REPORT ON THE SIXTH MEETING OF THE

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

JULY 24, 2009 IN BRUSSELS

1. INTRODUCTION

The EC-U.S. High-Level Regulatory Cooperation Forum ("the Forum") held its sixth meeting in Brussels on 24 July 2009. This was the first meeting involving officials from the new U.S. Administration: one of its main purposes was for officials from both sides to get to know each other to facilitate future cooperation.

Both sides look forward to achieving enhanced levels of cooperation in regulatory matters, both through the work of the Forum and as a result of actions initiated in the Forum.

The Forum had an ambitious agenda. As well as looking at activities which had been launched previously, it addressed new areas of cooperation and initiated activities in areas where the prospects for cooperation are promising. It was agreed that the Forum should meet again in October, ahead of the next meeting of the Transatlantic Economic Council ("the TEC") to monitor progress on the initiatives and prepare its report to the TEC.

The Forum followed the established pattern of a closed government-to-government session attended by senior officials from the European Commission and the regulatory agencies of the U.S. Administration in the morning followed by a public session with stakeholders in the afternoon, hosted by BusinessEurope.

2. CLOSED GOVERNMENT-TO-GOVERNMENT SESSION

The agenda for the meeting was divided into three parts:

- Update on Current Regulatory Reform Efforts and Priorities;
- Ongoing High Level Regulatory Cooperation Forum Initiatives;
- Possible Future Directions.

2.1. Update on Current Regulatory Reform Efforts and Priorities

2.1.1. Situation in the U.S.

The U.S. Administration is committed to a regulatory policy which aims to protect the health and safety of U.S. citizens, the environment and national economic security. It is looking for smarter ways of regulating and has tasked the Office of Management Budget (OMB) with conducting a regulatory review. This should not cause any delays in current regulatory activity and should lead to accelerated procedures in the future.

The Executive Order which provides the basis for centralized regulatory review by OMB's Office of Information and Regulatory Affairs (OIRA) was issued in 1993. President Obama has initiative a review of thatExecutive Order, and the Administration has carried out a public consultation (this is the first time an Executive Order has been the subject of a consultation), in line with the drive for greater transparency and accountability.

The U.S. Administration is working towards greater and broader public participation in government, aiming to increase collaboration in rule-making. The newly created position of Chief Technology Officer has been given the job of exploiting new communication tools (such as Web 2.0) to increase participation by the U.S. public in consultations.

This has already resulted in consultations reaching a wider audience of respondents. A consequence of this is that the U.S. Administration is reviewing the way information can be found using search engines, to meet the needs of people who are not familiar with the traditional ways of organising consultations. This is an area which is of common interest and will be discussed further.

As part of this initiative, the Administration is reviewing its policy on the use of "cookies." Until now, OMB's policy has been to prohibit (with very limited exceptions) the use by agencies of cookies on privacy grounds. However, public attitudes are changing and a new balance between privacy and service improvement may be struck. This is an issue which is also of interest in the EU and will be discussed further between the two sides.

The Administration is reflecting on how the Freedom of Information Act (FOIA) should apply to submissions received in response to public requests for documents. Currently submissions are not released if they satisfy any of the criteria in the FOIA. The Administration now intends to assess whether disclosure is likely to cause harm, and only in cases where this is likely will submissions be kept confidential.

The U.S. Administration has created several cross-cutting web-sites to make it easier for the public to access information and contribute to consultations: regulations.gov is the main portal for regulatory matters; business.gov is the portal for the business community to access federal, state and local information; data.gov gives access to a large range of government-generated information; and recovery.gov gives details of how recovery funds are being spent.

2.1.2. Situation in the EU

The European Commission's Better Regulation programme has two main strands: a review of the body of EU legislation (the "acquis") with a view to simplifying it and an effort to reduce the administrative burden of legislation.

The simplification programme produced a list of legislation which should be simplified. Every year the Commission adopts proposals to simplify measures on the list and periodically reviews progress.

The administrative burden reduction programme aims to ways in which the cost of complying with the requirements of legislation can be reduced. For example, requirements to maintain records in order to be able to demonstrate compliance may create an excessive burden for very small enterprises. A recent public consultation

inviting suggestions for burden reduction met with a large response and the Commission is now analysing the results.

In addition, the Commission's Better Regulation principles have resulted in wide-ranging consultation mechanisms being put in place and the introduction of impact assessment as a tool for guaranteeing the quality of proposals. Impact assessment has been discussed in previous Forums and is further addressed below.

