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2005 Roadmap for U.S.-EU Regulatory Cooperation

The United States and the EU have highlighted at past U.S.-EU Summits the increasing importance of improved regulatory cooperation between U.S. and European Commission authorities for a strong transatlantic relationship. Stakeholders on both sides of the Atlantic have called upon the governments to expand and deepen these activities. In many cases U.S. and European Commission regulators already have active and constructive expert dialogues – and substantial cooperation is underway. Yet there remains much work to be done to better realize the mutual benefits of more extensive and effective U.S.-EU regulatory cooperation.

In June 2004, the United States and European Commission issued the Roadmap for U.S.-EU Regulatory Cooperation to provide a framework for cooperation on a broad range of important horizontal and sectoral areas. Implementation of the 2002 U.S.-EU Guidelines on Regulatory Cooperation and Transparency and the Regulatory Cooperation Roadmap have yielded good progress in a number of regulatory areas, but the scope for potential cooperation is far broader. Our objective is to build upon successful regulatory dialogues and promote effective cooperative mechanisms. For each policy context identified, we will consider the most appropriate instruments to advance cooperative work, while also reflecting lessons learned from past experiences. We aim to promote better quality regulation, minimize regulatory divergences, increase consumer confidence, and facilitate transatlantic commerce, while respecting the regulatory autonomy of each party.

This 2005 Roadmap outlines a range of proposed cooperative initiatives that the United States and the European Commission intend to advance in the coming year – both specific sectoral activities, as well as horizontal initiatives to address cross-cutting matters. This work will evolve as each side continuously examines areas of mutual interest for regulatory cooperation, and considers input from interested transatlantic stakeholders. Further information about a number of these cooperative activities is available at:

http://www.ustr.gov/World_Regions/Europe_Mediterranean/Europe/Section_Index.html and http://europa.eu.int/comm/enterprise/enterprise_policy/gov_relations/internatl_regul_coop_eu_us/index.htm

I. Regulatory Cooperation: Horizontal Initiatives

A. OMB-EC Dialogue:

Establish an informal dialogue led jointly by the U.S. Office of Management and Budget (OMB) and the relevant services of the European Commission to discuss general regulatory policies and practices of mutual interest. This dialogue could include relevant regulatory authorities in the U.S. Government and the European Commission, as appropriate. This dialogue will address, subject to mutual agreement, such topics as good regulatory practices, transparency provisions and public consultation, impact assessment methodologies, and risk assessment methodologies. Through such

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exchanges, U.S. and European Commission officials will gain an enhanced understanding of each other's regulatory practices, which could encourage compatible regulatory practices and tools.

B. U.S.-EU Experts Exchange Program:

Identify resources and mechanisms to promote exchanges of U.S. and European regulatory experts in specific areas/projects of mutual interest that otherwise cannot be funded through existing regulatory agency budgets. In the short-term, the United States could leverage existing programs such as the State Department's International Visitor Program and the Fellowship of Hope program. The European Commission will explore availabilities within its existing mechanisms. Over the longer-term, funding should be sought to support a fund dedicated to U.S.-EU personnel exchanges. To maximize support for the creation of such a program, it should be promoted as a cross-cutting initiative to enhance the transatlantic economic relationship.

II. Regulatory Cooperation: Sectoral Activities

1. Pharmaceuticals

1.1 Human medicinal products

Objective: Cooperation between the U.S. 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.

Progress/Results: 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. Facilitated by the FDA-DG Enterprise and Industry-EMA confidentiality arrangement signed in 2003, our authorities concluded in September 2004 an Implementation Plan for Medicinal Products for Human Use under which they have promoted scientific personnel exchanges and joint meetings; shared respective draft guidance documents on a variety of issues, including drug safety issues, adverse reactions, drug manufacturing quality and policy issues. Under the Implementation Plan, FDA and the EC also initiated a pilot program to support parallel scientific advice on pharmaceuticals. FDA, DG Enterprise and Industry and EMA continue to collaborate effectively on the harmonization of technical requirements for registering pharmaceuticals through the International Conference on Harmonization (ICH).

