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Transatlantic Economic Council Report to the EU-U.S. Summit 2008

Review of progress under the framework for advancing transatlantic economic integration between the European Union and the United States of America

White House News

Believing that transatlantic economic integration will maximize economic benefits for their citizens through competition and stronger growth, while maintaining high standards of safety and protection, at their last summit meeting in April 2007, the leaders of the European Union (EU) and the United States of America (United States) committed their governments to increasing the efficiency and transparency of transatlantic economic cooperation and to accelerating the reduction and elimination of barriers to international trade and investment with the ultimate objective of achieving a barrier free transatlantic market.

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

The TEC was requested to report annually to the EU-U.S. Summit leaders on the TEC's achievements (part 1) and on areas where more progress is needed (part 2).

1. TEC Achievements

The outcomes of two TEC meetings so far show the firm commitment of both sides to reach their common objective of greater economic integration. The meetings have shown clear signs of steady progress towards a more convergent transatlantic regulatory environment in a number of priority areas.

The regular and close contacts between the European Commission and the U.S. government in the context of the TEC have allowed both sides to deepen their political dialogue and offered a platform to informally discuss strategic issues of common interest.

Representing the most important bilateral economic relationship in the world, built on shared values, including a belief in open economies, unfettered competition, the rule of law and well-regulated markets with a high level of safety and protection, the TEC is mindful that the European Union and the United States lead by example as to how to overcome economic barriers both in their bilateral relationship and in the world economy.

Since the 2007 Summit meeting, the TEC has

- adopted working arrangements on its composition, working methods, and relations with stakeholders. legislators and regulators;
- convened a Group of Advisers comprised of the heads of existing transatlantic dialogues to provide input and guidance to the TEC on priorities for transatlantic economic integration; the Co-chairs of the TEC have consulted this Group of Advisers before each meeting of the TEC and informed them of the TEC's accomplishments afterwards;
- appointed senior officials and heads of regulatory agencies as members of the EU-U.S. High-Level Regulatory Cooperation Forum; the Forum has met twice over the past year, serving as a platform for

exchanging best regulatory practices within and between sectors and for seeking early upstream consultation and more compatible regulatory approaches to upcoming regulatory matters and decisions;

assembled in Washington on 9 November 2007 and on 13 May 2008 in Brussels, reflecting the high-level
political commitment to transatlantic economic cooperation on both sides of the Atlantic and demonstrating
the intention of the European Commission and U.S. government to move rapidly towards achieving their
common objectives in the areas mentioned in the following sections.

1.1. Fostering Cooperation and Reducing Regulatory Burdens

The TEC is committed to:

- removing barriers to transatlantic commerce;
- rationalizing, reforming, and, where appropriate, reducing regulations to empower the private sector:
- achieving more effective, systematic and transparent regulatory cooperation to reduce costs associated with regulation to consumers and producers and to enhance consumer confidence and safety;
- removing unnecessary differences between our regulations to foster economic integration;
- reinforcing the existing transatlantic dialogue structures in regulatory cooperation both by intensifying sector-by-sector EU-U.S. regulatory cooperation and the dialogue between the European Commission services and the U.S. Office of Management and Budget (OMB) on methodological issues.

Over the past year, the European Commission and the U.S. government have taken the following steps to reduce barriers to transatlantic economic integration:

The EU-U.S. High-Level Regulatory Cooperation Forum convened on 8 November 2007 and on 25 April 2008 and discussed closer cooperation in matters of product safety, early warning systems concerning forthcoming regulation that may be of common interest, regulatory issues presented by new technologies, impact and risk assessments methodologies, and the role of public consultations in the regulatory process.

The EU-U.S. High-Level Regulatory Cooperation Forum submitted its report "Towards enhanced cooperation between the European Union and the United States of America on the safety of (imported) products" to the TEC, including concrete recommendations on how to overcome current constraints on effective information sharing.

The exchange of non-confidential (and, in some sectors, confidential) information regarding product recalls and other market removals for safety reasons is well established. The importance of discussing the exchange of confidential (pre- or post-recall) information in additional sectors has been acknowledged, paying due attention to the need for confidentiality arrangements.

