

**REGULATORY WORKING GROUP GUIDELINES  
EXECUTIVE ORDER 13609  
“PROMOTING INTERNATIONAL REGULATORY COOPERATION”**

**June 26, 2015**

[Executive Order 13609, “Promoting International Regulatory Cooperation”](#) (the Executive Order), calls on the Regulatory Working Group (the Working Group) to issue guidelines on the applicability and implementation of the Executive Order. In accordance with Section 2(e) of the Executive Order, the following guidelines were developed to address a number of responsibilities that the Executive Order gives to the Working Group and to agencies. Specifically, the guidelines provide answers to questions concerning:

- international regulatory cooperation activities that are reasonably anticipated to lead to significant regulatory actions,
- significant and cross-cutting international regulatory cooperation activities,
- the promotion of good regulatory practices (GRPs), and
- other provisions in Sections 2 through 6 of the Executive Order.

The Working Group will review and update these guidelines as necessary. For purposes of this Executive Order, the Working Group operates by consensus.

**Section 2(a)**

**1. What is the role of the Regulatory Working Group in implementing Executive Order 13609?**

As established by Section 4(d) of [Executive Order 12866, “Regulatory Planning and Review,”](#) the Working Group serves, where appropriate, as a forum to discuss international regulatory cooperation activities covered by the Executive Order. The scope of regulatory cooperation activities covered by the Executive Order comprises bilateral, regional, and multilateral processes in which governments engage in various forms of collaboration and communication with respect to regulations, but explicitly excludes any regulatory cooperation activities developed, coordinated, or conducted pursuant to authorities identified in Section 6 of the Executive Order, such as those concerning international trade policy. See the responses to Questions 12 and 29 below.

The activities that the Working Group shall examine, as appropriate, include:

- appropriate strategies for engaging in the development of regulatory approaches through international regulatory cooperation, particularly in emerging technology areas (when consistent with section 1 of the Executive Order);

- best practices for international regulatory cooperation with respect to regulatory development, and, where appropriate, information exchange and other regulatory tools; and
- factors that agencies should take into account when determining whether and how to consider other regulatory approaches under Section 3(d) of the Executive Order (see response to Question 25).

To inform its discussions, the Working Group may commission analytical reports and studies by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB), the Administrative Conference of the United States (ACUS), or any other relevant agency. In addition, the Administrator of OIRA may solicit input from any interested stakeholder, including representatives of business, nongovernmental organizations, and the public.

The Working Group will not duplicate the efforts of existing interagency bodies and coordination mechanisms and will ensure that its work is consistent with, among other things, U.S. trade policy and guidance as formulated by the Office of the United States Trade Representative (USTR) in consultation, as appropriate, with the Trade Policy Staff Committee (TPSC), its appropriate subcommittees, or the Trade Policy Review Group (TPRG).

## **2. Who comprises the Regulatory Working Group?**

The 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 the Executive Order, the Working Group shall also include a representative from USTR and, as appropriate, representatives from other agencies and offices. For most meetings of the Working Group in which the focus of discussion is international regulatory cooperation, OIRA anticipates that the OIRA Associate Administrator or Deputy Administrator will serve as the chair and that agency representatives will designate “Seconds” to attend in their place. Depending on the meeting agenda, Working Group Seconds will be joined by agency officials who are involved directly in particular international regulatory cooperation activities. In addition, a staff-level International Regulatory Cooperation Committee will serve as a primary coordinating mechanism for activities of the Working Group covered by the Executive Order.

## **3. What kinds of international regulatory cooperation issues will be discussed by the Working Group? How will the Working Group prioritize issues for discussion?**

As described in Section 2(a) of the Executive Order, the Working Group shall serve, where appropriate, as a forum for discussion and coordination among U.S. Government agencies with respect to:

- international regulatory cooperation activities that are reasonably anticipated to lead to significant regulatory actions, as determined by the agency (see response to Question 4); and

- efforts throughout the Federal Government to support significant, cross-cutting international regulatory cooperation activities involving multiple agencies across the government, such as the work of the Regulatory Cooperation Councils with Canada and Mexico; and the promotion of GRPs internationally.

As appropriate, the Working Group shall also examine, among other things:

- appropriate strategies for engaging in the development of regulatory approaches through international regulatory cooperation, particularly in emerging technology areas (where consistent with Section 1 of the Executive Order);
- best practices for international regulatory cooperation with respect to regulatory development, and, where appropriate, information exchange and other regulatory tools; and
- factors that agencies should take into account when determining whether and how to consider other regulatory approaches under Section 3(d) of the Executive Order (see response to Question 25).

The Working Group will select international regulatory cooperation issues for discussion based on suggestions and input provided by affected agencies and the public. The Working Group will prioritize those issues most likely to involve:

- international regulatory cooperation activities supporting efforts of U.S. regulators and their foreign counterparts to address shared health, safety, labor, security, or environmental issues or challenges; and
- demonstrably unnecessary differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts that may impair economic growth, innovation, competitiveness, and job creation.

