

Joint Report on the Roadmap for EU-US Regulatory Cooperation

At the June 2005 EU-US Summit, the United States and European Commission issued the Roadmap for EU-US Regulatory Cooperation to provide a framework for cooperation on a broad range of important horizontal and sectoral areas. Under this ongoing multi-year initiative, US and European authorities aim to build effective mechanisms to promote better quality regulation, minimize unnecessary regulatory divergences to facilitate transatlantic trade and investment and increase consumer confidence in the transatlantic market.

This joint report highlights key Roadmap achievements over the past year and highlights some future work that the United States and the European Commission intend to advance in the coming year – both specific sectoral activities as well as horizontal initiatives. This work will evolve as each side continuously examines areas of mutual interest for regulatory cooperation, and considers input from interested transatlantic stakeholders.

Since the 2005 EU-US Summit, we have advanced EU-US regulatory cooperation in three principal ways:

- 1) We established the EU-US High-Level Regulatory Cooperation Forum and held its initial meeting in Brussels on "good regulatory practices" in January, followed by a meeting in Washington D.C in May on "best cooperative practices and regulatory workplans." As a result, we have developed a set of Best Cooperative Practices to guide regulators and complement our Guidelines on Regulatory Cooperation and Transparency.
- 2) We initiated a dialogue between the US Office of Management and Budget and relevant experts in the European Commission to address horizontal regulatory management issues (e.g., transparency, risk assessment, impact assessment, public consultation) in order to improve our understanding of each others' regulatory systems and practices.
- 3) US, European Commission, and, where relevant, European Community regulators are pursuing a broad range of sector-specific activities covered by the Roadmap for EU-US Regulatory Cooperation. We achieved notable progress in a number of areas, including pharmaceuticals, consumer product safety, and energy efficiency. We are building on this successful work by pursuing cooperation on new topics (see report annex).

Further information about cooperative activities under this initiative is available at:

http://www.ustr.gov/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/Section_Index.html

http://europa.eu.int/comm/enterprise/enterprise_policy/gov_relations/internatl_regul_coop_eu_us/index.htm

I. EU-US High-level Regulatory Cooperation Forum

- We established the High-level Regulatory Cooperation Forum as a platform for activities related to promoting cooperation on cross-cutting regulatory cooperation topics and developing a future cooperative agenda.
- We conducted two High-level Regulatory Cooperation Forum events: 1) Conference on Good Regulatory Practices in January 2006, hosted by the European Commission in Brussels; 2) Conference on Best Cooperative Practices and US and EC Regulatory Workplans in May 2006, hosted by the US Government in Washington D.C.
- Based on Forum discussions and the experiences gained through a wide range of EU-US regulatory cooperation activities, we developed an agreed set of Best Cooperative Practices ([link](#)) to guide regulators and complement the EU-US Guidelines on Regulatory Cooperation and Transparency.
- Through our exchanges, we identified a range of new topics for regulatory cooperation to pursue under selected sectoral dialogues (see report annex).
- Building on the success of the first two meetings, we will continue this exchange at future Forum events and other conferences.

II. Horizontal Initiatives

A. OMB-EC Dialogue:

- We established an informal dialogue led jointly by the US Office of Management and Budget (OMB) and the relevant services of the European Commission to discuss general regulatory policies and practices of mutual interest, and promote a better understanding of our respective regulatory systems.
- The OMB-EC Dialogue met in September 2005 (Washington) and January 2006 (Brussels) to discuss good regulatory practices, with a focus on transparency provisions and public consultation, and our respective impact assessment methodologies.
- Building on extensive exchanges, we are comparing our respective guidelines for conducting impact assessments.
- In the coming year, the Dialogue is considering to conduct a comparison of our respective risk assessment methodologies.
- We will explore how our horizontal dialogue on good regulatory practices (e.g., transparency, impact assessments) can feed more effectively into ongoing sectoral dialogues.

B. EU-US Experts Exchange Program:

- Our horizontal and sectoral dialogues in the past year have underscored the importance of promoting more extensive exchanges of US and EC regulatory experts.
- We intend to enhance mechanisms to promote exchanges of US and European regulatory experts in specific areas/projects of mutual interest that otherwise cannot be funded through existing regulatory agency budgets.
- We are working to target such exchanges to specific priority areas of regulatory cooperation, such as discrete topics identified in the Roadmap for Regulatory Cooperation.

