

## EU-US Regulatory Cooperation

### Best Cooperative Practices

US and European regulators are pursuing cooperation in an increasing number of sectors across a broad spectrum of policy approaches – from informal information exchanges – to structured sectoral dialogues – to binding mutual recognition agreements. In recent years, we have dramatically expanded the scope of EU-US regulatory cooperation activities to include horizontal as well as numerous sectoral topics. We have highlighted the importance of such cooperation at past EU-US Summits and through specific initiatives such as the Roadmap for EU-US Regulatory Cooperation. Some regulatory cooperation activities have proven particularly successful, while others have encountered various constraints. As we strive to improve and deepen our regulatory cooperation, it is important that we learn from our activities that work well and those that lag.

Based on the experiences gained through a wide range of EU-US regulatory cooperation initiatives in recent years, we have distilled an agreed set of Best Cooperative Practices. These suggested best practices are intended to complement the [EU-US Guidelines on Regulatory Cooperation and Transparency](#). In addition to serving as a guide for regulators pursuing successful cooperative approaches, the practices also could be used informally by regulatory authorities in the future to assess the quality and sufficiency of individual cooperative efforts.

#### *1. Define clearly the specific Scope of Cooperation and Regulatory Context*

- Clearly define the scope and objectives of the agreed cooperative activity. A brief agreed written work plan or terms of reference outlining the specific cooperative effort is often useful in this regard.
- Confirm the mutual interest and commitment of relevant key US and European regulators to pursue cooperation on the identified topic. Absent the continued engagement of the key officials from each side, well-intentioned cooperative ventures can founder.
- Ensure the specific US and EU regulatory regimes for the identified issue provide sufficiently similar structural and policy basis for regulatory cooperation. Cooperation often is easier in sectors where the United States and the EU maintain analogous regulatory environments (e.g., regulation at the US federal level and European Community level) and similar regulatory approaches.
- As a key element of all sectoral dialogues, regulators should be encouraged to conduct regular information exchanges about planned or contemplated regulations. Cooperation tends to be easier and more effective for topics that are very early in the regulatory planning stage – especially in cases where each side may be contemplating new regulations.

## ***2. Identify appropriate Mechanisms for Confidence Building and Cooperation***

- Examine the spectrum of policy instruments/approaches available for regulatory cooperation and select the specific approach most appropriate to the specific regulatory context and objective. The appropriate approach tends to depend on the specific regulatory context and cooperation objective. In many cases, an initial approach based on informal dialogue and information exchanges can lead to more structured and deeper cooperation supported by formal MOUs or agreements, to ensure continuity in cooperation.
- Establish an effective relationship between US and EC “regulatory peers”. Such a relationship between peers – including not only senior regulatory officials, but also agency staff experts, engineers, economists – can provide valuable feedback for each side’s regulatory efforts.
- Develop cooperation making full use of existing examples of instruments to facilitate dialogue. Through our existing EU-US regulatory dialogues, we have developed a range of informal and formal instruments to facilitate data and information exchanges that can be leveraged to support more detailed and intensive regulatory cooperation activities. Cooperative models such as the Guidelines for Information Exchange and on Administrative Cooperation on consumer product safety<sup>1</sup>, as well as instruments to facilitate the sharing of non-public information, such as confidentiality arrangements<sup>2</sup>, provide especially useful approaches.
- Consult on data collection procedures and, if appropriate, cooperate on the actual data collection to save time and resources. While interpretation of such data may differ, a common factual basis for decision making can contribute to more consistent regulatory approaches.
- Focus on incentives for regulators to promote cooperation. Regulatory cooperation can yield better quality regulation and result in regulatory efficiencies. Successful cooperative activities tend to be structured in a manner that provides ongoing added value for US and EU regulators – in terms of saved resources and better regulation. Agency review of the benefits and costs of EU-US regulatory divergences for significant rulemakings may increase incentives to promote specific cooperation activities.

