European Commission

Transatlantic Trade & Investment Partnership Advisory Group

Meeting report, 5 April 2016

Trade

1. Introduction

The Commission provided updates to the Advisory Group on the state of play of the negotiations following the 12th round that took place in February. The sectors negotiations received a particular focus in the discussion.

2. Sectors

Mr I. Iruarrizaga gave an update on sectors following the 12th round of negotiations. The Commission explained that the round went well and that the US showed engagement. The EU and the US are now focusing on developing texts in all nine sectors, with the first EU proposal due to be tabled during the next round. The precise schedule for developing EU proposals will depend on the content and continued discussions between EU and US regulators.

The following sectors were discussed:

Engineering

Mr P. Neira explained that the regulatory systems in the EU and the US are quite different in terms of conformity assessment and how standards are used in legislation, meaning EU engineering companies often face significant costs. Generally speaking the US regulates at the federal level in some of the areas of concern to the EU, but many areas are regulated at sub-federal level. He noted that the Commission was in contact with the industry on both sides of the Atlantic.

Information and Communications Technology (ICT)

Of the seven areas under discussion in this sector, Mr. Neira explained that two have been proposed by the EU and five by the US. One of the US regulators, the Federal Communications Commission, has engaged in constructive discussions with the Commission on the two areas proposed by the EU, namely software defined radio and specific absorption rates for mobile phones. Consumer interest has been noted regarding the latter.

On e-accessibility, which is among the five areas proposed by the US, the US Access Board (USAB) is currently finalising a new standard and once this is public, the Commission will be able to compare it with the EU standard. Regarding market surveillance, there is ongoing cooperation on how to tackle non-compliant products. On e-health, this is about monitoring the existing work between DG Connect and the US authorities, especially the US Department of Health and Human Services (US HHS), for which the roadmap has been recently updated. On encryption, it is difficult to engage since some Member States are reluctant to discuss.

Cars

Mr. Iruarrizaga explained that there is a common understanding between the EU and the US that certain automotive regulatory issues should be dealt with in TTIP. The last round served to advance the technical work and review the different regulatory areas related to safety (based on the three test cases) to determine how they should be addressed. There is ongoing work with the US National Highway Traffic Safety Administration (NHTSA) to decide whether there can be agreement on equivalence or on harmonisation in specific areas of regulation. The Commission clarified that this will be done in full compliance with the EU's international commitments (the UNECE conventions). Mr. Iruarrizaga described the identification of common rules in some areas together with the US as a step towards future global harmonisation in Geneva. Overall, he added that the 12th round had brought positive developments but that there was still considerable technical work ahead.

The following points were raised in discussion:

- One member inquired about when the test case on crashworthiness would be published, and asked for further detail about the specific regulations under consideration, as well as how the eventual chapter would be structured. Mr. Iruarrizaga agreed to check the status of the test case, and explained that the specific regulations are considered step by step. Work has started on the architecture of the chapter, and a draft would be made available in a timely manner for the group. Intersessional work continues to follow up matters discussed during the previous round and to prepare the next: it makes sense to report on this in line with the rounds, though if significant steps are taken then the group could be informed.

- One member asked for additional details on equivalence of regulations, and wondered whether harmonisation is really practical. Mr. Iruarrizaga explained that the approach taken by the EU and the US was to determine whether the effects of their respective regulations are broadly equivalent and whether further data is needed to confirm it. On harmonisation, three areas have already been identified and they will constitute the first challenge to the possibility of an expedited harmonisation process. The Commission clarified that whatever is harmonised, the EU and US will work together to do so also in the UNECE format, since the objective is to work as far as possible towards a multilateral system.

- One member questioned how this objective could be reached, given that the US and EU do not agree on the concept of an international standard. Mr. Iruarrizaga recognised the longstanding disagreement between the EU and the US on this point, but explained that both parties were looking at equivalence or harmonisation of actual regulations (not the standards that support them) in the automotive TTIP discussions. The EU has noted to the US side that as well as working together to project bilateral harmonisation efforts into the UNECE system, this must not detract from the EU's work under the 1958 UNECE agreement (the US being only party to the 1998 UNECE agreement).

Chemicals

Mr K. Berend gave an overview to the group of the discussions in the 12th round. He emphasised that there was now rather good understanding on possible common objectives, which were largely based on those initially proposed by the EU with some further work still needed on cooperation related to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Regarding the pilot projects, he informed that Member States had confirmed that the work had not led to delays or a significant increase in workload, instead the information obtained from US experts had been found useful for their own evaluation work.

- One member expressed an interest in hearing more about the nature of the exchanges between the Member States and the US during the work on pilot projects. The member also clarified that concerns about delays were not related to the pilot projects but rather to how this may lead to formal regulatory activity. Mr Berend explained that the exchanges had first taken the form of telephone conferences initiated by the Commission to put experts in touch and had continued with individual contacts, with a lot of information-sharing. He also highlighted that the work on, for example, priority substances does involve deadlines on the EU side, which had been met and not delayed by discussions with the US.