2.2. Ongoing High Level Regulatory Cooperation Forum Initiatives

2.2.1. Impact Assessment

The Secretariat-General of the EC explained the impact assessment procedure following the revision of the Commission Guidelines. The revision had been the subject to a public consultation and two particular concerns had been addressed: the handling by the Commission of submissions in response to public consultations and the way in which SME impacts are assessed.

The Commission's impact assessment procedure follows a three-pillar approach: economic, social and environmental. The principle of proportionality is applied when conducting investigations. The "think small first" principle requires that SME impacts be properly considered and investigated in depth if they are likely to be significant. In some cases, the result of an impact assessment has shown that proposals should not be put forward.

An internal steering committee ensures that an impact assessment addresses all relevant issues, and the Impact Assessment Board (IAB) reviews the final report. The IAB issues an opinion on an impact assessment. This opinion and the impact assessment are made public when a legislative proposal is published.

If the IAB criticises an impact assessment, it will usually be revised before the proposal is put forward or adoption. However, the advice is not binding and the impact assessment may be presented without changes; the College of Commissioners may decide to adopt the proposal in the face of the criticisms or ask for it to be reviewed.

A key feature of an impact assessment is that it considers a range of options and explains why the final choice was made. There have also been cases where, as a result of the findings of an impact assessment, it has been decided that no legislative proposal is needed.

The Commission intends to report on its experience with the new impact assessment guidelines in 2010.

OIRA invited comments on its trade and investment impact assessment mechanism in 2008 and reported the results in January 2009. OIRA is now reflecting on its next steps.

2.2.2. Standards in Regulations

Both sides reported progress on drafting their respective reports on the use of standards in regulations and anticipate that the reports will be available by the time of the next Forum meeting. It was also agreed that the report will include a jointly-drafted section which sets out the differences in the systems, identifying barriers

which these give rise to and highlighting any other problems which have been identified.

The Commission is also opening discussions with China on the use of international standards in regulations. The EU policy on standards as a tool for enhancing competitiveness is evolving: the Communication "Towards an increased contribution from standardisation to innovation in Europe" which was adopted in March 2008 will be followed by another on modernising ICT standardisation in the EU. A public consultation on this latter Communication is open until 15 September 2009.

The Commission has convened the Expert Panel for the Review of the European Standardisation System ("Express") to provide strategic recommendations on the future of the European standardisation system. This panel will report shortly and its recommendations will be discussed at an open conference to take place on 14 October in Brussels in the context of world standards day.

2.2.3. Risk Assessment

The dialogue between the OMB and the EC on risk assessment has broadened to include other partners such as Canada and gave rise to the Global Risk Assessment Dialogue, held in November 2008.

This event resulted in a decision to establish four teams to pursue its objectives in preparation for a second global meeting in late 2010. These teams will address:

a) weight of evidence/uncertainty/RA terminology;

b) emerging issues and challenges; and

c) exposure assessment.

A progress report on the establishment, composition and objectives of these teams should be prepared in time for the next Forum meeting, for submission to the TEC.

2.2.4. Import Safety

The U.S. Food and Drug Administration (FDA) intends to strengthen the existing collaboration with the European Medicines Agency (EMEA) in the inspection of active pharmaceutical ingredient manufacturing facilities. The next step will be to continue the pilot on joint inspections and to explore accepting the results of each other's inspections. The FDA has established a presence in India, China, the EU and Central America.

The FDA is also open to extending cooperation to the monitoring of clinical trials and to further collaboration in a number of areas such as medical devices, cosmetics nano-materials and tobacco.

The U.S. is currently reviewing its approach to food safety with legislation being debated in Congress. Congress is considering easing restrictions on the release of confidential data to regulatory authorities as well as requiring the establishment of product tracing systems.

In the EU, the Directive on the safety of toys now has to be implemented. Since the EU and the U.S. are both working to implement greater protection in this area, there is considerable scope for collaboration.

The report on enhanced cooperation on the safety of (imported) products submitted to the second meeting of the TEC (13 May 2008) contained a number of recommendations. A report was made to the third meeting of the TEC (12 December 2008) detailing progress on these recommendations. This report should be updated in time for the next Forum meeting and any problems in following the recommendations should also be reported.

There is a growing level of cooperation between EU customs services and the U.S. Customs and Border Protection to keep dangerous products out of their respective markets. The Commission intends to request a mandate to negotiate an agreement which will further facilitate information sharing.

2.3. Possible Future Directions

The Forum discussed areas of regulation where upstream coordination would reduce the risk of barriers arising in the future.

