

United States – European Commission

High-Level Regulatory Cooperation Forum

10th Meeting 7 and 8 June 2011

The 10th meeting of the EC-U.S. High-Level Regulatory Cooperation Forum was held in Brussels on 7 and 8 June 2011. The co-Chairs were Heinz Zourek, Director-General of the Enterprise and Industry DG of the European Commission and Michael Fitzpatrick, Associate Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget in the Executive Office of the President.

I. Government-to-Government Session

Better Regulation Issues

Common Understanding of Regulatory Principles and Best Practices

In its meeting of 17 December 2010, the Transatlantic Economic Council (TEC) invited the High-Level Regulatory Cooperation Forum to draft a joint statement in which the United States (U.S.) and the European Commission (EC) reaffirm their shared commitment to the following regulatory principles, as embedded in the EC's Communication on Smart Regulation and Impact Assessment Guidelines, and Executive Orders 12866 and 13563 in the U.S.:

- (1) evidence-based policy-making for all regulatory measures¹ likely to have significant impacts, with consideration of all relevant benefits and costs;
- (2) transparency and openness, allowing participation by citizens and stakeholders;
- (3) analysis of relevant alternatives;
- (4) monitoring and evaluation of the effectiveness of existing regulatory measures;
and
- (5) use of approaches that minimize burden and aim for simplicity.

The Forum adopted a [joint statement](#) on regulatory principles and best practices at its 10th meeting, which will lay the groundwork for further cooperation. Both sides agreed to ensure an open process when developing or changing regulatory measures and to highlight or “flag” domestic regulatory measures that may impact international trade and investment. In addition, OMB noted recent [guidance](#) from OIRA Administrator Cass Sunstein and Deputy U.S. Trade Representative Miriam Sapiro to provide at least a 60-day comment period for proposed regulatory measures.

The Forum also agreed to continue discussions on increasing transparency in the existing notification procedures under the WTO agreements on technical barriers to trade and on

¹For the EC, this applies to both proposed laws and implementing legislation; whereas for U.S this is limited to implementing regulations issued by the Executive Branch.

sanitary and phytosanitary measures with a view to reaching consensus by the time of the next TEC meeting on aspects that could be improved.

Action Items:

- Continue discussions on increasing transparency in the existing notification procedures under the WTO agreements on technical barriers to trade and on sanitary and phytosanitary measures with a view to agreeing on aspects that could be improved by the next TEC meeting.

Ex-Post Evaluation of Regulatory Measures

United States

U.S. Agencies have drawn up plans for the review of regulatory measures in response to [the](#) President's Executive Order 13563, which ordered an unprecedented governmentwide review of existing regulations. On 25 April, 2011, OMB provided guidance, [OMB Memorandum M-11-19, "Retrospective Analysis of Existing Significant Regulations."](#) to the agencies when drafting their plans. The U.S. Government expects the resulting reviews to lead to significant savings as burdens are reduced. Review of regulations will be a continuing requirement and Administration priority, as agencies will be submitting semi-annual reports on their progress to ensure continuing accountability and implementation.

These retrospective plans are available for public consultation online here: <http://www.whitehouse.gov/21stcenturygov/actions/21st-century-regulatory-system>. A particular feature of this public comment process is that respondents were asked to give examples of regulations that create unnecessary burdens and to estimate the cost of these burdens. In addition, the U.S. noted that agencies are expected to conduct ex post review in perpetuity. This initiative is expected to result in billions of dollars in cost-savings in the coming years.

Commission

The Commission views ex-post evaluation of regulatory measures as an essential element of Better Regulation. In 2011, 170 individual financial and regulatory measures are scheduled for ex-post evaluation and a further 120 are to be reviewed in 2012. The Commission also believes that reviews can sometimes usefully look at the interaction of related measures, rather than just focusing on one measure, and has developed the concept of the "Fitness check." In a Fitness check the totality of measures applicable to a particular field of activity is reviewed. Four Fitness checks have been launched. The Commission has been active in the reduction of administrative burden. Measures already proposed by the Commission aim to reduce the burden by 30%.

Action Items:

- Continue discussions on the ex post evaluation initiatives and share best practices.

Standards

The European Commission presented the standardization package, which was adopted on 1 June 2011. There are two elements to the package. The first element is a strategic paper setting out how standards will be used to support policies such as EU 2020 and

major challenges such as climate change. The second element sets out improvements to the standards-setting process designed to speed it up and to improve opportunities to provide input, for example through the annual standardisation work programme.

The European Commission has proposed a list of priority areas for cooperation in the development of standards. There is already recognition of the need to cooperate in standards relating to e-vehicles and collaboration relating to energy-efficiency requirements relating to certain product groups is advancing well. The U.S. will respond to the rest of the Commission proposals before the co-chairs' conference in October.