The EU-U.S. High-Level Regulatory Cooperation Forum also submitted the final joint OMB/Secretariat General report "Review of the Application of EU and U.S. Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment" to the TEC. The report seeks to advance the goal of ensuring that impact assessments and analyses of future regulations take due account of the impact of such regulations on international trade and investment.

Since the TEC's November 2007 meeting, the Occupational Safety and Health Administration (OSHA) has met with domestic and foreign stakeholders – including several meetings with European Commission counterparts – to better understand and discuss systems and issues related to conformity assessment (CA) of electrical products, including suppliers declaration of conformity (SDoC). On the basis of these meetings, OSHA has decided to publish a new request for information (RFI) concerning the use of SDoC for certain electrical and electronic equipment used in the workplace. Further, as an additional step to facilitate trade in electrical products with respect to

conformity assessment procedures for the safety of such products, in April 2008 OSHA proposed to increase the number of locations where product certification functions can be performed by Nationally Recognized Testing Laboratories.

At the TEC meeting in November 2007, the subject of the treatment of poultry meat with pathogen reduction substances was discussed. The European Commission has undertaken to act on this issue before the next EU-U.S. Summit, after receiving scientific advice. In this sense, the Commission consulted the European Food Safety Authority on the possible effects of the treatment on antimicrobial resistance and the Scientific Committee on Health and Environment and the Scientific Committee on Emerging and Newly Identified Health Risks on the environmental risk and on the risk of emergence of microbial resistance associated with the use of these substances. The Commission has reviewed these scientific opinions and, in the light of those opinions, which provide no scientific basis for the continuation of the import ban, it will in the coming weeks come forward with a proposal for allowing the use of pathogen reduction treatments for poultry meat in the EU Member States and in imported poultry products. In line with its previous commitment, the Commission will actively solicit Member State and European Parliament support and will make best endeavours to achieve the final adoption of the relevant EU legislation before the next TEC meeting, planned for autumn 2008.

The European Commission and the U.S. government will seek to intensify their cooperation on agriculture, sanitary and phyto-sanitary measures, and food safety, and the TEC will review the state of progress at its next meeting.

The U.S. Federal Communications Commission plans to initiate a rulemaking to consider allowing suppliers declarations of conformity for products that currently require certification and have a good record of compliance with relevant requirements.

The U.S. Food and Drug Administration (FDA) and the European Commission have agreed to meet regularly to further their cooperation in the peer review of unvalidated alternative methods to animal testing used to determine the safety of cosmetic ingredients (including some products regulated in the United States as drugs and in the European Union as cosmetics). The next expert meeting will be held in July 2008.

A first set of specific projects on medicinal products have been agreed following the administrative simplification workshop held in Brussels in November 2007. These results will provide important benefits for industry, patients, and regulatory authorities. The collaboration on inspections will result in more effective use of resources and a higher safety level of products from third countries. Work will continue to identify other areas for intensified collaboration. In addition, U.S. and EU authorities have recently announced a series of successes in their work on biomarker development and validation for various medicinal product development purposes. Finally, FDA and the European Medicines Agency (EMEA) have agreed recently on an implementation work plan for veterinary medicinal products regulation and have agreed on a process for offering parallel scientific advice to veterinary medicinal products manufacturers that wish to receive such advice simultaneously from the FDA and EMEA.

The European Union and the United States have achieved good progress in their co-operation on auto safety with the recent adoption - in March 2008 - of two Global Technical Regulations (GTRs) on glazing and head restraints at the United Nations Economic Commission for Europe (UN-ECE). Furthermore, they are committed to work towards the adoption of GTRs on electronic stability control and pedestrian protection this year.

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 European Commission and the United States government have continued their bilateral cooperation on chemicals regulation. In addition they have cooperated in multilateral fora. In relation to the EU's Registration, Evaluation, and Authorization of Chemicals (REACH) regulation and its implementation, they agreed to continue their discussion of issues including the placing of products

on the candidate list, the "Only Representative" provision, and openness and transparency in REACH Implementation Projects. The Commission acknowledges that REACH presents an unprecedented challenge both for European and third country producers and will therefore, within its competence, undertake the necessary steps to ensure transparent implementation, legal certainty and non-discriminatory trade.

