

# US-EU Regulatory Cooperation

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## Approaches and Experiences

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# What is Regulatory Cooperation?

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US and European regulators actively pursue cooperation through a broad range of sectoral activities and policy tools in the area of TBTs

- Regulator to regulator engagement – most often on prospective regulation
- Policy spectrum from ad hoc, informal information exchanges – to structured dialogues – to binding government agreements (e.g., MRAs)
- Appropriate approach selected depends on policy context and objective



# Rationale

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- In US-EU trade relationship, with relatively low tariffs, non-tariff barriers are an increasingly important factor to address
- Deeper US-EU regulatory cooperation is viewed as essential activity to promote more compatible transatlantic regulatory approaches and enhanced economic ties



# Objectives

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- Promote better quality regulation
- Minimize unnecessary regulatory divergences
- Reduce unnecessary regulatory burdens
- Facilitate trade; minimize trade frictions
- Increase consumer confidence



# Tools and Approaches

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United States and EU have pursued a variety of policy initiatives over past decade which feature regulatory cooperation in the area of TBTs as key element:

- ❑ US-EU MRA (1998)
- ❑ Transatlantic Economic Partnership (1998)
- ❑ Guidelines for US-EU Regulatory Cooperation and Transparency (2002)
- ❑ US-EU Positive Economic Agenda (2002)
- ❑ US-EU Economic Initiative (2005)
- ❑ Framework for Enhancing Transatlantic Economic Integration (2007)
- ❑ Transatlantic Economic Council (2007)



# Main Elements

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Three main elements for promoting US-EU cooperation in the TBT field:

- Regulatory Cooperation Roadmap (sectoral dialogues and sector-specific agreements)
- OMB-EC Dialogue on good regulatory practices (methodological dialogue)
- Regulatory Cooperation Forum – senior-level platform for cross-cutting issues

Political oversight provided through the Transatlantic Economic Council and the US-EU Summit.



# Sectoral Cooperation

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To advance sectoral cooperation, the US and EC have developed:

- Roadmap for Regulatory Cooperation provides a framework for specific activities in 15 different TBT sectors (e.g., pharmaceuticals, telecommunications equipment, food safety, auto safety).
  - Focus generally on prospective regulations (or even earlier).
  - Cooperation often leverages work in plurilateral fora (e.g., ICH).
  - Aim to reduce TBTs and promote compatible regulatory approaches
- Guidelines for Regulatory Cooperation promote procedural steps for more effective dialogues (e.g., consultations, data sharing).
- Arrangements to permit sharing of non-public information between regulators has facilitated cooperation in key areas such as pharmaceuticals, medical devices, food safety.



# Sectoral Cooperation: Examples

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Some illustrations of US-EU sectoral cooperation in past year:

- Pharmaceuticals -- intensified cooperation on vaccines, pharmacovigilance and counterfeit medications; agreed common format for orphan drug designations
- Auto safety -- dialogue initiated to streamline adoption of global regulations, including cooperation on specific GTRs
- Marine equipment -- established a two-way alert system for unsafe equipment and agreed to expand the product scope of MRA
- Consumer products -- established a program for sharing information on recalls of unsafe products





# OMB-EC Dialogue

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- Dialogue established in 2005 between the US Office of Management and Budget (OMB) and relevant experts in the European Commission (led by Secretariat General)
  
- Focus is to address methodological issues (e.g., impact assessment) in order to improve our understanding of each others' regulatory systems and practices
  
- Ongoing work includes:
  - Comparison of respective practices on impact assessments
  - Exchanges of respective regulatory workplans



# Regulatory Cooperation Forum

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- High-Level Regulatory Cooperation Forum was established in 2005 as a platform for senior-level regulators to promote cooperation on cross-cutting regulatory topics – such as new technologies or policy developments that may impact multiple authorities on each side.

Current Forum activities include:

- Joint report on respective regulatory impact assessment guidelines
- Cooperation on safety of imported products



# TEC

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- The Transatlantic Economic Council (TEC) provides minister-level political guidance for implementation of the 2007 Framework for Advancing Transatlantic Economic Integration.
- Initial meeting was in November 2007 – with next meeting in May 2008.
- A number of regulatory cooperation objectives are being advanced for May meeting, for example:
  - promote acceptance of SDoC for electrical products in US
  - joint scientific validation of alternatives to animal testing
  - mitigate trade impacts stemming from implementation of EU's new chemicals regulation (REACH)



# US Experiences

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Through variety of approaches over the past decade, US-EU regulatory cooperation efforts have dramatically expanded:

- Cooperation now far deeper and broader – more decentralized and routine
- Confidence-building between regulatory counterparts is essential
- No “magic wand” – regulatory cooperation is technical, hard work
- Focus on prospective regulations is far easier than existing regulations
- No “one size fits all” approach – specific context matters
- Replicate models that work well – apply to other sectors/dialogues
- Near-term, practical results are key to maintain momentum/support
- Expectations management: benefits accumulate – robust over time



# EC Experiences

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TEC provides a new, superior method because:

- ❑ Highest level political commitment (US, EC Presidents)
- ❑ Stakeholder-driven agenda – ongoing stakeholder involvement
- ❑ Political oversight of technical negotiations



# Lessons Learned

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Based on experience advancing US-EU regulatory dialogues, the Forum identified the following “Best Cooperative Practices” in 2006:

- Define scope of cooperation clearly
- Identify appropriate mechanisms for cooperation
- Cultivate senior-level support for cooperative activity
- Provide sufficient resources to support cooperation
- Provide transparency and opportunity for stakeholder input
- Promote dialogue between own regulators on best cooperative practices



# Further Information

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- [http://www.ustr.gov/World\\_Regions/Europe\\_Middle\\_East/Europe/US\\_EU\\_Regulatory\\_Cooperation/Section\\_Index.html](http://www.ustr.gov/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/Section_Index.html)
- [http://ec.europa.eu/enterprise/enterprise\\_policy/inter\\_rel/eu\\_us/index\\_en.htm](http://ec.europa.eu/enterprise/enterprise_policy/inter_rel/eu_us/index_en.htm)