

REPORT OF THE TENTH ROUND OF NEGOTIATIONS

FOR THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP

(Brussels, 13–17 July 2015)

Summary

The tenth negotiating round took place in Brussels from 13 to 17 July. Talks covered a broad range of subjects across the three TTIP pillars.

On market access discussions covered services, rules of origin, market access goods text and agriculture market access text. No discussions took place on tariffs or procurement during this round. Second services offers were exchanged and the EU also tabled its first services text proposal.

All regulatory issues were discussed including regulatory co-operation/coherence, TBT, SPS, and the nine sectors under consideration. Technical progress was made in the regulatory pillar but there remains significant work ahead.

All rules issues were discussed during the week, with the exception of sustainable development/labour & environment and investment protection and its dispute resolution. On Sustainable Development, the EU highlighted that it will present its text proposal in September. Constructive discussions took place on competition, state owned enterprises, subsidies and SMEs.

In light of the G7 conclusions, parties agreed to work inter-sessionally in many areas. The 11th round will take place in the third quarter in the United States, the venue and dates remain to be finalised.

Date: 29/07/2015

Details by negotiating area

1. Market Access

Services

Ahead of the Round, the EU submitted a proposal for a text (Title on trade in services, investment and e-commerce; the proposal includes a placeholder on investment protection pending further progress on EU internal discussions on the matter) and both sides exchanged revised offers. The discussions aimed at a better understanding of the respective proposals and interests.

Agriculture

The two sides had in depth discussions on the EU proposed wine text, the U.S. proposed spirits text, and other non-tariff issues.

Trade in Goods

Parties continued to discuss elements of the Goods text. The discussion in this round focused on the articles related to customs duties, licensing, and some definitions.

Rules of Origin

The Parties discussed rules of origin procedures (Section B) on the basis of an oral presentation by the EU. The parties made progress in the consolidation of texts concerning General Provisions.

The Parties started discussions in detail on rules relating to textiles & clothing, though texts were not exchanged yet.

2. Regulatory Component

SPS

The Parties started text negotiations, making good progress on four Articles. It was agreed to continue work inter-sessionally.

Regulatory Coherence/Co-operation

Negotiating teams continued question-answer sessions on the EU and US texts, exploring in more detail the objectives sought, scope covered, relationship with other chapters and the practical aspects of implementation of the provisions proposed. The discussion was attended by a large number of Commission services and US regulators sharing their experiences and also benefitted from presentations each side provided to

29/07/2015 Page 2 of 6

enhance understanding of each other's systems and recent developments. The EU side inter alia provided information on its improved planning and information tools introduced by the recently adopted Better Regulation Package; the US side presented its recent Guidance on executive Order 13609, "Promoting international regulatory cooperation" issued by the Office of Information and Regulatory Affairs.

TBT

The US and the EU continued to discuss how to improve the frameworks that regulate conformity assessment issues, this is to say how it is verified that a product complies with the applicable technical regulations dealing with health, safety and any other legitimate public goals. The parties also discussed issues on standards and transparency, in particular regarding the possibilities open to their respective stakeholders to participate in the other party's standardisation processes. Thee parties discussed how to strengthen 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. Finally the parties discussed how to establish a framework for increased cooperation on TBT issues.

Cars

Constructive discussion on the four aspects that are being discussed regarding the regulatory approach to motor vehicles in the EU and US: the possibilities for recognition of equivalence of regulatory approaches; the revision of working methods of the UN 1998 Agreement; possibilities for expedite harmonization and cooperation in Research.

Chemicals

Further progress was noted with regard to two pilot projects on chemicals (concerning assessment of priority chemicals as well as classification and labelling of substances). The US presented an initial example for a further pilot project on analysing differences in the calculation of the classification of mixtures with possible consequences for safety data sheets. The EU and US discussed the elements proposed in the draft outline text of the EU.

Pharmaceuticals

Detailed discussions on pharmaceuticals with participation from EU and US regulatory agencies took place. Key topics covered, progress on respective GMP (Good Manufacturing Practices) systems assessment, cooperation on biosimilars, generics, finalisation of the reform of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the exchange of confidential information between regulators.

29/07/2015 Page 3 of 6

Medical devices

EU and US updated each other on the recent developments regarding the areas of cooperation under discussion in TTIP (Medical Devices Quality Management System audits, Unique Device Identification (UDI) and Regulated Product Submission (RPS). They acknowledged good progress made in these areas so far at international level. The Parties will reflect on how to translate these three agenda points into specific deliverables to be achieved within TTIP negotiations.

Cosmetics

One of the main objectives 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.

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.

ICT

The parties exchanged information on the different ongoing 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. Both parties agreed that in order to engage in these regulatory cooperation discussions it was necessary to identify areas of cooperation which are 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 Parties continued the dialogue on regulatory corporation in a range of areas, such as global zoning, Maximum Residue Level (MRL) harmonisation, or extrapolation of field study results and agreed to continue discussions at expert level.

29/07/2015 Page 4 of 6

3. Rules

Energy and Raw Materials

EU and US focussed in Round 10 on the scope of Raw Materials as well as Modes of Cooperation for Energy and Raw Materials. Furthermore, the EU and US discussed the working methods to structure the talks in the next months.

Customs and Trade Facilitation

The Customs and Trade Facilitation negotiating group continued work and made further progress on the consolidated text of the chapter.

IPR

Parties had productive discussions on IPR, with substantial amount of time devoted to border measures and other joint interest items. As in previous rounds, both sides also explored a range of technical questions and exchanged updates on the respective legislative processes. The US gave an overview of the IP-relevant text in the TPA and the EU provided the same regarding EP Resolution on TTIP.

GIs

Exchanges continued on the assessment of possible conflicts related to the EU GI shortlist on the US territory (pre-screening) and on legal alternatives to the U.S. trademark system. The U.S. remained non-committal.

SMEs

Progress made in the consolidation of the text proposal, with the section on cooperation provisions nearly agreed. Constructive discussions on the article on "exchange of information" and the presentation of different EU and US websites. US presented a proposal on institutional set-up, which will be discussed further in the next round.

State to State Dispute Settlement

The chapter aims at establishing an effective mechanism for resolving any disputes between the Parties on the interpretation and application of the Agreement. Discussions on the state to state dispute settlement focussed on the rules of procedure, on the EU's proposal for a voluntary and complementary mediation mechanism and on the compliance phase. Good progress made in the further consolidation of respective text proposals into a joint text and elaborating elements of compromise on those aspects where both text proposals differ substantially.

29/07/2015 Page 5 of 6

Competition

EU and US continued discussions exploring possible common language for the competition chapter (including on procedural fairness) on a non-prejudice basis.

The discussions allowed to further identify possible agreements and outstanding issues.

Subsidies & State Owned Enterprises (SOEs)

The EU and the US exchanged views with regard to the EU proposed text on subsidies. As regards SOEs, discussions took place on the substantive provisions of the respective text proposals. These exchanges allowed to further clarify the respective positions with regard to these provisions.

29/07/2015 Page 6 of 6