April 2007

Joint Report on the Roadmap for US-EU Regulatory Cooperation

At the June 2005 US-EU Summit, the United States and European Commission issued the Roadmap for US-EU Regulatory Cooperation to provide a framework for cooperation on a broad range of important horizontal and sectoral areas. Over the past two years, U.S. and European authorities have expanded significantly our cooperative activities and established effective mechanisms under this ongoing initiative to promote better quality regulation, minimize unnecessary regulatory divergences to facilitate transatlantic trade and investment and increase consumer confidence in the transatlantic market. We highlighted main Roadmap activities in a joint report issued at the June 2006 US-EU Summit.

This Joint Report focuses on key Roadmap activities since June 2006 and highlights some future work that the United States and the European Commission intend to advance in the coming year. This work will evolve as each side continuously examines areas of mutual interest for regulatory cooperation, and considers input from interested transatlantic stakeholders.

Horizontal Cooperation

- U.S. and EC authorities have agreed to promote the application of the *U.S.-EU Guidelines for Regulatory Cooperation and Transparency* through the identification of a few specific pilot projects in 2007. Experience gained by regulators applying these Guidelines could provide a basis for wider application and more ambitious cooperation.

OMB-EC Dialogue

- Experts from the Office of Management and Budget (OMB) and the EC finalized a joint comparison of our respective practices on impact assessments, and agreed to conduct regular exchanges of our respective regulatory workplans.

Pharmaceuticals

- We are building significantly upon the intensive cooperative efforts among the U.S. Food and Drug Administration (FDA), DG Enterprise and Industry, and the European Medicines Agency (EMEA) on matters related to ensuring the safety, quality, and efficacy of pharmaceutical products under the current Confidentiality Arrangement and corresponding Implementation Plan. In the past year, FDA, EMEA and DG Enterprise experts engaged in over 800 interactions on almost 200 topics, and conducted nearly 20 scientific staff exchanges and visits.

- FDA and EC experts are collaborating on an update of the current "Implementation Plan for Medicinal Products for Human Use" based upon experience gained in the past year and work by both sides. FDA and the EC plan to issue a revised Implementation Plan in June 2007.

- Our experts are continuing the Pilot Program on parallel scientific advice for pharmaceuticals and the cooperative program on joint advice for pharmacogenomics. FDA and the EC are currently working on joint guidance for parallel designation of orphan (rare diseases) medical products.

- FDA and the EC are working to intensify our cooperation in 2007 in the areas of vaccines (including preparedness for influenza pandemic), pediatric medicines, oncology, counterfeit medicines and pharmacovigilance.

- FDA and the EC have agreed to continue sharing with each other new developments regarding similar biological medicinal products and the regulatory framework and scientific basis for medicines safety monitoring.

- FDA and DG Enterprise have agreed to conduct a bilateral workshop with industry in Fall 2007 in Brussels to address better regulation through US-EU cooperation on administrative simplification in the regulation of medicinal products. The workshop will aim to identify opportunities for administrative simplification through US-EU cooperation and provide a basis for developing roadmaps for harmonization work.

Medical Devices

- In Spring 2007, FDA and DG Enterprise experts resumed discussions on resolving the status of the US-EC Mutual Recognition Agreement annex on medical devices and expanding a more productive bilateral collaboration process on medical devices.

- Our experts have agreed to expand the existing regulatory cooperation and exchange of information by developing a confidentiality arrangement that allows for the sharing of non-public information between FDA and DG Enterprise and Industry. FDA and DG Enterprise aim to conclude this confidentiality arrangement by Summer 2007.

- Following the signing of a confidentiality arrangement, our experts plan to share information on product recalls, vigilance and serious incidents linked to the use of medical devices in the EU and US, and on clinical investigations. FDA and DG Enterprise are exploring sharing regulatory perspectives on scientific and policy issues concerning medical devices, e.g., phthalates, dental amalgam, combination products and nanotechnology, as resources permit.

Cosmetics

- FDA and DG Enterprise initiated formal bilateral regulatory cooperation discussions in the area of cosmetics. Our regulators have agreed to expand the existing Exchange of Letters to include cosmetics and over-the-counter drugs, some of which are regulated as cosmetics in the EU, to allow the sharing of confidential information. FDA and the EC

aim to conclude a confidentiality arrangement by Summer 2007 to include information exchanges relating to cosmetics products.

- FDA and the EC continue to engage in the Cosmetics Harmonization and International Cooperation (CHIC) process with Canada and Japan. FDA and foreign counterparts are exploring possible industry participation in a revised international process.

- Our respective experts continue the collaboration between the US Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the European Centre for the Validation of Alternative Methods (ECVAM) on the pursuit of developing and validating alternative test methods. In addition, we continue efforts to promote innovation on approaches to reduce the need for animal tests for cosmetics products.

- FDA and EC experts are discussing specific regulatory cooperation in the area of UV filters and color additives.

Chemicals

- The U.S. Environmental Protection Agency (EPA) and the EC have initiated a dialogue to promote the sharing of knowledge and work toward regulatory convergence on scientific, technical, and chemicals management challenges, including those relating to the REACH implementation projects (RIPs), as appropriate. EPA and the EC developed an agreed workplan in April 2007 outlining specific areas of cooperation to be pursued in 2007 and beyond.

