European Commission-United States High-Level Regulatory Cooperation Forum

Report of the 8th Meeting

Brussels, 29-30 June 2010

The European Commission-United States High-Level Regulatory Cooperation Forum (the Forum) met for the 8th time under the co-chairmanship of Heinz Zourek, Director-General for Enterprise and Industry, and Michael Fitzpatrick, Associate Administrator of the Office of Information and Regulatory Affairs (OIRA), which is part of the U.S. Office of Management and Budget (OMB). The European Commission hosted the meeting, which was the first to be held under the second Barroso Commission and the third for the Obama Administration. The meeting followed the established pattern of a closed government-to-government session followed by an open session organised by and for stakeholders.

I. Government-to Government Session

The government-to-government part of the Forum was held over two half-days, twice as long as in the past, which allowed time for more exploration of issues of particular common interest. As in previous Forum meetings topics addressed ranged from cross-cutting issues such as stakeholder consultation to more specific sectoral issues relating to "upstream" (i.e., early) coordination in drafting regulations (rulemaking) relating to new applications of technology.

At the time of the Forum the date of the next meeting of the Transatlantic Economic Council (TEC) had not been set, although it was assumed that there would be another meeting of the Forum before that meeting took place. During the Forum meeting the future contribution of the Forum to TEC objectives was discussed. Without prejudice to any decisions taken by the TEC at its next meeting (the first to be co-chaired by EC Commissioner Karel de Gucht) it was expected that the TEC would on the one hand mandate certain projects through the channel of the Forum and on the other hand provide political support where it is needed to reduce burdens arising from differences in regulation. In addition, the U.S.-EU Summit, to be held in November in Lisbon, was considered likely to touch on regulatory issues and task the TEC to move some of those issues forward. However, the Forum will continue to address regulatory issues and launch common activities on its own initiative.

Better Regulation Issues

European Commission Perspective – Better Regulation in the new Commission

President Barroso has set the priorities for the new Commission with regard to Smart Regulation. The Commission will continue to build on the success of its integrated approach to impact assessment. The system has demonstrated its effectiveness in supporting evidence-based decision making within the EU institutions. Over the last

three years both the scope of application and the quality of the assessments have shown a very positive development. In the current economic situation, employment and social impacts are particularly important, and the Commission will work towards reinforcing its analysis of such impacts. For this purpose specific guidance has been developed for Commission services and is publicly available through the Commission's dedicated impact assessment website.

Under the new Commission a concerted effort will be made to strengthen the ***ex-post evaluation of legislation*** to match the quality standards of and investments made for the Commission's impact assessment system. The Commission wants to inform its decision-making by high-quality policy analysis throughout all phases of the policy cycle (preparing initiatives – adoption – implementation – enforcement - evaluation). It is essential to establish to what extent existing legislation (and policies in a broader sense) have been effective. On the basis of good and systematic evaluations proper lessons can be drawn on the need and how to improve best legislation. For the years to come, the Commission will give more emphasis to implementation and compliance aspects.

After a transition period all Commission policies should in principle be subject to proper evaluation before revision proposals can be launched. It is important that evaluation involves and engages all relevant stakeholders, whether they are affected parties (businesses, citizens) or public authorities involved in the implementation and enforcement of the rules. The Commission will also ensure maximum synergies between its evaluation and impact assessment system.

An important development is the carrying out of ***'fitness checks'*** on the regulatory framework in a number of important policy areas. When the Commission presented its Work Program for 2010 it identified four priority areas in which these exercises will be undertaken: industrial policy, environmental policy, social policy and transport policy. This will entail a broad analysis of all important aspects of the performance of the regulatory framework in specific sectors. Where necessary additional policy evaluations will be carried out, aiming at improving the overall performance of the regulatory framework for businesses and citizens in that particular area.

United States Perspective – Behaviorally Informed Approaches

The Obama Administration has established three priorities that govern its behaviourally informed approach to regulatory policy. First, it has approached regulatory problems not with dogma or guesswork, but with the best available evidence of how people really behave. Second, it has used cost-benefit analysis in a highly disciplined way, as a pragmatic tool for cataloguing, assessing, reassessing, and publicizing the human consequences of regulation – and for obtaining public comment on our analysis. Third, it has promoted transparency and open government in unprecedented ways.

