U.S.-EU HIGH-LEVEL REGULATORY COOPERATION FORUM

REPORT TO THE TRANS-ATLANTIC ECONOMIC COUNCIL

ON THE FIFTH MEETING OF THE FORUM

HELD OCTOBER 15, 2008 - WASHINGTON DC

Introduction

The United States (U.S).- European Union (EU) High-Level Regulatory Cooperation Forum ("the Forum") held its fifth meeting in Washington DC on Wednesday, October 15, 2008. The past three Forums have been held in conjunction with the semi-annual Trans-Atlantic Economic Council ("the TEC"), and this report will be submitted to the next meeting of the TEC, scheduled for December 2008.

The day-long Forum was divided into two sessions; the first session was a closed government-to-government meeting between senior officials from the European Commission and regulatory agencies of the U.S. Administration. Senior career staff were also encouraged to attend with their principal in anticipation of the 2009 transitions for both the U.S. and EU. The second session included a public panel discussion with stakeholder representatives hosted by the U.S. Chamber of Commerce.

Session I: Closed Government-to-Government Session

The agenda for the EU and U.S. officials included discussions on four topics:

1. Import Safety - Implementing U.S. and EU recommendations from the May 2008 Forum report on import safety information sharing.

2. Regulatory Analysis/Impact Assessment - Implementing U.S. and EU recommendations from the May 2008 Forum report on considering international trade and investment effects in regulation.

3. Risk Assessment – Update on July 2008 Transatlantic Risk Dialogue meeting and the Global Risk Assessment Dialogue held in November 2008.

4. Standards in Regulations – Discussion of the use of voluntary standards in support of regulation in the U.S. and the EU, including discussion of the terms of reference for a proposed joint report.

1. Import Safety

The Consumer Product Safety Commission (CPSC) reported progress on the implementation of the Consumer Product Safety Improvement Act (CPSIA) (Pub. L. No. 110-314) signed in August 2008. CPSC is charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products under the agency's jurisdiction.

Certain requirements in the CPSIA have significant international impacts and the Forum continues to facilitate discussions on three issues 1) certification and third party testing requirements and lab capacities, 2) identifying opportunities for aligning EU/ U.S. mandatory safety requirements and related standards, and 3) engaging legislators on the value of using voluntary consensus standards when drafting laws instead of writing prescriptive language on specific standards which could inhibit innovation and become outdated.

The Food and Drug Administration (FDA) reported on improved information sharing between the EU and U.S. FDA is committed to building capacity outside of the United States and established the agency's "Beyond our Borders" initiative. The initiative facilitates the building of stronger cooperative relationships with FDA's counterpart agencies around the world and enhanced technical cooperation with foreign regulators.

FDA is establishing permanent offices overseas including: 1) China, 2) India, 3) Middle East, 4) Latin America, and 5) Europe. These offices will allow greater interaction between inspectors and manufacturers to help assure that products meet standards for safety and manufacturing quality.

FDA also demonstrated progress with information sharing with the onset of a pilot trilateral inspection (EU/U.S./Australia) of an active pharmaceutical ingredients plant in China. The plant manufactures base ingredients ("bulk drugs") that are ultimately made into pharmaceuticals. The pilot trilateral inspection leverages resources to help ensure product safety.

The U.S. Customs and Border Protection (CBP) reported on the importance of information sharing for the enforcement roles. CBP depends on agencies like CPSC and FDA and their European counterparts to identify standards that have been violated, for example in food or toys.

CBP's enforcement role requires data and information sharing cooperation to protect global supply chain and critical infrastructure.

The European Commission (EC) reported on recent progress on product safety cooperation. Areas where cooperation already takes place and areas where more collaboration is desirable have been identified. Potential barriers to cooperation (such as confidentiality requirements) have also been identified. The EC noted that the CPSIA opens the door to more information sharing.