In discussing these issues, the Working Group will take into account such considerations as the protection of public health, welfare, safety, and the environment, as well as the promotion of economic growth, innovation, competitiveness, efficiency, and job creation. As elaborated in the responses to Questions 12 and 29, discussion and coordination of issues through the Working Group shall not duplicate the efforts of existing interagency bodies and coordination mechanisms and excludes regulatory cooperation activities developed, coordinated, or conducted pursuant to authorities identified in Section 6 of the Executive Order.

#### **4. How should an agency determine whether an international regulatory cooperation activity is “reasonably anticipated to lead to significant regulatory actions”?**

Agencies should review their international regulatory cooperation activities to determine whether any of those activities are reasonably anticipated to result in a regulatory action as defined in Executive Order 12866—whether in the form of a new regulation or a change in an existing

regulation. Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a regulation that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866.

See the response to Question 15 for more information on publicly reporting these activities in the agency’s Regulatory Plan. See the response to Question 16 for more information on determining “significant international impacts.”

#### **5. What is a “significant, cross-cutting international regulatory cooperation activity?”**

A central goal of the Executive Order is to strengthen internal U.S. Government coordination of international regulatory cooperation activities via the Working Group. A “significant, cross-cutting international regulatory cooperation activity” is one that raises issues of significant interest to multiple agencies or that would significantly implicate a stated policy or position of the Administration. In either case, interagency coordination is generally necessary to develop and advance consistent U.S. Government positions and strategies in international fora.

In those cases where more than one agency has a significant interest in a “significant, cross-cutting international regulatory cooperation activity” and:

- (a) interagency coordination is not explicitly assigned to an existing body or mechanism,
- (b) there is a lack of coordination among multiple existing bodies or mechanisms, or
- (c) a relevant agency deems existing coordination bodies or mechanisms to not be functioning effectively,

agencies may recommend to the OIRA Administrator that the Working Group assume a coordinating role, or the OIRA Administrator may so recommend to the Working Group. The OIRA Administrator and any interested Working Group member will consult with affected agencies and interagency bodies and forward the results of such consultations to the Working

Group. The Working Group shall consider the results of such consultations in determining, via consensus agreement, whether to accept the recommendation.

For example, it may be appropriate for the Working Group to take a coordinating role in cases where agencies are discussing a significant, cross-cutting regulatory issue in multiple international fora. Although separate interagency mechanisms may exist for establishing the U.S. position in each forum, if these mechanisms cannot adequately ensure that the United States is presenting consistent positions across fora, the Working Group can provide a coordination mechanism. The issue could be substantive (e.g., what U.S. regulatory policy should be in a particular context), procedural (e.g., what international regulatory cooperation activity would most effectively achieve the desired policy objective), or both.

Examples of international fora in which cross-cutting, international regulatory cooperation activities may take place include the Organization for Economic Cooperation and Development's (OECD) Regulatory Policy Committee and the Economic Committee of the Asia-Pacific Economic Cooperation (APEC). The Working Group will also identify other significant cross-cutting international regulatory cooperation activities, as appropriate.

## **6. What is a Regulatory Cooperation Council?**

The United States currently participates in two Regulatory Cooperation Councils (RCCs) that address significant, cross-cutting international regulatory cooperation activities: the United States-Canada Regulatory Cooperation Council<sup>1</sup> and the United States-Mexico High Level Regulatory Cooperation Council.<sup>2</sup> The President and his respective counterparts in Canada and Mexico directed the creation of these RCCs with a mandate to engage in sector-specific regulatory cooperation.

The United States considered Canada and Mexico to be viable RCC partners because of their institutional capacity to plan and implement an RCC Work Plan in collaboration with the United States and their adoption of internationally recognized GRP principles that the United States has endorsed (see response to Question 7, below). Specifically, both the Canadian and Mexican governments have administrative bodies with executive authority—similar to that of the U.S. Executive Branch—over the development, promulgation, implementation, and enforcement of regulations. Moreover, the executive authorities in all three governments share consistent approaches to regulatory transparency, public participation, evidence-based analysis and decision making, use of standards in regulation, and conformity assessment. For example, all three executive authorities solicit and consider public comments on the text of regulatory proposals—as well as the regulatory impacts assessments (RIAs) that may support them—before they issue final regulations.

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<sup>1</sup>The Terms of Reference for the United States—Canada Regulatory Cooperation Council were finalized on June 3, 2011. They can be found at [http://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-canada\\_rcc\\_terms\\_of\\_reference.pdf](http://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-canada_rcc_terms_of_reference.pdf).

<sup>2</sup>The Terms of Reference for the United States—Mexico High Level Cooperation Council were finalized on March 3, 2011. They can be found at [http://www.whitehouse.gov/sites/default/files/omb/oira/irc/high-level\\_regulatory\\_cooperation\\_council-terms\\_of\\_reference\\_final.pdf](http://www.whitehouse.gov/sites/default/files/omb/oira/irc/high-level_regulatory_cooperation_council-terms_of_reference_final.pdf).

