Cooperation

Agency	Roles and Responsibilities
Department of Commerce (Commerce)	The role of Commerce’s International Trade Administration (ITA) in international regulatory cooperation is generally to coordinate with industry to obtain its input on U.S. producers’ concerns about global competitiveness and market access. ITA also has a role in some international regulatory cooperation initiatives, such as regulatory cooperation councils and has responsibility for monitoring compliance with nonagricultural international trade agreements to which the United States is a party. Commerce’s National Institute of Standards and Technology (NIST) is responsible for notifying the World Trade Organization (WTO) of proposed regulations that could have trade impacts and serving as the U.S. national enquiry point for the WTO Agreement on Technical Barriers to Trade (TBT Agreement). Per the National Technology Transfer and Advancement Act, NIST is also responsible for coordinating federal, state, and local technical standards and conformity assessment activities with the same activities of the private sector. The goal is to eliminate unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures.
Department of State (State)	The Secretary of State is responsible, on behalf of the President, for ensuring that all proposed international agreements of the United States are fully consistent with U.S. foreign policy objectives. According to State, no agency of the U.S. government may conclude an international agreement, whether entered into in the name of the U.S. government or in the name of the agency, without prior consultation with the Secretary or his designee.
United States Trade Representative (USTR)	USTR leads U.S. trade policy and coordinates the efforts of U.S. agencies to reduce barriers to trade such as discriminatory foreign regulations. It also represents the United States in international trade forums such as the WTO, oversees U.S. implementation of trade agreements, and monitors compliance with trade commitments. To prevent regulation-related trade barriers, it has promoted adoption of good regulatory practice guides by international economic forums.
Office of Management and Budget (OMB)	OMB coordinates interagency review of significant rulemakings. OMB also plays a leadership role in government-wide international regulatory cooperation initiatives, such as regulatory cooperation councils. Under Executive Order 13609, the Regulatory Working Group (RWG), chaired by OMB’s Office of Information and Regulatory Affairs (OIRA), provides a forum for international regulatory cooperation.
Department of Agriculture (USDA)	USDA is the national enquiry point for the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), coordinates U.S. government comments on foreign SPS regulations, and notifies the WTO of U.S. regulations that may have trade impacts. USDA houses the U.S. government offices for coordination with Codex Alimentarius Commission, World Organization for Animal Health, and International Plant Protection Convention, the three international standard setting bodies referenced by the SPS Agreement.

Source: GAO analysis of agency documents.

U.S. regulatory agencies have varying missions, such as protecting public health or safety, and engage in multiple activities to fulfill their missions. Statutes establish agencies’ missions and establish the scope and limits of each agency’s authority. Agencies often implement their statutory missions by developing, issuing, and enforcing regulations. Agencies may also need to comply with multiple procedural and analytical requirements during the rulemaking process that precedes the issuance of regulations,

including participation in interagency review and coordination processes summarized in table 1.

Regulatory Context

Regulation is one of the principal tools that the U.S. federal government uses to implement public policy. Underlying federal regulatory actions is the long-standing rulemaking process established by the Administrative Procedure Act (APA).⁹ This act establishes broadly applicable federal requirements for informal rulemaking, also known as notice and comment rulemaking.¹⁰ At a high level, domestic rulemaking activities governed by the APA generally include four basic phases:

1. Consideration of regulatory action: The agency gathers information to determine (1) whether a rulemaking is needed and (2) the range of regulatory options.¹¹
2. Development and issuance of proposed regulation: The agency drafts a proposed regulation, including the preamble (the portion of the regulation that informs the public of the supporting reasons and purpose of the regulation) and the language in the regulation. The agency also begins to address analytical and procedural requirements and engages in interagency coordination and OMB review, where required. After these are complete, the agency publishes the proposed regulation in the *Federal Register* and requests comments from the public.
3. Development and issuance of final regulation: The agency responds to public comments, completes analytical and procedural requirements, engages in interagency coordination and OMB review where required, and publishes the final regulation in the *Federal Register*.
4. Implementation of final regulation: The agency enforces compliance with the final regulation and monitors its performance.

⁹Pub. L. No. 79-404, 60 Stat. 237 (1946), codified in 1966 in scattered sections of title 5, United States Code. Some agencies, such as CPSC, have statutory rulemaking requirements that add processes and steps beyond those required by the Administrative Procedure Act. See, e.g., 13 U.S.C. § 2058.

¹⁰The APA describes two types of rulemaking, formal and informal. Formal rulemaking includes a trial type “on-the-record” proceeding. Most federal agencies use the informal rulemaking procedures outlined in 5 U.S.C. § 553.

¹¹A retrospective review of an existing rule may prompt this consideration.

Various executive orders and guidance establish agencies' processes that govern international regulatory cooperation activities. Executive Order 12866 established the basic principles and processes that help guide and coordinate regulatory actions by executive agencies (other than independent regulatory agencies).¹² Three components of the order are especially relevant to current regulatory cooperation efforts. First, the order established general principles for government regulation, including that agencies should assess the costs and benefits of available regulatory alternatives. Second, the order established centralized review and coordination of rulemaking, particularly by (1) requiring agencies to submit draft significant regulations to OMB's Office of Information and Regulatory Affairs (OIRA) for interagency review before they are published¹³ and (2) establishing the RWG to serve as a forum to assist agencies in identifying and analyzing important regulatory issues¹⁴ Third, the order required agencies to compile and make public their regulatory agendas and plans, which include identifying the anticipated effects of forthcoming regulations. Executive Order 13563 reaffirmed the principles, structures, and definitions governing contemporary regulatory review that were established by Executive Order 12866.¹⁵ Particularly relevant to this report, the order states that the regulatory system must promote competitiveness, and it also expanded expectations for agencies to retrospectively review their existing regulations.

OMB periodically issues guidance to executive agencies on implementing executive orders. One key example related to the regulatory review orders discussed above is OMB Circular A-4, issued in 2003. The circular provides OMB's guidance on the development of regulatory analysis as

¹²Exec. Order No. 12866, Regulatory Planning and Review, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

¹³Executive Order 12866 defines significant regulatory actions to include those that are likely to result in a rule that may have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, or create a serious inconsistency or otherwise interfere with an action taken, or planned by another agency.

¹⁴This working group is chaired by the OIRA Administrator, and it consists of representatives of leadership in each agency that the OIRA Administrator has determined has significant domestic regulatory responsibility. Per Executive Order 13609, the RWG includes a representative from USTR and, as appropriate, representatives from other agencies and offices.

¹⁵Exec. Order No. 13563, Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821 (Jan. 21, 2011).

required under Executive Order 12866 and related authorities, defining good regulatory analysis and standardizing the way benefits and costs of federal regulatory actions are measured and reported. The circular includes a brief paragraph about considering the impacts of federal regulation on global markets and trade. In May 2011, USTR and OMB released a joint memorandum restating U.S. trade obligations and provided additional guidance to agencies on how to carry them out. In particular, the joint memorandum stressed the importance of agencies' attention to regulatory analysis requirements in prior executive orders and OMB Circular A-4, as well as avoiding unnecessary barriers to trade as specified in the Trade Agreements Act. The memo also encouraged agencies to engage in international collaboration activities.

Trade Context

Some U.S. international regulatory cooperation efforts occur within the context of trade policy and negotiations. Reducing foreign regulatory barriers to trade is a key U.S. trade objective. In support of this objective, international agreements and U.S. legislation enacting them encourage and guide agencies' participation in some international regulatory cooperation activities. For example, the Uruguay Round Agreements Act codifies the WTO Agreement on Technical Barriers to Trade (TBT Agreement) and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and includes additional international regulatory cooperation responsibilities.¹⁶ Several of the most salient obligations are briefly described below.¹⁷

- TBT Agreement:¹⁸ For technical regulations, the TBT Agreement requires members to use international standards or the relevant parts of them as a basis for technical regulations where available and appropriate, and, in certain instances, notify the WTO of proposed regulations with possible trade impacts and consider comments received before finalizing those regulations. Further, the TBT Agreement states that regulations should be no more trade restrictive than needed to fulfill a legitimate objective.

¹⁶19 U.S.C. § 3511.

¹⁷Fuller explanations of these agreements may be found at: http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm

¹⁸Specifically, TBT Agreement art. 2.2, 2.4, and 2.9.

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- SPS Agreement:¹⁹ For SPS measures (including measures to protect animal or plant life from pests, diseases, or disease-causing organisms as well as to protect human or animal life), the SPS Agreement requires members to base their measures on existing international standards, or where the measure results in a higher level of protection, allows members to maintain or introduce their own standard if there is a scientific justification. Members are also required to ensure that their regulations are applied only to the extent necessary to protect human, animal, or plant life or health. Members are to notify the WTO at an early stage in the rulemaking if a proposed regulation differs from an international standard and may have a significant trade impact on other members, in order to receive comments for consideration.
 - Free Trade Agreements (FTA): According to USTR, FTAs, such as the U.S. Korea Free Trade Agreement, build on the disciplines of the TBT Agreement, by providing for greater transparency. Some U.S. FTAs also provide that interested parties and persons should be given opportunities to comment on proposed measures. According to Commerce officials, most of these bilateral trade agreements also provide for more timely notification mechanisms than multilateral mechanisms such as the TBT Agreement. Most of these bilateral trade agreements also provide for more timely notification mechanisms than multilateral mechanisms.

In addition to these finalized agreements, the United States has offered proposals in ongoing Trans-Pacific Partnership negotiations toward a trade agreement among 11 participating nations to promote transparency. More recently, on February 13, 2013, President Obama and European Union (EU) leaders announced their intention to launch negotiations on a Transatlantic Trade and Investment Partnership. According to USTR, the goals of the partnership include reducing the cost of differences in regulation and standards by promoting greater compatibility, transparency, and cooperation.

¹⁹See Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instrument - Results of the Uruguay Round, 1867 U.N.T.S. 493, 33 I.L.M. 1125 (1994) [hereinafter referred to as the SPS Agreement]. Specifically, SPS Agreement art. 2, 3, 5, 7, and Annexes A and B.

U.S. Agencies Engage in Six Primary Categories of International Regulatory Cooperation Activities

All agencies in our study reported that they engage in a range of international regulatory cooperation activities. These activities include U.S. agencies and foreign counterparts sharing scientific data, developing and using the same international regulatory standards, and recognizing each other's regulations as equivalent. Cooperation can address both existing and avoid future regulatory differences. These activities generally fall into six broad categories, as shown in table 2 below. See appendix II for details on the illustrative examples.