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<sup>1</sup> Developed between the US Consumer Product Safety Commission and the European Commission’s Directorate General for Health and Consumer Protection. Available at: [http://www.ustr.gov/assets/World\\_Regions/Europe\\_Middle\\_East/Europe/US\\_EU\\_Regulatory\\_Cooperation/asset\\_upload\\_file656\\_7235.pdf](http://www.ustr.gov/assets/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/asset_upload_file656_7235.pdf)

<sup>2</sup> Developed between the US Food and Drug Administration, the European Commission’s Directorate General for Enterprise and Industry and the European Medicinal Evaluation Agency. Available at: [http://www.ustr.gov/assets/World\\_Regions/Europe\\_Middle\\_East/Europe/US\\_EU\\_Regulatory\\_Cooperation/asset\\_upload\\_file573\\_7148.pdf](http://www.ustr.gov/assets/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/asset_upload_file573_7148.pdf)

- Promote informal channels of communication between regulatory officials and their staff. Regular contacts by US and EU regulators at the staff level are important for building confidence between regulators and deepening cooperation activities. Efforts to promote informal staff contacts through email, teleconferencing and video-conferencing should be encouraged. The participation of agency experts – such as engineers and economists – in these exchanges should be encouraged, as appropriate.
- Make full use of the expertise of overseas staff employed by regulatory authorities in helping to advance cooperation by establishing strong working relationships and cooperative dialogues with their foreign regulatory counterparts.

### ***3. Cultivate Senior-level USG and EU Support for selected Cooperative Activity***

- Senior-level USG and EU interest and participation is often a critical factor in developing and maintaining successful long-term cooperation. Senior-level government support – both within regulatory authorities, as well as outside – is an important factor for maintaining the continuity in cooperative ventures, ensuring that adequate resources are provided to support/expand cooperation, and providing political visibility and recognition for valuable work.

### ***4. Provide sufficient Resources to Support Cooperation***

- US and EU regulatory authorities should leverage ongoing multilateral/plurilateral cooperation efforts where possible – as well as other existing bilateral cooperation efforts – to advance cooperation objectives. US and EU regulatory authorities should meet on the margins of multilateral cooperation fora or conferences to fully take advantage of opportunities to promote bilateral and multilateral cooperation.
- To conserve limited resources, regulatory authorities should make use of technology, such as video-conferencing, in order to limit travel costs and maximize the participation in the dialogues of relevant experts on each side.
- Develop and/or expand expert exchanges and training to support EU-US regulatory cooperation efforts. The exchange of regulatory experts between US and EU authorities can be helpful in promoting stronger understanding of respective regulatory environments, priorities, and approaches – and supporting more intensive and effective cooperation.
- Ensure that the regulatory efficiencies and other benefits from such cooperation are quantified and publicized within regulatory agencies and governments more generally. While cooperation is valuable in its own right, acknowledging concrete benefits is important to building government and public support for the utility of regulatory cooperation.

***5. Provide Transparency and Opportunity for Stakeholder Input***

- Many of the most effective regulatory cooperation activities provide interested stakeholders information about ongoing cooperation and a meaningful opportunity to provide input into the government dialogues. Authorities should build into government regulatory dialogues a regular informal briefing and/or consultation with interested stakeholders.
- A process to enhance the transparency of such cooperative dialogues can promote not only better quality regulation, but also permit broader public recognition of the results and benefits of regulatory cooperation initiatives.

***6. Promote intra-agency Dialogue/Exchange on Best Cooperative Practices***

- Regulators can learn constructively from comparing the different experiences of their US and EU regulatory colleagues pursuing cooperation. Informal dialogues or exchanges among regulators on each side aimed at promoting the sharing of experiences and cooperative models among regulators should be encouraged.
- Regulators should review periodically the operation of existing regulatory cooperation activities and suggest improvements to these Best Cooperative Practices.
- Agencies are encouraged to review the extent to which they take steps recommended in these Best Cooperative Practices, and consider plans for increasing recommended actions.