

TRANSATLANTIC ECONOMIC COUNCIL

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

The Transatlantic Economic Council (TEC) today held its third meeting since its establishment in April 2007 in the Framework for Advancing Transatlantic Economic Integration Between the United States of America and the European Union (“the Framework”).

The meeting took place against the background of the global financial crisis and its repercussions on the real economy. Both sides stressed that a strong transatlantic partnership is now more important than ever.

Based on the Framework, the TEC has given new political impetus to U.S.-EU economic cooperation. Its focus on regulatory cooperation and a limited number of lighthouse projects has been welcomed by stakeholders.

While the Framework calls for the TEC to meet at least once a year, it was agreed at the TEC’s second meeting, on May 13, 2008, that an additional meeting in 2008 would be useful to help provide momentum and secure the continuity of the TEC after changes in leadership in both the United States and the European Union in 2009.

The third meeting of the TEC confirmed its promise as a forum for pursuing the goals identified in the Framework. It demonstrated that the TEC can promote stronger transatlantic economic integration by focusing the attention of the U.S. Government and the European Commission on:

- ensuring coordination and, where appropriate, development of compatible regulatory approaches generally, as well as in the development and application of specific regulations;
- resolving specific bilateral issues; and
- advancing common interests and addressing common challenges involving third countries.

The progress report issued at the conclusion of the TEC meeting in May identified commitments and ongoing work in each of the areas mentioned above. The leaders of the United States and the European Union, meeting at the U.S.-EU Summit in June 2008, welcomed the work of the TEC and stated that it is essential that both sides follow through on their commitments as outlined in the TEC’s Progress Report to the Summit. Today, the TEC reviewed the status of those commitments and work and concluded that, in general, the United States and the European Union are continuing to make incremental progress. However, the TEC also acknowledged that progress to date in resolving some

key issues has been inadequate.

Developments of note in particular matters on the TEC's work program are set forth in the Annex to this report.

The Annex illustrates the broad range of issues that have been addressed under the TEC process during its first 18 months. In addition to these issues, there are many others that U.S. and EU stakeholders have identified as being suitable for TEC consideration. However the risk that the TEC agenda could become diffuse and unmanageable has to be recognized. Therefore the TEC today agreed that certain principles should guide the development of the TEC agenda in the future. These principles may also give further structure to the TEC's work and thus promote the TEC's continuity.

In particular, the TEC should focus on matters falling within the three areas identified above. Moreover, in assessing whether it is appropriate to make any particular issue part of the work of the TEC, the United States and the European Commission should give priority to issues:

- that are discrete and readily identifiable, rather than general and abstract;
- that have been identified as priorities by businesses and consumers;
- where substantial economic benefits can be expected from a successful outcome; and
- for which a specific solution, such as a change to existing rules and practices, has already been identified in technical consultations between the responsible agencies in the United States and the European Union, which solution is likely to be advanced through the provision of political direction by the TEC.

Both sides agreed that the TEC should not duplicate or replace existing U.S.-EU regulatory dialogues in specific fields, and that the TEC should support and encourage work in these existing dialogues.

Based on the experience over the first 18 months of the TEC, the current leadership of the TEC believes that adherence to these guiding principles can facilitate the TEC's success.

Strengthening transatlantic economic integration is a complex, multi-faceted challenge. It requires the United States and the European Commission to work together in numerous regulatory areas, and it requires each side to take account of the objective of strengthened transatlantic economic integration in its own regulatory initiatives. Over the course of the past 18 months, the TEC has played an important role in advancing these efforts.

ANNEX TO TEC PROGRESS REPORT STATUS OF TEC AGENDA ITEMS

On December 12, 2008, the TEC took note of progress towards meeting the objectives of the Framework for Advancing Transatlantic Economic Integration Between the United States of America and the European Union (“the Framework”) in the following areas:

