



## **REPORT OF THE NINTH ROUND OF NEGOTIATIONS FOR THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP**

(New York, 20–24 April 2015)

### **Summary**

The ninth negotiating round took place in New York (20-24 April). The negotiating sessions encompassed a very broad range of subjects with a view to consolidate the work in all three pillars of the negotiations. The round focused particularly on the regulatory and rules pillars.

On market access, technical discussions have continued on tariffs and public procurement. The round has not covered the services area, in which negotiators are preparing for an exchange of revised offers ahead of the next negotiating round.

In the regulatory cluster, discussion continued on all horizontal aspects (SPS, TBT and Regulatory Coherence). The EU side presented its [revised proposal for regulatory cooperation](#), including at sub-central level. In the area of TBT, both sides outlined steps that could be taken on conformity assessment.

In-depth technical discussions continued on all nine sectors covered by the regulatory pillar.

In the rules area, all issues have been covered except Trade and Sustainable Development/Labour/Environment for which the EU aims to present a text by the July round. Incremental progress was made in some areas, notably on customs and trade facilitation, energy and raw materials and state to state dispute settlement. The two sides also discussed the two papers put forward by the EU in the field of IPR.

As in previous rounds, the two negotiating teams organized and attended a stakeholder session attended by some 160 civil society representatives.

The tenth negotiating round is expected to take place in July in Brussels.

## **Details by negotiating area**

### **1. Market Access**

#### **Tariffs**

A joint session on agricultural and industrial tariffs took place. A thorough product-by-product review of the first tariff offers was conducted, enabling both sides to provide further explanations on the rationale behind the treatment of particular categories in their respective offers.

#### **Agriculture**

Parties continued discussions on agricultural issues, including on wine, spirits and non-tariff issues.

#### **Trade in Goods**

Both sides worked constructively to narrow differences in the respective text proposals. The discussions focused on the articles related to waiver of customs duties, remanufactured goods, import & export restrictions/licensing and some definitions related to customs duties.

#### **Public Procurement**

The two days of technical discussions focused on the text of the chapter (disciplines applicable to covered procurement) and clarifications of existing market access commitments.

### **2. Regulatory Component**

#### **SPS**

After an exhaustive discussion that helped to further understand the respective text proposals, it was agreed to discuss how to organise further work on the text. In addition, the Parties reviewed the state of pending applications for market access.

#### **Regulatory Coherence**

The EU presented its [revised text on regulatory cooperation](#) containing a number of clarifications as regards the scope as well as specific provisions on non-central regulatory acts. Both sides agreed to further reflect about the most appropriate institutional provisions on regulatory cooperation and to identify priorities for future cooperation, while striking the right balance between avoiding any duplication and overly bureaucratic procedures and respecting each side's regulatory sovereignty to set the appropriate policy objectives and protection standards.

## **TBT**

The US and the EU discussed how to improve the frameworks that regulate conformity assessment issues, i.e. how the compliance of a product with the applicable safety technical regulations is verified. The parties also discussed standards and transparency, in particular the possibilities open to their respective stakeholders to participate in the other party's standardisation processes. Finally the parties discussed how to bring added value to the World Trade Organisations Technical Barriers to Trade notification system by increasing the amount of technical regulations that are notified and the follow-up that is provided to those notifications.

## **Cars**

The EU and US continued discussions on the four areas of the negotiations, with progress on the '98 Agreement on global harmonization and exploration of common safety rules. Discussions also continued on a methodology for equivalence, based on the [test case](#) provided by the Commission on vehicle lighting and vision. Further discussion is needed on the approach for mutual recognition.

## **Chemicals**

Some progress was achieved for two pilot projects on chemicals (concerning assessment of priority chemicals as well as classification and labelling of substances), and indications given about a third pilot project on analysing differences in safety data sheets. Some general questions were broached related to the EU [outline for possible provisions on chemicals](#) that had been submitted at Round 7.