In domains ranging from nutrition and obesity to automobile safety to credit markets to energy efficiency, the U.S. has been using disclosure as a low-cost, high-impact regulatory tool. The results to date have been noteworthy. Consider that, in the first year of the Clinton Administration, the net benefits of economically significant final regulations were -$400 million, and that in the first year of the Bush Administration, the corresponding number was -$300 million. In the first year of the Obama Administration, preliminary estimates suggest that the net benefits were $3.1 billion.

Empirical, behaviourally informed approaches rely heavily on evidence from psychology. For example, human beings often suffer from inertia, demonstrating a tendency to procrastinate, even when they can gain significantly from a change. People are also greatly influenced by the decisions or informational signals of others around them. For this reason, they can fall victim to *informational cascades*, which occur when people disregard their private knowledge and follow the apparent wisdom of those who have gone before them.

An understanding of psychological findings has numerous implications for regulatory policy. Consider, for example, the significant power of starting points, or default rules, for social outcomes. In many other domains, it might be possible to achieve regulatory goals by selecting the appropriate default rules. And where it is not possible or best to change the default, we can have a similar effect merely by easing people's choices.

In the 2010 Information Collection Budget (ICB) Data Call, OIRA highlighted several burden reduction initiative areas that use behavioral approaches. These include the use of electronic communications and e-signatures, and "fillable fileable" forms or data systems that reduce transaction costs and simplifying information collection. The Data Call also emphasized administrative simplification through the elimination of duplicative requirements and streamlined processes.

On June 18, 2010, OIRA released a new guidance on Disclosure and Simplification as Regulatory Tools, distributed to all agencies. The guidance sets out specific principles to inform disclosure policies and separate principles to inform measures (including default rules and automatic enrollment) designed to reduce complexity, ambiguity, and paperwork burdens.

Evidence-based regulation is attuned to the fact that some risks are large and others are small. Some precautions are burdensome and some are not. Before acting, regulators should "look before they leap," in the sense of obtaining a clear understanding of the likely effects of what they propose to do. Science, including social science, is critically important. These uncontroversial points suggest a particular defense and understanding of cost-benefit analysis. It is not possible to do evidence-based, data-driven regulation without assessing both costs and benefits, and without being as quantitative as possible. At the same time, OMB also recognizes the role of three factors that are not always fully included in cost-benefit analysis: the interests of future generations; distributional considerations; and fairness.

Armed with an accurate understanding of human behaviour, we have suggested fresh, effective, low-cost methods for achieving regulatory goals. Seeing cost-benefit analysis as a pragmatic tool, we have emphasized the importance of science and economics, of eliminating unjustified burdens, and of ensuring that benefits justify the costs. Stressing the importance of transparency, we have sought to engage the public in evaluating regulation.

Use of voluntary standards in regulations

The Forum has been looking at the way in which regulators in the U.S. and the EU use standards to support regulatory objectives, including a comparison of how voluntary standards are defined. The work was initiated at the 5th meeting of the Forum in October 2008; at this meeting a joint report was discussed.

It has become clear that the differences in the way that regulators in the two jurisdictions define and use standards, as well as the way in which bodies that produce standards and the results of their work are recognized, cannot be easily reconciled in mature areas of regulation. At the June 2010 Forum, a number of those divergences were identified in a U.S. paper, and included issues around transparency, stakeholder input, the balance between industry and government-crafted standards, and the role of standards in regulation. Both sides acknowledged the difficulty in convincing the other to abandon respective positions regarding international standards. The Commission has undertaken to respond to specific comments made by the U.S. side.

Nonetheless, participants stressed the need to identify areas of agreement and focus on extending cooperation in areas of common ground. A possible way forward might be to identify needs for new standards in a regulatory context and find new cases for cooperation in the areas of eco-design, energy, natural use energy, and automobiles. Co-chairs also expressed the view that there is considerable scope for employing common standards and conformance testing procedures in emerging areas of regulation and as a means of promoting innovation

Both sides have identified concerns raised by stakeholders about access to the procedures by which standards are made. This is a question which requires further examination, and the possibility of bringing it to the TEC for discussion at the policy level was raised by a number of participants.

Transparency – Consultation Mechanisms and Dissemination of Information

President Obama has made transparency and public consultation a centrepiece of his administration. On his first full day in office, January 21, 2009, he issued a Memorandum on "Transparency and Open Government" reaffirmed the Administration's commitment to open government. The President stated that "Knowledge is **widely** dispersed in society….My Administration will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use."

The President's Memorandum called for the development of recommendations by the Chief Technology Officer for an Open Government Directive to be issued by OMB. OMB issued the Directive in December 2009, instructing departments and agencies on specific actions that implement the principles outlined in the President's memorandum - transparency, participation, and collaboration. The Directive imposed a number of specific and ambitious requirements for agencies. These included publishing online at least three new, high-value data sets at Data.gov, and creating open government webpages to serve as gateways activities related to the Directive.