- **Investment:** The U.S. and European Commission participants in the Investment Dialogue have agreed to identify issues of concern with respect to bilateral investment measures and to develop lists of priority third country investment barriers. The Dialogue also welcomed adoption, and encouraged application, of the Generally Accepted Principles and Practices developed by the International Working Group of Sovereign Wealth Funds and the OECD’s Guidelines for Recipient Country Investment Policies Relating to National Security as well as the OECD’s ongoing Freedom of Investment Project and its emphasis on enhanced peer monitoring of country practices. These issues will form the basis for future discussions in the Dialogue.
- **Accounting Standards:** In the context of the Framework, the U.S. Government and the European Commission have made further progress towards the objective “to promote and seek to ensure conditions for the U.S. Generally Accepted Accounting Principles (U.S. GAAP) and International Financial Reporting Standards (IFRS) to be recognized in both jurisdictions without the need for reconciliation by 2009 or possibly sooner.” In November 2007, the U.S. Securities and Exchange Commission (SEC) took the decision to abolish the requirement for reconciliation to U.S. GAAP for foreign companies using IFRS as issued by the International Accounting Standards Board (IASB). Furthermore, on November 14, 2008, the SEC published for public comment a proposed Roadmap that could lead to the use of IFRS by U.S. issuers beginning in 2014. On June 6, 2008, the European Commission sent two draft Regulations to the European Parliament proposing a decision on U.S. GAAP as being equivalent to IFRS. On November 14, the European Securities Committee voted to grant equivalence to U.S. GAAP, following the resolution adopted by the European Parliament on October 23, 2008. The proposals will now pass to the European Parliament and Council for formal opinions and then to the Commission for adoption. The Commission should adopt the final decision before the end of 2008.
- **Securities Regulatory Regimes:** In February 2008, the SEC and the European Commission agreed to work together to define a process that will lead to the mutual recognition of U.S. and EU securities regimes. The issue will be taken up again in 2009. The TEC endorsed this work and encouraged the parties to conclude this first phase as soon as possible in order to start with the comparability assessment of the U.S. and EU securities regime in 2009.
- **Insurance/ Reinsurance:** During meetings in 2008, the United States and the European Union continued to work toward seeking resolution of outstanding issues for U.S. and EU insurance companies operating in each other’s jurisdiction, including focus on reform of the collateral rules applied to EU and other third country reinsurers that are not licensed in the United States, and on proposals regarding the treatment of third country insurers and reinsurers in the European Commission’s Solvency II Framework Directive Proposal.

- **High-level Regulatory Cooperation Forum:** The Forum convened on November 8, 2007, on April 25, 2008, and on October 15, 2008 and discussed closer cooperation in matters of product safety, regulatory issues presented by emerging technologies, impact analysis and risk assessment methodologies and the use of international standards in regulation.
 - **Developing the Standards Dialogue:** The TEC asked the Forum to conduct a study outlining the broad legal and institutional framework of U.S. and EU approaches to the use of standards in support of regulation. The Forum discussed these issues at its October 2008 meeting and committed to report its findings and conclusions to the TEC in 2009, and include several in-depth sectoral case studies.
 - **Taking Account of the Impact of Proposed Regulations on International Trade and Investment:** On the basis of the recommendations in the joint paper prepared by U.S. Office of Management and Budget (OMB) and the Secretariat General of the European Commission, both sides have amended and strengthened their requirements to ensure better analysis of and greater transparency about the effects of proposed regulations on international trade and investment. The European Commission has included provisions in its revised Impact Assessment Guidelines that require that for all major policy proposals the perspective of international trade and investment is adequately analysed. The United States will include, for the first time, an “international flag,” in the Fall 2008 version of the U.S. Regulatory Plan and Unified Agenda of planned U.S. regulatory activities. This flag will indicate whether a U.S. Government agency expects a regulatory action under development to have an impact on international trade or investment or otherwise be of international interest. OMB also has developed a draft document for public comment elaborating on how U.S. agencies should meet their obligations to analyze international effects in regulatory impact analyses for proposed and final rulemakings.
 - **Import Safety:** The Forum submitted its progress report on the implementation of the report “Towards enhanced cooperation between the EU and the U.S. on the safety of imported products,” which was endorsed at the May 13, 2008 TEC meeting. Further results have been achieved in a number of areas, as follows:
 - The U.S. Consumer Product Safety Improvement Act was enacted on August 14, 2008. The additional statutory authority thereby gained by the U.S. Consumer Protection Safety Commission (CPSC) for confidential information sharing with product safety authorities in third countries should pave the way for increased bilateral cooperation in the non-food consumer product area.
 - Following the recommendation contained in the above report, the CPSC and the European Commission’s Directorate-General for Enterprise and Industry (DG ENTR) and Directorate-General for Health and Consumers (DG SANCO) set up a Toy Safety Working Group as a focal point to discuss toy import safety related matters. The Working Group has met three times, on May 29, July

22, and November 12, 2008.