## **Pharmaceuticals**

The progress of the task force in charge of assessing the equivalence of EU and US Good Manufacturing Practices (GMP) systems was reviewed. Audits of Member States GMP inspectorates observed by US FDA took place and will continue during 2015. The EU will audit the US inspectorate in September 2015. Other areas such as biosimilars, generics and international cooperation were discussed. The EU welcomed the first authorisation of a biosimilar by FDA. EU committed to submit a proposal for cooperation on generics ahead of next round.

## **Medical devices**

The EU presented its [position paper on medical devices](#) recently published in the web site. The US asked clarifications on the mutual recognition of quality management system audits concept (one of the objectives detailed in the paper) and its relation with the international Medical Devices Single Audit Programme (MDSAP). The EU noted that while it is committed to MDSAP work, a legal basis needs to be established for it to be able to accept audit reports carried out by US inspectors (TTIP could serve as such

legal basis). Both sides took stock of progress on the two other TTIP priorities (Unique Device Identifier -UDI and Regulated Product Submission - RPS). Next steps were agreed for each topic.

### **Cosmetics**

The main EU objective for cosmetics remains the approximation of safety assessment methods and the streamlining of the authorization procedure in the US for ingredients such as UV-filters. In this respect, both sides agreed that further technical discussions among scientists are necessary in order to approach requirements and methods for safety assessment of cosmetic ingredients. Fostering work at international level was also highlighted as an important strand of work. A number of actions have been agreed and technical exchanges will continue over the next months.

### **Textiles**

Discussions on textiles labelling and on textile safety requirements continued. The Parties discussed collaboration on the labelling of textile fibre names and on silk flammability testing. Further cooperation on voluntary textile standards is under discussion. The US indicated strong interest in progress on non-regulatory issues in this sector, i.e. tariffs and rules of origin.

### **ICT**

The parties exchanged information on the different on-going ICT initiatives in the EU and the US on the areas of semantic and syntactic compatibility of health records, encryption, e-labelling, cooperation in market surveillance and e-accessibility.

### **Engineering**

The EU and the US continued to discuss possible areas of regulatory cooperation in the engineering sector. The US provided feedback on some of the proposals, noting that in order to engage in these regulatory cooperation discussions it was necessary to find areas of cooperation economically significant and where the regulatory structure would be similar. The US and the EU committed to keep looking for possible examples of cooperation.

### **Pesticides**

The discussions aimed to further explore the scope for collaboration without duplicating work in other fora. It was agreed to do further intersessional work and to consolidate the basis for collaboration, notably in the area of pesticide residues.

### **3. Rules**

#### **Energy and Raw Materials**

The EU and the US discussed in a constructive manner an extensive list of issues related to the potential scope of energy and raw materials topics to be covered in TTIP. The discussions have been without prejudice to the issue of whether or not there should be a separate chapter in TTIP or whether issues discussed should be addressed through specific provisions in TTIP for energy and raw materials sectors.

#### **Customs and Trade Facilitation**

Further progress was made on the consolidated text and negotiators agreed to pursue discussions on matters that would benefit from enhanced customs cooperation between the EU and the US.

#### **IPR**

The discussions focussed on the two proposals submitted by the EU ahead of the round on international IPR treaties and on IPR Customs Enforcement. The first is a list of international Treaties to which the two sides would adhere in the TTIP Agreement, while the second proposal aims to combat trade in counterfeit goods by ensuring appropriate enforcement at the borders. A list of Treaties that a proposal of existing international Treaties to which they will (re)commit in the TTIP Agreement. The two sides also explored a range of technical questions and exchanged updates on the respective legislative processes. The US presented new items in the cooperation area, specifically addressing the angle of SMEs.

#### **GIs**

The two sides had difficult discussions on GIs. The U.S. remained non-committal. Exchanges continued on legal alternatives to the U.S. trademark system.

#### **SMEs**

The section on cooperation provisions is agreed in principle, subject to final review. Discussions also continued on transparency/exchange of information provisions.

#### **Dispute Settlement**

Constructive discussions continued on the state-to-state dispute settlement chapter, which aims at establishing an effective mechanism for resolving any disputes between the Parties on the interpretation and implementation of the Agreement. During the ninth round both side made further progress on developing compromise text and continuing discussions on the compliance phase.