These RCCs, per their terms of reference, are co-chaired by the OIRA Administrator and a high-level representative of a similarly situated agency in the partner country's government. The RCC co-chairs work closely with their respective trade and foreign affairs agencies—in the United States, these are USTR and the Departments of Agriculture, Commerce, and State—and the agencies and ministries with legal authority to implement any of the agreed-upon initiatives.

The co-chairs of the RCCs must engage as necessary with the specific regulatory agencies and ministries to address policies and issues for which the regulatory agencies and ministries are responsible. Through this process, the United States and its RCC partners identify sectors for cooperation that will yield significant net benefits and develop and implement cooperation work plans. The development of work plans are governed by the GRPs referenced below in response to Question 7 and by the following key principles, reflected in the terms of reference of the two existing RCCs:

- maintaining the sovereignty of the United States and the RCC partner to carry out their regulatory functions according to their respective domestic laws and policy priorities and subject to the availability of resources;
- simplifying regulations to the extent possible, reducing unnecessary requirements, and encouraging regulatory alignment without compromising public health and safety, environmental protection, or national security objectives;
- increasing regulatory transparency and promoting public participation to ensure that any member of the public can participate in the rulemaking process and have a meaningful opportunity—by which we mean one that can still genuinely affect the outcome—to provide views, expertise, and data in response to solicitations for public comment on the text of regulatory proposals and supporting documents;
- strengthening the analytical basis of regulations; and
- increasing relevant technical cooperation, including science and research collaboration.

The Working Group may serve as a forum to consider the merits of establishing additional RCCs in the future.

## **7. What are good regulatory practices?**

The term “good regulatory practices” refers to internationally recognized processes and procedures that can be used to improve the quality and cost-effectiveness of domestic regulations. GRPs address practices aimed at (a) increasing regulatory transparency and accountability by promoting public participation to ensure that stakeholders can share their views, expertise, and data during the development of regulations; (b) strengthening the analytical basis of regulations through robust analysis of their impacts; and (c) certain administrative procedures that govern intragovernmental coordination of rulemaking activity. The United States has endorsed important statements that reflect broad international support for GRPs, such

as (a) the [2005 APEC-OECD Integrated Checklist on Regulatory Reform](#), (b) the [2011 APEC Leaders' Statement: The Honolulu Declaration - Toward a Seamless Regional Economy \(Annex D\)](#), and (c) the [2012 Recommendation of the Council of the OECD on Regulatory Policy and Governance](#). The United States, through the Working Group or otherwise, may decide to endorse additional documents.

In the United States, many GRPs are embodied in U.S. law and administrative policies that have been developed over decades. These include the following laws, executive orders, and OMB guidance:

- [Administrative Procedure Act](#)
- [Unfunded Mandates Reform Act](#)
- Executive Order 12866, “Regulatory Planning and Review”
- [Executive Order 13563, “Improving Regulation and Regulatory Review”](#)
- Executive Order 13609, “Promoting International Regulatory Cooperation”
- [Executive Order 13610, “Identifying and Reducing Regulatory Burdens”](#)
- [OMB Circular A-4, “Regulatory Analysis”](#)
- [OMB Circular A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”](#)
- [OIRA Memorandum on “Disclosure and Simplification as Regulatory Tools”](#)

## **8. How should the United States promote GRPs internationally?**

U.S. agencies—including regulatory agencies, OMB, USTR, the State Department, and the Commerce Department—often participate in international fora in which GRPs are discussed, including activities carried out pursuant to USTR’s statutory authorities for trade policy. These international fora, which include the Regulatory Policy Committee of the OECD, the APEC Committee on Trade and Investment and its sub fora, the APEC Economic Committee, and the RCCs, provide opportunities to share best practices and experiences. When U.S. officials discuss ways to promote GRPs and explain U.S. implementation of GRPs in such fora, their presentations and positions should be consistent with the domestic laws (including regulations), Administration policies, executive orders, and OMB guidance set out in the response to Question 7.

Various strategies to promote GRPs have been used in the past. For example, when the U.S. hosted APEC in 2011, USTR worked with other agencies to advance a U.S. proposal to strengthen the implementation of GRPs throughout the Asia-Pacific region. U.S. officials made several presentations in various APEC fora, discussing the U.S. experience with GRPs and encouraging APEC members to base regulatory choices on careful analysis and to subject them to public scrutiny as a way to increase regional economic integration, economic growth, and job creation. APEC Leaders endorsed the initiative in November 2011 and pledged to take steps to improve internal coordination of rulemaking, to strengthen mechanisms for assessing the impact of new and existing regulations, and establish procedures for meaningful public consultation on regulatory proposals. In addition, U.S. officials have conducted numerous meetings, in person and via videoconference, with foreign officials to discuss GRPs generally and to assist with specific initiatives. GRPs are also an important element of U.S. trade agreements, where USTR



works to secure commitments to GRPs from U.S. trading partners and to establish dedicated fora, such as bilateral committees and working groups, to further cooperation with trading partners on GRPs and other regulatory issues following the entry into force of a trade agreement.