- In September 2008, the CPSC and DG SANCO and DG ENTR conducted a series of joint outreach seminars in China on U.S. and EU safety requirements for clothing, toys, and electrical products with a view to promoting compliance with the applicable safety requirements. This joint initiative was followed by a high-level trilateral meeting hosted by Commissioner Kuneva in Brussels in November to continue the common agenda.

- **Transatlantic Risk Dialogue:** In November 2007, OMB and the U.S. Office of Science and Technology Policy (OSTP) began conversations with DG-SANCO to facilitate an international dialogue on risk analysis. Both sides agreed to encourage cooperation at the technical and scientific level in order to arrive at a common understanding among the EU and U.S. regulatory authorities of how to measure risk across all areas of regulation and to use consistent analytical tools for this purpose.
 - In July 2008, OMB and OSTP hosted over 60 participants for a day and a half of government-to-government discussions on risk analysis issues.
 - In November 2008, DG SANCO hosted the 1st International Conference on Risk Assessment, a two-day “Global Risk Assessment Dialogue” in Brussels.

- **Supplier’s Declaration of Conformity (SDoC):** Following through on its commitment at the May 13, 2008 TEC meeting, on October 20, 2008, the U.S. Department of Labor published in the Federal Register a request for information to aid it in determining whether an SDoC regime would be a viable alternative or supplement to its current, third-party laboratory based regime for certifying certain electrical products as safe for the workplace.

- **Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH):** At the May 13, 2008 meeting of the TEC, the European Commission agreed to undertake the necessary steps, within its competence, to ensure transparent implementation, legal certainty and non-discriminatory trade under REACH. Also at the May 13, 2008 meeting, the European Commission committed to take concrete action to ensure that trade in cosmetics and personal care products is not disrupted by REACH implementation. The United States welcomed these commitments, and takes note of the European Commission’s adoption of the *Commission communication on the enquiry and registration under Regulation (EC) No 1907/2006 (REACH) of substances that were lawfully on the market before 1 June 2008 but which do not have phase-in status on December 9, 2008*. The United States welcomed the assurances provided by the EU TEC co-chair that, within its competence, the European Commission is taking the necessary steps to fulfill the commitments referred to above. The United States also welcomed the EU TEC co-chair’s assurances that the European Commission will work with Member States and the European Chemicals Agency to ensure both that registrants will, working with ECHA, have adequate time to submit relevant information and that REACH is implemented in a manner that is transparent and non-discriminatory.

- **Poultry:** At the May 13, 2008 TEC meeting, the European Commission committed to propose, before the EU-U.S. Summit of June 2008, changes to EU regulations that

will allow the use of pathogen reduction treatments for poultry meat in the EU Member States and in imported poultry products. In line with its previous commitments in this area, and following the receipt of opinions from the Scientific Committee on Health and Environment and the Scientific Committee on Emerging and Newly Identified Health Risks, the Commission committed to actively solicit Member State and European Parliament support and to make best endeavours to achieve the final adoption of the relevant EU legislation before the next TEC meeting. The Commission adopted its proposal on May 28, 2008. However, in communications to the EU TEC co-chair in May and November 2008, the U.S. TEC co-chair stated that the proposal does not address the U.S. concerns because it includes conditions that would deny U.S. producers access to the EU market. At the meeting of the Regulatory Committee on June 2, 2008, the Member States' experts unanimously rejected the Commission proposal. The European Parliament also expressed opposition to any modification of the status quo. Subsequently, the Commission submitted the proposal to the Council. The Council Presidency has drafted a Council Decision rejecting the proposal, which is due to be put before the next Agriculture Council. On the assumption that the Agriculture Council will reject the Commission proposal, the United States encourages the two sides to work together on a new proposal.

- **Intellectual Property Rights (IPR) Enforcement:** The United States and the European Union (together with others) continue to negotiate an Anti-Counterfeiting Trade Agreement to enhance international leadership on IPR enforcement and cooperation. Additionally, the United States and the European Union are eager to continue their successful co-operation on IPR enforcement. U.S. and EU IPR enforcement experts are deepening their information-sharing about key countries, such as China and Russia, by means of joint IP networks of diplomats. These networks contribute to improving IPR enforcement abroad, including through outreach to small- and medium-sized enterprises in key markets. Customs cooperation also continues actively and cooperation with the private sector is increasing.
- **International patent law harmonisation:** The United States Patent and Trademark Office and the European Commission agree that efforts can be stepped up to advance patent global harmonisation.
- **Mutual Recognition of Trade Partnership Programs:** In March 2008, U.S. and EU customs authorities agreed on a roadmap for achieving mutual recognition in 2009 of their respective secure trade programs (the Customs-Trade Partnership Against Terrorism program in the United States, and the Authorized Economic Operator program in the European Union). Progress continues. U.S. Customs and Border Protection together with the European Commission's Taxation and Customs Union Directorate General have drafted an "abridged version" of the roadmap, which they expect to release to industry and other stakeholders by the end of 2008. At its meeting in March 2008, the Joint Customs Cooperation Committee (JCCC) agreed to establish mutual recognition of trade partnership programs in 2009, consistent with the roadmap.
- **100% scanning:** At the May 13 and December 12, 2008 TEC meetings, the European Commission reiterated its concerns regarding the U.S. legislation requiring 100 percent scanning of containers bound for U.S. ports starting in 2012. The