III. Sectoral Activities

1. Pharmaceuticals

1.1 Human medicinal products

Objective: Cooperation between the US Food and Drug Administration (FDA), DG Enterprise and Industry/Pharmaceuticals Unit and the European Medicines Agency (EMA) on matters related to ensuring the safety, quality, and efficacy of pharmaceutical products.

In the past year, FDA, DG Enterprise and Industry and the EMA substantially enhanced their regulatory dialogue and expanded their exchange of information and data on pharmaceuticals.

- FDA, DG Enterprise and Industry and EMA pursued a broad range of robust cooperative work outlined in the Implementation Plan for Medicinal Products for Human Use, including sharing of regulatory and inspectional information, scientific exchanges, and parallel scientific advice.
- FDA and EMA pursued a pilot program to support parallel scientific advice on pharmaceuticals. After successful work on five drugs in the past year, this pilot program was renewed in 2006.
- FDA and EMA initiated cooperation in a new area in the past year – pharmacogenomics. In May 2006, FDA, EMA and the EC issued agreed principles for processing joint FDA-EMA voluntary genomic data submissions, including joint briefings for sponsors. This process helps ensure that regulatory authorities are familiar with issues arising from the integration of pharmacogenomics in drug development and that industry has an opportunity to hear scientific perspectives from FDA and EMA.

- FDA, DG Enterprise and Industry and EMEA are collaborating effectively on the harmonization of technical requirements for registering pharmaceuticals through the International Conference on Harmonization (ICH). Over 50 harmonized guidelines have been issued to date on various issues of pharmaceutical quality, safety, efficacy and electronic exchange of information. At the Steering Committee meeting in November 2005, discussion began on strategies to make the process more efficient. Discussions on the “Future of ICH” will continue at the next meeting in Yokohama in June 2006.
- FDA and EC experts plan to intensify cooperation in the next year, with particular focus on vaccines (including preparedness for influenza pandemic), medicines for children; medicines for rare diseases (‘orphans’), oncology, pharmacogenomics and counterfeit medicines.
- FDA and EC experts plan to hold a workshop in 2007 on better regulation of medicinal products through transatlantic dialogue.

1.2. Veterinary medicinal products

Objective: Enhance the existing regulatory dialogue between the FDA and the European Commission and the European Medicines Agency (EMA), building upon ongoing cooperative activities in the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH).

- FDA, the European Commission, and EMA are pursuing cooperation on: 1) harmonized guidelines for regulatory requirements where significant differences exist among VICH members; 2) the global response to significant emerging issues and science that impact on regulatory requirements within VICH regions and/or adopted VICH guidelines; and 3) promotion of consultation and communication mechanisms that result in wider international awareness and acceptance of VICH guidelines.
- Through a nine step process, VICH has finalized 41 guidance documents since its start. Expert Working Groups meet throughout the year and report their progress to the VICH Steering Committee.
- The 17th VICH Steering Committee met to oversee and manage harmonization activities in Japan, October 31-November 1, 2005. The 18th VICH Steering Committee meeting, first meeting of the Phase II of the VICH process, was held in London at EMA, May 31 – June 1, 2006. The 19th VICH Steering Committee will be held in Washington in January 2007.

2. *Automobile Safety*

Objective: Cooperation between the US National Highway Traffic Safety Administration (NHTSA) and DG Enterprise and Industry/Automobile Unit in areas of automobile safety regulations.

- NHTSA-DG Enterprise and Industry are pursuing regulatory cooperation on safety of hydrogen fuel cell vehicles and vehicle compatibility.
- We are exploring cooperation on the regulatory approaches for electronic stability control systems and collision avoidance systems.
- We are discussing ways to promote a science-based approach to global technical regulations under the United Nations 1998 Agreement.

3. *Information and Communications Technology Standards in Regulations*

Objective: Cooperation between the US Department of Commerce and DG Enterprise and Industry and DG Information Society and Media on the use of information and communication technology (ICT) standards in accordance with the Terms of Reference established in March 2004.