EU-U.S. cooperation on developing biofuels is advanced and on-going, following a common work plan agreed in February 2008. A White Paper on Internationally Compatible Biofuel Standards has been developed with the cooperation of European, American and Brazilian standards bodies. It carefully delineates those aspects of technical standards for biofuels that are already more or less compatible, those aspects that would be too difficult to make compatible, and those aspects that can be brought into closer alignment through continued effort. Additionally, U.S., EU and Brazilian measurement experts are working to develop common standards for calibrating and validating the accuracy of measurement results. This work complements ongoing standards efforts in the private sector and will enable purchasers globally to verify test results for biofuels they purchase.

The EU and the United States signed a comprehensive air transport agreement at the EU-U.S. summit in April 2007. That agreement was provisionally applied as of 30 March 2008 and is already delivering major benefits to our consumers, airlines, communities, and economies. As envisioned in the agreement, a second stage of negotiations, aimed at further liberalization, will begin on 15/16 May 2008.

1.2. Lighthouse Priority Projects

The European Commission and U.S. government have pursued work on the priority issues for transatlantic economic integration identified at the April 2007 Summit (the so-called "Lighthouse projects"), and the TEC has achieved progress on a number of them.

1.2.1. Intellectual Property Rights

The EU-U.S. cooperation on IP enforcement has been a success story. In the past year, the activities have focussed in particular on joint enforcement efforts at the WTO and in third countries, in particular in China and Russia; joint organisation of seminars in Russia (digital piracy), in Latin America and in ASEAN countries; and development of IP networks of EU and U.S. diplomats in third countries, starting with Russia and China. Closer customs co-operation, including joint border enforcement actions, has been an area of particular attention this year, namely the first joint customs cooperation project (Operation INFRASTRUCTURE) was a success. In addition, the United States and the European Union are working together and with other trading partners to negotiate a strong Anti-Counterfeiting Trade Agreement, which they will seek to conclude by the end of 2008.

Further, the United States Patent and Trademark Office and the European Commission have agreed to a roadmap to advance global patent harmonization. During the remainder of 2008, they will elaborate on the roadmap to identify implementation options and engage in consultations with stakeholders.

1.2.2. Secure trade

The European Commission and the United States Government recalled their commitment to the multi-layered, risk based approach in supply chain security and to fully implementing the U.S.-EU Joint Customs Cooperation Committee Roadmap Towards Mutual Recognition of Trade Partnership Programs, adopted on 6 March 2008. The United States Customs and Border Protection (CBP) and the European Commission will work to implement the Roadmap and achieve mutual recognition of the U.S. and EU supply chain security programs – that is, the U.S. Customs-Trade Partnership Against Terrorism (C-TPAT) and the EU Authorized Economic Operator (AEO) program – in 2009, including by exchanging best practices and cooperating on

supply chain security measures.

The United States and EU have also put in place the agreed exchange of customs officials specialising in risk management, starting by stationing in April 2008 EU customs officials at the U.S. National Targeting Center – Cargo.

The European Commission and the U.S. government will include in their discussions on secure trade the issue of the eventual implementation of the U.S. legislation on 100% scanning of containers. The European Commission recalled its concern about this issue and took note that certain U.S. legislators have flagged their willingness to look into this issue.

1.2.3. Financial Markets

In the 2007 "Framework for Advancing Transatlantic Economic Integration," the U.S. government and the European Commission confirmed their common 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." The U.S. Securities and Exchange Commission (SEC) in November 2007, 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), and solicited comment on the possibility of allowing domestic companies to file using IFRS. The European Commission will propose a decision on the equivalence of U.S. GAAP in the course of 2008. To this end, a European Commission working paper on convergence between IFRS and third country national GAAPs has been prepared. This working paper reflects the advice by the Committee of the European Securities Regulators (CESR), which takes a positive stance towards accepting U.S. GAAP as being equivalent to IFRS. The EU and the United States will also continue to monitor the situation in the coming months in the framework of the informal Financial Market Regulatory Dialogue (FMRD).

