

Horizontal Co-operation

General

October 2009

The United States and the EU continue to work towards removing unnecessary differences in regulation by deepening collaboration, sharing best practices, and jointly extending expertise to support third-country regulatory efforts. The Office of Information and Regulatory Affairs (OIRA) in the U.S. Office of Management and Budget (OMB) and the Commission Based their work on a joint report from May 2008 on how both sides address trade and investment impacts in their respective regulations. The Commission Impact Assessment Board actively monitors this in its quality control of the Commission Impact Assessments. The EU followed with revised guidelines to ensure that such impacts are considered; in the United States, regulations that have international impacts are specially flagged.

Substantial progress has been achieved between U.S. and EU regulators in the High-Level Regulatory Cooperation Forum (HLRCF). The Forum met twice in 2009, during July and October. During its July 24 meeting, the Forum reviewed progress in the areas of impact assessment, the use of standards in regulation, risk assessment, and import safety. Energy efficiency standards were among the issues discussed during the July and October 26 meetings. The two sides agreed to develop an inventory of regulations and initiatives in this area. OIRA and DG Enterprise presented papers during the October 26 meeting describing the U.S. and EU approaches to the use of voluntary standards in support of regulation. Both sides also discussed the usefulness of continued dialogue regarding developments related to the risk analysis and regulation of nanomaterials.

These discussions in the HLRCF were reported to the October 27 TEC meeting. Contacts between OIRA and the U.S. Office of Science and Technology Policy (OSTP) with the Commission's Directorate of Health and Consumer Affairs (DG SANCO) to facilitate an international dialogue on risk analysis, led to risk analysis discussions starting in July 2008 that included representatives from the United States, EU, and Canada. In January 2009, OMB, SANCO, and Canadian government risk managers reinstated the practice of weekly conference calls to ensure progress in work groups that will develop white papers in three focus areas: 1) development of a framework for exposure assessment; 2) uncertainty and terminology; and 3) new/rapid approaches to risk assessment. The risk assessment papers are expected to be available for broad discussion in 2010.

December 2008

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.

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. 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.

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.

May 2008

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 postrecall) 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.

November 2007

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.