European Commission considers this legislation to be a potential new trade barrier, imposing significant costs on economic operators, which will not bring any benefit in terms of supply chain security. Nevertheless, the United States and the European Commission recognize the need for enhanced cooperation on a multi-layered, risk-based approach.

- **Sustainability and Greenhouse Gas Reduction Criteria for Biofuels:** The United States and the European Commission today welcomed the continued collaboration among U.S. and EU experts concerning the development of science-based sustainability criteria for biofuels. They looked forward to this collaboration continuing in the future. The United States underscored the importance of adhering to science-based sustainability criteria.
- **E-accessibility:** U.S. Government and industry representatives are participating in the European Standards Organization's process to develop accessibility requirements for the public purchase of information and communications technology products and services.
- **Radio Frequency Identification Technologies (RFID):** In September 2008, the U.S. Department of Commerce supported a Transatlantic Symposium on the Societal Benefits of RFID, and the U.S. Federal Trade Commission held a Transatlantic RFID Workshop on Consumer Privacy and Data Security. During the Symposium, the United States and the European Commission agreed to endorse the OECD policy principles on RFID as a basis for best practices for the public and private sectors. They also announced a joint pilot project for tracking radioactive isotopes, and they proposed to explore and pursue other pilot projects. The European Commission is planning to organise a similar symposium in Brussels in Spring 2009.
- **Internet protection for consumers:** The U.S. Federal Trade Commission and the European Commission continue to work on an agreement to enforce consumer protection laws.
- **Active Pharmaceutical Ingredient (API) Tri-Party Pilot Program:** The United States and the European Union (together with Australia) have finalized the terms of reference for an agreement to jointly plan inspections of API production facilities in third countries over the eighteen months beginning November 2008. By sharing inspection reports and leveraging each other's resources in this manner, it is expected that more information can be obtained than by each party following its own inspection plan alone. The inspection component of this program started in November 2008. Moreover, the first "test-case" joint inspection between the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) of an API plant in China has been recently concluded. Results of that inspection are pending.
- **Advanced Therapies Cooperation:** In August 2008, FDA and EMA launched a technical level work "cluster" on advanced therapy medicinal products. These are new medical products based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). This new work cluster builds on the ongoing FDA-EMA workplan, which already included work clusters on pediatric drugs, vaccines, oncology drugs, orphan drugs, drug safety, and pharmacogenomics.

- **Embeds at FDA/EMEA:** FDA and EMEA have agreed to co-locate a senior-level agency representative/expert within each other's offices to work on medical product regulatory issues. This exchange is expected to begin as soon as all logistical and foreign ministry arrangements for such bilateral in-country placements can be finalized. It is hoped that this will occur in late 2008 or early 2009.
- **Alternatives to Animal Testing for Cosmetic Ingredients:** In September 2008, the United States and the European Union (together with Canada and Japan) agreed on the cooperative Framework on Alternative Tests, which will form the basis by which the bodies within these four regions that are responsible for scientifically validating proposed new alternative tests will work together to do so for their respective regions (setting priorities, sharing results, and leveraging each other's resources and expertise).
- **Auto Regulations:** On June 16, 2008, the U.S. National Highway Traffic Safety Administration and the European Commission's DG-Enterprise and Industry concluded a Memorandum of Cooperation (MOC) in the field of motor vehicle regulations. Under the MOC, the two sides agreed to strengthen their cooperation in the development and enforcement of vehicle regulations, including safety and certain aspects of fuel economy regulations and in the identification of safety-related defects and non-compliances. The two sides also agreed to jointly promote greater international harmonization of vehicle regulations under the aegis of the United Nations.