Table 2: Categories of International Regulatory Cooperation Activities by U.S. Agencies

Activity	Description	Illustrative examples
Information sharing and scientific collaboration	Agencies share information with their foreign counterparts on scientific data and regulatory approaches.	<ul style="list-style-type: none"> Pesticide Tolerance Crop Grouping Revisions Program Chemical Data Information Sharing Consumer Product Safety Pilot Alignment Initiative
Development and use of international standards	Agencies participate in international standards setting bodies and incorporate international standards into rulemaking as appropriate.	<ul style="list-style-type: none"> World Forum for the Harmonization of Vehicle Regulations UN Subcommittee on the Transport of Dangerous Goods International Competition Network
Equivalency agreements	The United States enters into an agreement with another country to recognize their regulations and deem them equivalent to those of the United States.	<ul style="list-style-type: none"> National Organic Program Equivalency Agreements Equivalency Determinations for the Import of Meat, Poultry, and Egg Products
Strengthening capacity of developing countries	Most agencies in our study provide technical assistance to developing countries. Agency officials said they work with countries to strengthen their regulatory systems, among other reasons, to improve the safety of products imported into the U.S.	<ul style="list-style-type: none"> Food and Drug Administration Federal Trade Commission Animal and Plant Health Inspection Service
Work sharing with foreign counterparts	Agencies work with foreign counterparts on projects to share resources to implement regulations and avoid duplicating effort.	<ul style="list-style-type: none"> Food and Drug Administration Coordination on Inspections Animal and Plant Health Inspection Service Joint Animal Health Site Visits to Third Countries
Coordination on voluntary programs	Agencies cooperate with foreign counterparts on voluntary programs.	<ul style="list-style-type: none"> Efficient End-use Electrical Equipment Implementing Agreement, Solid State Lighting Annex

Source: GAO analysis of agency documents and interviews.

International regulatory cooperation activities involve bilateral and multilateral governmental relationships and participation in third-party organizations, such as standards-setting bodies. For example, some agencies in our study participate in international organizations, such as

the World Organization for Animal Health (OIE)²⁰ or the International Organization for Standardization (ISO).²¹ International cooperation activities may be formal or informal, ranging from participation in international organizations established by international agreements to informal regulatory information sharing and dialogues. International regulatory cooperation activities may also occur on a government-wide basis and address multiple sectors. For example, the U.S.-Canada Regulatory Cooperation Council (RCC) is an effort to increase regulatory transparency and coordination between the two countries. Action plans exist in the areas of agriculture and food, transportation, health and personal care products and workplace chemicals, the environment, and cross-sectoral issues. Similarly, OMB, Commerce, and other federal agencies also participated in the Asia-Pacific Economic Cooperation (APEC) effort to share and promote good regulatory practices, such as transparency and centralized review of regulations, among APEC economies.

Agencies Cooperate Internationally to Fulfill Regulatory Missions

Agency officials said they engage in international regulatory cooperation activities primarily because they are operating in an increasingly global environment and many products that agencies regulate originate overseas. For example, according to FDA's Global Engagement Report, the United States imports 80 percent of active pharmaceutical ingredients and imports of FDA-regulated products have grown dramatically in recent years. FDA reported that the agency engages in international cooperation activities to ensure products produced overseas are safe for U.S. consumers. Similarly, CPSC operates in an increasingly global environment. According to CPSC, the value of U.S. imports under

²⁰The World Organization for Animal Health (formerly the Office International des Epizooties) is recognized by the SPS Agreement. Founded in 1924, the OIE has six main missions: (1) to ensure transparency in the global animal disease situation, (2) to collect, analyze and disseminate veterinary scientific information, (3) to provide expertise and encourage international solidarity in the control of animal diseases, (4) within its mandate under the WTO SPS Agreement, to safeguard world trade by publishing health standards for international trade in animals and animal products, (5) to improve the legal framework and resources of national veterinary services, and (6) to provide a better guarantee of food of animal origin and to promote animal welfare through a science-based approach.

²¹The International Organization for Standardization (ISO) is an independent, non-governmental organization made up of members from the national standards bodies of 163 countries and 3,368 technical bodies. International standards give specifications for products, services and good practice, in areas such as food safety, computers, agriculture, and health care.

CPSC's jurisdiction has skyrocketed in recent years, with imports from China more than quadrupling from \$62.4 billion in 1997 to \$301.0 billion in 2010. Moreover, in fiscal year 2012, 4 out of every 5 consumer product recalls or 345 of 439 recalls involved imported products, making imports a critical focus for CPSC.

Agencies also cooperate with foreign counterparts in an effort to gain efficiencies. For example, EPA participates in an initiative on pesticides through the Organisation for Economic Co-operation and Development (OECD) that has resulted in regulatory efficiencies. OECD also reported that, by accepting the same test results OECD-wide, unnecessary duplication of testing is avoided, thereby saving resources for industry and society as a whole.²² A 2007 study for the OECD Working Group on Pesticides estimated resource savings of 33 to 40 percent as a result of joint review by three to five countries, compared with each country working alone. The study noted that the savings from reducing duplicative expert evaluation work significantly outweighed the marginal increase for project management, coordination, and travel.²³ These tools and approaches facilitate work sharing for regulators and help avoid costly, duplicative testing by ensuring that the data developed and submitted in one country can be used by other countries in reaching their regulatory decisions.²⁴

Agencies' efforts to cooperate on regulatory programs through cooperative activities may also have the effect of facilitating trade and supporting the competitiveness of U.S. businesses. FDA officials said that international regulatory cooperation and harmonization has public health benefits, promotes regulatory efficiency, and both also have indirect

²²OECD, *International Regulatory Co-operation: Case Studies, Vol. 1: Chemicals, Consumer Products, Tax and Competition* (OECD Publishing: 2013), accessed 5/14/2013 <http://dx.doi.org/10.1787/9789264200487-en>.

²³For more information on EPA's international efforts related to pesticides and food safety, see EPA, *The Value of Countries Working Together to Regulate Pesticides and Food Safety: Achieving Public Health and Environmental Protection through International Collaboration*, EPA 735-K0-9001 (Washington, D.C.: April 2009).

²⁴Our prior work also found that coordination among domestic and foreign financial regulators improved the quality of rulemakings. For example, these coordination efforts likely eliminated duplication and helped fill regulatory gaps to limit risks migrating to unregulated markets. See GAO, *Financial Regulatory Reform: Regulators Have Faced Challenges Finalizing Key Reforms and Unaddressed Areas Pose Potential Risks*, [GAO-13-195](http://www.gao.gov/products/GAO-13-195) (Washington, D.C.: Jan. 23, 2013).

competitiveness advantages for companies. FDA officials said that public health regulatory and competitiveness goals are often complementary: by upholding and enforcing scientifically valid standards, public health is protected and promoted at the same time that companies benefit from a level playing field that should make their products more competitive. Moreover, bringing a quality, safe, effective new drug to market faster yields health benefits for individuals because they have access to the drug sooner as well as trade benefits for industry, which has access to more markets.

In addition, U.S. agency officials said that when they participate in international standards development, an existing U.S. regulation or policy approach may be used as the basis for the international standard. When other countries adopt U.S. approaches to regulations, it can lower compliance costs and support competitiveness for U.S. businesses. For example, EPA's Office of Air and Radiation (OAR) officials said that OAR worked within the World Forum for Harmonization of Vehicle Regulations (WP.29) to urge the use of a U.S. regulation as the basis for a global regulation on test procedures for off-highway construction vehicle engines. OAR officials said U.S. manufacturers supported this effort because U.S. manufacturers sell equipment internationally, and complying with one set of regulations reduces their fixed costs.

2012 Executive Order Outlines New Processes for International Cooperation, but Agencies Could Benefit from Additional Collaboration

There are four interagency review processes routinely used to identify and review regulations that could have trade or competitiveness impacts and to encourage international regulatory cooperation.

- OMB officials said that a process for interagency coordination with OMB, USTR, State, and Commerce on regulations is the centralized regulatory review process under Executive Orders 12866 and 13563. USTR officials said they work with agencies as needed on regulatory issues that have an international impact prior to the interagency regulatory review process. However, the interagency review process ensures OMB, USTR, State, and Commerce another opportunity to provide input on any proposed significant regulation from agencies whether or not international impacts were raised earlier. Independent agencies are not required to participate in the interagency review process.
- The May 2012 Executive Order 13609 on promoting international regulatory cooperation establishes processes for agencies to report on efforts in this area. The order requires agencies that are required to submit a regulatory plan to report a summary of their international

regulatory cooperation activities that are reasonably anticipated to lead to significant regulations in their regulatory plans. It also requires agencies to identify regulations with significant international impacts in the Unified Agenda, on [Reginfo.gov](http://www.reginfo.gov),²⁵ and on [Regulations.gov](http://www.regulations.gov).²⁶

- Generally, all U.S. federal agencies are required to consult with State before concluding international agreements.²⁷ Among other things, State is responsible for ensuring that any proposed international agreement is consistent with U.S. foreign policy. State officials said that the Secretary of State must be consulted on international regulatory cooperation issues involving the negotiation or signing of international agreements or arrangements.
- The Trade Agreements Act, as amended, requires U.S. agencies to coordinate in specified circumstances,²⁸ including with USTR on standards-related trade measures as part of their overall statutory responsibilities.

Current interagency review processes are designed to trigger reviews in certain instances, such as when agencies' international regulatory cooperation activities include significant regulations, international agreements, and trade mechanisms. Many of the international regulatory cooperation activities reported in our study would not trigger these

²⁵The General Services Administration's Regulatory Information Service Center and OMB's OIRA established [Reginfo.gov](http://www.reginfo.gov) to assist users who want to find federal regulatory information such as regulatory agendas and regulatory plans including brief synopses and timetables for action on rules that federal departments and agencies are considering. See <http://www.reginfo.gov/public/>.

²⁶The federal government launched [Regulations.gov](http://www.regulations.gov) in 2003 to enable citizens to search, view, and comment on regulations issued. See <http://www.regulations.gov/#!home>.

²⁷22 C.F.R. § 181.4(a).

²⁸For example, USTR is required to coordinate international trade policy issues that arise as a result of implementation of the WTO TBT agreement. USTR is also required to inform and consult any federal agencies having expertise in the matters under discussion or negotiation in coordinating U.S. discussions and negotiations with foreign countries for the purpose of establishing mutual arrangements with respect to standards-related activities. USTR also must consult with the cited agency and members of the interagency trade organization if a foreign government makes a representation to the USTR alleging that a U.S. standards-related activity violates U.S. TBT obligations. Commerce and USDA must coordinate with USTR with respect to TBT international standards-related activities that may substantially affect the commerce of the United States. Furthermore, with regard to TBT obligations, the Secretaries of Commerce and USDA have a role in assuring adequate representation of U.S. interests in international standards organizations, and encouraging cooperation among federal agencies so as to facilitate development of a unified U.S. position.

processes, such as activities related to information sharing and scientific collaboration, capacity building, or the use of international standards in regulations that are not significant.

