European Commission-United States High-Level Regulatory Cooperation Forum

Report of the 9th Meeting

Washington DC, 16 December 2010

The European Commission-United States High-Level Regulatory Cooperation Forum (the Forum or HLRCF) met for the 9th time on December 16, 2010, under the co-chairmanship of Heinz Zourek, Director-General for Enterprise and Industry, and Cass Sunstein, Administrator of the Office of Information and Regulatory Affairs (OIRA), a component of the U.S. Office of Management and Budget (OMB). The United States hosted the meeting, which was the second to be held under the second Barroso Commission and the fourth for the Obama Administration.

The meeting followed the established pattern of a closed government-to-government session followed by an open session organized by and for stakeholders. On December 17, 2010, the Forum co-chairs participated in the Transatlantic Economic Council (TEC) meeting and presented a summary of the previous day's discussions. Regulatory cooperation was a key part of the TEC agenda, highlighting the need to reduce non-tariff barriers to trade (NTBs) if the U.S. and the EU are to advance the TEC's goals of promoting economic growth and job creation.

I. Government-to-Government Session

The government-to-government part of the Forum involved more than a half-day of discussions. Although many participants favored the extended format (1.5 days) recommended and established at the June 2010 meeting in Brussels, the timing of the December meetings was such that the extended schedule was not possible. However the EU and U.S. will discuss reverting to the extended format in future meetings. Similar to previous Forum meetings, agenda topics ranged from cross-cutting issues such as use of voluntary standards and better regulation issues, to more timely sectoral issues such as energy efficiency standards and Energy Star.

Overall, both the U.S. and EU participants thought that the Forum was a success, with concrete actions which can be implemented in the near future.

Better Regulation Issues

The European Commission has set out plans to further improve the quality and relevance of EU legislation. It will evaluate the impact of legislation during the whole policy cycle: when a policy is designed, when it is in place, and when it is revised. The Commission will work with the

European Parliament, Council and Member States to encourage them to apply "smart regulation" in their work.

It will also strengthen its work on the implementation side of policies by making legislation clearer and more accessible, and will work with Member States, for strict enforcement of it. For this purpose the Commission will give more specific attention to these aspects in ex post evaluation, it will provide implementation plans for the transposition of new EU legislation, and make more effective use of complaints received from citizens and businesses (for example through SOLVIT).

EU overview of *ex post* review of regulations

The Commission will **target the whole policy cycle** by attaching more importance to the **ex-post evaluation** of existing legislation and policies. Evaluation of effectiveness of existing measures and policies is a fundamental step in developing new initiatives. All significant proposals for a revision or new measure should, in principle, be based on evaluation of the existing policy-framework. Evaluation of existing regulation will be performed in partnership with the Member States.

To increase transparency, the evaluations planned to be carried out in the future in the different policy areas are made publicly available on Europa website. The indicative multi-annual evaluation planning for 2010-2015 includes a total of 144 regulatory measures.

The Commission described its **"fitness checks" initiative**, a new, more comprehensive and holistic approach for ex post review. The initiative will manage the quality of regulations throughout the cycle, set a more thorough process to evaluate the effectiveness of significant and/or new regulations, and will look to improve the current framework, which provides a piecemeal review of regulations.

Fitness check pilots will be conducted in a number of regulatory areas between now and 2012, including: (1) employment and social affairs; (2) the internal market for aviation; (3) environmental policy – protection of fresh water resources; (4) industrial policy.

The Commission also reported on the EU Court of Auditors and their review of the **implementation of regulatory impact assessment (RIA)**. Their report was generally positive and considered the EC's use of RIA as a "good practice." However, other institutions are not consistently implementing this tool, and the Court of Auditors recommended that, in order to be effective, RIA must be used throughout the EU.

There are also efforts underway to **strengthen the voice** of citizens and stakeholders input. For example, in 2012, the EC will extend its public consultation process from eight weeks to twelve weeks. In addition, the EC will review its RIA and consultation processes, looking in particular at: the publication of forward planning of consultations; the quality of consultation documents; the use of tools such as "Your Europe", the European Business Test Panel, SME panels, the Register of Interest Representatives and the interactive policymaking tool (IPM) and other Web 2.0 applications.

The U.S. mentioned the President's recent challenge to look for ways to reduce regulatory burden, including **burden reduction initiatives** for small businesses, and allowing electronic submissions vs. paper. Over seventy initiatives have been identified across the government, which will result in an estimated reduction of 20 million burden hours.