One objective of the Working Group is to build on previous strategies to develop and promote GRPs. The relative importance of different GRPs may vary by context, and the Working Group will work closely with USTR—which also promotes GRPs pursuant to its trade agreement authorities—to ensure a consistent policy approach and to coordinate U.S. positions and activities related to GRPs.

## **9. Why are GRPs relevant to international regulatory cooperation?**

GRPs are an essential foundation for successful cooperation among countries to improve regulatory quality, meet shared health, safety, labor, security, environmental, and other challenges, reduce regulatory burdens, and promote broader economic interests. GRPs that are prerequisites for effective international regulatory cooperation include:

- **Regulatory Transparency and Public Participation.** Making the text of regulatory proposals, as well as the RIAs that analyze the text, available for public scrutiny and comment is necessary to enable the public to provide the sort of detailed comments needed for effective, evidence-based analysis and decision making. Transparency and public participation can also help regulators achieve common regulatory objectives in ways that minimize potentially unnecessary divergences and identify unintended consequences of regulation that may unnecessarily hamper international trade and investment. Also, when regulators engage in sectoral initiatives with trading partners, domestic and foreign stakeholders can provide useful input on priorities and information about the practical realities of implementation.
- **Internal Coordination.** To cooperate effectively with each other, governments must have robust institutions and procedures in place that support and enforce GRPs government-wide. This reinforcement of GRPs begins with high-level political support for GRPs, including strong institutional arrangements and procedures to ensure a coherent approach to regulation across agencies. Coordinated and transparent regulatory planning—through, for example, the publication of a regulatory agenda that includes details about planned regulatory actions and milestones—can help make regulation more transparent and predictable, allowing for early notifications that facilitate upstream regulatory cooperation.
- **Regulatory Analysis.** The comparison of the costs and benefits, both qualitative and quantitative, of various regulatory alternatives can help regulators select, when appropriate, the alternative that maximizes net benefits. Similarly, through the identification and analysis of regulatory alternatives, regulators can consider a range of options, relying on a strong base of evidence that can inform cooperative efforts with foreign regulators to minimize unnecessary regulatory differences.



If another government's regulatory process is not sufficiently guided by GRPs, it will be more difficult for that country to gather public input and perform analyses at the level of detail needed for successful regulatory cooperation with the United States. For example, if another country does not obtain public comments on a proposed regulatory action, including both the text of the proposal and the regulatory impact analysis developed to support it, it is more difficult for U.S. regulatory authorities to cooperate with its counterparts in that country. Further, if another country does not have a strong evidence basis for its decision making, or lacks a record on which its decision making is based, cooperation is likewise more difficult. Even in such cases, however, opportunities to share best practices and build a foundation for future regulatory cooperation may still exist. Moreover, because there may be various approaches and practices for implementing GRPs, U.S. agencies are encouraged, as appropriate, to learn lessons for improving regulatory analysis and transparency from the regulatory systems of other nations.

#### **10. Under what circumstances should the United States engage in the development of regulatory approaches through international regulatory cooperation?**

Any regulatory approach that the United States advances through international regulatory cooperation must be consistent with existing U.S. law and policies. Any decision by the Working Group to promote a specific regulatory approach will necessarily be context-specific. Before U.S. Government entities engage in an international regulatory cooperation activity that the Working Group will coordinate (see responses to Questions 1, 3 and 5), they should coordinate strategies through the Working Group and disseminate those strategies to the affected interagency bodies and relevant agencies to ensure consistency and prevent duplication.

When engaging in the development of regulatory approaches to emerging technology through international regulatory cooperation, the United States should ensure that, consistent with applicable law and international obligations, such approaches are consistent with the first general principles of regulation identified in Executive Order 13563:

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas.

While circumstances will vary from case to case, international regulatory cooperation to support the development of new, innovative technologies should be guided by the following principles:

- encouraging appropriate collaborative international research efforts, particularly multilateral efforts;
- communicating U.S. regulatory approaches clearly to other nations, as appropriate; and
- sharing and developing relevant information, as appropriate and permitted by law, to support the development of higher quality regulations and the implementation of GRPs.

When coordinating international regulatory cooperation activities, the Working Group should also consider technical work from other interagency processes, especially when considering strategies in emerging technology areas. For example, international regulatory cooperation concerning the regulation of nanotechnology is currently informed by the technical discussions that take place in the Nanotechnology Working Group of the U.S. Emerging Technologies Interagency Policy Coordination Committee.