US and EC experts agreed on a rolling work plan and work is well underway on many of the tasks envisioned. Key accomplishments include:

- Conducted two successful international workshops within the framework of the ICT dialogue on e-accessibility: one on public procurement and one on conformity issues related to the accessibility of ICT products and services.
- The US Access Board will review the standards for electronic and information technology covered by section 508 of the Rehabilitation Act and by section 255 of the Telecommunications Act. The US Access Board will issue an invitation to the European Commission to participate in the relevant Federal Advisory Committee to ensure coherence in requirements to the greatest extent possible.
- The EC has launched a mandate to the European Standards Organizations for developing a standard for accessibility of ICT products to be used in public procurement. This mandate specifically calls for coordination with US developments.
- In the second half of 2006, an exchange of information is planned, and a study tour is being considered, focusing on how US government agencies determine/demonstrate that ICT products conform to requirements. The EC is interested in learning from US government and industry experience on conformity assessment.

- Both sides are working to identify better methods to assess and quantify progress made in providing greater access to ICT products and are interested in exchanging experiences.

4. *Cosmetics*

Objective: Cooperation between the US Food and Drug Administration (FDA) and DG Enterprise and Industry/Cosmetics Unit regarding: (a) alternative (i.e., non-animal) testing methods; (b) respective regulatory approaches applied in the areas of hair dyes and sunscreen ingredients (UV filters); and (c) other projects of mutual interest.

- FDA and the EC are pursuing cooperation in cosmetics and certain over-the-counter drugs harmonization activities under the Cosmetics Harmonization and International Cooperation (CHIC) process.
- In the framework of CHIC, FDA and DG Enterprise and Industry are exchanging extensive information on the respective regulatory systems, safety concerns, and alternative test methods, including the discussion on the establishment of a rapid alert system to exchange data on adverse reactions.
- The US Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the European Centre for the Validation of Alternative Methods (ECVAM) are collaborating closely on the development and validation of alternative test methods to animal testing for cosmetic ingredients.

5. *Consumer Product Safety*

Objective: Cooperation between the US Consumer Product Safety Commission (CPSC) and DG Health and Consumer Protection in association with DG Enterprise and Industry regarding the safety of consumer products.

CPSC and DG Health and Consumer Protection launched a senior-level dialogue and signed an exchange of letters in February 2005 to implement mutually agreed Guidelines for Information Exchange and Cooperation intended to strengthen bilateral communication and to improve U.S and EU consumer health and safety protection. In the past year, CPSC and DG Health and Consumer Protection have built upon these Guidelines through pursuit of a range of specific cooperative projects in the area of consumer product safety, including:

- Joint support for the International Consumer Product Health and Safety Organization (ICPHSO) and creation of the International Consumer Product Safety Caucus (ICPSC) for government regulators to discuss international consumer product safety issues of common concern.

- Collaboration on strategies to increase regulatory compliance of products manufactured in China, including training opportunities.
- Cooperation on standards for child-resistance mechanisms for cigarette lighters.
- Sharing of product recall information involving magnetic toys and lead in jewelry.
- Enhanced cooperation and understanding in the area of science-based risk assessment. Joint investigation into the respective risk assessment analyses concluded in certain cases.

6. *Consumer Protection Enforcement Cooperation*

Objective: Develop mutual assistance mechanisms in the field of cross-border consumer protection enforcement cooperation. Build on the existing informal dialogue between the European Commission/DG Health and Consumer Protection and the US Federal Trade Commission (FTC) in the ways foreseen by article 18 of Regulation 2006/2004 on consumer protection cooperation (CPC), including through the possible establishment of a EU/US mutual assistance agreement.

- Congress has considered, and the Senate has passed, legislation mirroring the CPC provisions on cross-border consumer protection enforcement. FTC and DG Health and Consumer Protection are laying the groundwork for enhanced effective cooperation.

7. *Unfair Commercial Practices*

Objective: Establish regulatory dialogue between the FTC and DG Health and Consumer Protection on unfair commercial practices. This dialogue will aim at increasing convergence in this area.

- In October 2005, DG Health and Consumer Protection studied extensively how the FTC has implemented its laws against unfairness and deception. Since then, DG Health and Consumer Protection has shared with FTC updates on its process for transposing the Unfair Commercial Practices Directive.

8. *Nutritional Labeling*

Objective: Cooperation between FDA and DG Health and Consumer Protection on issues of mutual interest in the field of nutritional labelling.

- Experts from FDA and DG Health and Consumer Protection are engaged in discussions on regulatory issues relating to health claims, nutrition labeling, fortification, supplements, and infant formula. Specific areas under discussion include: 1) possible collaboration on the EU's Estimated Average Requirement (EAR) and the US Recommended Daily Allowances (RDA) for nutrients; and 2) cooperation on food labels.