U.S. Overview of *ex ante* review of regulations

Administrator Sunstein proposed moving forward on regulatory cooperation on three levels: (1) agreeing on a set of good regulatory principles, (2) improving use of existing mechanisms, and (3) creating new mechanisms. The Commission reacted positively, expressing the desire to reinforce principles and broaden the sharing of experience. Both sides agreed to have an agreement on regulatory cooperation, including possibly a Terms of Reference.

The discussion went more in-depth on possible cooperation and both sides agreed to reaffirm five **regulatory principles**:

(1) transparency and openness, allowing participation by stakeholders and the public;
(2) consideration of costs and benefits;
(3) careful analysis of alternatives, including less stringent and more stringent;
(4) selection of the least burdensome approach; and
(5) use of flexible tools, promoting freedom of choice and free markets.

The U.S. outlined **current cooperation mechanisms** already in place, such as the semi-annual Unified Agenda (UA) and annual Regulatory Plans. These forward-looking planning tools, available on-line, show the agencies' future regulatory actions and the timeline for these actions. The EC shared that they have a similar tool, called Roadmaps. It was recommended that, before the next Forum, both the U.S. and EU review the Unified Agenda and Roadmaps to compare the timing of planned regulatory activities in specific sectors and discuss specific aspects of the regulatory efforts, not just general issue areas**.**

Additional U.S. mechanisms include the Administrative Procedure Act's notice and comment process, which requires that agencies consider all comments, including those from foreign governments and outside parties. The U.S. also described "E.O. 12866 meetings," which are meetings involving OIRA, the regulating agency, and outside parties on draft regulations that OIRA is reviewing under Executive Order 12866. Under this provision of E.O. 12866, OIRA will grant requests to meet with outside parties to discuss any draft rule under review by OIRA. Administrator Sunstein noted that foreign governments could take greater advantage of this opportunity. The rules that are eligible for meeting requests are listed on the "OIRA Dashboard," which is available on www.RegInfo.gov.

OIRA is also prepared to discuss **new cooperation mechanisms** to expand the ways in which the EU and U.S. can work together. A few ideas that the U.S. is considering include a commitment that OIRA's senior leadership would meet with EU regulators who have concerns about U.S. regulations under OIRA review; collaboration with the EU on new "early warning" processes of regulations that would provide sufficient time for input, particularly on standards-

related activities; and developing an online "international flag" to identify those rules on the OIRA Dashboard that are expected to have significant international effects.

Mr. Zourek expressed interest in providing reciprocal tools, and will consult with the EU Secretariat General, but saw "no problems moving forward."

Action Items:

- By the end of February 2011, both sides arranged to work toward an agreement on regulatory cooperation on three levels: (1) agreeing on a set of good regulatory principles, (2) improving use of existing mechanisms, and (3) creating new mechanisms.
- Before the next Forum both sides also agreed to review the U.S. Unified Agenda and the EU Roadmaps to compare timing of specific sectors and discuss specifics parts of the regulatory efforts, not just general issue areas**.**

Use of Voluntary Standards in Regulations

Both sides acknowledged the differences between the EU and the U.S. on the use of voluntary standards in regulations, but agreed to "build bridges" between the two approaches. Renate Weissenhorn, from DG Enterprise, opened the session by noting that, despite "our agreement to disagree," we still had much to discuss, announcing that that the EC is working on a **new proposal for standardization system reform**. The four major aims of the proposal are to: 1) make the process more efficient for SMEs and stakeholders, 2) speed up the standardization process, 3) better link standards to the policy objectives, and 4) translate the connection between standards and innovation/research.

Although the proposal must go through the EU political process, the EC will welcome U.S. review and comment on the proposal. The EC also encouraged the U.S. generally to strengthen its participation in international standards bodies. The U.S. indicated that it already has a very robust participation in international standards development.

Jeff Weiss from the Office of the United States Trade Representative (USTR) also expressed the U.S.'s interest in finding **practical ways to move forward** in addressing differences on the use of voluntary standards in regulations. He argued that, when the U.S. and EU agree on certain standards, others countries are more likely to adopt them and it is less likely that new poles of standards development will emerge to restrict trade.

Transparency is essential in order to reduce non-tariff barriers and to increase stakeholder participation. However, timing of transparency is important. Acknowledging that both sides should take better advantage of existing mechanisms—such as the Unified Agenda and Roadmaps—to identify areas in which new standards do not necessarily need to be established, it is often preferable to instead cite "the best" available standard. As innovations increase, so should our interest in stakeholder participation.

The Commission reiterated its current efforts to develop a number of mechanisms that would lead to greater transparency of and accessibility to the EU's regulatory regime, including expanded timelines for public feedback and consultation and earlier advance signaling of regulations and directives in the pipeline.