**11. What are best practices for facilitating international regulatory cooperation, particularly with regard to information exchange?**

Although a well-established area of activity, there are few recognized best practices for facilitating international regulatory cooperation. The U.S. experience, however, suggests a number of factors that may be relevant to achieving successful outcomes (see response to Question 6) in international regulatory cooperation. As already discussed in the response to Question 9, GRPs are clearly best practices in the context of international regulatory cooperation.

Another key practice that the Working Group has identified as critical for successful international regulatory cooperation is information exchange. The practical details of exchanging information among countries participating in international regulatory cooperation can raise a number of complex policy and legal issues. Internal procedural rules and protection of confidential information are just some examples of issues that participants will have to work out. U.S. agencies engaged in regulatory cooperation with foreign counterparts must maintain the confidentiality of pre-decisional materials that are the subject of internal Executive Branch deliberations, and recognize that international counterparts may have similar preferences or obligations. Going forward, the Working Group may explore (a) the considerations relevant to a U.S. agency's decision whether it will share with another U.S. agency the trade secret, confidential commercial, and/or financial information that the agency received from a foreign regulator, or (b) how it can best promote necessary information sharing with a foreign regulator while appropriately protecting confidential or commercially sensitive information.

The Working Group will continue to review best practices aimed at facilitating international regulatory cooperation and explore how such practices can guide agencies. The Working Group's review will take into account available resources, as well as lessons learned from past and ongoing activities. Best practices will likely be context-specific, and the Working Group will aim to identify best practices that make international regulatory cooperation more effective and efficient while drawing on experience to provide a framework for resolving specific practical challenges that may arise. The Working Group will also consult with relevant domestic and international stakeholders, where feasible and appropriate.

## Section 2(c)

### **12. How will the Working Group ensure that it will not duplicate the efforts of existing interagency bodies and coordination mechanisms? How will the Working Group identify and interact with the existing interagency bodies and coordination mechanisms?**

Pursuant to Section 2(c) of the Executive Order, the Working Group “shall not duplicate the efforts of existing interagency bodies and coordination mechanisms.” Other interagency bodies and coordination mechanisms for regulatory cooperation activities that may exist include those carried out pursuant to the statutory authorities set out in Section 6 of the Executive Order, including those concerning international trade policy. See response to Question 29 below.

To ensure that the Working Group avoids such duplication while serving its coordination function, the Working Group will need to stay informed about the important international regulatory cooperation activities in which the U.S. Government is engaged. To this end, the Working Group will serve as a coordinating and information-sharing body, as delineated in the response to Question 3. To facilitate such information sharing, the Working Group’s International Regulatory Cooperation Committee will meet monthly to discuss activities covered by the Executive Order and OIRA will participate in the TPSC and TPRG, as appropriate.

In addition, before seeking to coordinate an international regulatory cooperation activity, the Working Group will consult with the relevant agency (or agencies) as a first step toward determining whether the activity falls within the scope of an existing regulatory cooperation activity, interagency body, or coordination mechanism and whether the Working Group would duplicate the efforts of that body or mechanism if it were to engage in such coordination.

Even when the Working Group is not the lead coordinating entity, it can provide a forum for any interested agency to present any of the international regulatory cooperation activities it leads, with a view to exploring when and how input from other agencies can be useful to an existing process to ensure U.S. Government priorities are being met.

The Working Group will work closely with USTR to ensure that any regulatory cooperation activities developed or coordinated through the Working Group do not affect or impair USTR’s statutory authorities and responsibilities. If a question arises as to whether the Working Group or USTR (in consultation, as appropriate, with the TPRG) should coordinate a particular regulatory cooperation activity—or work on it jointly, as the case may be—USTR and OIRA will discuss the matter together, as appropriate, with any other agencies involved. In its role as a member of the TPSC, OMB will provide information on the Working Group’s current and planned regulatory cooperation activities to ensure these activities are consistent with Sections 4(c) and 6 of the Executive Order.

## **Section 2(d)**

### **13. Under what circumstances will the Working Group commission analytical reports and studies by OIRA, the Administrative Conference of the United States (ACUS), and other relevant agencies?**

The Working Group may request that OIRA, ACUS, or other relevant agencies develop analytical reports and studies to inform its deliberations and improve coordination of rulemaking and consultations with the public. The Working Group may develop a consensus-based process and criteria for determining whether and from whom to commission these reports and studies in particular circumstances.

### **14. How and when will OIRA solicit input from representatives of business, nongovernmental organizations, and the public?**

The OIRA Administrator may solicit input from any interested stakeholder, including representatives of business, consumer groups, nongovernmental organizations, trading partners, and the public, on a periodic basis on any matter falling within the scope of the Executive Order. OIRA has established a dedicated e-mail address ([international-oira@omb.eop.gov](mailto:international-oira@omb.eop.gov)) for feedback. In addition, OIRA will work with regulators to ensure that the RCC Work Plans identify opportunities for stakeholder engagement.

Additionally, individual agencies may decide to seek input from interested stakeholders on new opportunities for international regulatory cooperation. When connected to the work of the RCCs, these outreach mechanisms should be identified in the RCC Work Plans. Agencies are encouraged to identify opportunities to provide input through other means as well, for example, through *Federal Register* notices or posts on Open Government Webpages.