In addition, 29 major agencies published Open Government Plans describing steps to improve transparency and ensure public participation and collaboration. Plans are available on agencies' "/open" pages and the 29 can be accessed via www.whitehouse.gov/open. All 29 Plans were evaluated by external watchdog groups. While the results of the evaluations were somewhat mixed, watchdog groups responded favourably to the initial Plans. The previous week, OMB and other agencies posted updated 1.1 versions of their Plans that addressed areas of weakness identified by the external evaluators.

The Open Government Directive also instructed OIRA to review existing OMB policies , such as Paperwork Reduction Act (PRA) guidance and privacy guidance, to identify impediments to open government and to the use of new technologies and, where necessary, issue clarifying guidance. In response to this instruction, OIRA issued a number of guidance memoranda. Here are four examples:

1. Social Media and the PRA: To advance the goal of promoting greater openness in government, this memorandum explains that agencies can, consistent with the PRA, use social media and web-based interactive technologies to engage with the public in multiple ways. Among other things, it explains that the PRA does not apply to general solicitations of public views and feedback; that certain types of contests and prizes are not subject to PRA; and that the PRA does not apply to ratings and rankings of posts and comments by website users. This guidance addresses questions frequently asked both by the public and by agencies seeking to use social media to promote participation and collaboration.

2. Increasing Openness in the Rulemaking Process – Use of the Regulation Identifier Number (RIN): Regulatory information online is currently difficult to access and navigate, in part because several websites publish portions of that information at different stages in the rulemaking process. To promote transparency and to help aggregate information, this memorandum provides that agencies should use the Regulation Identifier Number (RIN) on all relevant documents throughout the entire "lifecycle" of a rule. We expect that this requirement will help members of the public to find regulatory information at each stage of the process and will promote informed participation.

3. Improving Electronic Rulemaking Dockets: This memorandum titled "Increasing Openness in the Rulemaking Process – Improving Electronic Dockets" promotes greater openness in the regulatory process. More specifically, this provides guidance to agencies in compiling and maintaining comprehensive electronic regulatory dockets on Regulations.gov, in order to give members of the public improved access to information on which agencies rely in making decisions relevant to rulemaking. This guidance is consistent with the purposes and requirements of the Electronic Government Act of 2002, Section 206.

4. M-10-22, Guidance for Online Use of Web Measurement and Customization Technologies: This memorandum allows agencies to use web measurement and customization technologies to improve the Federal government's services online while also safeguarding the privacy of the American public visiting government websites. The new policy makes clear that there are only two uses for which agencies may employ these technologies: (1) to conduct measurement and analysis of usage, or (2) to customize the user's experience. The memorandum allows agencies to collect personally identifiable information during the use of such technologies only when the user "opts in" and provides voluntary consent. Before such consent can be given, however, agencies must undergo a 30-day notice and comment period on their proposed use of the information.

In addition to the Open Government Initiative, the U.S. Government is modernizing its regulatory notice-and-comment procedures and developing a 21st Century approach to stakeholder participation. The concept of stakeholder participation is well established in the U.S. The Administrative Procedure Act of 1946 requires that agencies go through a

notice and comment process open to all members of the affected public, both U.S. and foreign. Before agencies can issue a final regulation, they must respond to the public comments, make sure that the final regulation is a logical out-growth of the proposal and the public record, and is not arbitrary or capricious. The public record is used by the courts in settling any challenge to the regulations brought by the affected public.

The public may monitor and participate in the rulemaking process by reading the *Federal Register*, sometimes referred to as the legal newspaper of the Executive Branch of the Federal government. The *Federal Register* was created by the Federal Register Act in 1934. It is published by the Office of the Federal Register with the National Archives and Records Administration (NARA), and is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents.

Based on this "Regulations 1.0" model, we are hard at work on Regulations 2.0. The goals of Regulations 2.0 are to provide more convenient, public-centred ways of obtaining input on regulatory proposals, and to improve and modernize well-established legal and administrative procedures so that it is easier for members of the public to participate in the development of regulations.

Regulations.gov is the U.S. Government's online portal providing regulatory docket information from nearly 300 Federal agencies. On this site you can:

- Search for a regulation such as a proposed rule, final rule or Federal Register notice.
- Submit a comment on a proposed regulation.
- Sign up for e-mail alerts about a specific regulation or subscribe to RSS feeds by agency of newly posted Federal Register notices.
- Quickly access regulations that are popular, newly posted or with closing public comment periods.