Both sides agreed to produce a **joint statement on standards in regulation** — subsequently drafted and agreed to on December 16 — which emphasizes enhancing transparency and meaningful stakeholder participation in the U.S. and EU's respective processes for developing standards and regulations. The joint statement (provided in the appendix to this report) committed the two sides to developing by the next Forum meeting a set of proposals to implement these principles.

Action Items:

- Both sides agreed to a "Joint Statement on Standards in Regulation"
- The joint statement committed the two sides to developing by the next Forum meeting a set of proposals to implement these principles.
- When appropriate, the EU will engage U.S. regulators for comments on the proposal for standardization reform.

Energy Efficiency

Jacek Truszynski, from DG Energy, outlined current efforts to cooperate on establishing energy efficiency standards and harmonizing testing protocols in three product groups: commercial refrigerators, transformers, and solid state lighting. Truszynski said the three products were initial selections for collaboration.

Roland Risser from the U.S. Department of Energy (DOE) reiterated his agency's interest in expanded cooperation and said that technical experts from the two agencies met earlier in the week and had made progress. The collaboration on commercial refrigerators and transformers can likely show significant progress by the next Forum. However, both DG Enterprise and DOE wanted to set realistic expectations about the time it takes to establish testing requirements, and clarify that a common standard is not necessarily the goal, although both sides agreed that would be ideal, if possible. Risser said solid state lighting would be the more difficult area of work, given the newness of the technology and need for development of new test procedures.

DOE also highlighted other fora in which the U.S. and EU focus on energy efficiency collaboration, including U.S.-EU Energy Council and the Clean Energy Ministerial's Super-efficient Equipment and Appliance Deployment (SEAD) initiative.

A joint declaration on energy cooperation was to be signed at the Transatlantic Economic Council (TEC) on Dec 17, 2010. Both sides agreed to make substantial progress by next summer's Forum.

Action Items:

- Make substantial progress, including movement toward common test methods, by the next Forum on regulations or standards governing the three products: commercial refrigerators, transformers. Including timelines and milestones.
- A joint declaration on energy cooperation was to be signed at the Transatlantic Economic Council (TEC) on Dec 17, 2010.

Point of Purchase Labeling

U.S. Food and Drug Administration (FDA) Commissioner Margaret Hamburg reviewed U.S. approaches to labeling, highlighting graphic image labels on cigarette packaging and point of purchase nutritional food labels. Hamburg said the FDA has a January 11, 2011, deadline to develop new labels for cigarette packages that will target high risk groups such as young adolescents. On food labeling, she said FDA efforts to update nutritional information were part of a broader effort by the First Lady and the Administration to address childhood obesity and the burden of preventable illness due to poor nutrition.

EU Delegation Minister-Counselor for Health Bernard Merkel said efforts to harmonize food labeling in the EU are advancing, with proposals now in the co-decision process, but views are divergent on a number of issues and so reaching an agreement was taking some time. In relation to tobacco labeling, the Commission hoped to have a proposal ready by the end of 2011 for a revision of the Tobacco Products Directive which covered textual and pictorial warnings. He noted that it could be useful to share empirical evidence with the FDA on "what works" in regard to the labeling of food and tobacco products. The two sides agreed to explore potential areas of cooperation. One area suggested was looking at methodologies to quantify salt and fat intake.

Action Items:

- Explore potential areas of cooperation on labeling of food and tobacco products, including common principles (such as simplicity, clarity, and meaningfulness) and sharing of empirical evidence about costs and benefits.

Supplier's Declaration of Conformity (SDoC)

The U.S. Occupational Safety and Health Administration (OSHA) presented its long awaited conclusions and response to the EU regarding the Commission's 2008 proposal for OSHA to adopt Supplier's Declaration of Conformity (SDoCs) for the safety of electrical products. OSHA had decided **not to initiate rulemaking to allow for SDoCs**, and thus will maintain its third-party certification system.[1] OSHA stressed that the decision to continue with third-party

[1] The OSHA Notice was published on December 17, 2010 and the complete docket can be viewed at http://www.regulations.gov/#!docketDetail;dct=FR+PR+N+O+SR;rpp=10;so=DESC;sb=postedDate;po=0;D=OSHA-2008-0032

certification should not be taken as an implication that the U.S. believes the SDoC system is not safe for the EU.

Summarizing the reasons behind the conclusions, OSHA cited the lack of data "showing that electrical products in an SDoC system present a "low risk" of injury, and expressed concern that SDoC relied heavily on post-market surveillance, which was more likely to allow nonconforming products in the marketplace. OSHA also didn't find data that confirms SDoC meets the "high degree of protection" requirement in the OSH Act.