## **Section 3(a)**

### **15. What information should an agency include in its Regulatory Plan summary of international regulatory cooperation activities that are reasonably anticipated to lead to significant regulatory action?**

Section 3(a) of the Executive Order provides that, to the extent permitted by law, and consistent with the principles and requirements of Executive Orders 12866 and 13563, each agency must, if required to submit a Regulatory Plan pursuant to Section 4(c) of Executive Order 12866, include in that Plan a summary of its international regulatory cooperation activities that are reasonably anticipated to lead to significant regulations,<sup>3</sup> with an explanation of how these activities advance the purposes of Executive Orders 13563 and 13609.

This summary should include the type of international regulatory cooperation activity (e.g., RCC Work Plan, regulator dialogue, or representing the United States in international standards

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<sup>3</sup>Section 4(e) of the Executive Order defines “significant regulation” as “a proposed or final regulation that constitutes a significant regulatory action.”

development or intergovernmental organizations), a description of the work being undertaken, and to the extent possible the:

- affected sectors of the economy;
- interested parties, including key stakeholders; and
- significant regulatory action that the activity may lead to and how the benefits of the anticipated significant regulatory action justify its costs, recognizing at this stage of development this information may not yet be available.

If the agency's Regulatory Plan includes a discussion of an anticipated significant regulatory action, it should, when appropriate, include the regulatory action in the Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda), and the summary should include the relevant time frame for the regulatory action. If there is not yet a Unified Agenda entry for the action, then the agency should cite the statute under which the action will be promulgated.

Each agency should also explain, to the extent possible, in its Regulatory Plan, how each activity that is reasonably anticipated to lead to a significant regulatory action will promote the stated goals of Executive Orders 13563 and 13609, which may include how the planned activity:

- protects public health, consumers, welfare, safety, and/or the environment while promoting economic growth, innovation, competitiveness, and/or job creation;
- addresses any demonstrable, unnecessary differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts where differences are not necessary and that may impair economic growth, innovation, competitiveness, and job creation;
- contributes to the meeting of shared challenges involving health, safety, labor, security, the environment, and other issues; and
- can be at least as protective as approaches that would have been adopted in the absence of such cooperation.

### **Section 3(b)**

#### **16. What is a “significant international impact?”**

Agencies currently identify regulatory actions with international impacts as part of their Unified Agenda. OIRA guidance for determining “international impacts” suggests that agencies consider whether the regulation is expected to have significant international trade and investment effects, or is otherwise expected to be of interest to the United States' international trading partners.

In identifying those regulations that have a *significant* international impact—for purposes of Sections 3(b) and 3(d) of the Executive Order—agencies should consider the magnitude of these impacts, in a global economic context, taking into account the following factors, as feasible and appropriate:

- impacts on international economic activity, including trade flows;
- impacts on a specific product, group of products, or products in general;
- impacts on a specific service, group of services, or services in general;
- impacts on health, safety, labor, security, the environment;
- the likely anticipated costs and benefits of the regulation; and
- whether the regulation would bring the United States into or out of alignment with a relevant international standard, guide, or recommendation.

In order to identify significant regulations that may have significant international impacts, agencies should, at a minimum, use their internal review process for their Unified Agenda submissions as a mechanism to consider these factors. When questions arise regarding potentially significant international effects, agencies should consult with USTR and other relevant TPSC agencies regarding impacts on trade and with the appropriate OIRA desk officer regarding other international effects.

The Working Group notes that the simple fact that a regulation would increase costs to U.S. importers and exporters would not, in and of itself, be a reason to consider a regulation as having a significant international impact. Effects on U.S. imports and exports would continue to be a normal part of OIRA’s review of significant proposed and final regulations under Executive Orders 12866 and 13563.

To facilitate implementation of the Executive Order, OIRA will work with agencies to address issues that arise in identifying and quantifying significant international impacts.

**17. When would OIRA designate a regulation as “significant” under Executive Order 12866, based on its international impact?**

The Executive Order amends neither the definition of “significant” in Executive Order 12866 nor the process by which OIRA designates regulations as “significant.” OIRA will continue to consider all relevant, available information when making a significance designation, including any information concerning possible significant international impacts, as discussed in the response to Question 16.

**18. How should an agency ensure that regulations having significant international impacts are identified (or “flagged”) in the Unified Agenda, on [www.RegInfo.gov](http://www.RegInfo.gov), and on [www.Regulations.gov](http://www.Regulations.gov)?**

Agencies currently identify regulatory actions with international impacts as part of their Unified Agenda development processes, which are coordinated by the Regulatory Information Services Center within the General Services Administration. As discussed in the response to Question 16, agencies will also identify those regulations that have a “significant” international impact

pursuant to Sections 3(b) and 3(d) of the Executive Order. Offices that manage [www.RegInfo.gov](http://www.RegInfo.gov) and [www.Regulations.gov](http://www.Regulations.gov) will establish processes to use data from the Unified Agenda to populate these websites with such information.