Next Steps: FDA, DG Enterprise and Industry and EMA will proceed with the broad range of robust cooperative work outlined in the Implementation Plan, including sharing of regulatory and inspectional information, scientific exchanges, and parallel scientific advice. The FDA and EMA have also started cooperation in a new area of parallel advice -- pharmacogenomics. FDA, DG Enterprise and Industry and EMA will consider additional issues for possible cooperation.

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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).

Next Steps: The FDA and the European Commission and the EMA will cooperate, where appropriate, 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. FDA leads US activities on all matters except for the veterinary biologics activities led by USDA.

2. Automobile Safety

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

Progress/Results: Under the NHTSA-DG Enterprise and Industry regulatory dialogue established by a June 2003 exchange of letters, we have agreed to pursue regulatory cooperation on safety of hydrogen fuel cell vehicles and vehicle compatibility. Our authorities are discussing other possible topics.

Next Steps: Develop agreed workplans for these regulatory cooperation projects and proceed with implementation. Consider additional topics that may be suitable for cooperation, such as future collision mitigation technologies, electronic stability systems and harmonisation at the global level of dummies used in side-impact crash tests. Discuss 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 U.S. Department of Commerce and DG Enterprise and Industry and DG Information Society on the use of information and communication technology (ICT) standards in accordance with the Terms of Reference established in March 2004..

Next Steps: Develop work plans and time tables for the topics identified under this dialogue. Initial projects under this dialogue include information exchange on e-accessibility, security, and biometrics.

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4. Cosmetics

Objective: Cooperation between the U.S. 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.

Progress/Results:

- General regulatory cooperation in the field of cosmetics: FDA and the EC have re-energized cooperation in cosmetics and certain over-the-counter drugs harmonization activities under the Cosmetics Harmonization and International Cooperation (CHIC) process. The last meeting took place in March 2005, where new terms of reference to guide future cooperation were developed and approved. In the framework of CHIC, FDA and DG Enterprise have exchanged extensive information on our 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

- Alternative methods to animal testing: The U.S. 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.

Next Steps: The cooperation on the development of alternative methods needs further strengthening through bilateral contacts with the aim of mutual acceptance of alternative methods. FDA and DG Enterprise and Industry will continue to discuss other important issues in the field of cosmetics regulation, such as cosmetics labelling, standardized labelling for sunscreens and the regulation of hair dyes in the framework of bilateral meetings and within the multilateral CHIC-process, which has proven a valuable multilateral forum for discussion.

5. Consumer Product Safety

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

Progress/Results: CPSC and DG SANCO launched a senior-level dialogue and signed an exchange of letters in February 2005 to implement mutually agreed Guidelines for Information Exchange intended to strengthen bilateral communication and to improve U.S and EU consumer health and safety protection.

Next Steps: Building on the Guidelines for Information Exchange, develop an agreed implementation plan for a program of specific cooperative projects to be pursued in the area of consumer product safety, which might include the exchange of rapid alerts.

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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 SANCO and the U.S. 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.

Next Steps: Congress has considered, and the Senate has passed, legislation mirroring the CPC provisions on cross-border consumer protection enforcement. Upon passage of such legislation, a Recommendation of the European Commission endorsing the negotiation of an agreement with the US could be proposed to the Council.

7. Unfair Commercial Practices

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

Next steps: DG SANCO to present the recently adopted Directive on unfair commercial practices to the FTC and compare it with U.S. federal law on unfair practices.

8. Nutritional Labeling

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

Progress/Results: Experts from FDA and DG SANCO 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 U.S. Recommended Daily Allowances (RDA) for nutrients; and 2) cooperation on food labels.

Next Steps: Identify specific activities for cooperation on technical issues such as reference values for nutrient labeling, nutrient definitions, and energy conversion factors. Pursue a confidentiality arrangement to facilitate the sharing of non-public information in this subject area.