Pharmaceuticals

Ms. I. Kaizeler set out the EU's first proposal for a pharmaceuticals annex. She explained that the EU has to adapt its approach from previous trade negotiations where pharmaceuticals were covered, because the US is a highly sophisticated regulatory partner. The key articles include provisions on authorisation, inspections, exchange of regulatory information, and regulatory cooperation, reflecting the areas already discussed between the EU and the US.

- One member queried whether the EU's Joint Audit Programme (JAP) would be made available to the US Food and Drug Administration (FDA). Mr S. Goux clarified that the FDA does not want to carry out separate Member State audits: instead, the idea is that FDA relies on audits carried out under the JAP. Mr Goux confirmed that the EU would continue to make funding available to Member States to facilitate the FDA's observation of inspections under the JAP to confirm the way forward.

- One member asked about the US reaction to the EU's recent proposal on generic medicines , highlighted that regulatory cooperation should not only focus on faster market access but on creating tangible benefits for patients, consumers and payers in terms of reducing prices of medicines, and commented on various aspects of the draft, namely ensuring the voluntary nature of the chapter by adapting the language, the right to regulate, universal access to affordable medicines (for which the member

recommended including the word "affordability"), exchange of information between regulators, trade secrets, clinical trials, and the institutional and procedural aspects of regulatory cooperation between members. The member questioned the need for TTIP language on regulatory cooperation in pharmaceuticals, given that exchanges between the European Medicines Agency (EMA) and the FDA are proving productive already, and suggested that the Commission look only into what is necessary to improve the cooperation between these two agencies. The member insisted that specific reference should be made to the EU regulation on clinical trials to ensure that the trade secret elements in TTIP would not affect the high level of EU standards on clinical trials transparency. The member stressed that in the context of regulatory cooperation process, the scope of cooperation should be clearly defined, the wording should not contain binding obligation on Member States, private interest stakeholders should not be allowed to set the agenda of cooperation between regulators, and participating in consultation may prove challenging for public interest NGOs. The Commission agreed that cooperation is already functioning well, but that TTIP would ensure it could continue to do so, with appropriate resources and prioritisation. The Commission also clarified that while a legal basis is indeed not needed for the cooperation between the EMA and the FDA, it is necessary for other aspects such as inspections and exchange of non-public information to support regulatory decision-making. On generics, the US will react at the next round.

- On the subject of good manufacturing practices (GMP) inspections, a member asked if the EU and the US would agree on inclusion in TTIP (as the Commission wishes) or if it would be done in parallel. Mr. Goux confirmed that it would be included in TTIP, as reflected in the draft article on inspections.

- One member suggested that taking into account the concerns in the public health community regarding a possible inclusion of pricing and reimbursement provisions in TTIP, it would be useful to explicitly mention that they are excluded. The Commission confirmed that there is no intention from the EU side to include pricing and reimbursement related measures in TTIP.

- Another member felt strongly that it is essential that regulated industry be given the opportunity to comment on a work program and suggest possible areas for future cooperation. The horizontal regulatory chapters and sectoral annexes should clearly delineate the responsibilities of the actors involved (who does what). The Commission confirmed that the precise delineations between horizontal and sectoral texts would be fixed in due course as the work develops in both areas.

The Commission announced an extension of the deadline for advisors to send comments. Further discussions could take place bilaterally on the more detailed points.

Medical devices, Cosmetics and Textiles

For timing reasons, the Commission did not give debriefings on the medical devices, cosmetics and textiles sectors, but took questions from members.

- One member inquired about progress in the medical devices sector. Ms. Kaizeler responded that discussions continue but pending the adoption of the EU Regulations on medical devices the Commission was not yet in a position to draft a medical devices annex.

- On cosmetics, one member asked whether harmonisation work had started on the list of banned substances. Ms. Kaizeler replied that the Commission had no intention to harmonise with the US on this area. She commented more generally that the cosmetics sector is very important for EU companies but that the significant differences with the US system are proving challenging to work through. One member noted this is essentially down to the divergent positions on animal testing, and this should be acknowledged.

Mr. Iruarrizaga confirmed that all areas under discussion in sectors would be further addressed in detail when text proposals are put forward.

3. Access to documents and working methods

Some members of the group expressed their dissatisfaction with the lack of access to consolidated texts for the advisors. They felt that the value of the Advisory Group is significantly reduced without the texts and that the Commission should seek to encourage maximum transparency within the confines of the group, if necessary by taking a unilateral decision to provide access to consolidated texts. The Chair agreed to raise the issue once again with the US side, though noted it continues to be the case that US advisors cannot have access to consolidated texts. The EU would not take a unilateral decision to release consolidated texts since these are shared between the EU and the US. The Chair added that getting a sense of the issues at stake and how the EU is advancing on its objectives is more important for the advisors than precise text consultation, especially given that in many significant areas texts are yet to be developed (and so advisors will be consulted on EU proposals).

