EU-US HIGH-LEVEL REGULATORY COOPERATION FORUM

REPORT TO THE TRANSATLANTIC ECONOMIC COUNCIL

FOURTH MEETING OF THE FORUM, BRUSSELS, 25 APRIL 2008

I. Introduction

The EU-US High-Level Regulatory Cooperation Forum ("the Forum") held its fourth meeting in Brussels on Friday 25 April. This was the second meeting of the Forum since the establishment of the Trans-Atlantic Economic Council ("the TEC") at the US-EU Summit in April 2007, and a number of the subjects discussed at the meeting were identified at the first meeting of the TEC in November 2007 as priorities for EU-US regulatory cooperation.

This report will be submitted to the next meeting of the TEC on 13 May 2008.

The Forum meeting was divided into two parts: a closed session between senior officials from the European Commission and regulatory agencies of the US Administration, and an open session with stakeholder representatives hosted by Business Europe. The list of participants is attached in Annex 1.

II. Meeting between EU and US officials

The meeting between officials addressed four issues:

1. Strengthening cooperation and information exchange between the EU and US administrations on the safety of imported products;
2. Joint work on the methodology of risk assessment;
3. A joint report on the analysis of impacts on international trade and investment in EU and U.S. regulatory impact assessment guidelines;
4. Priorities for the future work of the Forum.

1. Strengthening cooperation and information exchange on the safety of products

The first TEC meeting asked the Forum to draw up a report on the current cooperation between US and EU regulatory agencies on the safety of products, and particularly those imported from third countries, and to consider possibilities for improving that cooperation, particularly concerning information exchange on unsafe products.

A draft report prepared by officials from several agencies on both sides was discussed by the Forum and final adjustments to it were agreed. The report describes the regulatory system in the United States and the EU in seven areas (motor vehicles, pharmaceuticals, cosmetics, toys, electrical equipment for consumer use, food and other consumer products), including customs measures relating to product safety. It outlines current levels of cooperation and information sharing between the regulatory authorities and announces or proposes additional steps to reinforce that cooperation.

The Report concluded that protection of confidential business information has been identified as the major issue to consider when increasing information exchange in all

sectors and areas examined in the report. Even where advanced confidentiality agreements are already in place to allow for some sort of exchange of confidential information (for example, pharmaceuticals and cosmetics), there is still scope for improvement. Engaging in a fuller exchange of confidential information requires legal changes in our systems and, hence, political will. First, in many cases the U.S. agencies concerned need to be given the statutory authority to engage in more extensive information exchange. Second, the EU and the Member States need to set up mechanisms to ensure that confidentiality is adequately protected across the network, so that the information received from the U.S. authorities can effectively reach all national market surveillance authorities and, conversely, information that is available at Member State level can also be fed into the circuit. Third, a mandate to expand the scope of existing information exchange agreements or to negotiate new enhanced agreements will be required. Such agreements should be based on reciprocity, define what types of information should be treated as confidential and provide for the necessary confidentiality

The Forum proposed to make the report public following its presentation to the TEC.

2. Risk assessment

The Forum discussed plans for a detailed comparison during 2008 of EU and U.S. practice and methodology in the area of risk assessment. Both sides agreed that every effort should be made to encourage cooperation at the technical and scientific level in order to reach a common understanding between the EU and U.S. regulatory authorities of how to measure risk in all areas of regulation and to use the same analytical tools for this purpose. Such a common understanding would not, of course, rule out policy differences between the EU and US approach in respect of risk management, that is, decisions concerning the level of acceptable risk in a given regulatory policy or system.

The Forum was informed that planning is well advanced for a joint workshop on risk assessment and management, to be organized in Washington on 10-11 July 2008, at which a number of issues relating to terminology and methodology would be discussed, and case studies for comparison of the results of the U.S. and EU approach would be identified. This would be followed by a major international conference in Brussels in November, to which experts from a number of third countries will also be invited. The Forum confirmed that it was important to promote joint leadership of the EU and U.S. in an international debate on risk assessment issues.

An interim report will be made to the TEC at its second meeting in 2008 on the basis of the outcome of the July workshop.

3. Impact assessment

The Forum was informed of the results of the public consultation on the draft report on the role of international impacts in the US and EU impact assessment guidelines that had followed its last meeting in November 2007. The final report will be presented to the TEC and made public shortly thereafter.

The EU side announced that in the light of the report it would be amending its impact assessment guidelines to take more account of the impacts that proposed policies may have on international trade and investment flows. On the U.S. side, OMB stated that they will be reminding agencies of the importance of their taking into appropriate consideration, in preparing their impact analyses for draft regulations, the impact that the intended regulation would have on trade and cross–border investment between the United States and other countries.

The next stage in EU-US cooperation in this area will be an examination of case studies. This will include looking at past examples of regulation, to see how the impact assessment guidelines of the other party might have affected the analysis, and at new regulations where an impact analysis conducted by the other party might be used as a first stage in impact assessment. Both sides are currently exploring suitable topics, and will report on (preliminary) results to the next Forum meeting.

The Forum agreed that the main focus of its work in the coming months would be risk assessment, in the light of the July workshop, as well as taking forward the case studies of impact assessment.

The EU side proposed that, in addition, the Forum discuss and examine in the coming year the use of voluntary standards, in particular international voluntary standards, in the regulatory systems of the EU and U.S., taking account of case studies in defined sectors. This would not only help both sides to come to a better understanding of bilateral regulatory problems but might also contribute to developing a common position in relation to third countries on standardization and regulatory issues. The U.S. side suggested that the scope of the study might need to be broader than that proposed by the EU, to include standards or norms developed outside voluntary standardization bodies. It was agreed that the terms of reference for this work should be elaborated before the next Forum meeting.

A further suggestion from the U.S. side concerned nanotechnology; it might be useful to check whether all interested agencies, and particularly those responsible for worker safety, had been able to contribute to the Forum's previous consideration of this subject. The Commission announced that it would shortly issue a Communication on regulatory aspects of nanomaterials and it was agreed that discussion of this issue could be resumed after the US side had had an opportunity to react to the Communication.

III. Meeting with stakeholders

In the open session of the Forum senior officials met a large group of stakeholder representatives to debrief them on the morning session and to discuss with them consultation and notice and comment procedures in the U.S. and EU regulatory process. Presentations were made by the Office for Information and Regulatory Affairs and the Secretariat-General of the Commission of the current rules for notice and comment and consultation of interested parties during the regulatory process. A panel of stakeholder

representatives and officials from both the US and EU then discussed possible improvements in both systems.