OMB and USTR also lead interagency forums on regulations and trade that have different responsibilities related to international regulatory cooperation. Executive Order 13609 assigns responsibilities to the Regulatory Working Group (RWG), chaired by OMB's Administrator of OIRA, to serve as a forum to discuss, coordinate, and develop a common understanding among agencies of U.S. government priorities for international regulatory cooperation. According to OMB officials, the RWG provides a forum to foster greater cooperation and coordination of U.S. government strategies, including those for promoting regulatory transparency, sound regulatory practices, and U.S. regulatory approaches abroad. OMB officials also said that the RWG is developing guidance to implement the executive order. USTR chairs the policy-level Trade Policy Staff Committee (TPSC), which maintains U.S. interagency mechanisms for trade policy coordination among State, Commerce, the Department of Labor, USDA, and other appropriate agencies. The TPSC identifies and addresses foreign government trade measures among other duties. USTR officials said USTR coordinates with agencies on trade issues related to regulations at the working level through the TPSC subcommittees on technical barriers to trade and sanitary and phytosanitary barriers to trade. USTR explained that these subcommittees are involved in supporting international regulatory cooperation by anticipating and resolving potential regulatory conflicts that could impair trade. USTR officials also noted that at the TPSC subcommittee level, USTR coordinates with officials from regulatory agencies in preparing for participation in international cooperation activities, such as APEC meetings, as well as regulators' involvement in international standards development. Nevertheless, some agency officials reported that greater coordination between regulatory forums and trade forums could improve outcomes. USTR officials also said there is uncertainty about the implementation of Executive Order 13609 and how it will relate to USTR's trade responsibilities. According to OMB officials, one of the main objectives of Executive Order 13609 is to improve coordination of international regulatory cooperation. They anticipate that forthcoming guidance on Executive Order 13609 will address

collaboration with the RWG and other interagency groups, particularly the TPSC.²⁹

Beyond these forums for interagency coordination, regulatory agency officials we interviewed said the current processes could benefit from better information sharing among agencies on the implementation of international regulatory cooperation activities and lessons learned. We have previously found that it is important to ensure that the relevant participants have been included in the collaborative effort, including those with the knowledge, skills, and abilities to contribute to the outcomes of the collaborative effort.³⁰ The RWG and TPSC are designed for high-level, government-wide policy discussions, and participants in the RWG and TPSC are higher level management or policy officials who may be somewhat removed from the technical activities that underpin rulemaking.

Regulatory agency officials we interviewed pointed out that additional ways to facilitate exchanges about best practices and day-to-day implementation would be helpful. An agency official said that there may be a benefit to having an interagency dialogue, working group, or other forum through which officials can share information on challenges and successes in implementing international regulatory cooperation. For example, officials said EPA and FTC both have regulations related to labeling and there may be opportunities that could result from sharing information and best practices with international regulators. Agency officials we interviewed identified another example illustrating the potential benefits of staff-level exchanges and information sharing during a multiagency meeting on this report. The officials that we interviewed said it is challenging to measure the outcomes of international regulatory cooperation activities and there is a need for an appropriate metric to show the value of funds spent on these activities. EPA officials we interviewed stated that in one case they successfully quantified the benefits from work with OECD's Mutual Acceptance of Data program. According to EPA, the implementation of this decision has saved both governments of 34 member countries and industry nearly \$225 million annually and also generated many nonquantifiable benefits, such as promoting animal welfare in chemical testing. Officials attending a GAO multiagency meeting said similar practices would be helpful to justify

²⁹As of July 30, 2013 the guidance has not been issued.

³⁰This is one of several key features outlined in [GAO-12-1022](#).

investments in international regulatory cooperation activities. Agency officials we interviewed said they found a multiagency meeting on this report useful in part because the meeting involved discussions of day-to-day implementation of these issues. Further, Commerce officials suggested that enhanced coordination among participants in these forums would also benefit from including existing interagency standards policy groups, such as the Interagency Committee on Standards Policy and the National Science and Technology Council's Subcommittee on Standards. Without some enhancements to the current forums for regulators and trade officials to collaborate, opportunities to share practices and improve safety and regulatory efficiencies and to reduce trade barriers could be missed. Agency officials said there is currently not a forum to meet this need.

Nonfederal Stakeholders Report Challenges to Providing Input into Agencies' International Regulatory Cooperation Activities

Although nonfederal stakeholder input into regulatory processes is important, the stakeholders we spoke with said it can be challenging for them to provide input into agencies' international regulatory cooperation activities because of the required resources and the difficulty of becoming aware of such activities. Congresses and Presidents have required agencies to comply with multiple procedural requirements in an effort to promote public participation in rulemaking, among other goals.³¹ For formal international regulatory cooperation, such as standards setting, according to nonfederal stakeholders, they can directly observe international meetings and provide input in some cases. However, nonfederal stakeholders told us that high levels of resources are required to participate in international meetings, which can limit participation in practice. For informal international cooperation activities, nonfederal stakeholders said it is even more challenging to track and provide input into the agencies' activities because some activities described to us by regulatory agencies precede the decision to regulate and therefore may not be transparent to the public. While it is generally challenging for nonfederal stakeholders to provide input into U.S. agencies' international regulatory cooperation activities, it is particularly important that

³¹For example, Executive Order 13563 states that regulations shall be adopted through a process that involves public participation and shall be based, to the extent feasible and consistent with law, on the open exchange of information and perspectives. The executive order also states that before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.

stakeholders at least have the opportunity to participate and advise agencies when those activities are anticipated to lead to the development of regulations. However, further complicating nonfederal stakeholders' efforts, there is no single source of public information on anticipated U.S. and foreign rulemakings with an international impact. For example, the Unified Agenda and OMB Regulatory Review Database both identify U.S. regulations that have an international impact. The Unified Agenda includes regulations under development or review, while the OMB Regulatory Review Database includes significant regulations submitted to OMB for review. In addition, the WTO maintains databases on certain member countries' proposed regulations related to technical barriers to trade and sanitary and phytosanitary measures—namely those self-identified as having potential trade impacts or involving divergence from international standards.

Agency officials we interviewed agreed that stakeholder involvement is important and nonfederal stakeholders are uniquely positioned to identify and call attention to unnecessary differences among U.S. regulations and those of its trading partners. Agencies and nonfederal stakeholders told us that the U.S.-Canada RCC has implemented practices to engage nonfederal stakeholders. For example, the 29 work plans that make up the RCC were developed in part from the response to a *Federal Register* request for public comments concerning regulatory cooperation activities that would help eliminate or reduce unnecessary regulatory divergences in North America that disrupt U.S. exports. Stakeholder outreach activities are also included in the work plans. OMB is also taking steps to increase the transparency of agencies' international regulatory cooperation activities and included new reporting requirements for agencies in Executive Order 13609. The order directs agencies that are required to submit a regulatory plan to include summaries of their international regulatory cooperation activities that are reasonably anticipated to lead to significant regulations.³² An agency official also cautioned it may not be realistic for agencies to report all international regulatory cooperation activities as many are informal in nature.

³²Not all international regulatory cooperation activities result in regulations and not all regulations are significant.

Agencies Consider International Regulatory Cooperation and Competitiveness during Rulemaking in Different Ways

International Regulatory Cooperation Activities Inform Different Phases of Rulemaking

Agency officials we interviewed reported that the outcomes from international regulatory cooperation can inform all phases of the rulemaking process, from affecting an agency's decision whether or not to regulate in a particular area to implementing and enforcing regulations. According to an agency official, there is no bright line that separates international regulatory cooperation activities from regulatory programs. For example, U.S. agencies share scientific and technical information with their foreign counterparts, which can inform all stages of the rulemaking process. In addition, information sharing can help inform an agency's decision on whether or not to regulate a product. When countries have differences in regulations in a particular area, there are opportunities to coordinate on the science underlying regulatory decisions in a particular area. EPA Office of Chemical Safety and Pollution Prevention (OCSPP) officials said that for chemical safety regulations, countries are working within different statutory and regulatory frameworks and different levels of acceptance of risk that can make it difficult to reach full agreement on a regulatory approach. In such cases, sharing information with foreign counterparts can facilitate agreement on a common understanding of the issue or on underlying technical or scientific issues. According to officials that we interviewed, OCSPP also focuses on transparency and good regulatory practices, which lead to commonality between policies, work sharing on scientific reviews, and greater harmonization in the long term.

Some international regulatory cooperation activities, such as the development of international standards or practices, can inform and contribute to the development and issuance of a proposed regulation. Certain U.S. agencies reported that they coordinate with organizations that develop international standards and may use these standards when developing domestic regulations. For example, DOT's Pipeline and Hazardous Materials Safety Administration (PHMSA) participates in the United Nations (UN) Transport of Dangerous Goods (TDG) Subcommittee, which develops UN Model Regulations for the

transportation of hazardous materials. In an effort to align with any changes to the UN Model Regulations, PHMSA considers these model regulations in a rulemaking every 2 years. As a result, related U.S. regulations are more closely aligned with trading partners and there are fewer country-unique regulations for businesses to comply with, which leads to improved safety results. According to PHMSA officials that we interviewed, when regulations are the same in different countries it enhances compliance and improves the efficiency of the transportation system by minimizing regulatory burdens and facilitating effective oversight. Similarly, Commerce officials pointed out that regulators often use common technical standards as the basis for regulation, which can reduce the burden on the regulated community.

Other international regulatory cooperation activities are related to the implementation of regulations, such as equivalency agreements that assure compliance with U.S. requirements and capacity building. For example, USDA's Agricultural Marketing Service (AMS) manages equivalency agreements for organic food labeling. The U.S. equivalence arrangement with the EU allows organic products certified in Europe or the United States to be sold as organic in either region. According to AMS officials, equivalency agreements result in expanded market access, fewer duplicative requirements, and lower certification costs for organic products. Previously, businesses that wanted to trade organic products had to obtain separate certifications for both the United States and EU, which meant a second set of fees, inspections, and paperwork. Agencies also engage in capacity building and provide technical assistance to countries to help foreign businesses comply with U.S. regulations when exporting to the United States. For example, FDA developed a comprehensive international food safety capacity-building plan in response to a requirement in the FDA Food Safety Modernization Act. The plan establishes a strategic framework for the FDA, describes an approach that is based on prioritizing risks to U.S. consumers, and focuses on addressing system weaknesses working with foreign government and industry counterparts and other stakeholders. Agencies also engage in work-sharing arrangements with their foreign counterparts to gain efficiencies in the implementation of regulatory programs. For example, under the United States-Canada Beyond the Border Initiative, USDA's Animal and Plant Health Inspection Service (APHIS) conducted a joint foot and mouth disease site visit in Colombia as part of the evaluation of Colombia's request to export fresh beef. Coordinated inspections allow agencies to leverage resources with their foreign counterparts to fulfill their regulatory responsibilities. OIRA also engages

in activities to strengthen the capacity of developing countries in several contexts, including APEC and work with Brazil, Vietnam, and Morocco.

Some international regulatory cooperation activities that U.S. agencies shared with us are on products that are not regulated by U.S. agencies. Agencies do not issue regulations through programs where participation is voluntary but still may coordinate with foreign counterparts. For example, DOE is working with other countries through the Efficient Electrical End-use Equipment (4E) Implementing Agreement on efficiency and performance criteria and metrics, test methods, and qualified testing laboratories for new technology for solid state lighting. DOE officials said coordination on solid state lighting is important, because without a common agreement, it would be more difficult for products to enter the world market. Standardized labeling also helps customers understand the product they are buying and how its efficiency compares with other products.

While Executive Orders and Guidance Encourage U.S. Agencies to Consider Competitiveness Impacts during Rulemaking, There Is No Requirement to Conduct a Separate Analysis

For regulations deemed significant under Executive Orders 12866 and 13563, U.S. agencies are required to assess the costs and benefits, but there is no requirement for agencies to conduct a separate analysis on competitiveness impacts when developing regulations. Among the general principles of regulation under Executive Order 13563 is that the U.S. regulatory system should promote economic growth, innovation, competitiveness, and job creation. Moreover, according to executive orders on regulatory review, among the possible effects that agencies should consider are the significant adverse effects on the ability of U.S. companies to compete in domestic and foreign markets. Moreover, OMB Circular A-4's discussion on global competitiveness states: "The role of Federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully." Further, these executive orders and related guidance do not apply to independent agencies.³³ The concept of competitiveness is a general one, referring to the set of institutions, policies, and human and natural endowments that allow a country to remain productive.