In addition, OSHA estimated that implementing an SDoC system could cost the U.S. Government an estimated $360 million, and noted that OSHA lacked the enforcement authority necessary for an SDoC system, such as the power to issue product recalls or bans.

OSHA reiterated that their application process to become a Nationally Recognized Testing Laboratory (NRTL), is the same for foreign or domestic entities, and that NRTLs don't present unique barriers since they apply equally to all products, regardless of country of origin.

OSHA acknowledged that the EC participant did not have adequate time to review the published notice. However moving forward, OSHA is prepared to provide the EC with detailed briefings on their findings and conclusions, and has offered for U.S. economists to meet with EC economists to discuss the details of the cost-benefit analysis. OSHA is also prepared to discuss types of valid statistical data that would be needed to evaluate SDoC.

DG Enterprise expressed disappointment with OSHA's conclusion, but suggested that the two sides explore working on an effort at mutual recognition of product certificates. It added that products on both sides of the Atlantic have a good safety record. The EC looked forward to seeing the specifics on the cost figures ($360 million), which on the surface seemed inaccurate, and that an SDoC system is actually lower in overall costs than a third-party system, when considering the costs to manufacturers.

OSHA published a notice containing its analysis in the Federal Register on December 17, 2010, and it committed to provide a detailed briefing for the Commission regarding the notice. (Note: On February 2, 2011, OSHA reached out to the Commission and invited the Commission to work with OSHA to set up a time for the briefing.) (OSHA notice is available at: http://edocket.access.gpo.gov/2010/pdf/2010-31695.pdf)

The parties agreed to future discussions once the EC had reviewed OSHA's decision more carefully.

Action Items:

- Although the EU disagreed with the U.S.' decision not to initiate rulemaking to allow for Suppliers' Declarations of Conformity (SDoCs) on product safety, both sides agreed to continue exchanging information in view of future possible discussions.

Nanotechnology and Risk Assessment

Michael Fitzpatrick, Associate Administrator for OIRA, updated the Forum on accelerated and robust U.S. efforts to develop a consensus approach to nanotechnology. He noted the recent U.S. Government submission in response to the Commission's request for input on its proposed definition of "nanomaterial". He expressed appreciation for the opportunity to comment and emphasized that the U.S. response, in the form of questions, was designed to begin a dialogue with the Commission" on nanotechnology.

The EC was encouraged by both the U.S. response and increased activity on nanotechnology and said the Commission was "being pushed by Parliament" to move faster on defining nanotechnology. The two sides agreed to take a **risk-based approach** on regulating nanotechnology, which represented a more advanced approach compared to looking at hazards alone. The two sides also agreed to look at the **best available science** on nanotechnology, and to continue to **share best practices** and research.

OIRA plans to participate in the 2nd International Global Risk Dialogue in January 2011, organized in Brussels by DG Health and Consumers. The EC encouraged more U.S. participation in the risk conferences. U.S. reiterated their on-going and active participation with the EU and Canada on the various risk assessment activities.

Action Items:

- Agreed on a risk-based approach, rather than a hazard-based approach to regulating nanotechnology
- Agreed to base analysis on the best available science
- Agreed to continue cooperation and sharing of best practices

Energy Star

DG Energy highlighted Commission efforts to work with the U.S. Environmental Protection Agency (EPA) as the U.S. begins to require third party certification for Energy Star products at the end of 2010. He said a Commission study **found a high level of compliance with Energy Star in the EU** and hoped to find a way forward—possibly mutual recognition—would be found to keep EU products on the market in the U.S. The EC commented that in addition to industry needing more lead-time to comply, the EU has a procurement requirement for Energy Star products and the third-party testing could add a new burden for SME's trying to gain government contracts.

The EC also asked what risk/impact assessment was conducted to support the changes to the program. EPA indicated that the Agency had many conversations with stakeholders and in response to these took steps to reduce potential burden. These steps include allowing for use of accredited in house labs and labs active in a Certification Body's supervised witnessed manufacturing program. Further, EPA relayed that the agency has recruited ample labs, certification, and accreditation bodies with the intention of driving down costs and reducing any delays to market.

EPA is the lead U.S. agency for the Energy Star program, and an EPA representative said their agency has been working with colleagues in DG Energy and that the organizations had reached agreement that DG Energy and EPA would **honor the current agreement that extends until December 2011,** including mutual recognition, but would work to ensure there are safeguards in place. Existing EU products would remain qualified until a new specification for that product category takes effect. None of the Energy Star IT product categories will see a new specification take effect in 2011. EPA committed to continue to work out a longer term solution with the EU.