The Joint Product Safety Outreach for toys, electrical equipment and clothing was recently conducted by CPSC and the EC in China. The pilot inspection in China had been very well viewed by the EC, which saw scope to expand this to other areas, for example pharmaceuticals and automotive products.

The EC reported on the status of new toy safety legislation, which was close to adoption. The new legislation would allow manufacturers to self-certify the safety of their products where well defined standards can be used as a reference. It did not foresee mandatory testing. This contrasts with the new U.S. CPSIA legislation which includes third party testing requirements for products related to children. Forum members agreed that there would be lessons to be extracted from comparing the impact and benefits of these different approaches.

2. Regulatory Analysis/Impact Assessment Update

Background

The Secretariat General of the EC and the Office of Management and Budget (OMB) prepared a paper reviewing the application of OMB Circular A-4, *Regulatory Analysis Guidance*, of September 17, 2003 and the EC's Impact Assessment Guidelines, with the goal of ensuring that assessment of future regulations takes due account of their impacts on international trade and investment. The report was presented in draft form to the High Level Regulatory Forum held in Washington, DC, on November 7, 2007. In addition, both OMB and the Secretariat General solicited comments from the general public on the draft version of this report. OMB and the Secretariat General modified the report in response to public comment, and submitted the final version of the paper to the TEC in May, 2008.

EU Progress on Report Recommendations

Updated Guidance on methodologies and procedures : From June 4 through July 25, 2008, the Secretariat General of the EC released for public consultation draft revisions to the Impact Assessment Guidelines. The Commission received more than 90 reactions to this public consultation, including 3 from the U.S. The major changes in the draft revised guidelines related to the conclusions of the joint OMB -EC report refer to:

- Increased emphasis on expected effects on international trade and investment; obligation to refer to international regulatory dialogues o r established international standards where they exist.
- Strengthened guidance for consultation (including non -EU citizens and businesses) and for reporting on consultation results.

The revised guidelines are now expected to become effective in January 200 9.

Third Strategic Review of Better Regulation in the EU: The Commission has reviewed its Better Regulation policies and will present this in a Communication that will be further discussed by the Spring European Council in 2009.

Impact Assessment Board: The Impact Assessment Board is a body of high-level officials that was established by President Barroso in 2006 to scrutinize and improve the quality of the Commission's impact assessments. In the context of this work the Board has laid a stronger emphasi s on the adequate analysis of the possible impacts of Commission initiatives on international trade and investment.

U.S. Progress on Report Recommendations

International Impacts Indicator: The Report recognized "The value of timely announcement of plan ned legislative and regulatory initiatives." In order to help the public identify planned regulations of international interest, starting in fall 2008 the U.S. added an "international flag" to the *Unified Agenda* and *Regulatory Plan*. These semi-annual (Agenda) and annual (Plan) U.S Government publications provide uniform reporting of data on regulatory and deregulatory actions under development throughout the Federal Government, covering over 60 departments, agencies, and commissions. The public can now search both documents for a list of entries with international impacts, and will be able to combine such a search with other data elements, such as rulemaking by agency, whether or not the rule is economically significant, has small business impacts, or oth er information of interest.

International Impact Analysis Guidance: For the U.S., the report concluded that "regulatory agencies face both statutory and executive obligations to take international trade impacts into account when developing regulatory prop osals." Specifically, OMB guidance states that "Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully." (OMB Circular A-4, p. 6) The Report also recommended that "guidance should be provided on the type of analysis needed to provide decision makers with information on international trade and investment impacts."

In September, 2008, OMB released draft guidance for public comment. The guidance included analytical recommendations for agencies when considering the effect of draft regulations on international trade and investment, and closely follows the recommendations and discussions from the Report. The draft guidance was released as part of our 2008 draft Report to Congress on the Costs and Bene fits of Federal Regulation[1]. The comment period for this Report closed on November 10, 2008, and as of December 12 OMB is still evaluating public comments.

