June 2004

Roadmap for U.S.-EU Regulatory Cooperation and Transparency

As a key element of the EU-U.S. Positive Economic Agenda, U.S. and European Commission (EC) authorities continue to promote EU-U.S. regulatory cooperation, in particular through implementation of the EU-U.S. Guidelines for Regulatory Cooperation and Transparency as negotiated under the Transatlantic Economic Partnership (TEP). Implementation of the Guidelines has yielded good progress in a number of regulatory areas, but the scope for potential EU-U.S. cooperation is far broader.

In addition to pursuing current regulatory cooperation projects, we are working to identify additional specific cooperative projects, as well as horizontal initiatives and possible improvements to the scope and operation of the Guidelines. We will also endeavour to clarify the role of the Guidelines as a policy tool for EU and U.S. regulators in order to help our regulators define their own efficient approaches for promoting effective regulatory cooperation.

This EU-U.S. roadmap outlines a range of specific regulatory cooperation activities we jointly intend to pursue during the next year. Our work will evolve as each side continuously examines other areas of mutual interest for regulatory co-operation, and considers input from interested transatlantic stakeholders. The TEP Steering Group reviews the implementation and functioning of these Guidelines, as well as progress on regulatory co-operation in general, on an ongoing basis.

I Specific Sectoral Cooperation

A. On-going Cooperation

1. Pharmaceuticals

Objective: Cooperation between the U.S. Food and Drug Administration (FDA), DG Enterprise/Pharmaceuticals Unit and the European Agency for the Evaluation of Medicinal Products (EMEA) on matters related to ensuring the safety, quality, and efficacy of pharmaceutical products.

Next Steps: Expand the exchange of information and data on pharmaceuticals as agreed under the September 2003 arrangement between FDA, DG Enterprise and the European Agency for the Evaluation of Medicinal Products (EMEA). As part of this arrangement, engage in parallel scientific advice; promote scientific personnel exchanges and joint meetings; share respective draft guidance on drug safety issues, including adverse reactions; and examine cases where U.S. and EU authorities have adopted different approval decisions for specific drugs ("benchmarking exercises"). Consider additional issues for possible cooperation.

2. Auto Safety

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

Next Steps: Develop agreed workplans for the specific regulatory projects to be pursued under the NHTSA-DG Enterprise regulatory dialogue created under the June 2003 exchange of letters.

3. Information and Communications Technology Standards

Objective: Identify and pursue information exchange on the use of information and communication technology (ICT) standards in support of regulations.

Next Steps: Pursue cooperation on specific projects identified under a new EU-U.S. dialogue initiated in March 2004 and coordinated by the Commerce Department and DG Enterprise. Initial projects under this dialogue include e-accessibility, security, and biometrics.

4. Cosmetics

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

Next Steps: Pursue regulatory cooperation activities as outlined in agreed 2003 project workplan. Identify possible new areas for cooperation as part of the Cosmetics Harmonization and International Cooperation (CHIC) process

5. Consumer Product Safety

Objective: Cooperation between the U.S. Consumer Product Safety Commission (CPSC) and DG SANCO regarding safety notices and corrective actions of hazardous consumer products.

Next Steps: Pursue an arrangement between CPSC and DG SANCO to facilitate the sharing of data/information from the RAPEX System. RAPEX serves as a single rapid alert system for dangerous consumer products in Europe. All non-food products intended for consumers, or likely under reasonably foreseeable conditions to be used by consumers, are included within the scope of RAPEX, with the exception of pharmaceutical products.

6. Nutritional Labeling

Objective: Cooperation between FDA and DG SANCO on issues of mutual interest in the field of nutritional labeling.

Next Steps: Compare scope of nutritional labeling requirements in the United States and the EU. Identify specific activities for cooperation on technical issues such as reference values for nutrient labeling, nutrient definitions, and energy conversion factors.

B. New Cooperation

1. FDA-DG SANCO Regulatory Dialogue

Objective: Establish broad new FDA-SANCO regulatory dialogue. Identify specific regulatory cooperation projects of mutual interest.

2. Regulatory Dialogues between the European Commission and the U.S. Government involving European Regulatory Agencies

Objective: Examine improved regulatory co-operation in the following areas:

a. Establish regulatory dialogue between FDA, the European Commission, and the European Food Safety Authority (EFSA).

b. Enhance ongoing regulatory cooperation between the European Commission and FDA and the European Agency for the Evaluation of Medicinal Products (EMEA).

c. Explore possible new or enhanced regulatory dialogues in areas of mutual interest between the European Commission and the U.S. Government, involving, where appropriate, other relevant European Regulatory Agencies.

3. CPSC-DG SANCO Regulatory Dialogue

Objective: Establish a regulatory dialogue between CPSC and DG SANCO regarding the EU's revised General Product Safety Directive.

4. Eco-Design

Objective: Explore possible cooperation between the U.S. Environmental Protection Agency (EPA) and DGs Energy and Transport, Environment and Enterprise in the area of eco-design of energy-using products.

C. Additional Regulatory Discussions

Chemicals

Objective: Ongoing informal discussions, in the spirit of the Guidelines, between the U.S. Environmental Protection Agency (EPA), DGs Environment and Enterprise and relevant agencies on chemicals related issues of mutual interest.

Next Steps: Continue informal discussions, where appropriate, on issues of mutual interest both through bilateral exchanges and in the margins of other meetings, such as the OECD.

II Horizontal Initiatives

A. General Regulatory Policy – explore a regular informal dialogue between the relevant authorities of the European Commission and the U.S. Government on regulatory policy issues and practices of mutual interest. Examples could include: practices and procedures in regulatory processes, tools, transparency and public consultation and impact assessment methodologies.

B. Regulatory Workplans - establish a mechanism for regular exchange and discussion of annual U.S. and EC regulatory workplans. Such a review could help identify additional prospective areas for EU-U.S. regulatory cooperation.

C. U.S.-EC Regulatory Exchanges - identify resources and mechanisms to promote exchanges of U.S. and EC regulatory experts in specific areas/projects of mutual interest.

D. U.S.-EC Regulatory Seminar/Workshops - conduct seminars/workshops where U.S. and EC regulators can exchange views and raise awareness of our respective regulatory activities, priorities and approaches on issues of mutual interest.

E. Outreach Activities - identify and pursue approaches to promote: 1) broader visibility/awareness within the USG, EC and among transatlantic stakeholders of the Guidelines; 2) the importance of EU-U.S. regulatory cooperation; and 3) opportunities for stakeholders to propose regulatory cooperation activities under the Guidelines.

III Guidelines Expansions/Improvements

A. Consider expansion of the Guidelines' scope to:

1) more directly address standards-related matters;

2) address other regulatory activities not currently covered.

B. Develop a model confidentiality agreement that could be adapted, as appropriate, to support the sharing of confidential information under a range of EU-U.S. regulatory cooperation projects. A model agreement, based on the existing FDA-DG Enterprise confidentiality agreement for sharing information on pharmaceuticals, could be formally referenced in the Guidelines or be added as an annex to the Guidelines.

C. Identify possible improvements to Guidelines provisions that could further enhance its effectiveness and its role as a mechanism intended to support a broad range of EU-U.S. regulatory cooperation in areas of mutual interest.