³³According to OMB officials, Executive Order 13579 recognizes that while not a requirement, independent agencies should follow these principles as well.

Depending on the circumstances, the focus of analysis could vary. Here, in the context of international regulatory cooperation, improvements to competitiveness might arise from lowering the cost of a firm's compliance with other countries' standards or expanding access of U.S. products to foreign markets. However, documenting the effect of the removal of barriers on firm cost and sales presents challenges because data on individual firm performance may not be available and because the effect of the regulatory action may be difficult to isolate. Still, in some cases, it may be possible to describe effects in terms of magnitude and direction.

When agencies develop regulations related to international activities, officials from five of the seven agencies in our study told us that they consider competitiveness as needed. Officials from two agencies in our study provided examples of analysis of competitiveness impacts in the rulemaking record. Agency officials said competitiveness impacts for some rulemakings are likely to be indirect and may not rise to the level of inclusion in the rulemaking record. For example, according to officials, APHIS's regulations focus on preventing the introduction and spread of pests and diseases of livestock and plants. The officials explained it is difficult to point to any APHIS regulations that can be said to have a direct effect on the ability of U.S. businesses to compete in the marketplace. In another example, officials from DOT's PHMSA said their regulations related to pipeline safety are for pipelines within the United States. When included in the rulemaking record, competitiveness is likely to be a secondary or tertiary effect in rulemaking analysis. For example, according to OAR officials, most OAR rulemakings have few if any direct impacts on competitiveness. These impacts, if any, would likely be secondary or indirect. They said that competitiveness analysis, when appropriate, might examine whether increased production costs for a U.S. business may put it at a competitive disadvantage compared with a similar company in a different country that is not required to comply with a similar environmental regulation.

Some agency officials we interviewed said competitiveness impacts can be challenging to identify, difficult to quantify, and resource intensive to complete and that they do not have tools to consider competitiveness during rulemaking. According to DOT's National Highway and Traffic Safety Administration (NHTSA) officials, NHTSA has never addressed the competitiveness of U.S. businesses in any of its analyses. NHTSA does not have tools for analyzing the effects of its safety standards on the competitiveness of U.S. businesses. For at least 10 years, NHTSA and DOT's Volpe Center have attempted to create a consumer-marketing model to help estimate the impact of the fuel economy program on sales

and have been unsuccessful to date.³⁴ They said that trying to determine the impact on competition of a relatively small safety standard, when NHTSA cannot do it for the enormous fuel economy standard, does not seem to be a good use of resources.

However, officials from one agency we interviewed said that competitiveness impacts are assumed to exist when they are aligning regulations with trading partners, but agencies do not do a separate analysis. For example, according to PHMSA officials, PHMSA's harmonization rulemakings are premised on the assumption that harmonized standards reduce costs for businesses and therefore reduce barriers to trade. Specific cost-benefit analysis, however, is generally associated with comparing the estimated costs of a regulation with the safety and efficiency benefits associated with a specific change and not directly associated with competitiveness of U.S. businesses. Further, the TBT Agreement explains that using international standards as the basis of a technical regulation adopted for a specified legitimate objective shall be rebuttably presumed to not create unnecessary obstacles to international trade.³⁵

U.S. Agencies Report Considering International Standards during Rulemaking

Officials from all U.S. agencies said they consider international standards during rulemaking, which can help facilitate trade. For example, NHTSA considers other countries' standards and regulations when developing new regulations. The agency considers the research and test procedures that have already been developed internationally when considering how to develop Federal Motor Vehicle Safety Standards. Similarly, DOE officials said DOE's Appliance and Equipment Standards Program regularly adopts (in whole or part) product test procedures (or test standards) developed by a broad range of nongovernmental standards organizations, such as the American National Standards Institute, the Institute of Electrical and Electronics Engineers, ASTM International,³⁶ the

³⁴The Volpe Center is part of DOT's Research and Innovative Technology Administration. Its mission is to improve the nation's transportation system by anticipating emerging transportation issues and to serve as a center of excellence for informed decision making.

³⁵Legitimate objectives include: national security requirements; the prevention of deceptive practices; and protection of human health or safety, animal or plant life or health, or the environment. TBT Agreement, Art. 2.2 and 2.5.

³⁶ASTM International was formerly known as the American Society for Testing and Materials.

Illuminating Engineering Society, and others. Many of these test standards are referenced in, or used as the basis for, standards developed by organizations, such as the International Electrotechnical Commission, ISO, or other international standards-setting organizations. Agencies may also consider approaches taken by other countries. For example, in the development of a crib safety regulation, CPSC staff reviewed requirements of existing voluntary and international standards related to cribs. The primary standards currently in effect are CPSC standards for full-size cribs, which reference the ASTM voluntary standard; a Canadian standard; a European standard; and an Australian and New Zealand standard. ASTM considered the existing international standards in the development of the current ASTM voluntary standard.

The TBT Agreement includes requirements to use international standards or their relevant parts as the basis for technical regulation where available and appropriate; to participate in international standards development, within the limits of their resources; and to avoid unnecessary obstacles to trade.³⁷ Similarly, under the National Technology Transfer and Advancement Act of 1995, agencies are required to use technical standards that are developed or adopted by voluntary consensus standards bodies unless they are inconsistent with applicable law or otherwise impracticable.³⁸ If using standards other than voluntary consensus standards, agencies are also required to provide an explanation to OMB. Further, Executive Order 13609 on promoting international regulatory cooperation includes a requirement that for significant regulations that the agency identifies as having significant international impacts, agencies consider, to the extent feasible, appropriate, and consistent with law, any regulatory approaches by a foreign government that the United States has agreed to consider under a regulatory cooperation council work plan. DOT, CPSC, FDA, and USDA have some additional agency-specific documents related to considering international standards during rulemaking.³⁹

³⁷TBT Agreement art. 2.2, 2.4, and 2.6.

³⁸Pub. L. No. 104-113, § 12(d).

³⁹We have previously reported on CPSC's efforts related to voluntary standards, including international standards. See: GAO, *Consumer Product Safety Commission: A More Active Role in Voluntary Standards Development Should Be Considered*, [GAO-12-582](#). (Washington, D.C.: May 21, 2012).

Key Factors Can Positively or Negatively Affect the Outcomes of International Regulatory Cooperation Activities

Agency officials that we interviewed identified seven factors that have the greatest impact on improving the effectiveness of international regulatory cooperation. Some of these factors can facilitate agencies' efforts if present in international regulatory cooperation activities while others can also act as a barrier when absent. In an environment of constrained budgets, agencies may not be able to address the factors equally, so it is particularly important for agencies to focus on the factors that facilitate their efforts. Therefore, as part of our evaluation, we ordered the factors in table 3 below based on discussions and written responses from agencies.

Table 3: Key Factors Identified by Agencies that Affect International Regulatory Cooperation

Factor	Description
Dedicated resources	Agencies can develop relationships with foreign counterparts, monitor developments and attend meetings when resources for regulatory cooperation are made available.
Established processes	Documented processes such as forums, international procedures, and other international mechanisms can govern certain international cooperation activities.
High-level leadership	Leadership can set the direction, pace, and tone of agencies' international regulatory cooperation activities.
Scientific and technical exchanges	The sharing of scientific and technical information with foreign counterparts can support the enforcement of regulations through universal compliance requirements and testing but can also lay the groundwork for future coordination.
Stakeholder involvement	Nonfederal stakeholders' participation in regulatory cooperation can help identify opportunities, but the effectiveness of participants can depend on the needs of various nonfederal stakeholders.
Statutory authority	Statutory authority can encourage or restrict participation in certain international regulatory cooperation activities.
Early and ongoing coordination	Coordination prior to the promulgation of regulations can prevent the establishment of regulations with unnecessary differences, but international regulatory cooperation requires ongoing commitment to be most effective.

Source: GAO analysis of agency interviews.

Note: The factors are listed in order of the general priority expressed by agency officials in meetings with GAO.

As another part of our evaluation of these factors, we found that they align with each of the key features important for agencies to consider when implementing collaborative mechanisms. In September 2012, we identified features that agencies could benefit from considering when

implementing interagency collaborative mechanisms.⁴⁰ For example, we found that: (1) resources are a key feature because collaborative efforts can take time and resources in order to accomplish such activities as building trust among the participants, setting up the ground rules for the process, attending meetings, conducting project work, and monitoring and evaluating the results of work performed; (2) establishment of agreements in formal documents can strengthen an agency's commitment to working collaboratively; and (3) leadership is important to all collaborative efforts, but agencies have said that transitions within agencies or inconsistent leadership can weaken the effectiveness of any collaborative mechanism. We used those features as criteria to determine whether the seven main factors that agencies and stakeholders identified as affecting international regulatory cooperation reflected consideration of each of those issues. We applied these criteria by comparing agencies' characterizations of the seven key factors affecting international regulatory cooperation to the specific questions identified in our 2012 report for agencies to consider when implementing collaborative mechanisms. That comparison demonstrated that one or more of the seven key factors corresponded to each of the features of effective collaborative mechanisms.

Dedicated resources. Agencies in our study emphasized that international regulatory cooperation requires dedicated resources and long-term investments. Agency officials that we spoke with said that the initial stage of international regulatory cooperation is resource intensive because it includes developing relationships with foreign counterparts and addressing legal, policy, and technical differences. In our September 2012 report, we concluded that resources are a key feature to collaboration because it takes time and resources to build trust among participants, set up ground rules for the process, attend meetings, conduct project work, and monitor the results of the work.⁴¹ These agency officials also said that once the initial resources have been invested,

⁴⁰These features include (1) outcomes and accountability; (2) bridging organizational cultures; (3) leadership; (4) clarity of roles and responsibilities; (5) participants; (6) resources; and (7) written guidance and agreements. In our collaboration work, we define collaboration as any joint activity that is intended to produce more public value than could be produced when organizations act alone. We use the term collaboration broadly to include interagency activities that others have variously defined as cooperation, coordination, integration, or networking. See [GAO-12-1022](#) and GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

⁴¹[GAO-12-1022](#).

reoccurring cooperation after implementation of regulations may be less resource intensive to maintain through monitoring of developments in foreign countries and by directly participating in formal and informal meetings. USDA Foreign Agricultural Service (FAS) officials also pointed out that it can take a long time before payoffs or results from resources invested in international regulatory cooperation become apparent.

Agency officials that we interviewed also identified some challenges to securing and sustaining resources for international regulatory cooperation activities. For example, officials said that international cooperation may be viewed as too resource intensive to inform each individual regulatory activity. Officials also said that investment in international regulatory cooperation is viewed in some agencies as optional if it conflicts with other priorities and responsibilities when the same staff members are needed for other regulatory activities. One FAS official said that one of the greatest resource constraints is securing the availability of regulators in his department. Agency officials said that their foreign counterparts also face resource constraints that may affect their participation in two ways. First, resource constraints may limit their ability to participate in international regulatory cooperation activities. Second, such constraints may encourage foreign counterparts to leverage their limited resources with the United States and other partners when the issues line up with their own priorities.