- FDA and DG Health and Consumer Protection concluded a confidentiality arrangement in 2005 to facilitate the sharing of non-public information in this subject area.

9. *Food Safety*

a.1. Objective: Cooperation between the US Food and Drug Administration (FDA), DG Health and Consumer Protection and DG Enterprise and Industry on broad range of food safety issues of mutual interest.

- FDA and Health and Consumer Protection experts are pursuing specific regulatory cooperation projects in the areas of seafood and dairy.
- FDA and DG Health and Consumer Protection concluded an exchange of letters in June 2005 to facilitate the sharing of non-public data/information.
- FDA and DG Health and Consumer Protection concluded an implementation plan in September 2005 on the sharing of confidential information related to food safety, including guidance documents, documentation relating to controls, and information relating to notification system relevant to food safety.
- FDA and DG Health and Consumer Protection initiated in June 2006 an informal exchange on food nanotechnology cooperation.

a.2. Objective: Cooperation between DG Health and Consumer Protection and the US Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) on legislation concerning meat and meat products.

- FSIS, FDA and DG Health and Consumer Protection held a seminar focused on Hazard Analysis and Critical Control Point (HACCP). The meeting was successful and the main goal was reached. However it appeared evident that the two systems, although based on the same principles, are still different for important points.
- FSIS and DG Health and Consumer Protection are exploring how to concretely pursue equivalence between the respective Hazard Analysis and Critical Control Point (HACCP) based control systems for meat and meat products.
- FSIS and DG Health and Consumer Protection are exploring a new equivalence determination exercise between the relevant US and EU legislation.

b. Objective: Cooperation between FDA and the European Food Safety Authority (EFSA) on food safety issues, including information sharing on risk assessments.

- FDA and EFSA have initiated a cooperative dialogue.
- FDA and EFSA concluded a confidentiality arrangement to facilitate the sharing of non-public data/information relating to food issues.
- FDA is assisting EFSA in the development of a strategy for the conduct of microbial risk assessments.

c. Objective: Establish new regulatory dialogue between the USDA, EFSA and DG Health and Consumer Protection in order to provide greater transparency regarding each side's development of risk assessments for animal, plant, and consumer safety.

- USDA and EFSA are discussing approaches to risk assessments and future plans based on our common interest in promoting sound science.
- USDA and EFSA are exploring an exchange of staff to facilitate mutual understanding of each other's approach to the risk assessment process. In particular, this would include EFSA hosting an APHIS expert in risk analysis. In return APHIS offered to host an EFSA expert at one of APHIS' risk assessment centers in the United States.

10. Marine Equipment

Objective: Consistent with the objectives of the US-EC Marine Equipment MRA, enhance the regulatory dialogue between the US Coast Guard (USCG) and DG Energy and Transport and DG Trade¹ assisted by the European Maritime Safety Agency (EMSA) aimed at increased convergence of US and EU technical regulations for marine equipment.

- USCG and DG Energy and Transport are in the process of developing a two-way Alert System for the notification of urgent safety issues associated with marine equipment approved under the MRA.
- The MRA has enhanced communication and cooperation concerning the testing methods and proper certification of equipment safety to ensure their compliance with IMO standards.
- USCG and EC to explore achieving equivalent US and EU technical regulations for specific marine equipment and expanding the product scope of the US-EC Marine Equipment MRA.

¹ In this context, reference to DG Energy and Transport/DG Trade must be understood to include the necessary consultations with Member States within the EU.

11. Eco-Design

Objective: Cooperation between the US Environmental Protection Agency (EPA) and DGs Energy and Transport, Environment and Enterprise and Industry in the area of eco-design of energy-using products at the appropriate technical level.

- EPA and the EC to explore possibilities to share experience on respective approaches relative to: the eco-design of energy-using products (EuP), Integrated Product Policy (IPP), restrictions on hazardous substances (RoHS) and waste from electrical and electronic equipment (WEEE) and to exchange information informally on standards and other topics of mutual interest.
- EPA to share information informally on approaches and activities at EPA including the new IEEE standard 1680 Electronic Product Environmental Assessment Tool (EPEAT) and Design for Environment (DfE) program.

12. Chemicals

Objective: Pursue informal cooperative dialogue, in the spirit of the EU-US Guidelines on Regulatory Cooperation, between the US Environmental Protection Agency (EPA), DG Environment, DG Enterprise and Industry and DG Health and Consumer Protection and relevant agencies on chemicals related issues of mutual interest.