[1] This report can be found at http://www.whitehouse.gov/omb/inforeg/c osts_benefits/2008_draft_cb_report.pdf

3. Risk Assessment

In November 2007, OMB and the Office of Science and Technology Policy (OSTP) began conversations with DG-SANCO and the EU delegation to facilitate an international dialogue on risk analysis.

This dialogue builds upon the EU-U.S. High-Level Regulatory Cooperation Forum to encourage cooperation at the technical and scientific level in order to arrive at a common understanding on 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 in Washington, DC for a day and a half of government to government discussions on risk analysis issues. The meeting launched a discussion among stakeholders on the role and organization of risk analysis in the U.S., EU, and Canadian regulatory systems, addressed key methodological issues, and the new challenges for risk assessment.

On November 13-14, 2008 the European Commission's DG-SANCO hosted the 1st International Conference on Risk Assessment "Global Risk Assessment Dialogue" in Brussels, Belgium.

The Conference provided a venue for a global dialogue on risk assessment among risk assessment practitioners in government, academia and the private sector. The Global Risk Assessment Dialogue is intended to be the first of future, international bi-annual conferences and will build upon the Transatlantic Risk Assessment Dialogue of the European Commission with the U.S. and Canada. The U.S., EU, Canadian, Japanese, Chinese, Australian and Russian governments were all represented. An outcome of this meeting was a discussion of specific topic areas where further collaboration and joint products would be useful. Working groups identified specific topics relating to uncertainty and terminology, non-threshold carcinogens, exposure assessment, and emerging risks.

4. Standards in Regulations

The use of standards, including voluntary national and international standards in regulation, was first suggested for inclusion in Forum discussions by DG ENT at the Forum held in Brussels on April 25, 2008. In this session of the Forum, EU and U.S. agency participants summarized the use of standards in their regulatory activity.

In the U.S., Public Law 104-113, also known as the National Technology Transfer and Advancement Act of 1995 (NTTAA), is perhaps the most important piece of U.S. legislation affecting the regulatory use of standards In short, the NTTAA endorses the use of private sector standards to achieve public policy objectives, and directs U.S. Federal agencies on their use of private sector standards and conformity assessment practices. It instructs U.S. Federal agencies to use private sector consensus standards wherever possible, in lieu of creating government unique standards. The Act also charges the National Institute of Standards and Technology (NIST) with bringing together U.S. Federal agencies, as well as State and local governments, to achieve greater reliance on voluntary standards.

Further guidance on implementing the NTTAA is contained in OMB Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,* of February 10, 1998. This Circular instructs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. It also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. The aim of the Circular is to reduce to a minimum the reliance by agencies on government-unique standards.

Other legislation that affect standards adoption and use by specific federal agencies include:

- The Consumer Product Safety Act, which directs the CPSC to rely on voluntary consensus consumer product safety standards rather than promulgate its own standards;
- The Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), which requires the Secretary of Health and Human Services to adopt standards developed by the American National Standards Institute (ANSI)-accredited standards developers whenever possible;
- The Telecommunications Act of 1996 (Pub. L. No. 104-104) which contains several provisions that encourage Federal Communications Commission (FCC) reliance on private sector standards;
- The Food and Drug Administration Modernization Act of 1997 (Pub. L. No. 105-115), which contains provisions that allow the FDA in some instances to accept manufacturers' declarations of compliance to certain standards during the evaluation of premarket submissions for electrical medical devices.

These Acts of Congress set forth requirements and goals regarding federal usage of standards.

In terms of its international and regional obligations, the U.S. Government is a signatory to the World Trade Organization (WTO) agreements. One agreement, the Agreement on Technical Barriers to Trade (TBT Agreement), recognizes the important contribution that international standards and conformity assessment systems can make in improving production efficiency and facilitating international trade. This Agreement seeks to ensure that regulations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade. The TBT Agreement encourages countries to use international standards where appropriate, but the Agreement does not require countries to change the levels of protection that they consider appropriate.