### **Section 3(c)**

#### **19. What is an “unnecessary difference in regulatory requirements” between the United States and its major trading partners in the context of retrospective review of regulations?**

Section 3(c) of the Executive Order calls on agencies to consider, within the context of their retrospective review plans required by Executive Orders 13563 and 13610, regulatory reforms that address “unnecessary differences in regulatory requirements between the United States and its major trading partners...when stakeholders provide adequate information to the agency.” Agencies will also consider regulatory reforms “in other circumstances as the agency deems appropriate.”

An agency’s consideration of any such unnecessary regulatory difference must take into account domestic law, policies, and priorities, and should be guided by the policy set out in Section 1 of the Executive Order. Section 1 provides that “[i]n meeting shared challenges involving health, safety, labor, security, environmental, and other issues international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation.” What may be an “unnecessary difference” will be a context-specific inquiry and must be established by evidence provided by stakeholders, the agency in question, or both. Such evidence may show that the same (or greater) levels of sufficient protection can be maintained even while eliminating unnecessary regulatory differences.

It is understood that an agency may not have required information about the effects of keeping or eliminating regulatory differences on-hand. However, pursuant to Section 2 of Executive Order 13563, early engagement with affected stakeholders can help agencies gather and assess such information. Agencies should consult with USTR and other relevant TPSC agencies regarding whether a difference in regulatory requirements impairs the ability of U.S. firms to access foreign markets or participate in global supply chains.

#### **20. How should an agency determine if a stakeholder has provided “adequate information” that a difference in a regulatory approach is unnecessary?**

Consistent with the requirements of Executive Orders 12866 and 13563 and the guidance in OMB Circular A-4, agencies should analyze relevant information provided by stakeholders as part of the retrospective review process to determine if such information supports a conclusion that a difference between a U.S. regulatory requirement and a non-U.S. requirement is unnecessary and whether initiating a new rulemaking would be appropriate. As noted in the response to Question 19, the identification of an unnecessary difference between a U.S. and foreign regulation will be context-specific, and should generally be made by reference to domestic law, policies, and priorities.



**21. What is the process by which stakeholders can request that an agency consider reforms to existing significant regulations that address unnecessary differences in regulatory requirements between the United States and its major trading partners?**

Agencies should adhere to the process governing use of the “look back” mechanism set out in Executive Orders 13563 and 13610 and their respective procedures for considering reforms and modifications to regulations, as well as the long-standing notice-and-comment procedures required by the Administrative Procedure Act. If information provided by stakeholders is insufficient, agencies may request more detailed information.

**22. What factors should an agency consider when determining whether or not to address an unnecessary difference in regulatory requirements between the United States and a major trading partner?**

The agency should consider factors such as its relationship and experience with the foreign regulator, as well as the foreign regulator’s level of experience and expertise. The agency should also take into account any related administrative benefits and costs and potential resource constraints.

**23. What is a “major trading partner?”**

For purposes of the Executive Order, an agency may consider a number of factors when identifying another nation as a “major trading partner.” These factors include the volume and value of U.S. trade with that nation. Alternatively, trade in a specific sector may have particular importance to the United States, even where overall trade with a particular trading partner may not reach the upper tier in volume or monetary value. Whether the nation maintains a free trade agreement with the United States may also be relevant. Agencies should consult with USTR and with other relevant TPSC agencies on whether a nation should be considered a “major trading partner” in a particular context.

**Section 3(d)**

**24. What is a Regulatory Cooperation Council Work Plan?**

RCC Work Plans describe the sectoral initiatives that the United States and its RCC partner have agreed to, and they are developed through regulator-to-regulator consultation. The Work Plans include timelines, stakeholder engagement opportunities, and deliverables for implementing initiatives adopted under the RCC.

In implementing the Work Plans, U.S. agencies and their foreign counterparts are expected to identify mechanisms to address the unnecessary differences that are the focus of the Work Plans, and shall develop ongoing administrative mechanisms and processes to prevent the creation of unnecessary differences in the future.

**25. What does it mean for the United States to “consider” a regulatory approach by a foreign government under a Regulatory Cooperation Council Work Plan? When might it not be feasible or appropriate to do so?**

Executive Orders 12866 and 13563 and the Regulatory Flexibility Act require agencies to identify and evaluate alternative forms of regulation for significant regulatory actions and, for *economically* significant regulations, to assess the costs and benefits of reasonably feasible alternatives. In the process of considering reasonably feasible alternatives, the Executive Order requires agencies to 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 an RCC Work Plan. Such an approach may not be feasible or appropriate for consideration if it is inconsistent with statutory requirements or U.S. Government policy.

