EU U.S. HIGH-LEVEL REGULATORY CO-OPERATION FORUM

Joint Progress Report to the Transatlantic Economic Council Fall meeting

Washington, 12 December 2008

On the implementation of the conclusions and recommendations set out in the Report

TOWARDS ENHANCED CO-OPERATION BETWEEN THE EUROPEAN UNION AND THE UNITED STATES OF AMERICA ON THE SAFETY OF (IMPORTED) PRODUCTS

A. BACKGROUND

At its first meeting in November 2007, the Transatlantic Economic Council (TEC) identified the safety of imported products as a priority for future work, and asked the High-Level Regulatory Cooperation Forum ("the Forum") to draw up a report on the current cooperation between US and EU regulatory agencies on the safety of products, particularly those imported from third countries. The TEC also asked the Forum to consider possibilities for improving that cooperation, particularly concerning information exchange on unsafe products.

The 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 May 2008 TEC meeting. The TEC endorsed the conclusions and recommendations set out in the report.

The report described the regulatory system of the U.S. and of the EU in seven areas **(motor vehicles, pharmaceuticals, cosmetics, toys, electrical equipment for consumer use, other non-food consumer products and food)**, including **customs measures** relating to product safety. It confirmed that the U.S. and the EU have sound and comprehensive regulatory frameworks for consumer product safety in place.

The report then analysed in detail existing bilateral information exchange mechanisms in the field of consumer product safety. It showed that both the U.S. and the EU were dedicated to the timely sharing of relevant information and that there was a **good degree of useful cooperation** in various sectors. However, both sides identified a clear **need to improve the existing cooperation** in the short and long-term with a view to effective information sharing.

Protection of confidential business information was 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 was still scope for improvement.

On a general level, the 2007 report concluded that **engaging in a fuller exchange of confidential information therefore requires legal changes in our systems and, hence, the necessary political will to implement such changes.**

For each area / product sector under consideration, the report set out a number of **concrete recommendations on how to overcome current constraints on effective information sharing**. This brief report provides and update to the December 12, 2008, meeting of the TEC on progress made on these recommendations.

B. IMPLEMENTATION - STATE OF PLAY

The most significant developments since the last TEC meeting are described below.

1. General Non-Food Consumer Product Safety Matters

Following the recommendation contained in the Report for general non-food consumer product safety, The European Commission (EC)'s Directorate-general for Health and Consumers (DG SANCO) and the U.S. Consumer Product Safety Commission (CPSC) have together started studying the implications of the **Consumer Product Safety Improvement Act** (CPSIA) of 14 August 2008, which gives the CPSC the additional statutory authority required for sharing of confidential information with foreign governments and agencies. This should pave the way for increased bilateral cooperation in this area. The CPSC is looking into the necessary implementing policies in the area of confidentiality requirements.

Furthermore, DG SANCO and the CPSC have intensified their bilateral cooperation efforts, including the frequency of their informal conference calls on topical issues as well as exchange of information on new product safety recalls (publicly available information).

2. Toys

Following the recommendation contained in the Report for toys, the CPSC and the EC's Directorate-General for Enterprise and Industry (DG ENTR) and DG SANCO have set up a Toy Safety Working Group to function as a focal point to discuss toy import safety related matters.

The Working Group met three times by video conference, on 29 May, 22 July and 12 November 2008, and an in-person meeting was held during a joint mission to China (see next paragraph). The talks have increased mutual understanding and allowed to identify points for further discussion.

3. EU-U.S. Joint Product Safety Outreach to China

In addition to bilateral efforts, DG SANCO, DG ENTR and the CPSC conducted a series of joint outreach seminars in China between 19 and 24 September 2008 on EU and U.S. safety requirements for clothing, toys, and electrical appliances with a view to promoting the respect of the applicable safety requirements and enhancing further the safety of imported products.

This event was followed by a high-level trilateral meeting hosted by Commissioner Kuneva in Brussels on 17 November 2008 to continue the common agenda and send a strong political signal of the determination of all sides to keep product safety at the top of the international political agenda, recognising that open markets can only be built on strong and secure management of global product supply chains. As set out in the joint press statement, the priority areas for action include: product traceability and co-operation on safety standards for toys and children's products.

Considering the interdependence in this area, safety of consumer products is an established common concern, and adding tripartite initiatives to the existing bilateral contacts was therefore a logical step and an excellent example of successful follow-up to the Report.

4. Motor Vehicles

Following the recommendation contained in the Report for motor vehicles, on 16 June 2008 the U.S. National Highway Traffic Safety Administration (NHTSA) and the EC's DG ENTR concluded a **Memorandum of Cooperation (MoC) in the Field of Motor Vehicle Regulations**. The MoC builds upon the 2003 Exchange of Letters concerning regulatory cooperation in the field of motor vehicle safety.

Under the MoC, the parties agreed to strengthen bilateral cooperation and communication, including the exchange of information, concerning improvements and other developments in the areas of motor vehicle safety and fuel consumption technical regulations, within their respective authorities.

Four main areas of cooperation have been identified, as follows:

1. Development and establishment of technical regulations or related standards (*i.a.*, by promoting greater international harmonization of vehicle regulations under the aegis of the United Nations);

2. Post-implementation reviews of technical regulations or related standards;

3. Development and dissemination of consumer information related to motor vehicle regulations; and

4. Certification and enforcement, including the identification of safety-related defects and non compliances with technical regulations.

Under the MOC, DG ENTR and NHTSA expect to meet on an alternating basis, in the EU and the U.S., (including exchange meetings on special topics held during WP.29 Sessions).

5. Pharmaceuticals

The **Transatlantic Administrative Action Plan** agreed on 17 June 2008 between DG ENTR, the European Medicines Agency (EMEA) and the U.S. Food and Drug Administration (FDA) includes specific **projects on joint inspections and exchange of inspection data**, as follows:

1) DG ENTR/EMEA and the FDA will pilot joint inspections of companies manufacturing pharmaceuticals in the U.S. and in the EU and of companies manufacturing active pharmaceutical ingredients (API) in third countries.

2) DG ENTR/EMEA and the FDA will pilot the exchange of inspection schedules, results, and information on inspected manufacturing sites in order to attain more GMP (Good Manufacturing Practice) inspection coverage collectively and to better identify manufacturing sites producing active pharmaceutical ingredients in third countries.

Mutually agreed mechanisms for inspections of manufacturing sites producing API in third countries should avoid duplication of work and attain more GMP inspection coverage. By sharing inspection reports and leveraging each other's resources in this manner, it is expected that more information can thus be obtained by each party than following its own inspection plan alone.

In this context, DG ENTR/EMEA and the FDA (together with their counterpart in Australia) have finalized the terms of reference for an agreement to jointly plan inspections of API production facilities in third countries over eighteen months beginning November 2008. The inspection component of this program started in November 2008 and the **first "test case" joint inspection** between the FDA and the EMEA of an API plant in China has been recently performed.