Officials identified some opportunities for leveraging funds from other agencies to participate in international activities on an ad hoc basis. To encourage compliance with the TBT Agreement, U.S. law authorizes the United States Trade Representative and the Secretary concerned to make grants to and enter into contracts with any other federal agency to assist that agency in implementing programs and activities such as participating in international standards-related activities.⁴² For instance, one industry official said that agencies are going to have fewer resources and therefore should be interested in leveraging their resources with other countries as early as possible. Agency officials confirmed that there are opportunities for them to leverage funds from United States Agency for International Development (USAID) and State to participate in international meetings. In addition, USTR officials said that their agency is able to leverage funds that are not available to other U.S. agencies and

⁴²19 U.S.C. § 2545.

can match funds for regulators to meet with their foreign counterparts in an international setting, such as through APEC meetings. U.S. participation in international regulatory cooperation can be a multi-agency effort. However, officials from a different agency also cautioned that such funds tend to be limited to efforts that involve developing countries and expressed concern that they are unlikely to be used to support regulators' participation with the EU. With reductions to the federal budget, the money available to support regulatory cooperation may shrink.

Established processes. According to agency officials, having defined long-term processes and accountability mechanisms in place for working with foreign counterparts can facilitate international regulatory cooperation. Officials also said that such established processes can increase transparency for stakeholders and better enable input. Agencies said that defined processes developed through international agreements, including forums, international procedures, and other international mechanisms, are helpful. Agreements, such as the WTO SPS Agreement, require members to consider international standards during their process to develop regulations. The WTO SPS Agreement generally obligates members to base their regulations on sanitary or phytosanitary measures on international standards from Codex, OIE, or the International Plant Protection Convention unless they have scientific justification or have determined a different level of protection through a risk assessment. In our September 2012 report, we concluded that the establishment of agreements in formal documents can strengthen an agency's commitment to working collaboratively.⁴³ Similarly, officials from DOT's PHMSA said established processes for the UN TDG Subcommittee facilitate their cooperative efforts. The OECD also has established processes on chemicals in their rules. The binding nature of OECD rules ensures all countries abide by the requirements to accept data from other OECD members, which helps advance its international regulatory coordination efforts.

High-level leadership. Agency officials told us in our interviews that high-level leadership within an agency and leadership from outside the agency can facilitate international regulatory cooperation, but a perceived lack of high-level commitment or changing priorities can serve as barriers. One academic expert said that the only way that international regulatory

⁴³[GAO-12-1022](#).

cooperation will work is with high-level attention from the White House, OMB, USTR, and the State Department. In addition, OMB officials we interviewed said high-level support and leadership is essential to the success of international regulatory cooperation. They also stressed that regulatory agencies must have buy-in themselves, rather than be coerced into international regulatory cooperation by outside agencies. Similarly, Commerce's International Trade Administration (ITA) officials said that executive orders and presidential initiatives, such as Executive Order 13609, the U.S.-Canada RCC, the U.S.-Mexico High Level Regulatory Cooperation Council, APEC leaders' meetings, and the North American Leaders Summit, have increased visibility, encouraged action from the regulatory community, and prioritized events related to international regulatory cooperation. Agency officials said that commitment of resources is an indicator of top-level support. Agencies also said that active participation by agency leadership with foreign counterparts can expedite and facilitate progress at key points. FDA officials said that, in their experience, when the heads of agencies have an ongoing active relationship with their counterparts in foreign countries, international regulatory cooperation is more likely to produce results.

Agencies told us that it can be challenging when leadership priorities change, such as when a new administration establishes different priorities, because international regulatory cooperation activities are long-term efforts. Shifting political priorities can lead to short-term commitments that can make it difficult for agencies to see projects through to the end. Officials said that agencies need high-level commitment, but if it wanes agencies can be left part way into a long-term project. In our September 2012 report, we concluded that, given the importance of leadership to collaborative efforts, transitions and inconsistent leadership can weaken the effectiveness of any collaborative mechanism.⁴⁴

Scientific and technical exchanges. Sharing scientific and technical information facilitates international regulatory cooperation and includes coordination on testing, enforcement, and compliance issues, but, as explained later, can also be restricted by statutory authority. The FTC provides technical assistance to other countries in developing their regulatory policies. When countries disagree on the appropriate policy or

⁴⁴[GAO-12-1022](#).

standards, they can sometimes find agreement on the underlying scientific and technical basis for regulations. According to FDA officials, the regulations for medical products are more science based, while those for food are more culture based, so FDA has more success with international coordination on medical products. Collaboration and sharing of data can lay the groundwork for future coordination. An independent advisory agency developed a report that stated that the mutual trust between regulators is an opportunity for work sharing because agencies do not have to duplicate tests or science which allows them to share their workload with foreign counterparts, move limited inspectors or transfer other resources to areas of greater need. However, some statutes may restrict scientific and technical exchanges because of limits on the disclosure of information with foreign counterparts which is further discussed within the section on statutory authority.

Stakeholder involvement. Agencies we interviewed identified coordination with nonfederal stakeholders, such as industry groups, academic experts, and consumer groups, as a facilitator of international regulatory cooperation. An FDA official said that nonfederal stakeholders may be uniquely positioned to identify unnecessary differences in regulations and standards between countries and help agencies prioritize which differences would be most meaningful to address from their perspective. For example, FTC officials said that in developing the work products of the International Competition Network (ICN) a significant number of business users and nongovernmental advisors bring attention to issues, provide outside perspectives, help produce work products, and encourage implementation, even though government agencies are the members that ultimately accept the work by consensus.

Some agency officials and nonfederal stakeholders reported challenges to stakeholder involvement. Regulatory cooperation can be more difficult to resolve when nonfederal stakeholders have conflicting viewpoints about regulations. For example, USDA officials said there can be challenges when consumer advocacy groups and business advocacy groups have different views that lead to lawsuits to prevent international regulatory alignment. USDA officials said that the support for a U.S.-Canada pilot project for meat inspection was divided between businesses that supported it and consumer groups that did not. In addition, one industry group found that some regulatory agencies were unwilling to actively engage foreign counterparts and U.S. industries to discuss U.S. regulatory requirements that are adopted by other countries. A different industry representative said that a regulatory agency he works with independently created a division dedicated to international telecom issues

to work with foreign counterparts and developed a modular approval, which gives industry more flexibility and shortens the time for product approvals.

In addition, a consumer advocacy stakeholder said that it would be helpful to set government-wide policies and definitions through a notice and comment period. For example, federal agencies do not employ the same definition of “equivalency,” and it would be helpful if there was a specific government-wide policy that stated that the result of international regulatory cooperation cannot lower domestic standards.

Statutory authority. Agencies we interviewed said that statutory authority may facilitate or limit their international regulatory cooperation activities. For example, DOT PHMSA officials said that statutory authority may mandate agency participation in international standards organizations. An industry stakeholder said it would facilitate cooperation if the underlying statutory authorities of agencies clearly permitted them to engage in trade activities. However, when statutes are prescriptive regarding domestic or rulemaking requirements, they can limit agencies’ ability to make changes to regulations that align with a foreign trading partner. For example, agency officials said that statutes mandating use of specific technologies can remove the flexibility to coordinate with foreign counterparts. EPA officials also said that, in many instances, the Clean Air Act requirements may limit the degree to which domestic regulations can be altered to accommodate or conform to foreign or international standards or approaches. Statutes that mandate completion of rulemakings within short time frames can also limit agencies’ ability to engage in harmonization. For example, CPSC officials said it was challenging to work with other countries to reach consensus when CPSC had been mandated by the Consumer Product Safety Improvement Act of 2008 to issue a large number of regulations in a short time frame, which limited the amount of time they had to work with foreign counterparts.

Some agency statutes may limit disclosure of company-specific information with foreign counterparts. This can prevent U.S. agencies from sharing certain reports and scientific information with trusted foreign counterpart agencies. In a previous report, we stated that, although the addition of section 29(f) to the Consumer Product Safety Information Act was intended to encourage information sharing, CPSC expressed concern that restrictive language in this section hindered its ability to

share information.⁴⁵ An official from EPA OCSPP said that an important first step to scientific and technical exchanges with foreign counterparts is removing existing legal, regulatory, or policy hurdles that limit or prohibit data sharing between governments. For example, NHTSA officials we interviewed said that they have many research, testing, and enforcement activities that include restrictions on the transfer of information, which has been a barrier to international regulatory cooperation. They said that when a company discovered defects in tires in Germany, the information was not immediately available in the United States to prevent injuries because of an information-sharing restriction. Agency officials also noted that, in addition to the removal of U.S. agency information-sharing restrictions, it is essential that the hurdles that exist in other countries also be removed.

Early and ongoing coordination. Early and ongoing coordination with foreign governments in emerging areas before regulations are in place may facilitate international regulatory cooperation. Agency officials we interviewed said early and ongoing efforts are important to maintain progress. OMB officials said it is easier to prevent unnecessary differences than remove existing differences in regulations. For example, CPSC attends multilateral forecasting sessions with other countries to engage foreign counterparts before the rulemaking and standards setting process begins. According to agency officials we interviewed, it is more efficient for CPSC to align and prevent different regulatory approaches with other jurisdictions before the U.S. notice and comment rulemaking process begins. In another example, State officials we interviewed said there is a need for international regulatory coordination to take place as early as possible, before too many regulations are established in each country. They said there are opportunities to avoid unnecessary differences in regulations for nanotechnology, which can be applied to many types of products. Currently, there are no entrenched regulatory systems that would hinder cooperation on developing new standards. Industry officials also said that it is important to coordinate on requirements early by reviewing countries' regulatory differences, because fundamental differences between countries may require changes on an issue-by-issue basis. They also urged early coordination because regulatory agencies in other countries are establishing standards when the manufacturing process has already been developed in the

⁴⁵[GAO-13-150](#).

United States, which does not work well for them within today's markets. One academic representative we interviewed said it is much easier for agencies to coordinate with trading partners on new regulations than on existing regulations.

According to agency officials we spoke with, early and ongoing coordination with foreign counterparts also can identify issues that are not ready for international regulatory cooperation. It is important to coordinate early with their counterparts when there are differences between the openness of the United States' and other countries' rulemaking processes. Officials noted that, while other countries have the opportunity to comment whenever a U.S. regulation is proposed, U.S. agencies and nonfederal stakeholders may not have similar opportunities to comment on foreign regulations.

Conclusions

With trade expanding and regulatory challenges growing, in recent years the President and U.S. agencies have undertaken multiple initiatives to focus attention on the importance of international regulatory cooperation. While the executive order on promoting international regulatory cooperation focuses on reducing trade barriers by reducing unnecessary differences in regulations with U.S. trading partners, we found in our review that U.S. agencies carry out numerous and diverse international regulatory cooperation activities to improve the effectiveness of regulations, gain efficiencies, and avoid duplicating work. The examples agencies shared with us show that their efforts often achieve both trade and regulatory efficiency goals. Ultimately it is clear that international regulatory cooperation requires interagency coordination. No one U.S. agency has the expertise or processes to effectively conduct these activities. Not only must regulatory agencies collaborate with other U.S. agencies, but they need to effectively collaborate with their foreign counterparts and affected nonfederal stakeholders.