The following points were raised in discussion:

- One member pointed out that US advisors have access to EU texts, as many of these are publicly available, unlike the situation for EU advisors.

- One member suggested that the draft architecture of the texts – for example chapters and article titles – could be made available to the advisors. The Chair felt that this would be worth exploring on a reading room basis.

- One member suggested that the group be given at least a snapshot of the negotiations area by area so as to be able to comment and know where things really are. The Chair replied that the group meetings (as well as the public round reports) already do this to an extent, but a written snapshot for the group could be considered. He also recommended that advisors continue to contact EU negotiators directly for bilateral calls or meetings. This is particularly important to be able to get feedback on how advice has been taken into account.

- One member advised the Commission to publish its texts more quickly so as to avoid leaks, arguing that some papers only become interesting because of the fact that they are leaked. The Chair agreed that this is regrettable, but explained that in some cases publication is delayed because the idea is to publish a proposal simultaneously with a package of explanatory documents, and this takes extra time.

- One member asked if there was still time for the Advisory Group to comment on the various texts that were published online by the Commission in March 2016. The Chair answered that comments are always welcome, but noted that some of these documents are quite old (though have been previously available to advisors in the reading room).

- One member requested more details about the nature of the work performed during the intersessional meetings and said the Advisory Group should be kept up to date on this. The Chair explained that these meetings mostly focus on organizing the work of the next rounds; sometimes some negotiators travel to the other side to undertake more substantive negotiations. This is reported on at the next round.

4. Any other business

- **Procurement:** The Chair announced that in response to insistent claims by the US that the EU procurement market is more closed than the American one, the Commission is preparing some factual information on comparative openness in both markets. This will be shared with the Advisory Group.

- **Services:** One member asked which topics were discussed on services during the February round and if there was progress on mutual recognition for architecture and auditing. The Chair highlighted that there had been some progress, but there continue to be some significant differences of opinion: he recommended that the member contact the lead negotiator for specific details.

- **Rules of origins and customs:** One member raised the idea of organizing a specific Advisory Group meeting on rules of origin and customs and trade facilitation, explaining

that these topics are significant for SMEs and quite crucial to the success of TTIP. The Chair agreed to pursue this.

- **Energy and raw materials:** One member inquired about progress on the energy and raw materials discussions. The Chair explained that the February round had proven disappointing on this point and that the Commission was still trying to convince the US to include energy-specific provisions in TTIP. Another member suggested organizing specific Advisory Group meetings on this subject in the future, as well as on sustainable development, as the EU starts to develop texts.

- **Sustainability Impact Assessment (SIA)**: One member expressed concerns about the real value of the forthcoming draft interim SIA and hoped that it would serve to support the negotiating process. Another member noted concerns about the quality of engagement with the contractor. The Commission encouraged advisors to continue to engage with the contractor and provide feedback.

- **CETA**: The Chair explained that the Commission would present the CETA text to the Council in June, and in doing so express a view on the mixity of the agreement. Signature could take place in during the EU-Canada summit in autumn 2016, and it will be up to the Council to take the procedure forward.

- **Provisional application:** One member noted considerable confusion among stakeholders about the provisional application of CETA. The member quoted a press article which claims that the ISDS mechanism in CETA will be provisionally applied and that companies will be able to use it even before ratification takes place. The member asked how the Commission was responding to these claims. The Chair replied that this was totally inaccurate, that a vote in the European Parliament would be needed, and then the Council could decide on provisional application. The Chair also explained that the Commissioner frequently rebuts these false claims made around CETA.

Attendees

Members of the TTIP Advisory Group

BASSO Daniele (Labour and Trade Union, alternate for Guido Nelissen)
BERGELIN Erik (Manufacturing, alternate for Ivan Hodac)
BOWLES Edward (Services)
DE POUS Pieter (Environment)
FEDERSPIEL Benedicte (Consumers)
HINZEN Louis (Food and drink, alternate for Mella Frewen)
JENKINS Tom (Labour and trade union)
KERNEIS Pascal (Services)
KLEIS Johannes (Consumers, alternate for Monique Goyens)
LOGSTRUP Susanne (Health)
MASSAY-KOSUBEK Zoltán (Health, alternate for Nina Renshaw)
NOTHNAGEL Ilja (Small Business)
PETIT Arnaud (Agriculture, alternate for Pekka Pesonen)
QUICK Reinhard (Manufacturing)
SANTOS Luisa (Business)
TOUBEAU Cecile (Environment, alternate for Jos Dings)

Commission officials

GARCIA BERCERO Ignacio	Chair, TTIP Chief Negotiator
DAWKINS Miranda	Official
FERLET Guillaume	Trainee
GOUX Sébastien	Official
GÜLLNER Lutz	Official
IRUARRIZAGA DIEZ Ignacio	Official
KAIZELER Ivone	Official
MUSALL Benjamin	Official
NEIRA Pablo	Official
TALKO Wojtek	Official