TRANSATLANTIC ECONOMIC COUNCIL

REVIEW OF PROGRESS UNDER THE FRAMEWORK FOR ADVANCING TRANSATLANTIC ECONOMIC INTEGRATION BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN UNION

At their April 2007 Summit meeting, the leaders of the United States of America (U.S.) and the European Union (EU) committed their governments to strengthening transatlantic economic integration, with the goal of improving competitiveness and the lives of our people through a multi-year programme of cooperation that emphasizes results and provides accountability.

The leaders of the United States of America and the European Union agreed on a Framework for Advancing Transatlantic Economic Integration ("the Framework") and established the Transatlantic Economic Council (the "Council") to oversee the efforts outlined in the Framework, with the goal of accelerating progress and guiding work between U.S.-EU Summits.

Since the Summit meeting, the Council has:

- agreed to adopt a work programme by the end of 2007, including timelines and expected achievements, with the goal of achieving the objectives of the Framework, drawing initially from the existing work programme under the 2005 US-EC Economic Initiative;
- adopted working arrangements on its composition and operations, including its relations with stakeholders, advisors and regulators; and
- convened a Group of Advisers comprised of the heads of existing transatlantic dialogues to provide input and guidance to the Council on priorities for pursuing transatlantic economic integration; the Co-chairs of the Council consulted this Group of Advisers before the first meeting of the Council on November 9, 2007.

This first progress report by the Council demonstrates the intention of the U.S. and EU to move rapidly towards achieving their common objectives.

I. Fostering Cooperation and Reducing Regulatory Burdens

The Council today affirms its commitment to removing barriers to transatlantic commerce; to rationalizing, reforming, and, where appropriate, reducing regulations to empower the private sector; to achieving more effective, systematic and transparent regulatory cooperation to reduce costs associated with regulation to consumers and producers; to removing unnecessary differences between our regulations to foster economic integration; and to reinforcing existing transatlantic regulatory cooperation dialogues by intensifying both sector-by-sector U.S.-EU regulatory cooperation and dialogue between the U.S. Office of Management and Budget and the European Commission on methodological issues.

In connection with the first plenary meeting of the Council, the U.S. government and the European Commission have taken the following steps to reduce barriers to transatlantic economic integration.

- On November 8, 2007, the U.S. Office of Management and Budget (OMB) and the European Commission issued for public comment a draft joint Secretariat-General-Office of Information and Regulatory Affairs report on their respective regulatory impact assessment guidelines in relation to impacts on trade and investment with the goal of ensuring that assessments of future regulations take due account of their impact on international trade and investment.
- The U.S. government and the European Commission have appointed as permanent members of the U.S.-EU High-Level Regulatory Cooperation Forum senior officials and heads of appropriate regulatory agencies and directed them to report on risks or benefits from different regulatory approaches in specific cases; the Forum convened on November 8, 2007, and discussed closer cooperation on import safety and closer collaboration prior to considering new or amended regulations, including on understanding risks. Cooperation on the safety of imported products will be a priority in the future work of the Council.
- The European Commission and the United States Government express their strong willingness to resolve the issue of pathogen reduction treatments for poultry carcasses. The Commission has taken first steps towards a solution by requesting advice from the relevant scientific committees. The European Commission is committed to making a proposal for definitively resolving this long-standing issue before the next U.S.-EU Summit, after receiving the scientific advice.
- Earlier this year, the U.S. Food and Drug Administration (FDA) and the European Commission concluded confidentiality arrangements and a joint work plan in the areas of cosmetics and medical devices. In addition, the previously signed cooperation arrangement and joint work plan between the FDA, the European Commission, and the European Medicines Agency in the areas of human and animal drugs and human biologics was renewed and expanded. These arrangements will expand bilateral cooperation, ease regulatory burdens while maintaining high standards of public health protection, and facilitate the promotion of public health by the introduction of new products through intensified upstream regulatory cooperation in these product categories.
- The FDA and the European Commission have also agreed to cooperate more closely in the peer review of validation studies of alternative methods to animal testing for cosmetics, which should contribute to reduce animal tests.
- The United States and the European Commission have reached agreement on a common format for data submission to FDA and European Agency for the Evaluation of Medicinal Products for orphan drug designations. This will simplify the process for applying for orphan drug designation in both jurisdictions.
- The European Commission and the United States have underlined their commitment to intensify cooperation on chemicals. They will undertake an analysis of the potential impact of regulations on transatlantic trade in chemicals and chemical products and of how any such impacts might be reduced while maintaining a high level of protection of health and the environment. They will also encourage steps to ensure the transparency of the implementation of regulatory regimes. Working through the U.S. Environmental Protection Agency and its European Commission counterparts, they will examine the means of increasing cooperation within the OECD with a view to accelerating work on key issues linked to regulation of chemical substances.
- In 2008, the U.S. Federal Communications Commission will review electronic products and information and communication technology products subject to mandatory third party testing to allow suppliers declarations of conformity for products with a good record of compliance with

relevant standards, and report on progress to the Transatlantic Economic Council at its next meeting.

- By the time of the next meeting of the Transatlantic Economic Council, the U.S. Occupational Safety and Health Administration will pursue discussions with the European Commission and will report on progress made to facilitate trade in electrical products with respect to conformity assessment procedures for the safety of such products.
- In order to reduce unnecessary costs for transatlantic trade, the European Commission has proposed legislation that would allow the continued import of products into the EU with dual labelling of measurement units.
- The United States and the European Commission, working with Brazil, made progress in identifying areas of convergence in international standards for pure biofuels, that is, for pure bioethanol and biodiesel, and the experts have reached preliminary agreement on the areas in which existing standards are compatible and are identifying areas in which progress can be made in 2008, to be covered in the recommendations they will produce before the end of the year.
- The European Commission has launched a study to identify the benefits of removing barriers to transatlantic trade and investment, the results of which are expected in 2008 and will inform the future deliberations of the Council.
- The European Commission will release a communication on providing access to information to patients on legal pharmaceuticals, and will table a legislative proposal allowing such access to the European Parliament and Council as soon as possible in 2008 in line with the Commission's 2008 legislative work programme.