Overall coordination of international regulatory cooperation activities is now handled by discrete processes with somewhat different focuses. U.S. regulatory agencies focus primarily on their missions to protect public health and safety and the environment, while USTR and Commerce, among others, focus on trade. Therefore, it is important for the U.S. government to effectively coordinate these interagency activities. Our work at agencies engaged in regulatory cooperation efforts shows there are opportunities to augment existing guidance and mechanisms that could further promote and improve international regulatory outcomes. For example, U.S. regulatory agency officials emphasized the benefits of

sharing information on lessons learned and best practices with their peers. However, they believe the current processes are designed for top-level collaboration and do not sufficiently address the day-to-day implementation of international regulatory cooperation. U.S. agencies and nonfederal stakeholders also noted the importance of stakeholder input in the success of international regulatory cooperation. Yet it is challenging for stakeholders to stay apprised of agencies' activities and therefore provide input to agencies. Key next steps could focus on identifying tools to measure outcomes as well as to document savings from more efficient use of government resources. In an environment of constrained resources it is even more important for agencies to share knowledge on the effective implementation of international regulatory cooperation.

Recommendation for Executive Action

To ensure that U.S. agencies have the necessary tools and guidance for effectively implementing international regulatory cooperation, we recommend that the Regulatory Working Group, as part of forthcoming guidance on implementing Executive Order 13609, take the following action:

- Establish one or more mechanisms, such as a forum or working group, to facilitate staff level collaboration on international regulatory cooperation issues and include independent regulatory agencies.

Agency Comments and Our Evaluation

We provided a draft of this report to Commerce, CPSC, DOE, DOT, EPA, FTC, HHS, OMB, State, USDA, and USTR for their review and comment. We received written comments on the draft report from DOE, and CPSC in which they agreed with the recommendation to the RWG. Their comments are reprinted in Appendices III and IV. In an email received on July 30, 2013, the Deputy General Counsel, Office of Management and Budget, stated that OMB had no comments on the recommendation in this report. However, OMB provided technical comments which we incorporated as appropriate. Commerce, CPSC, DOE, FTC, HHS, State, USDA, and USTR also provided technical comments which we incorporated as appropriate.

We are sending copies of this report to OMB (which chairs the RWG), Commerce, CPSC, DOE, DOT, EPA, FTC, HHS, State, USDA, USTR, and other interested parties. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-6806 or sagerm@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Sincerely yours,

A handwritten signature in black ink that reads "Michelle Sager". The signature is written in a cursive, flowing style.

Michelle Sager
Director, Strategic Issues

Appendix I: Objectives, Scope, and Methodology

Our objectives were to (1) provide an overview of regulatory agencies' international cooperation activities, (2) examine ways that agencies incorporate outcomes from international regulatory cooperation activities and consider competitiveness during rulemaking, and (3) examine factors identified by agencies and nonfederal stakeholders that act as facilitators or barriers to international regulatory cooperation and considering competitiveness. To address these objectives, we selected seven U.S. regulatory agencies out of 60 U.S. agencies that are included in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda), that issued regulations with international impacts and four U.S. agencies with government-wide international coordination responsibilities. Based on several sources we identified likely regulatory agencies that issue regulations related to international trade. For example, we reviewed the 2010 and 2011 Unified Agenda and data from the 2011 World Trade Organization (WTO) Technical Barriers to Trade (TBT) Information Management System. We also reviewed all major regulations from 2011.¹ We categorized the regulations with an international impact into regulatory subject areas such as product safety, environmental, energy, transportation of products, food, medical devices, drugs, and aviation. The reason we categorized the regulations was to select groups of regulations that affect global trade in products. In addition, we excluded categories from our scope, such as taxation/taxes, patents, arms trade, international waters, and trade agreements. We also tested the databases used in agency selection by reviewing related documentation, interviewing knowledgeable agency officials, and tracing a sample of entries to source documents. We concluded the data were sufficiently reliable for the purposes of this report. We also considered recommendations from federal agency officials in selecting regulatory agencies. From these varied efforts, for our review we selected the Department of Energy (DOE), Food and Drug Administration (FDA), Department of Transportation (DOT),² Environmental Protection Agency

¹The Congressional Review Act defines a major rule as one that has resulted in or is 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 U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. 5 U.S.C. § 804(2).

²Also including subagencies National Highway Traffic Safety Administration (NHTSA) and the Pipeline and Hazardous Materials Safety Administration (PHMSA).

(EPA),³ and Department of Agriculture (USDA)⁴ as well as two independent regulatory agencies including the Consumer Product Safety Commission (CPSC) and the Federal Trade Commission (FTC). These views are not generalizable to all U.S. agencies. Based on our background research and suggestions from federal agencies we selected four agencies with government-wide international coordination responsibilities: Office of Management and Budget (OMB), Office of the United States Trade Representative (USTR), Department of Commerce (Commerce), and Department of State (State).⁵ Furthermore, using criteria based on our September 2012 report on interagency collaborative efforts, we also compared agencies' documents and testimonial evidence about their international regulatory cooperation activities to the seven key features that we found agencies should consider when implementing collaborative mechanisms to corroborate the agencies' findings.⁶

To obtain viewpoints outside of government, we chose 11 U.S. nonfederal stakeholders which consisted of academics, organizations representing businesses, consumer advocacy groups, standards setting organizations and industry representatives, based on their recent reports or from comments they made on international regulatory cooperation. We originally selected one of each type of nonfederal stakeholder group based on published views on international regulatory cooperation and recommendations from agencies in our study but decided to add more nonfederal stakeholders to our selection criteria to represent a diverse range of members that represent business promotion, consumer advocacy perspectives and neutral parties. These views are not generalizable, but provided insights on international regulatory cooperation.

³Also including subagencies Office of Air and Radiation (OAR) and the Office of Chemical Safety and Pollution Prevention (OCSPP).

⁴Also including subagencies Animal and Plant Health Inspection Service (APHIS), Agricultural Marketing Service (AMS), Food Safety and Inspection Service (FSIS), and Foreign Agricultural Service (FAS).

⁵USDA, which is a regulatory agency, also has a coordinating role as the national enquiry point for the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

⁶GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

For federal agencies and nonfederal stakeholders chosen for this engagement, we conducted interviews and gathered documentation such as concrete examples, facilitators, barriers, goals, outcomes, and stakeholder involvement related to international regulatory cooperation activities, rulemaking and global competitiveness. We used this documentary and testimonial evidence to identify government-wide and agency-specific requirements related to rulemaking outcomes for international regulatory cooperation and global competitiveness and determined how these selected agencies consider related issues. After analyzing our evidence for common themes and patterns, we developed a summary document of factors that are facilitators or barriers to international regulatory cooperation and held two meetings for agency officials to reflect upon the meaning of the factors, and confirm their importance. We summarized information gathered at these group meetings to better describe the agencies' perspectives. Throughout this report, we use specific, selected examples to illustrate agency processes and practices.

The scope of our inquiry was not comprehensive, generalizable, or designed to be a complete catalog of international regulatory activities. We conducted this performance audit from March 2012 to August 2013, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Examples of International Regulatory Cooperation Activities

Agencies provided us with examples of their international regulatory cooperation activities. The examples below illustrate the types of activities that agencies engage in to fulfill their regulatory missions and are not meant to be a comprehensive catalog of agency activities in this area.

Information Sharing and Scientific Collaboration

Agencies share information with their foreign counterparts on scientific data and regulatory approaches.

Pesticide Tolerance Crop Grouping Revisions Program

Agency: Environmental Protection Agency's (EPA) Office of Chemical Safety and Pollution Prevention (OCSPP)

Description: OCSPP shares information with the North American Free Trade Agreement (NAFTA) partners and the international organization Codex on its Pesticide Tolerance Crop Grouping Revisions Program. EPA regulates pesticides by setting limits on the amount of pesticides that remain in or on foods marketed in the United States under the Federal Food, Drug, and Cosmetic Act. The Pesticide Tolerance Crop Grouping Revisions Program enables the establishment of tolerances for a group of crops based on residue data for certain crops that are representative of the group. Representatives of a crop group or subgroup are those crops whose residue data can be used to establish a tolerance on the entire crop group or subgroup.

The project involves several interrelated multiyear efforts, including (1) one with NAFTA partners in Canada and Mexico to revise the existing crop groups in EPA's regulations (40 CFR 180.41) to add new crops and create new groups and subgroups; and (2) one in which NAFTA partners are working with international stakeholders to modify the Codex crop groups, to support global trade and the use of data extrapolation. Petitions to revise the NAFTA crop grouping regulations are developed by the International Crop Grouping Consulting Committee, a group of more than 180 crop, agrichemical, and regulatory experts representing more than 30 countries and organizations. NAFTA partners also are working cooperatively with international stakeholders to revise the Codex system of classification of foods and animal feeds and to revise the Codex crop groups. Involvement by NAFTA member countries in the Codex process should help standardize commodity terminology and crop groupings within the global context.

Outcomes: Approved revisions to crop group regulations are formalized in the United States through rulemaking. EPA is currently working on its fourth crop grouping proposed regulation. Crop groupings also facilitate international trade, including the market for pesticide products and the crops treated. Pesticides with established tolerances in the United States can be sold for use on crops grown in other countries that intend to import those crops to the United States. Crops imported in the United States with pesticide residues that do not have an established U.S. tolerance are subject to enforcement action.

Organisation for Economic
Co-operation and
Development (OECD)
Chemical Safety

Agency: EPA's Office of Chemical Safety and Pollution Prevention (OCSPP)

Description: The United States has participated in the OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology, an organization with over 30 member countries, for more than 30 years. Specific information sharing activities include:

- OECD eChem Portal: OCSPP shares information on industrial chemicals and various data systems. The OECD eChem Portal allows simultaneous searching of reports and datasets by chemical name and number and by chemical property. The portal provides direct links to collections of chemical hazard and risk information prepared for government chemical review programs at the national, regional, and international levels. The portal also provides, when available, classification results according to national/regional hazard classification schemes or to the Globally Harmonized System of Classification and Labeling of Chemicals.
- OECD (Quantitative) Structure-Activity Relationships [(Q)SARs] Toolbox: OCSPP's (Q)SARs are methods for estimating properties of a chemical from its molecular structure. The toolbox is a software application for governments, chemical industry, and other nonfederal stakeholders to fill gaps in (eco)toxicity data needed for assessing the hazards of chemicals.

Outcomes: According to EPA, these tools and approaches reduce compliance costs for nonfederal stakeholders, facilitate work sharing for regulators, and help avoid costly, duplicative testing by ensuring that the data developed and submitted in one country can be used by other countries in reaching their regulatory decisions. These activities do not directly result in rulemakings, but can inform rulemaking activities.

Pilot Alignment Initiative
(PAI) on Consumer
Product Safety

Agency: Consumer Product Safety Commission (CPSC)

Description: CPSC participates in an international pilot alignment initiative with staff from the central consumer product safety authorities of Australia, Canada, the European Union, and the United States. This ad hoc group is not aligned formally with any existing multilateral forum. The participants are to seek consensus positions on the hazards to children and their potential solutions for three products: corded window coverings, chair-top booster seats, and baby slings. The goal of this initiative is to bring about effective, aligned safety requirements for these products to reduce injuries and save lives. The consensus positions could be considered and developed for implementation in each jurisdiction, according to the jurisdiction's preferred model, whether through regulation or voluntary standards. Officials said that the consensus papers for baby slings and chair-top booster seats are in progress.