- Our experts are exploring possible exchanges, consistent with available resources, of information and personnel between EPA, the relevant regulators in the Commission, and the future European Chemicals Agency (ECHA) to foster exchange of practices and assessment methodologies.

- EPA and European regulators are expanding U.S.-EU cooperation in advancing the ongoing activities in the OECD, e.g., on risk assessment, Good Laboratory Practices (GLP), Globally Harmonized System of Classification and Labelling of Chemicals (GHS), study templates, information technology for data submissions, as well as on alternative test methods (QSAR), test methods and risks of manufactured nanomaterials.

Automobiles

- The U.S. National Highway Traffic Safety Administration (NHTSA) and DG Enterprise have initiated a dialogue in the form of an annual bilateral meeting to discuss common challenges in the area of vehicle safety and fuel economy. The objective is to harmonize regulations either bilaterally or on a multilateral basis as a way to reduce barriers to transatlantic trade while promoting safety and fuel economy.

- NHTSA and DG Enterprise continue to promote a science-based approach to the establishment of Global Technical Regulations (GTRs) for automobiles under the 1998 Agreement in the UNECE framework. Our experts have agreed to expedite the establishment of GTRs while focusing efforts on subject areas which offer greater safety benefits and have the potential to reduce costs.

- NHTSA and DG Enterprise agreed in March 2007 to co-sponsor efforts under the UNECE 1998 Agreement to conclude and establish in 2008 a global technical regulation on electronic stability control systems for automobiles. This cooperation could greatly contribute to the reduction of car crashes and save lives.

Electrical Equipment

- DG Enterprise and Industry's Unit for Mechanical, Electrical and Telecommunications Equipment and the Occupational Safety and Health Administration's (OSHA) Office of Technical Programs and Coordination Activities have agreed to initiate discussions in the latter half of 2007 with a view to exchange information on suppliers' declaration of conformity and other topics of mutual interest in the area of conformity assessment for the safety of electrical equipment.

Consumer Product Safety

- U.S. Consumer Product Safety Commission (CPSC) expanded its product recall procedures in August 2006 to obtain international distribution information from companies conducting recalls. CPSC now notifies DG SANCO directly through established MOU channels if a recalled product is sold in the EU, as well as Prosafe (the European organization of market surveillance and compliance authorities) and relevant EU authorities. DG SANCO provides CPSC with reciprocal information on EU product recalls and other corrective measures taken in respect of dangerous products.

- Through expert exchanges of detailed scientific reports, compliance data, and cost-benefit analysis with CPSC, DG SANCO took a decision in 2006 requiring cigarette lighters to be child-resistant and banning certain lighters ("novelty lighters") especially appealing and therefore especially dangerous to children. These measures entered into force in 2007. DG SANCO also started reflections on RIP (reduced ignition propensity) cigarettes, based on earlier exchanges with CPSC.

- CPSC and DG SANCO are now sharing with their Chinese government counterparts best practices and traceability data of violative manufacturers with relation to Chinese manufactured product recalls and other corrective measures. This coordinated work with China helps leverage more effective pre-shipment conformity assessment to relevant US and EU safety requirements.

Information and Communications Technology Standards in Regulation

U.S. and EC experts continue to pursue an agreed workplan for cooperation on e-accessibility, including:

- The U.S. Access Board is reviewing the standards for electronic and information technology covered by section 508 of the Rehabilitation Act and by section 255 of the Telecommunications Act. Following the invitation from the U.S. Access Board, the EC is participating in the Access Board Advisory Committee to facilitate coherence in requirements to the greatest extent possible.

- The EC is finalizing a mandate to the European Standards Organizations for developing an inventory of accessibility requirements and an assessment of suitable testing and conformity schemes for accessibility of ICT products to be used in public procurement – the mandate is to permit USG participation in the process.

- Our experts are exploring possible study tours and consumer outreach to familiarize users and consumers with industry practices.

Telecommunications and Radiocommunications Equipment

Federal Communications Commission (FCC), DG Enterprise, and DG Information Society experts initiated a dialogue and cooperation on regulatory approaches relating to software-defined radio, cognitive radio, and ultra-wideband technology

Marine Equipment

- The US Coast Guard, DG Transport, and the European Marine Safety Agency agreed to establish a two-way alert system for sub-standard marine equipment – to be implemented by the end of 2007. The US and EC have agreed in principle to expand to product scope of the US-EU Marine Equipment Mutual Recognition Agreement, with potential additional products to be identified later in 2007.

Energy Efficiency

- EPA and the EC are pursuing cooperation on the basis of the renewed EU-US Energy Star Agreement for office equipment. Our regulators are exploring expansion of the agreement to include consumer electronics.

- The EC and the US, involving additional interested parties/countries, are pursuing a dialogue on energy efficiency measurement methods/standards and benchmarking, in particular for worldwide traded goods.

Eco-Design

- EPA and EC experts are exploring a dialogue or regular informal exchanges on issues relating to eco-design, the EU's development of its Energy-using Products (EuP) directive, and relevant EPA activities. The EC is offering to share the working documents for the eco-design Consultation Forum with the USG.

- EPA is pursuing consultations with the EC on the development of the EU's EuP implementating measure for computers, and is exploring opportunities to include longstanding cooperation on Energy Star work to further inform EuP criteria where applicable.

Nutritional Labeling

- FDA and DG SANCO completed an Implementation Plan under their confidentiality arrangement. Our experts held a joint meeting on nanotechnology in food to share perspectives on the issue.