In the EC, legislation focuses on mandatory safety requirements rather than on the specific means of achieving them. Standards are referred to as a means of meeting these requirements, but are not mandatory. A manufacturer may adopt another approach to meeting requirements. However, where a manufacturer can demonstrate compliance with the referenced standards, then they are protected from liability should the product subsequently fail. In the majority of cases, legislation references national or European standards which are identical to international standards. Manufacturers can in some cases make a declaration that their products conform to the relevant standards and are not required to submit the products to independent testing.

The EU is able to request the development of standards if there are no suitable standards already existing, by issuing a mandate to the European Standards Organisations (ESOs). This avoids the development of incompatible national technical regulations. Although the ESOs are composed of European national standardisation organizations (apart from the European Telecommunications Standards Institute ETS which has over 700 members from over 60 countries), the national bodies are open to commercial members.

Due in part to the diversity in the use of standards within and between the two systems, the Forum participants endorsed the production of a report of the U.S. and EU standard systems, which will be led by the U.S. NIST and DG ENT. The report will summarize and compare U.S. and EU law and policy on the use of standards in regulation, including mechanisms for incorporating standards in regulation, how they are used to meet regulatory objectives, stakeholder review in the use of standards, standards maintenance and updating, the use of standards in an international context, and sector level case studies.

Session II: Public Stakeholder Session

Organized by the U.S. Chamber of Commerce and hosted by an additional 11 stakeholder groups, the Forum held a public session attended by approximately 125 people. The session began with a brief overview of the closed session discussions by the Forum Chairs, who also answered audience questions.

This was followed by a stakeholder panel discussion on *Regulatory Cooperation During Transitions.* The panel focused on issues such as the value of the Forum, the importance of its work to date, and suggested Forum agenda issues for 2009 and beyond. Moderated by Sean Heather, U.S. Chamber of Commerce, the panel included:

- Dr. Dan Hamilton - Director, Center for Transatlantic Relations, Johns Hopkins University SAIS
- Jeffries Briginshaw - EU Executive Director, Transatlantic Business Dialogue
- Ed Mierzwinski - Consumer Program Director, U.S. Public Interest Research Group
- Michael Maibach - President and CEO, European American Business Council
- Gary Litman - Vice President, U.S. Chamber of Commerce

While generally endorsing the work of the Forum, the panel indicated that it was difficult to judge the success of the Forum's work to date for two reasons: 1) the need for better transparency to assess the impact the Forum on issues such as import safety, and 2) the lack of quick deliverables due to the long-term nature of the Forum's work.

The Panel and the audience participation offered several recommendations on ways to improve the Forum moving forward:

1) Increase transparency of Forum activities. Many stakeholders sought clarity as to the respective responsibilities of the Forum and the Transatlantic Economic Council. Some stakeholders were also uncertain about the role of the Forum, its mission, its program of work, and its accomplishments to date. There was a call for a better communication between Forum stakeholders, including a recommendation for the use of a designated Forum website.

2) In order to learn more about the methodological differences between the U.S. and the EU regulatory processes, stakeholders recommended that joint case studies be used to discuss the use of sound science and economic analysis, as well as the appropriate role for social considerations when regulating.

3) Public stakeholder recommendations for future Forum topics and programmatic work include:

- Using the Forum to build trust, nurture relationships, and start conversations amongst transatlantic regulators on emerging issues, such as nanotechnology and cloning, with an aim of preventing or limiting market distorting and conflicting regulatory approaches on either side of the Atlantic.
- A significant endorsement of the Forum's interest to develop a program of work on the role of voluntary standards in regulation, and a call for such a program to be developed in connection with stakeholders, including ANSI and the European Standards Organizations.
- A suggestion that the Forum find a way to engage the Transatlantic Legislator's Dialogue and other legislative bodies early in the regulatory cooperation process.