2.3.1. New Technologies

The Forum discussed regulation in the context of a **greener economy**. The discussion showed that there is a great deal of shared purpose in this area and that there is a degree of compatibility in some areas such as labelling of electrical appliances.

In the U.S. funding for the Department of Energy increased by $2 billion in 2009 and an additional $15 billion is foreseen for strategic green investment. There may be scope for cooperation between the EU and the U.S. in areas such as electric vehicles and battery charging standards.

President Obama has asked for a complete review of regulations relating to energy use, with a view to increasing savings. Congress is looking at how to expand the scope of energy-related regulation.

The Energy Star labelling scheme has achieved a high level of consumer recognition in the U.S. An initiative has also been launched to promote energy efficient buildings through the application of international standards.

In the EU, the European Commission is developing a green paper on promotion of environmental technologies. Energy-efficient products have been promoted in the EU through ecodesign legislation and energy efficiency labelling. Eco-labelling is a voluntary scheme which allows consumers to identify the best products. Consideration is being given to the use of fiscal incentives in future to promote the uptake of energy-efficient products, for example in building insulation.

There is considerable scope for transatlantic cooperation in this field as the aim of reducing energy consumption is common and consumers on both sides of the Atlantic use a similar range of products.

An inventory of regulations and initiatives in this area should be drawn up before the next Forum so that elements which can be jointly developed are identified as

well as potential barriers. Both sides agreed on the need to avoid development of incompatible regulations and requirements since the resulting market fragmentation would inevitably slow down the development of products.

The Forum also discussed approaches to regulating **nanotechnology**.

In the U.S. the National Nanotechnology Initiative is the legislation that authorizes 27 agencies and departments to meet monthly for coordination and facilitation of nanotechnology R&D. These meeting are conducted under the auspices of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee. The NSET supports commercialization of nano-enabled products, addresses horizontal issues such as terminology that may be used in marketing, social and environmental responsibility, and provision of information on nanotechnology to regulators as part of the evidence base for rule-making.

NNI is launching a review of the US nanotechnology environment, health and safety research strategy. Key areas to be addressed are the environment (Oct 6 – 7, 2009) human health and safety (November 17 – 18, 2009), risk management and engagement with the public (March 30 – 31, 2010), development of standards, the economic impact and international cooperation. (see website: nano.gov).

In the EU, the European Commission is working according to an action plan coordinated by its Research Directorate-General. A new plan is foreseen to cover the period 2010 to 2015. The Enterprise and Industry Directorate-General leads a working group looking at the existing regulatory framework to see if it is suitable for regulating nanotechnology. The current view expressed in a report to the European Parliament (EP) is that:

- It is unlikely that a single instrument can be drawn up to regulate nanotechnology;

- The existing legislation already imposes requirement for risk assessment and management;

- The difficulty in applying existing legislation to nanotechnology is that there is not yet enough knowledge available, raising the possibility that legislation may have to be fine-tuned in the future.

The EP agrees that there is no reason to impose a moratorium on nanotechnology but wants to see more research to fill in the knowledge gap. At present there is no risk identified, but products incorporating nanotechnology must be labelled so that consumers can make an informed choice.

The Commission is consulting with the FDA on nanotechnology in medical devices in order to develop common nomenclature.

Research into the risks of nanotechnology is an area where there is a good level of collaboration in the context of the risk assessment dialogue. There is also a very good level of cooperation in the OECD.

The discussion in the Forum revealed that both sides are reviewing their respective approaches to regulating nanotechnology. There is scope for considerable

divergence particularly as the knowledge base develops and technical discussions advance and these would have to be addressed at the political level.

The Forum should therefore consider the differences in the approach to regulating nano-materials and the barriers which prevent these differences from being resolved by regulators, as well as identifying areas where further cooperation is possible.

2.3.2. Mutual Recognition

The two sides agreed that past experience of using mutual recognition to reduce barriers to trade has been disappointing. However, there is strong interest in exploring areas where mutual recognition could be used as a flexible instrument to remove barriers, notably in sectors where harmonisation is unrealistic. The Forum should prepare a discussion in the TEC on this subject, addressing for example structural and legal impediments to enhanced mutual recognition.

As a first step, the Forum should agree at its next meeting on the structure of a report which looks at mutual recognition, drawing on past experience, in order to identify areas where mutual recognition could make sense. In these areas, the report could highlight the obstacles to mutual recognition which currently exist and what needs to be done (in terms of changes in legislation, mandates to agencies etc.) in order to make mutual recognition a feasible policy goal.

2.3.3. Next Meeting

The next meeting will take place on 26 October in Washington, D.C.