A joint statement by European Commissioner McCreevy and SEC Chairman Cox on the common willingness of the United States and EU to work together on mutual recognition in securities was released on 1 February 2008. Subsequently, SEC and the European Commission staffs have intensified their work on defining a process for carrying out a comparability assessment of EU and U.S. securities regimes which they hope to finalize by mid 2008. Thereafter, comparability assessments can begin. Mutual recognition in securities regulation would have the potential to facilitate access of EU and U.S. investors to a broader and deeper transatlantic market, increase the availability of information about foreign investment opportunities, promote greater diversification of securities portfolios, significantly reduce transatlantic trading and transaction costs, and increase oversight coordination among regulators. The TEC also encourages the implementation of other approaches to facilitate cross-border financial services, such as providing relief from local licensing requirements for securities firms engaging in cross-border business with certain sophisticated investors.

The TEC discussed issues related to enhancing the openness and competitiveness of global insurance and reinsurance markets while maintaining high levels of consumer protection through the promotion of more comparable, efficient, cost-effective and modern prudential regulatory standards and practices. Currently, U.S. and European regulators and supervisors are engaged in significant efforts to modernize insurance and reinsurance regulation and supervision. The TEC urged both sides to make significant strides by the end of 2008 to identify the steps that need to be taken to create a true level playing field for EU and U.S. insurance companies operating in each other's jurisdiction, including reform of the collateral rules applied to EU reinsurers currently operating in the United States and proposals regarding the treatment of third country insurers and reinsurers in the European Commission's Solvency II Framework Directive Proposal. These discussions should continue to take

place in the context of the FMRD, led by the European Commission and the U.S. Treasury, as well as between the National Association of Insurance Commissioners (NAIC), the Committee of European Insurance and Occupational Pensions Supervisors (CEIOPS) and the European Commission in the EU-U.S. Insurance Dialogue.

1.2.4. Innovation and Technology

Under the auspices of the EC-U.S. Task-Force on Biotechnology Research, a working group on bio-based products was established and several EC-U.S. scientific workshops paved the way to the identification of three joint research priorities related to innovative and eco-efficient bio-based products: plant cell walls in relation to bio-refining; plant oils as industrial feedstock; and biopolymers. The research projects selected in 2008 to address these priorities under the EC Research Framework Programme have a strong involvement of U.S. partners.

The November 2007 TEC meeting resulted in a commitment for the United States and EU to work together to improve international enforcement in the fight against fraud and illegal spam and spyware in light of the enactment of the Undertaking Spam, Spyware and Fraud Enforcement With Enforcers Beyond Borders Act of 2006 (the "U.S. SAFE WEB Act") and the adoption of Regulation (EC) No. 2006/2004 of the European Parliament and of the Council. U.S. and EU officials have since begun developing a mutual assistance agreement on the enforcement of consumer protection laws.

The U.S. and EU have agreed to undertake the development of a joint pilot project involving the use of radio frequency identification (RFID) technology to track radioactive isotopes and to explore a second joint pilot project on postal bag tracking. The U.S. and EU will hold a joint symposium on the societal benefits of RFID, together with a workshop on RFID and privacy, in September 2008.

In December 2007, the U.S. and EU conducted an exchange of innovation experts on the mechanisms by which energy and sustainability are driving innovation within the European Union.

1.2.5. Investment

At its November 2007 meeting, the TEC launched an Investment Dialogue aimed at reducing barriers to transatlantic investment and promoting open investment regimes globally. Through the Investment Dialogue, the United States and the European Commission have prepared a joint "open investment statement" for submission to the U.S.-EU Summit, in which they affirm their shared commitment to preserve and promote open investment policies at home and globally. The two sides are working to address the challenges of rising protectionism around the globe and have held productive discussions regarding sovereign wealth investment, U.S. and EU investment regimes, and third country investment regimes and barriers. The United States and EU will continue their work as outlined in the Investment Dialogue work plan.