9. Food Safety

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

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Progress/Results: In mid-2004, FDA and DG SANCO launched bilateral discussions aimed at: (a) understanding better our respective food safety systems; (b) building confidence; and (c) exploring new ways to accomplish food safety goals and regulatory cooperation projects of mutual interests. Senior officials at FDA and DG SANCO have conducted a number of productive meetings to advance this cooperative work. FDA and SANCO experts have identified specific regulatory cooperation projects in the areas of seafood and dairy. FDA and DG SANCO concluded an exchange of letters in June 2005 to facilitate the sharing of non-public data/information.

Next Steps: Identify additional specific regulatory cooperation projects and specific information to be shared.

a.2. Objective: Cooperation between DG SANCO and the U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) on legislation concerning meat and meat products.

Progress/Results: In September 2004, FSIS, FDA and DG SANCO had a seminar aimed at understanding better our respective food safety systems related to meat and meat products with particular regard to 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.

Next Steps: Continue the discussion between FSIS and SANCO in order to explore how to concretely pursue equivalence between the respective HACCP based control systems for meat and meat products.

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

Progress/Results: FDA and EFSA have initiated a cooperative regulatory dialogue and are pursuing a confidentiality agreement to facilitate the sharing of non-public information and data. FDA is assisting EFSA in the development of a strategy for the conduct of microbial risk assessments.

Next Steps: Conclude an arrangement between FDA and EFSA to facilitate the sharing of data/information.

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

Next Steps: Establish informal dialogue between USDA and EFSA with discussions targeting risk assessments methodologies and identifying possible areas for further discussion and sharing of information.

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10. Marine Equipment

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

Next Steps: USCG and EC to develop an agreed workplan for pursuing regulatory cooperation bilaterally and in the International Maritime Organization (IMO) aimed at achieving equivalent U.S. and EU technical regulations for specific marine equipment and expanding the product scope of the U.S.-EC Marine Equipment MRA.

11. Eco-Design

Objective: Cooperation between the U.S. 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.

Next Steps: 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). Consider other activities that may be of interest for further information exchanges.

12. Chemicals

Objective: Pursue informal cooperative dialogue, in the spirit of the U.S.-EU Guidelines on Regulatory Cooperation, between the U.S. 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.

Progress/Results: The U.S. EPA hosted the 2nd transatlantic environment conference on chemicals which addressed the EU's proposed REACH (Registration, Evaluation and Authorization of Chemicals) legislation, the globally harmonized system (GHS) for the classification and labeling of chemicals, pollution prevention techniques, access to information and genomics. EPA hosted EC experts on its approach to the risk assessment of new chemicals and integrated QSAR modeling programs. Further exchange of experience and training programmes could be explored for respective staff. The U.S. EPA and the European Commission are also collaborating in the OECD framework on the development of the Global High Production Volume (HPV) chemicals information Portal.

Next Steps: The EC and United States will continue to dialogue on the development of the Global HPV Portal.

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13. Energy Efficiency

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

Next Steps: The United States and EC will build on the Energy-Efficiency Labeling Programs for Office Equipment ("Energy Star") to encourage energy efficiency while retaining the philosophical basis and market-focused approach of the existing program. This program currently covers computers, monitors, printers, fax machines, copiers, scanners, and multi-function devices. Both parties are currently considering the conditions for renewing the Energy Star Agreement.

This year, and into next, the U.S. and the EC will cooperate on revising the specifications for imaging equipment (printers, copiers, scanners, fax machines, mailing machines, and multifunction devices) and computers. The intention of these revisions is to 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.

14. Telecommunications and Radiocommunications Equipment, Electromagnetic Compatibility

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

Next Steps: The FCC and EC to consult on regulatory developments in our respective markets and consider cooperative approaches for achieving consistent regulatory treatment of telecommunications and radiocommunications products whenever possible.

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 U.S.-EC MRA annex on medical devices.

Next Steps: FDA, the Office of the U.S. Trade Representative and DG Enterprise and Industry and DG Trade to discuss implementation of the U.S.-EC MRA annex on medical devices and develop an agreed approach for bringing the MRA annex into operation. In the context of the Global Harmonization Task Force (GHTF), our

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regulatory authorities will promote cooperative activities, including the preparation of guidance documents and compatible regulatory approaches for medical devices.