II. Lighthouse Priority Projects

The Council has actively pursued work on a number of priority issues for transatlantic economic integration identified at the April 2007 Summit (the so-called "Lighthouse projects") and can already report substantial progress on a number of them.

A. Intellectual Property Rights

We have agreed that by the next meeting of the Council, the U.S. Government and European Commission will agree on a roadmap to support and facilitate international patent law harmonization.

The U.S. government and the European Commission have agreed to combat counterfeiting and piracy by the following customs actions:

- Providing business with clear information on the procedures for seeking Customs IPR protection in the U.S. and the EU;
- Exchanging information on detection techniques, tools and seizures for IPR violations to improve the targeting of shipments containing counterfeit and pirated goods; and
- Undertaking joint control actions to disrupt trade in fakes, focusing particularly on commerce that threatens health and safety.

The U.S. and EC have also agreed to:

- work closely to launch and complete the Anti-Counterfeiting Trade Agreement negotiations;
- cooperate to encourage third countries to enhance their enforcement efforts;
- develop "IP networks" of U.S. and EU diplomats;
- increase collaboration with the private sector, including education and support to SMEs;
- enhance co-operation in multilateral organisations, such as the G8, the OECD and the WTO; and
- cooperate in implementing technical assistance programmes in third countries.

Further steps to strengthen cooperation will be developed by the next Council meeting.

B. Secure Trade

The U.S. government and the European Commission have agreed to work cooperatively to develop effective and mutually acceptable solutions to secure cargo trade. With this in mind, they have agreed on a joint roadmap setting out the key performance-based stages required to reach mutual recognition of U.S. and EU Customs-Trade partnership programs in 2009 or to report fully if there are serious difficulties preventing this. Mutual recognition will increase security in transatlantic trade and provide for enhanced customs treatment for economic operators who have invested in supply chain security.

They have also agreed to exchange customs officials specialising in risk management in order to improve supply chain security in the U.S. and EU. This exchange will focus initially on the stationing of EU customs officials at the U.S. National Targeting Center – Cargo.

C. Financial Markets

The U.S. Securities and Exchange Commission (SEC) and the EU Commission have made progress in seeking to ensure conditions for U.S. Generally Accepted Accounting Principles (US GAAP) and International Financial Reporting Standards (IFRS) to be recognized in both jurisdictions without the need for reconciliation by 2009 or possibly sooner. The SEC issued a Rule Proposal for comment in July 2007 to allow Foreign Private Issuers to file with the SEC financial statements prepared in accordance with IFRS without reconciliation to US GAAP. The EU Commission submitted its comments in October 2007. The EU side is preparing its "equivalence mechanism" to permit acceptance of third country accounting standards. In 2008, US GAAP will be assessed under this mechanism. In this context, both sides are working towards finding a mutually satisfactory solution in the interest of investors and issuers on both sides.

In light of our common interest in creating high-quality internationally accepted accounting standards and ensuring continued confidence in the International Accounting Standards Board (IASB), which develops the International Financial Reporting Standards (IFRS), we have jointly announced that we will work with other stakeholders to increase the accountability of the IASB.

The SEC and the European Commission have had a first exchange of views in the Financial Markets Regulatory Dialogue (FMRD) on their respective considerations of how and in which areas to establish mutual recognition of comparable regulatory regimes in the field of securities. These discussions will continue with a view to making significant progress in 2008 on a framework for future regulatory work in the transatlantic context. The Council welcomes continuing efforts under the FMRD to identify other approaches to facilitate cross-border trade in financial services.

D. Innovation and Technology

The U.S. government and the European Commission have

- conducted a high-level conference on innovation in health-related industries and a workshop on best practices in innovation policies; and
- continued their work in relation to nanotechnology in the OECD and other bilateral and multilateral venues; a multilateral dialogue has now also started regarding the use of nanomaterials in medical products and cosmetics.

E. Investment

On November 9, the United States and the European Commission formally launched an Investment Dialogue to reduce barriers to transatlantic investment and promote open investment regimes globally. The Investment Dialogue has held several preliminary meetings, and has agreed that the Investment Dialogue's work plan will include: (1) reviewing global investment trends, including sovereign wealth investment; (2) addressing protectionist pressures and barriers to global investment; (3) reducing barriers to transatlantic investment; and (4) facilitating progress on investment issues in the OECD.

III. The way ahead

While much has been achieved in the first six months of work, much remains to be done. We are confident that the Council will be able to demonstrate further substantial progress on the work programme by its second meeting in Spring 2008. A list of goals to be achieved over the coming months will be finalized by the end of 2007.

As the Council seeks to strengthen transatlantic economic integration, foster cooperation and reduce regulatory burdens, with the goal of increasing competitiveness and improving the lives of our people, the priorities for its work should reflect stakeholder input. The Council Co-chairs have today invited the Group of Advisers representing stakeholders to submit additional suggestions for the Council's work programme before the end of January 2008, in order to allow them to be discussed by the Council at its next meeting, and the Co-chairs will continue to work with the Group of Advisors in developing the Council's future work programme. The Council will review its work programme at that time and present a revised work programme at the next U.S.-EU Summit.