Of course, agencies may consider other approaches of major trading partners that are not included in a RCC Work Plan. Agencies are encouraged take into account whether these other approaches are consistent with the objectives set out in Section 1 of the Executive Order and whether the trading partner in question followed GRPs (see the response to Question 7) when developing the approach. In reaching these determinations, an agency is to rely on its own expertise and judgment, and is encouraged to consult with the relevant OIRA desk officer and, on questions about consistency of these other regulatory approaches with international trade obligations or their impact on trade, with USTR.

**Section 4(b)**

**26. How should an agency determine if a regulation may be of “significant interest to the trading partners of the United States?”**

To determine if a regulation may be of “significant interest to the trading partners of the United States,” an agency should, in addition to relying on its own expertise and judgment, consult with USTR as well as other TPSC agencies, including the Department of State, to the extent the relevant agency regularly interacts with U.S. trading partners with regard to the issue in international fora. Possible indicators of “significant interest” include (a) a trading partner raises or has a communicated stake in a U.S. regulation in a bilateral, regional, or international forum, or (b) a regulation would cause changes in the trade of specific products or services beyond normal year-to-year fluctuations in the value of trade. Given that regulations with “international impacts” are flagged in the Unified Agenda, [www.RegInfo.gov](http://www.RegInfo.gov), and [www.Regulations.gov](http://www.Regulations.gov), U.S. trading partners have an opportunity to review upcoming regulatory actions and identify potential effects and areas of upstream regulatory cooperation. Foreign governments and stakeholders have the same ability to participate in the regulatory review process under Executive Order 12866 that domestic U.S. entities have. Similarly, to the extent that other governments use or adopt similar mechanisms to disseminate regulatory information, agencies should review the regulatory agendas of their foreign counterparts.

## Section 4(c)

### **27. What are the “various forms of collaboration and communication” that are considered “international regulatory cooperation” under the Executive Order?**

A wide variety of activities could be considered to be “international regulatory cooperation,” including information exchange, work sharing, aligning regulatory requirements, scientific collaboration, and pilot programs. The preferred form of cooperation will vary based on circumstances. Not all of these will be “significant, cross-cutting international regulatory cooperation” activities. If the cooperative activity is reasonably anticipated to lead to the development of a significant regulation, then the activity would be subject to the Executive Order, unless excluded by Section 6.

Accordingly, agencies must give priority to identifying those international regulatory cooperation activities that are likely to lead to a significant regulation, recognizing that it will not always be possible to make such a determination in the early stages of international regulatory cooperation. Because agencies cannot disclose deliberative information during the course of any internal, Executive Branch deliberative process (e.g., an OIRA review of a draft, significant regulation), agencies should work to engage in consultations with foreign regulators prior to such internal deliberations where possible.

## Section 5

### **28. How should the Working Group seek to obtain information from, and work with, independent agencies?**

The OIRA Administrator will encourage independent agencies to participate in the activities of the Working Group and to follow the Executive Order. Given the cross-cutting nature and importance of the issues to be discussed in the Working Group, independent agencies will likely find their participation and contributions to be very useful in carrying out their regulatory missions.

## Section 6

### **29. What types of activities are not affected by the Executive Order and what other types of activities are not covered?**

Section 6(a) of the Executive Order states that the Executive Order does not impair or otherwise affect:

- the authority granted by law to a department or agency, or the head thereof;
- USTR’s authorities to coordinate and develop international trade policy and negotiations pursuant to section 411 of the Trade Agreements Act of 1979 (19 U.S.C. 2541) and section 141 of the Trade Act of 1974 (19 U.S.C. 2171), which concern *inter alia* the following:

- development and coordination of implementation of U.S. international trade policy and issuance and coordination of policy guidance to agencies on basic issues of policy and interpretation arising in the exercise of international trade functions;
  - consideration of international trade policy issues that arise as a result of implementation of the World Trade Organization (WTO) Agreements on Technical Barriers to Trade and Sanitary and Phytosanitary Measures and U.S. free trade agreements;
  - coordination of discussions and negotiations with foreign countries for the purpose of establishing mutual arrangements with respect to standards-related activities; and
  - coordination of international trade policy issues that arise as a result of, and development of international trade policy as it relates to, implementation of agencies' statutory obligations regarding standards-related activities under section 401 of the Trade Agreements Act of 1979.
- the Commerce Department's international trade activities under section 3 of the Act of February 14, 1903 (15 U.S.C. 1512), subtitle C of the Export Enhancement Act of 1988, as amended (15 U.S.C. 4721 et seq.), and Reorganization Plan No. 3 of 1979 (19 U.S.C. 2171 note);
- the State Department's authorization process for the negotiation and conclusion of international agreements under 1 U.S.C. 112b(c) and the State Department's implementing regulations (22 C.F.R. 181.4) and implementing procedures in the Foreign Affairs Manual (11 FAM 720);
- activities in connection with subchapter II of chapter 53 of title 31 of the United States Code, title 26 of the United States Code, or Public Law 111-203 and other laws relating to financial regulation; and
- the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.