OIRA and regulatory agencies are exploring a number of ideas to enhance online rulemaking:

- Videos to explain rules and the rulemaking process.
- A taxonomy of regulatory terms.
- "My Regulations" to allow users to tailor the way they interface with Regualtions.gov.

The U.S. Government will launch a beta version of the Federal Register 2.0 on July 26th, the 75th anniversary of the *Federal Register*. Last year, after the National Archives and Records Administration (NARA) made Federal Register data publicly available as a free, bulk download, outside groups including Princeton University and the non-profit Gov Pulse developed prototype improvements in the display and usability of the Federal Register. After the July 26th launch, the new online Federal Register will be tested and authenticated while the existing Federal Register remains available. After the new tool is tested and improved, NARA will apply to the joint committee on the Federal Register to have the new version accepted as an official version of the *Federal Register*. In addition to the improved look-and-feel and search capability, the new elements they are

working on include organization by themes, such as business and industry, environment, and international, making the Register more accessible to the lay reader. The *Federal Register* data will also be downloadable in XML (as well as traditional PDF versions) so that outside groups can create social media widgets for each entry. This would enable people to embed Federal Register notices in their blogs, wikis, Facebook pages, etc.

The **Commission's** Smart Regulation programme contains a number of specific elements that focus on increasing transparency and stakeholder involvement.

In the first place the European Commission has taken measures to further open up its policy development process. The Commission's Work Programme will not only inform about policy in initiatives that are to be expected in the following year, but it will include a multi-annual overview of planned major initiatives.

A major contribution to the increased transparency on planned policy work is made by the recently introduced practice of publishing ***Roadmaps*** for all upcoming Commission initiatives, which are likely to have significant impacts, on the Commission's public web pages. Roadmaps, very often published a year before the actual proposal is adopted by the Commission, present the initial problem description, objectives to be achieved, the available policy options, preliminary impact analysis, as well as essential information on the timing of major consultation activities and the further adoption process. The main purpose of Roadmaps is to inform stakeholders of initiatives in which they have an interest and to invite them to become actively involved in the impact assessment work at an early stage. In this way they will be able to contribute to the assessment of the underlying problem and to provide their input in the development of options for addressing it. So far the Commission has already published around 200 of these documents and feedback from stakeholders on the transparency and possibilities for early active involvement provided is very positive.

The Commission already applies comprehensive ***Minimum Standards for Consultation***, and it has adopted as good practice – as was already announced last year in the revised Impact Assessment Guidelines - that Commission services should go beyond the requirements in these Minimum Standards in particular circumstances. For complex or sensitive impact assessments that affect many businesses and citizens or if consulted over a holiday period the compulsory consultation period of 8 weeks should therefore be extended. Moreover, it is generally accepted that broad online consultations should be supported and complemented by more direct methods to involve stakeholders in earlier stages of the policy development process (conferences, hearings etc.).

The Forum discussed the operation of the **WTO Technical Barriers to Trade** notification mechanism, in particular the timing of notifications, the measures notified and the follow-up when comments are made. Both sides have concerns in this area and intend to examine this topic in more detail at a future Forum meeting.

Risk Assessment Dialogue

This dialogue originated in the Forum and has since been expanded to include partners from around the world. The Global Risk Assessment Dialogue conference which took place in Brussels in November 2008 is to be followed by a similar event in early 2011. Cooperation continues on aspects of risk such as harmonising terminology.

Upstream Coordination – Energy Efficiency

Cooperation between the European Commission and the Department of Energy led to the drawing up of an inventory of energy-efficiency initiatives. Both sides have agreed to focus on pilot actions of enhanced technical cooperation in regulation dealing with commercial refrigeration, solid state lighting and distribution transformers. For each of three product areas, the EC and U.S. organize information sharing discussions between technical teams working on active areas of collaboration at least once per quarter during periods of regulatory development and analysis. The primary objectives of these technical-level collaborations are to:

- Ensure both programs have ready access to the technology, product-testing, and market and other data and analyses used to support the development and implementation of product-specific test methods and minimum energy performance requirements,
- Harmonize US and EU product test methods when such harmonization is technically feasible, legally permissible, and consistent with other program objectives. When full harmonization is not feasible, the technical teams should aim to identify and adopt test methods that are sufficiently compatible to enable the performance of products tested in one jurisdiction to be compared to products tested in other jurisdictions,
- Work collaboratively on the development of new test procedures when adequate test procedures do not exist,
- Work collaboratively to support the adoption by recognized international bodies of mutually agreed upon test methods, and
- Harmonize minimum energy efficiency requirements when such harmonization is feasible, legally permissible, and consistent with other program objectives, such as the achievement of the maximum reduction in energy use and emissions that is economically justified in each jurisdiction.