The Forum discussed approaches to building bridges between the two systems for developing and using standards. Previous discussions have emphasized the fundamental differences between the two systems, ranging from the European legislative framework, to the U.S. law, policies and practices, how standards are used in regulatory measures and the definition of an international standard. There is a will on both sides to build bridges between the two systems, particularly in order to help ensure that compatible standards are developed quickly in order to keep pace with rapidly evolving technology.

Discussions involving the Commission, U.S. Government agencies, European Standardisation Organisations and possibly U.S. standards development organisations will continue. An update on these discussions will be provided to the Forum Co-Chairs during a digital video conference in October.

Action Items:

- Agreement on horizontal approaches to standards that are necessary to ensure the success of sectoral cooperation in standards development.
- The U.S. will respond to the rest of the Commission proposals before the co-chairs' conference.

Energy Efficiency

The Forum took note of a progress report on cooperation on the development of energy efficiency standards for the three product groups previously selected (distribution transformers, commercial refrigeration and some types of solid state lighting). This cooperation project will take some time to produce deliverables, given the detailed technical nature of the work undertaken, but already it is showing that the two administrations can reduce their own costs by sharing the work, independent of any cost savings to stakeholders which will eventually result from common specifications.

The Forum invited the participants in this project to produce a timetable for delivery of results, in cooperation with standards developers, and will examine this project at a future meeting to extract lessons on how to establish successful cooperation in other areas.

Action Items:

- Forum invited the participants in this project to produce a timetable for delivery of results, in cooperation with standards developers.
- The Forum will examine this project at a future meeting to extract lessons on how to establish successful cooperation in other areas.

Nanotechnology

The Forum provided the opportunity for further discussion on the Commission's forthcoming definition of nanomaterials. The U.S. also gave a presentation of its newly released guidelines on policy principles outlining an approach to regulating nanotechnology and nanomaterials.

Both sides agree on the need to favour a science-based, risk-based approach to regulation in this area similar to that used for "conventional" chemicals. While the EU chose to develop a regulatory definition of the term "nanomaterial" based on size alone to improve regulatory coherence and consistency across various legislative areas, targeted assessment of particular properties of nanomaterials will be essential for the risk assessment of nanomaterials.

Future regulatory measures should be based on scientific knowledge. Potential restrictions should normally be based on risk, not merely hazard. Some products may exhibit less risk in the nano size and some may have more risk, with materials regulated on a case-by-case basis and based on the best available science. Both sides agreed that communication is essential in determining what happens with nano, taking care that our governments do not communicate to the public that nano in general equals uncertainty that equals unacceptable risk.

Action Items:

- Develop initiatives to align regulatory approaches such that consistency exists for producers and stakeholders in the EU and US.

Upstream Coordination

The Department of Commerce informed the Forum that its public consultation on priorities for regulatory cooperation would be extended until August. As of the date of the Forum meeting, over thirty replies had been received covering a broad range of areas. U.S. Government agencies will analyse the replies and the results will be discussed between the Commission and the U.S. Government. The co-chairs will review this in their October digital video conference with a view to deciding how to proceed.

The Commission drew attention to its resource efficiency initiative, which will look (among other things) at the total energy consumption of a product from extraction of input materials to final disposal including recycling. This is likely to produce new regulatory developments where upstream coordination may bear fruit.

Action Items:

- The co-chairs will review the analysis of comments in their October digital video conference with a view to deciding how to proceed.

II. Stakeholder Session

Business Europe hosted the public stakeholders session following the Forum. In addition to the hosts, representatives from the Transatlantic Consumers Dialogue (TACD),

AmCham EU, firms and industry associations, and Brussels-based think tanks attended. U.S. Ambassador to the EU William Kennard made opening remarks and asked that all stakeholders “give thought on how to institutionalize the process the Forum offers.” The Forum Co-Chairs then briefed the group on Forum progress and next steps.

Compatible Regulatory Regimes

Following the Forum readout, the U.S. Chamber of Commerce outlined main proposals from a U.S. Chamber study on transatlantic regulatory cooperation, including mutual acceptance of established procedures regarding safe products, quantifying the cost to society of divergent regulatory measures, and a pilot program on mutual recognition in product safety looking at the automotive, chemicals’, and pharmaceuticals’ sectors.

Nanotechnology

The stakeholder session featured a panel on nanotechnology. TACD proposed a step-by-step, science-based approach to regulating nanotechnology, but, given gaps on research into long-term effects of nanomaterials on human health and the environment, one based on the precautionary principle. OMB provided an update on U.S. Government efforts, including the recent release of the memorandum to all executive departments on setting principles on regulating emerging technologies, with nano being one of the many technologies meant to be addressed. The goal is to assess multiple emerging technologies and protect health and safety, but do so in a way that does not hinder innovation.

Minimum Compliance Windows

Business Europe closed the session with a call for longer compliance periods for industry with respect to regulation, focusing on a number of examples (such as for REACH) of insufficient compliance windows that make it “difficult if not impossible” for industry to comply with regulatory measures on both sides of the Atlantic. The Forum was asked to consider the issue.