

EU strengthens cooperation with U.S. on cosmetics and medical devices

The European Commission and the U.S. government will from now on be able to exchange confidential information about the safety of cosmetics and medical devices. Today, the European Commission and U.S. Food and Drug Administration agreed confidentiality arrangements at a bilateral meeting in Brussels, enabling better health protection and easier trade between EU and U.S. Closer economic cooperation is the main aim of the new Transatlantic Economic Council (TEC), launched last week in Berlin. The TEC's work programme covers cooperation initiatives to harmonize standards and improve trade in the areas of Regulatory Cooperation, Intellectual Property Rights, Secure Trade, Financial Markets, Innovation and Technology and Investment.

Commission Vice-President Günter Verheugen, European chairman of the Transatlantic Economic Council and Commissioner for enterprise and industry policy, said: "At this year's EU-US summit we agreed to put in place a new 'Framework for transatlantic economic integration'. I'm pleased to see that our ongoing cooperation with US regulators is delivering tangible results for our citizens and businesses. EU and US will be able to exchange early information to protect public health, whilst taking away stumbling blocks for trade. In the field of cosmetics, today's agreement represents an important step towards our goal of accepting each other's alternative methods to animal testing."

The new confidentiality arrangements will allow exchange of information between the parties as part of their regulatory mandates in the field of cosmetics and medical devices. The types of information covered include:

- Advance **drafts of legislation** and/or regulatory guidance documents.
- **Post-marketing data and information** that could have an impact on the public health, such as vigilance data or information about impending regulatory actions.
- Information on **ongoing and emerging regulatory issues of health and safety** in the U.S. or the EU.

More information on regulatory cooperation with third countries in the field of cosmetics and medical devices can be found here:

http://ec.europa.eu/enterprise/cosmetics/index_en.htm

(for cosmetics) and

http://ec.europa.eu/enterprise/medical_devices/index_en.htm

(for medical devices).

Background

The trade relationship between the U.S. and the EU in the field of cosmetics and medical devices is strong: Around 7% of all cosmetic products in the U.S. are imported from the EU, which amounts to a trade volume of almost 3 billion EUR per year. U.S.-exports of cosmetics to the EU amount to approx 1.5 billion EUR. The bilateral trade volume in medical devices is balanced, with each trading partner exporting about 6.5 billion EUR to the other on an annual basis.