Action Items:

- Both sides would like to continue using Energy Star and agree to determine terms of a renewed Letter of Agreement between the U.S. EPA and the EC by December 2011.
- In light of third party certification requirements in the U.S., both sides agree to develop an approach to allow continued mutual recognition between the U.S. and EC, with safeguards, until the new Agreement is in place.

II. Stakeholder Session

Consistent with previous Forum meetings, the U.S. and EU governments joined consumer, labor, and business stakeholders at the U.S. Chamber of Commerce (Chamber) for a public stakeholder session.

Forum Update

Michael Fitzpatrick, Associate Administrator of the Office of Information and Regulatory Affairs (OIRA), a component of the U.S. Office of Management and Budget (OMB) and Heinz Zourek, Director-General for Enterprise and Industry summarized the morning session highlighting the various action items for each of the topic areas. Both thought the meeting had fruitful debate and provided a way forward to overcome difficulties and differences. In addition, both concurred that there was strong convergence on the desire to reduce burden on businesses and to support growth and job creation.

After the update, Chamber moderator Sean Heather, Executive Director for the U.S. Chamber's Global Regulatory Cooperation Project commented that he was impressed with the progress, especially on the agreements for establishing regulatory principles, discussions regarding Energy Star, and the risk-based approach on nanomaterials.

There were questions about the nanotechnology readout, asking whether the agreement to use a risk-based, rather than a hazard-based, approach meant that the two sides had agreed not to use the so-called "precautionary principle." Zourek responded that regulating on the basis of hazard vs. risk was a separate issue from the precautionary principle, which provides the ability to regulate when you don't know the risks and want to be on the "safe side." Hazard relates to products that you do not necessarily come into contact with. However, we must look beyond "size" and calibrate regulation based on risk. Fitzpatrick added that using the risk-based approach will result in a more nuanced regulatory response ranging from no regulation, to a full ban, to labelling or notifications.

Another question was in response to the standards reform process in the EU, asking why they are limiting their reform effort, namely lifting the limits of the three standard bodies, to information and communication technologies (ICT) standards. Zourek outlined the specific urgency for reform in the ICT arena. He also warned that if a proposal is too aggressive, it will make no progress. EU needs the changes quickly so the proposal needs to be feasible.

The Chamber offered their assistance with the on-going standard efforts. The Chamber is planning a "Better Standards Forum" next year and will engage various bodies that develop international standards**.**

There were also clarifying questions regarding the Energy Star discussion, asking if the agreement to extend the self-certification agreement through 2011 applies to domestic (U.S.) products. Truszczynski, from DG Energy, who is part of the Energy Star discussions with EPA, said that EPA is honouring the agreement with the EU for all existing product; however, the extension does not apply for U.S. manufacturers.

Future Suggested Program Work

Representatives from the International Centre for Technology Assessment, Consumer Union, Transatlantic Business Dialogue (TABD) and U.S. Chamber of Commerce offered their views on future Forum topics. Consumer groups suggested closer cooperation on nanotechnology and other emerging technologies (such as cloning), eMobility, and product recall data sharing. Industry groups emphasized the need to discuss producer compliance, supply chain issues, increased stakeholder involvement with Forum agenda, service sector issues, and greater advance notice of future regulatory change and/or implementation.

Energy Efficiency: A Case Study – What makes for good cooperation?

The meeting closed with a panel discussion on cooperation on energy efficiency led by representatives from the DOE and DG Energy. The Chamber recommended that the U.S. and EU quantify the market impact of cooperating on the three products to help "tell the story". The Chamber volunteered its services to help with an analysis. Another recommendation was for the U.S. Government to mention the collaboration into any Federal Register notice to show cross border efforts.

Appendix

U.S.-EU HLRCF Joint Statement on Standards in Regulation
December 16, 2010

- The United States Government and the European Commission recognize that each side has a different approach to the use of standards in regulation.

- However, the two sides agree on their need to enhance cooperation in this area as a way to minimize unnecessary divergences and reduce the incidence of non-tariff barriers to trade. Such efforts will also stimulate economic growth and job creation and strengthen the competitiveness of the transatlantic market.

- In this context, both sides agree on the importance of enhancing transparency and meaningful stakeholder participation in their respective processes for developing standards and regulations, as well as participation in the development of international standards.

- To build bridges based on the shared principles of transparency, stakeholder participation, and a commitment to international standards, the two sides agree to develop by the next Forum meeting a set of proposals to implement these principles.

- They also agree on the importance of ensuring compliance with these principles in other major economies.