Product Traceability, Toy Safety and General Consumer Product Safety

Cooperation in this area, where both sides share the goal of ensuring that products are safe and that dangerous products can be identified and removed from the market, is well established. The Consumer Product Safety Commission (CPSC) has constant contact with the Health and Consumers and Enterprise and Industry DGs on consumer product safety issues. The most robust demonstration of this cooperation is through the Toy Safety Working Group, established in 2007, which meets quarterly. The WG discusses implementation issues arising from the EU and U.S. respective legal frameworks for toy safety, explores areas for potential further convergence, such as closer collaboration on toy safety standards (e.g. testing methods for chemicals in toys), as well as possible joint outreach activities targeting Chinese manufacturers and traders. The latest initiative to emerge from this group involves coordination between technical staff looking at the use of cadmium and other heavy metals in toys. In future the group intends to look at a broader range of products which are used by or around children.

CPSC updated the Forum on U.S.-EU cooperation. They noted that CPSC Chairman Inez Tenenbaum appeared before the European Parliament's Internal Market and Consumer Affairs Committee (IMCO) to bring that body up to speed on latest developments, which include possible intensified engagement to discuss harmonization of standards on a select number of products, cooperation that could be expanded to

include other partners. On tracking and traceability, CPSC said it was clear from discussions in the recent International Consumer Product Safety Caucus (ICPSC) that a consensus had emerged that some undefined level of uniformity on traceability is desirable and would benefit consumers and that, working with key standards organizations, CPSC and the Commission could be prime movers going forward, perhaps by selecting a test product.

Cooperation on China continues to be strong. The U.S.-EU-China trilateral will be held October 24-25 in Shanghai, and will be led by CPSC Chair Tenenbaum and Commissioner Dalli. The goal is to work together to encourage China to adopt modern product safety standards and regulations and to ensure product safety all along the supply chain.

DG Health and Consumers described cooperation on product recalls, suggesting that joint product recalls are an objective. Informal discussions have taken place about the possibility of concluding an agreement to share confidential information on product recalls and withdrawals and steps are being taken to enable these discussions to proceed on a formal basis.

Successful efforts at broader cooperation have taken place. The U.S., EU, and Canada sent a trilateral letter to bodies responsible for developing window covering standards encouraging them to voluntarily adopt stronger and similar standards on window cords in the wake of a number of infant strangulations in the three jurisdictions. U.S., EU, and Canadian technical staff are currently working on this.

Point of Purchase labelling

The Forum looked at the use of labelling designed to influence consumer behaviour through the way information is presented and the possibility of exchanging best practices.

The FDA said it was soliciting public comments on point of purchase labelling. This could present an opportunity for the FDA, DG Health and Consumers and EU member states to share perspectives. FDA will update at the next forum. FDA also expressed interest in working with the EU on front of package labelling. Another question is how to take the data on the back of the package and reduce it to small type for the front.

As the First Lady has made childhood obesity her signature issue for this term, the Administration is looking at ways behavioural economics can inform this discussion and address the challenge. U.S. industry is taking this seriously and major U.S. retailers are interested. The Administration's obesity task force report is evidence based and recommends how industry and government can work together. Commissioner Dalli and HHS Sec Sibelius have a dialogue on obesity and will coordinate a global forum on obesity to be held in 2011 in Brussels.

Labelling of tobacco products, particularly the use of messages and images which highlight the health risks associated with their use and the need to prevent misleading claims (e.g. "light") being made, is a common concern. The EU has considerable experience in this area and has developed a library of materials which can be licensed for use on packaging. US and EU authorities responsible for regulating such messaging are presently working together to share lessons learned and gained knowledge in this important public health arena.

Food labelling is another area where there will be scope for cooperation, although at this time the EU legislation is still under discussion as are US regulations. Both sides recognise the need to avoid poor nutrition choices which contribute to long-term health problems and are looking for ways that choices can be guided using simply-presented, independent, actionable information.

Experience gained in other areas can also be brought to bear: the U.S. National Institute for Standards and Technology has many years of experience in designing clear labelling information. Cooperation on labelling will be developed further.