According to CPSC officials, the PAI jurisdictions worked for 18 months to reach consensus positions on corded window coverings, but the project fell short of CPSC's expectations. Officials said that the technical teams from five jurisdictions agreed in principle that "no exposed cords" was the best solution to the strangulation hazard, but the European Commission had already publicly expressed an opposing position regarding the elimination of cords. CPSC officials said that when the PAI work began, the European Commission had already moved into policy development and soon thereafter issued a mandate to the European Committee on Standardization explicitly permitting safety devices to keep exposed cords out of reach of children. As a result, the consensus paper recognized "no exposed cords" as the best solution but did not call for their elimination as a consensus approach.

Outcomes: According to CPSC officials, the PAI can result in similar product safety requirements at a high level of safety among the jurisdictions participating in the initiative.

Development and Use
of International
Standards

Agencies participate in international standards-setting bodies and incorporate international standards into rulemaking as appropriate.

World Forum for the
Harmonization of Vehicle
Regulations (WP.29)

Agencies: Department of Transportation's (DOT) National Highway Traffic Safety Administration (NHTSA) and Environmental Protection Agency's (EPA) Office of Air and Radiation (OAR)

Description: WP.29 is a permanent working party created more than 50 years ago in the United Nations (UN) that administers three international agreements on motor vehicles: (1) the 1958 Agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment, and parts which can be fitted and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions, (2) the 1997 Agreement concerning the adoption of uniform conditions for periodical technical inspections of wheeled vehicles and the reciprocal recognition of such inspections, and (3) the 1998 Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment, and parts which can be fitted and/or be used on wheeled vehicles. The WP.29 develops Global Technical Regulations that are used in member countries' regulations and works as a global forum allowing open discussions on motor vehicle regulations. NHTSA and OAR participate in the development of global technical regulations. Nongovernmental organizations may also participate in a consultative capacity in WP.29 or in its working groups.

Outcomes: NHTSA officials said WP.29 participation contributes to safety in the United States because NHTSA leverages research with other countries. Global Technical Regulations increase alignment between countries. As a result, manufacturers have fewer country-specific regulations to comply with when participating in foreign markets. NHTSA uses Global Technical Regulations in rulemaking. For example, NHTSA issued a final rule in August 2012 on motorcycle brake systems safety standards to add and update requirements and test procedures and to harmonize standards with a global technical regulation for motorcycle brakes.

OAR officials said that OAR participated in an effort that focused on test procedures for off-highway construction vehicle engines. According to officials, this effort was undertaken after the completion of a domestic regulation. U.S. manufacturers supported using U.S. regulation as the basis of the Global Technical Regulation because U.S. manufacturers sell equipment internationally, and complying with one set of regulations reduces their fixed costs. Over 5 years OAR successfully worked within the WP.29 to make the U.S. regulation the basis of the WP.29 Global Technical Regulations. As a result, it has become the de facto standard around the world.

UN Subcommittee on the
Transport of Dangerous
Goods (TDG
Subcommittee)

Agency: Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA)

Description: PHMSA participates in the TDG Subcommittee, which, according to PHMSA, is facilitated by two treaties: the Chicago Convention on International Civil Aviation and the International Convention for the Safety of Life at Sea. Officials said the TDG Subcommittee was established because there was a need for international coordination on the transport of dangerous goods. Participants in the TDG Subcommittee include 29 countries with voting status and numerous countries and nongovernmental organizations with observer status. The TDG Subcommittee reviews proposals from voting member countries and observers in relation to amendments to the UN Model Regulations and issues relevant to its work program. PHMSA represents the United States at these meetings and formulates U.S. positions based on feedback from U.S. industry, the public, and other government agencies. PHMSA ensures coordination on U.S. positions, taking into account the interests of the DOT administrations and other government agencies. PHMSA's staff provides the technical support and resources to ensure that the positions taken are sound and justified based on pertinent data, technical analyses, and safety rationales.

Outcomes: PHMSA considers the standards developed by the TDG Subcommittee in a rulemaking every 2 years in an effort to harmonize with international changes. For example, in January 2013, PHMSA issued a final regulation on harmonization with international standards for hazardous materials. PHMSA amended the Hazardous Materials Regulations to maintain alignment with international standards by incorporating amendments, including changes to proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, air transport quantity limitations, and vessel stowage requirements. The resulting cooperation leads to aligned regulations with trading partners, fewer differences in regulations businesses must comply with, and improved safety results (e.g., common labels for hazardous materials). Harmonization of international and domestic standards enhances compliance and improves the efficiency of the transportation system by minimizing regulatory burdens and facilitating oversight. International harmonization of hazardous materials regulations plays a significant role in enhancing safe transportation through improved regulatory consistency.

International Competition Network (ICN)

Agency: Federal Trade Commission (FTC)

Description: In October 2001, the FTC, Department of Justice (DOJ), and 13 other antitrust agencies founded the ICN to provide a venue for agencies that regulate competition issues worldwide to work on competition issues of mutual interest. The ICN has a broad membership—127 agencies from 111 jurisdictions, which includes most of the world’s competition agencies. The ICN works exclusively on competition issues; develops consensual, nonbinding recommendations and reports to bring about procedural and substantive convergence; and provides a significant role for nongovernmental advisors from the business, legal, consumer, and academic communities, as well as experts from other international organizations. The ICN is organized into working groups composed of agencies and nongovernmental advisors. Current working groups address unilateral conduct, mergers, cartels, agency effectiveness, and competition advocacy. The FTC led the merger working group’s work on notification and procedures, which developed a set of eight guiding principles and 13 recommended practices for merger notification and review.

Outcomes: A major accomplishment of the ICN is that numerous members adopted key aspects of ICN recommended practices, such as those concerning merger thresholds. According to FTC officials, the objective was to enhance the effectiveness of each jurisdiction’s merger review practices and processes and promote procedural convergence, thereby reducing unnecessary private and public costs and burdens associated with merger review. FTC officials said FTC has not done any rulemaking to implement the ICN recommendations because the recommendations are consistent with U.S. approaches to merger notification and review processes.

Equivalency Agreements

In some cases, the United States may enter an agreement with another country to recognize other’s regulations and deem them equivalent to those of the United States.

National Organic Program (NOP) Equivalency Agreements

Agency: United States (USDA) Agricultural Marketing Service (AMS)

Description: The AMS manages equivalency agreements for organic food labeling. For example, the United States has an equivalency arrangement with the European Union (EU), generally referred to as the Partnership, under which organic products certified in Europe or the United States may

be sold as organic in either region. For retail products, labels or stickers must state the name of the U.S. or EU certifying agent and may use the USDA organic seal or the EU organic logo. Under the Partnership, according to USDA, the EU and the United States agreed to work on a series of technical cooperation initiatives to promote organic production and establish common practices for assessing and recognizing organics programs of third countries.

Outcomes: According to USDA officials, the EU-U.S. organic equivalency arrangement reduces the cost of certification for organic producers and handlers because producers and handlers only need to be certified under one standard (either USDA organic regulations or EU organic regulations) but can now access and sell in both markets. Another outcome is that considering the respective countries' standards as "equivalent" facilitates international trade of organic products. According to AMS officials, equivalency agreements will result in expanded market access; reduce duplicative requirements and lower certification costs for the trade in organic products; and decrease the burden of administration. The agreements are also expected to open new possibilities for trade. Previously, operations that wanted to trade organic products on both sides of the Atlantic had to obtain separate certifications to meet both standards, which meant a second set of fees, inspections, and paperwork. Additionally, in most cases, the Partnership will provide exporters the opportunity to serve both the U.S. and EU markets from a single inventory of organic products.

Equivalence Determinations for the Import of Meat, Poultry, and Egg Products

Agency: USDA Food Safety and Inspection Service (FSIS)

Description: Food safety equivalency evaluations are based on provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures, which appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations, signed in Marrakech April 15, 1994. Under the agreement, World Trade Organization (WTO) member countries shall accord acceptance to the sanitary and phytosanitary measures of other countries (even if those measures differ from their own or from those used by other member countries trading in the same product) if the exporting country demonstrates to the importing country that its measures achieve the importer's appropriate level of sanitary and phytosanitary protection.

FSIS makes determinations of equivalence by evaluating whether foreign food regulatory systems meet the level of protection provided by the U.S.

domestic system. FSIS evaluates foreign food regulatory systems for equivalence through document reviews, on-site audits, and port-of-entry re-inspection of products at the time of importation. FSIS regulations list 46 countries as eligible to export meat, 9 countries as eligible to export poultry, and 2 countries as eligible to export egg products to the United States.

Outcomes: According to FSIS officials, the equivalency determination program has several benefits. One benefit is that the equivalence process requires communication and participation by U.S. regulators with the regulators in the country seeking (or already having) equivalence, which usually leads to positive relationships between the two countries and other intangible benefits. Another benefit to U.S. businesses is that it gives them more market capacity where they obtain raw materials, finished products, or both, which provides for potential costs savings through the use of these additional choices for eventual sale to U.S. and other consumers. U.S. consumers benefit because countries determined to be equivalent are providing meat, poultry, and egg products that are as safe as domestic products because the products meet U.S. appropriate levels of protection. These additional products may also be less expensive than products produced with U.S.-sourced ingredients.

Strengthening Capacity of Developing Countries

Most agencies in our study provide technical assistance to developing countries. Agency officials said they work with countries to strengthen their regulatory systems, among other reasons, to improve safety of products imported into the United States.

Food and Drug Administration (FDA): Strengthening Global Regulatory Systems and Capacity

Agency: FDA

Description: FDA undertakes activities to improve the capacity of governments to manage, assess, and regulate products within increasingly complex supply chains. According to FDA officials, FDA works to strengthen the global regulatory system and is a source of expertise that engages in global dialogue and initiatives with regulatory counterparts, development agencies, and global health partners. FDA is developing an operating model that relies on building a global safety net using four principles: global coalitions, global data systems, enhanced risk analysis capacities, and leveraging the efforts of public and private third parties. FDA's Global Engagement Report outlines how FDA supports and collaborates with regulatory systems around the globe. While neither mandated nor funded as an international development or

training organization, FDA works with bilateral and multilateral partners, domestically and internationally, to strengthen regulatory systems capacities and competencies in various parts of the world in an effort to ensure products that will be imported into the United States will be made safer and supply lines more secure. Examples of some of FDA's efforts include development of information-sharing platforms and the provision of evidence tools and expertise that contribute to strengthening regulatory systems.

- In response to Section 305 of the FDA Food Safety Modernization Act (FSMA), the FDA developed an international food-safety capacity-building plan. The plan establishes a strategic framework for the FDA and presents an approach based on prioritizing risks to U.S. consumers. It focuses on addressing weaknesses in a food safety system in partnership with foreign governments, industry counterparts, and other stakeholders.
- FDA supported the World Health Organization (WHO) in developing a global monitoring and surveillance system for substandard, falsified, and counterfeit medical products. The system was piloted in 10 countries over 3 months in 2012. This system will be scaled up globally in the coming year.
- FDA is actively involved in efforts to strengthen regulatory capacity through its joint efforts with the World Bank, the WHO, the Gates Foundation, Asia-Pacific Economic Cooperation (APEC), the African Union, and others in the private and public sectors. By bringing its regulatory and scientific expertise to these efforts, FDA can better leverage the expertise of its partners to engage more efficiently and broadly in enhancing regulatory capacity globally. Examples of such initiatives include the World Bank/APEC initiative on food-safety capacity building and the World Bank/Gates Foundation/WHO/African Union efforts to enhance and rationalize regional regulatory capacity in various African economic communities, starting with the East African community.