- The US EPA and the European Commission are together leading and will continue to collaborate in the OECD Chemicals Committee's work on the development of the Global Chemicals Portal, among other pertinent and emerging issues. The US High Production Volume Information System (HPVIS) recently came online and will be one of the national databases contributing to the Portal.

13. Energy Efficiency

Objective: Building upon the existing cooperative dialogue between the US Environmental Protection Agency (EPA), US Department of Energy and the European Commission's DG Energy and Transport, engage on a broad range of energy efficiency issues of mutual interest.

- We have finalised the negotiations on a new EU-US agreement on Energy Star for office equipment. The new agreement will contain more ambitious energy efficiency criteria. We plan to sign this Agreement by fall 2006.

- The US and the EC have revised the energy efficiency criteria for imaging equipment (printers, copiers, scanners, fax machines, mailing machines, and multifunction devices) and computer monitors. These revisions make the specifications more stringent, such that ENERGY STAR qualified models represent the top performers in the market without a sacrifice in features or performance. The revision of the energy efficiency criteria for computers will be finalized soon. We will continue our efforts to keep the criteria up to date in order to further foster energy efficiency in office equipment.
- We intend to pursue further cooperation on energy efficiency on the basis of the renewed EU-US Energy Star Agreement.

14. Telecommunications and Radiocommunications Equipment, Electromagnetic Compatibility

Objective: Building on existing regulatory dialogues between the US Federal Communications Commission (FCC) and the European Commission, and the US-EC Mutual Recognition Agreement (MRA), pursue enhanced cooperation on regulatory approaches in the areas of telecommunications, radiocommunications equipment and electro-magnetic compatibility.

- The FCC and the EC are consulting on regulatory developments in our respective markets and will consider cooperative approaches for achieving consistent regulatory treatment of telecommunications and radiocommunications products.
- FCC and EC will pursue a dialogue on regulatory approaches relating to software-defined radio and cognitive radio and on radio spectrum policy.

15. Medical Devices

Objective: Enhance the existing regulatory dialogue between the FDA and DG Enterprise and Industry and DG Trade on medical devices, building upon ongoing cooperative activities in the Global Harmonization Task Force (GHTF) and consistent with the objectives of the US-EC MRA annex on medical devices.

- Our regulatory authorities are promoting cooperative activities in the Global Harmonization Task Force (GHTF), including the preparation of guidance documents and compatible regulatory approaches for medical devices.
- We have agreed to expand the FDA-DG ENTR-EMEA confidentiality arrangement to include exchanges of information relating to medical devices.
- We are pursuing implementation of the US-EC MRA annex on medical devices and an agreed approach for bringing the MRA annex into operation.
- We are exploring the possible expansion of the product scope of the EU-US MRA annex of medical devices to include in-vitro diagnostic devices.

Annex: New Topics for EU-US regulatory cooperation in 2006/2007

1. Horizontal OMB-EC dialogue:

- Finalise joint comparison of our respective practices on impact assessments
- Compare notes and approaches on how to carry out risk assessments
- Consider potential training schemes on better regulation topics
- Compare respective rule-making procedures – linkages with other studies
- Conduct exchange and discussion of our respective regulatory workplans
- Explore how horizontal dialogue on good regulatory practices (e.g., transparency, impact assessments) can feed more effectively into ongoing sectoral dialogues

2. Sector-specific dialogues:

Pharmaceuticals:

- Intensify cooperation, with particular focus on vaccines (including preparedness for influenza pandemic), medicines for children; medicines for rare diseases ('orphans'), oncology, pharmacogenomics and counterfeit medicines
- Hold workshop in 2007 on better regulation of medicinal products through transatlantic dialogue

Telecommunications and Radiocommunications equipment

- Promote dialogue/cooperation on regulatory approaches relating to software-defined radio and cognitive radio and on radio spectrum policy

Energy Efficiency

- Pursue cooperation on the basis of the renewed EU-US Energy Star Agreement

Medical Devices

- Expand the FDA-DG ENTR-EMEA confidentiality arrangement to include exchanges of information relating to medical devices
- Expand the scope of the US-EC MRA annex to include in-vitro diagnostic devices

Marine Equipment

- Establish a two-way alert system for sub-standard marine equipment
- Expand the product scope under the EU-US MRA

Automobile Safety

- Explore cooperation on the regulatory approaches for electronic stability control systems and collision avoidance systems