2. The way ahead

The TEC's working arrangements have proved to be a successful innovation which has given new political impetus to EU-U.S. economic cooperation with the objective of overcoming disagreements. A number of goals identified in the 2007 Framework have been achieved in the first year of its work. However, much remains to be done. The first year has confirmed that regulatory cooperation and economic integration entail arduous technical work to be successful and require the continued attention of and commitment by the political leadership to press for progress. This is a long-term project.

The TEC underlines that, as its central objective is to remove unnecessary constraints on and provide a common

regulatory environment for transatlantic economic activity, the priorities for its work should be stakeholder-driven. The TEC emphasises its appreciation of the counsel it has received from its Group of Advisors and of the Group's efforts to reach out to the wider stakeholder communities and to convey in a broad and balanced fashion the views of citizens, consumers and producers on both sides of the Atlantic.

The TEC emphasises the importance of upstream regulatory cooperation to minimize unnecessarily divergent regulatory approaches. The High-Level Regulatory Cooperation Forum has proved its value as a unique platform to bring together top officials involved in sectoral and horizontal regulatory dialogues to exchange views and identify best practices, to build trust and confidence among regulators, and to foster effective working relationships. The TEC has welcomed the reports and presentations of the Forum co-chairs, which allowed the TEC to gain greater insights into the technical complexities of regulatory convergence.

The TEC underscores that transatlantic economic integration and the reduction of regulatory burdens can be constrained by existing legislation or new legislative initiatives. The TEC's efforts would benefit from more active engagement between the legislatures on both sides of the Atlantic. The TEC underlines the importance of a structured, institutionalised dialogue between the European Parliament and U.S. Congress, so that legislators are more vigilant of the potential impacts on transatlantic trade and investment stemming from their legislative work and avoid initiatives that might undermine transatlantic economic integration efforts.

The 2007 Framework recognized the multi-year nature of our work program. In order to bring the initiatives launched in 2007 to fruition, the TEC resolves to continue our work on all elements of the Framework, giving particular attention to intellectual property rights, secure trade and financial markets, and to take stock of progress in a third meeting before the end of this year.

The United States and the European Union share the largest economic relationship in the world. They also share core values, including a belief in the importance of open economies, transparency and the rule of law. These bonds are strong. They inform the U.S. and EU approach to each project they pursue. It is because of the breadth and depth of what unites the United States and the European Union that they expect the TEC to continue playing a vital role in the U.S.-EU relationship.

The European Commission and the United States government affirm their strong commitment to ensure the continuity of the TEC process as the key joint governance mechanism for the transatlantic economy into the future.

Annex:

• U.S.-EU Open Investment Statement

ANNEX

U.S. - EU Open Investment Statement

Today we jointly affirm our commitment to promoting open investment policies at home and abroad and acknowledge that these policies are fundamental to our prosperity. As the global investment environment evolves, with new roles for some actors and the challenges and opportunities that this brings, it is important that there be confidence both in the system and in the actors. We affirm that openness to investment serves as a touchstone for us as we set policies, address new challenges, and interact with our partners around the world.

The benefits of international investment are clear. International investment spurs the development and introduction of new technologies and business methods and provides for healthy competition that fosters innovation. This investment brings to an economy jobs, expertise, increased productivity, and a wider range of goods and services at competitive prices.

An open economy, including an open international investment regime, is indispensable to fostering sustainable economic growth. Investment policies should be non-discriminatory and provide investors clear guidance on any investment restrictions. Countries should avoid new restrictions and strive to eliminate existing restrictions. These principles are cornerstones of our respective investment regimes, and we encourage others to commit to them

too.

We recognize our responsibility in resisting protectionist sentiment at home and in working together to oppose protectionism abroad. Barriers to international investment deprive the global economy and the economies of countries that erect those barriers of a vital source of economic growth.

An open investment environment is compatible with policies that address genuine national security concerns. Measures that address national security concerns should be transparent, predictable and proportionate to the national security concern identified, and precisely circumscribed so as to avoid unduly disrupting the flow of investment.

We note the growth of investments by government-controlled investors such as sovereign wealth funds. We welcome commercially-driven investment from these investors and note the importance of transparent investment policies.

As two of the world's largest sources and recipients of international investment, we are committed to promoting the free flow of investment and the critical role it plays in strengthening both the transatlantic and the world economy.

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