Federal Trade Commission (FTC) Technical Assistance

Agency: FTC

Description: According to FTC officials, the FTC, in coordination with, among others, USAID, U.S. Trade and Development Agency, and the Department of Commerce, establishes relationships with developing countries and provides technical assistance. FTC helps countries develop and enhance their regulatory frameworks by encouraging convergence with international standards. FTC's technical assistance program helps explain how competition, truthful advertising and marketing, and sensible

privacy frameworks advance economic efficiency, consumer welfare, and consumer choice. To this end, FTC assists developing countries in their transition to market-based economies and their development of competition and consumer protection agencies and sharing approaches to enforcement that are consistent with this goal. As part of its efforts, the agency routinely provides input to its foreign counterparts about the drafting and adopting of domestic legislative frameworks regarding competition, consumer protection, and privacy. FTC also works to build the capacity of its foreign counterparts to implement these frameworks and promote their proper enforcement.

Animal and Plant Health
Inspection Service
(APHIS) Capacity Building

Agency: APHIS

Description: APHIS participates in international regulatory capacity building to help other regulatory entities meet U.S. standards and protect health. Officials said APHIS actively builds international partners and meets with foreign regulatory officials bilaterally and multilaterally. For example, APHIS runs six to seven courses a year where it invites foreign officials to the United States for training on U.S. processes. APHIS officials said that APHIS annually trains 100 to 150 individuals from other countries. The officials said these trainings provide education and resources to foreign counterparts and build a network of individuals to support U.S. efforts worldwide and help other countries comply with U.S. regulations. APHIS also participates in multilateral capacity building on SPS. Officials said, under the SPS agreement, there is a responsibility to work with developing countries and APHIS has officials located overseas who informally work with partners on a daily basis. APHIS also has formal training programs overseas and in the United States.

Work Sharing

Agencies work with foreign counterparts on projects to share resources to implement regulations and avoid duplicating efforts.

FDA Coordination on
Inspections

Agency: FDA

Description: FDA partners with foreign counterparts to coordinate on inspection activities. Foreign counterparts include:

- European Medicines Agency (EMA): Significant opportunities exist for FDA and EMA to leverage their inspection resources, and they are exploring this potential through a series of activities. They observed

each other's inspections and jointly inspected manufacturing sites in the United States and the European Union (EU). Through this work, FDA and EMA are building a foundation for understanding, trust, and data-driven decisions in the area of inspections.

- **EMA and Australia's Therapeutic Goods Administration:** In 2009, FDA joined the EMA and Australia's Therapeutic Goods Administration to conduct a pilot program—the Active Pharmaceutical Ingredient Inspection Pilot—to demonstrate the potential for leveraging their inspection resources. Before the pilot, these agencies had been conducting separate inspections at the same overseas manufacturing sites—often within just months of one another—to assure that the safety and quality of the drugs were not jeopardized by poor manufacturing practices. Under the pilot, the three agencies planned and conducted joint inspections at participating foreign facilities and shared information from inspections they had conducted over the past 2 to 3 years. These exchanges have allowed FDA to redeploy inspection resources and alerted FDA to sites requiring heightened scrutiny. Since then, FDA has engaged in similar projects with additional counterparts.
- **Health Canada:** FDA also works with Canada on Third-Party Inspection/Audits. To enable closer regulatory cooperation, FDA and Health Canada (HC) initiated the Pilot Multi-purpose Audit Program in 2006. The pilot explored the potential benefits to medical device manufacturers and the agencies of using a single third party for inspections audits to simultaneously meet FDA and HC regulatory requirements for systems quality. It was anticipated that a multipurpose audit could reduce the overall time spent on site by an official agency audit/inspection team, thus reducing the regulatory burden for industry. FDA and HC conducted 11 joint audit/inspections under the pilot; 10 of these were assessed for program benefits. The results showed that the joint approach reduced the time-in-facility spent at participating manufacturers by about one-third, on average, compared with the estimated time required for separate FDA and HC audits/inspections. In addition, FDA and HC gained a better understanding of their auditing/inspection approaches, providing a foundation for leveraging inspection resources in the future.
- **New Zealand's Ministry for Primary Industries:** In December 2012, FDA signed an international arrangement with New Zealand's Ministry for Primary Industries recognizing each other's food safety systems as providing comparable degrees of food safety assurance. This arrangement was reached after a significant amount of time was spent by both parties working on regulatory systems recognition assessments. Systems recognition involves reviewing a foreign country's food safety regulatory system to determine if it provides a

similar set of protections to that of FDA and that the food safety authority provides similar oversight and monitoring activities for food produced under its jurisdiction. Outcomes of these reviews may be used by FDA to make risk-based decisions regarding foreign inspections, admitting product into the U.S., and follow-up actions when food safety incidents occur .

Outcomes: Coordinated inspections allow FDA to leverage resources with their foreign counterparts to fulfill their regulatory responsibilities.

Joint Animal Health Site Visits to Third Countries

Agency: USDA's Animal and Plant Health Inspection Service (APHIS)

Description: As part of the United States-Canada Beyond the Border Initiative, APHIS and Canada conducted a joint site visit in Colombia for a foot and mouth disease evaluation and produced a joint report as part of the evaluation of Colombia's request to export fresh beef in October 2011. The United States and Canada are developing procedures for conducting future joint site visits and the exchange of information related to animal health evaluations. APHIS and Canada will also be identifying other opportunities to share evaluation results.

Outcomes: According to APHIS officials, outcomes could involve the United States and Canada developing risk evaluations that are based in part on a joint site visit.

Voluntary Programs

Agencies cooperate with foreign counterparts on voluntary programs that are not part of agencies' regulations.

Efficient Electrical End- use Equipment Implementing Agreement, Solid State Lighting Annex

Agency: Department of Energy (DOE)

Description: DOE's international coordination on solid state lighting is done in large part through the International Energy Agency (IEA) Efficient Electrical End-Use Equipment (4E) Implementing Agreement, which was launched in 2008 and undertakes a range of analytical and information gathering and dissemination activities related to government regulation and labeling of appliances and equipment. The IEA was established under the Agreement on International Energy Program. Thirteen countries from the Asia-Pacific, Europe, North America, and Africa have joined together under the forum of 4E to share information and transfer experience to support good policy development in the field of energy

efficient appliances and equipment. 4E also initiates projects designed to meet the policy needs of participants, enabling better informed policy making.

Officials said they worked with the 4E Annex on Solid State Lighting for several years on performance characteristics and testing procedures during which time they developed a network of laboratories that would perform independent testing that could be voluntarily adopted by foreign governments. Solid state (or LED) lighting is a new technology that has cost and performance characteristics that are developing rapidly. The goal of the annex is to develop simple tools to help government and consumers worldwide identify which solid state lighting products have the necessary efficiencies and quality levels to reduce the amount of energy currently consumed by artificial lighting. DOE is working with other countries to identify efficiency and performance criteria and metrics, test methods, and qualified testing laboratories that might be used in product labeling or standards activities related to these products.

Outcomes: According to DOE officials, this coordination is important because the adoption of performance standards and test procedures will help determine the products that can be marketed and sold around the world. They said without a common agreement on key characteristics for this new technology, it would be difficult for products to enter the world market. Standard labeling helps customers understand the product they are buying and how its efficiency compares with other products. The results of cooperation on solid state lighting will not necessarily be reflected in DOE's regulations. DOE does not regulate this product at this time, although it has proposed a test procedure that might be used to support the Energy Star program or other initiatives.

Appendix III: Comments from the Department of Energy



Department of Energy

Washington, DC 20585

July 26, 2013

Ms. Michelle Sager
Director, Strategic Issues
U.S. Government Accountability Office
Washington, D.C. 20548

Dear Ms. Sager:

Thank you for the opportunity to respond to the U.S. Government Accountability Office (GAO) report entitled: "International Regulatory Cooperation: Agency Efforts Could Benefit from Increased Collaboration and Interagency Guidance" (GAO-13-588). DOE agrees with GAO's recommendation that the Regulatory Working Group (RWG) include in its forthcoming guidance to agencies on Executive Order 13609 tools to enhance collaboration, such as mechanisms to facilitate staff level dialogues and sharing of best practices. DOE plans to continue to participate in the Interagency Regulatory Working Group and to follow guidance provided on Executive Order 13609 to enhance staff level collaboration as appropriate.

More detailed technical comments are attached for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Hogan".

Kathleen B. Hogan
Deputy Assistant Secretary
For Energy Efficiency
Energy Efficiency and Renewable Energy

Enclosure



Printed with soy ink on recycled paper

Appendix IV: Comments from the Consumer Product Safety Commission



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

July 26, 2013

Ms. Michelle Sager
Director, Strategic Issues
U.S. Government Accountability Office
411 G Street, NW
Washington, DC 20548

Dear Ms. Sager:

The U.S. Consumer Product Safety Commission (CPSC) appreciates the opportunity to review and provide comments on the draft U.S. Government Accountability Office report "International Regulatory Cooperation: Agency Efforts Could Benefit from Increased Collaboration and Interagency Guidance."

The draft report (1) provides an overview of U.S. regulatory agencies' international cooperation activities; (2) examines ways that U.S. agencies incorporate outcomes from international regulatory cooperation activities and consider competitiveness during rulemaking; and (3) examines factors identified by U.S. agencies and stakeholders that act as facilitators or barriers to international regulatory cooperation.

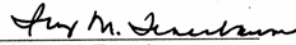
We agree with the conclusions and support the recommendation for the Regulatory Working Group, as part of forthcoming guidance on implementing Executive Order 13609, to establish one or more mechanisms, such as a forum or working group, to facilitate staff level collaboration in international regulatory cooperation issues and include independent regulatory agencies. Staff anticipates such a forum or working group would be beneficial to enabling collaboration on international regulatory issues and looks forward to participating, consistent with CPSC's statutory mission and authorities.

Thank you again for providing us with the opportunity to comment on the draft report.

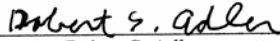
CPSC Hotline: 1-800-638-CPSC (2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

Page 2

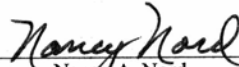
Sincerely,



Inez M. Tenenbaum
Chairman



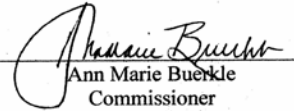
Robert S. Adler
Commissioner



Nancy A. Nord
Commissioner



Marietta S. Robinson
Commissioner



Ann Marie Bueckle
Commissioner

Appendix V: GAO Contact and Staff Acknowledgment

GAO Contact

Michelle Sager, (202) 512-6806 or sagerm@gao.gov

Acknowledgments

In addition to the contact named above, Tim Bober (Assistant Director), Claude Adrien, Melissa Emrey-Arras, Lynn Cothorn, Kim Frankena, Joseph Fread, Debra Johnson, Barbara Lancaster, Andrea Levine, Grace Lui, Susan Offutt, and Cynthia Saunders made key contributions to this report.

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