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Council of the European Union
General Secretariat

Brussels, 8 May 2015

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MEETING DOCUMENT

from : Commission
to : Trade Policy Committee
Subject : TTIP: Written report of the 9th round

Delegations will find attached a note by the Commission services on the above-mentioned subject.

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EUROPEAN COMMISSION
Directorate-General for Trade

Brussels, 8 May 2015

[redacted]

NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE

SUBJECT: **TTIP*: Written report of 9th round***

[redacted]

OBJECTIVE: ***For information***

REMARKS: TTIP: Delegations will find enclosed the written report of the 9th round.

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TTIP

REPORT OF THE NINTH NEGOTIATING ROUND

NEW YORK, 20-24 APRIL 2015

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- **INTRODUCTION AND GENERAL COMMENTS**

- **1) SUMMARY REPORT**

The negotiating sessions encompassed a very broad range of subjects, (i) market access discussions covered tariffs and procurement only, as the services teams are focusing on preparing the implementation of the 20 March agreement, (ii) regulatory discussions covered all areas (regulatory coherence/co-operation, TBT, SPS and all nine sectors and (iii) all rules issues covered except sustainable development/labour/environment for which both sides aim to exchange texts by July round and will work inter-sessionally.

Details per negotiating area:

1.Market Access

Market Access tariffs

A joint session on agricultural and industrial tariffs took place. The US suggested developing a new basket of tariff lines (T), to be liberalised but under modalities to be negotiated at a later stage. Further clarification questions were raised on best practice in FTAs. A thorough product-by-product review of the first tariffs offers was then conducted, enabling both sides to provide further explanations on the rationale behind the treatment of particular product categories in their respective offers.

MA Agriculture

The EU recalled the key elements of the wine text and urged the U.S. to further engage on the matter. On spirits, the U.S. presented a textual proposal on regulatory commitments, in particular labelling. Further exchange was held on possible ways to address key non-tariff issues identified by the EU and discussed in earlier rounds.

MA Goods

Productive exchanges on the consolidated text with a view to removing brackets. The discussion focused on the articles related to waiver of customs duties, re-manufactured goods, import & export restrictions/licensing, and definition of customs duties. Further intersessional work by both parties is needed.

Public Procurement

Most of the discussions focused on text proposals. There was also a brief discussion on the way forward in procurement negotiations where the US confirmed that they still have a time-out with regard to discussing market access in procurement while they will carry out internal consultations.

US also reiterated their constitutional constraints with regard to State procurement. However, the negotiations ended with a relatively constructive discussion on clarifying existing market access commitments.

2.Regulatory Cluster

Regulatory Cooperation

The EU presented its revised text on regulatory cooperation containing a number of clarifications as regards the scope as well as for the first time specific provisions on non-central regulatory acts. The US asked a number of preliminary questions with regard to the non-central level. The US signaled readiness in principle to engage in a bilateral cooperation mechanism from the early stages, including specific methods of exploring regulatory compatibility in sectors, while the details would need to be carefully considered. The US is also reflecting about the most appropriate institutional structure to implement the provisions of the regulatory cooperation chapter and identify priorities for future cooperation, while flagging the need to build on experiences learned in the SPS and TBT context and to avoid any duplication and overly bureaucratic procedures.

SPS

After a further round of questions and answers that were aimed at further understanding the respective text proposals, it was agreed to start work on the Annexes. In addition, the Parties reviewed the state of pending applications for market access and discussed possible areas for further action. Both sides agreed to consider identifying areas where specific trade concerns can be solved, in accordance with each side's regulating framework, within the next twelve months.

Technical Barriers to Trade (TBT)

Most of the session focused on conformity assessment. The parties discussed the recent additional US text on conformity assessment. The EU explained its concerns with some elements of the US proposal. The parties discussed the update of the US Occupational Health and Safety Authority third party conformity assessment scheme for electrical product. The US provided an update, explaining the issues that are being considered in the ongoing review of the scheme. A draft will be put for public consultation before the end of June, however remains unclear whether the EU concerns will be addressed.

On standards, the EU replied to questions from the US on the recent updating of the Commission's Vademecum on European standardisation. The EU enquired about the ongoing review of the Office of Management and Budget Circular A-119 which is the key guidance document to Federal agencies on the use of standards in support of regulation. The US could not discuss the substance of the revised circular, but indicated that it should be finalised in the coming months. On transparency, the EU recalled its main requests: it pressed the US to notify or at least provide an early warning on TBT relevant Congress Bills, and to engage in a dialogue on comments received from the EU under

the TBT notification procedure, and to provide appropriate written feedback.

Chemicals

Discussions were productive. Some progress was noted on two pilot projects on chemicals (concerning priority substances assessment as well as classification and labelling), and clear indications given about next steps for a third on safety data sheets. There was also an initial exchange of views on the EU outline for possible chemicals provisions.

Cars

Progress was made on the 1998 Agreement on global harmonisation by establishing a common position paper with clear guidelines. Openness was expressed towards exploring experimental harmonisation between selected EU and US vehicle regulations where this was supported by mutual research. Further discussion is needed as to the approach for mutual recognition.

Pharmaceuticals

Discussions on Good Manufacturing Practice equivalence assessment are progressing. Audits of MS GMP inspectorates observed by US FDA took place and will continue during 2015. EU will audit the US inspectorate in September 2015. An assessment of Conflict of Interest rules is also ongoing. Next operational steps were agreed. Other areas such as biosimilars, generics and international cooperation were discussed. EU committed to submit a proposal for co-operation on generics ahead of next round.

Textiles

Discussions on textiles labelling and on textile safety requirements continued. The US expressed openness to collaborate with the EU on the labelling of textile fibre names and to address EU concerns on silk flammability. Further co-operation on voluntary textile standards is under discussion. US noted strong interest in progress on non-regulatory issues in this sector, i.e. tariffs and rules of origin.

Medical Devices

The EU presented its position paper on medical devices recently published online. The US asked for 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). EU noted that while committed to MDSAP work, a legal basis needs to be established for the EU 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

Some difficult challenges lie ahead mainly due to the fact that several cosmetics products are

classified as over the counter drugs in the US (significant different way of regulating and authoring cosmetics products in the EU and in the US). There are a number of UV filters (widely used in the EU in daily creams or make up products) that have not been authorized in the US. Therefore, EU products containing these UV filters cannot enter the US market. Both sides agreed to continue scientific exchanges between EU and US experts with the aim to understand better each other's approach for safety assessment of UV filters and other ingredients.

Engineering

The EU and the US continued to discuss possible areas of regulatory cooperation. The US provided feedback on some of the proposals already presented noting that these had raised little interest among their stakeholders. The US urged the EU to find economically significant areas of cooperation where the regulatory systems are similar. Both sides agreed to request further input from industry.

ICT

The parties exchanged information on the different ongoing ICT initiatives in EU/US on the areas of e-health, encryption, e-labelling, cooperation in market surveillance and e-accessibility. Once again the exchange of information was positive, but there was no conclusion on whether or how to address the various issues in TTIP.

Pesticides

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

3. Rules

IPR

Parties had productive discussions on IPR, particularly regarding the two text proposals submitted by the EU: on International IPR treaties and on IPR Customs enforcement. Both proposals were well received by the U.S. who signalled thinking along similar lines. Both sides also explored a range of technical questions on patents and plant variety protection and exchanged updates on the respective legislative processes for trade secrets, copyright and trademarks. The US presented new ideas in the cooperation area, addressing specifically the angle of SMEs.

GIs

The U.S. side signalled strong concerns about the revision of Lisbon agreement conducted in the WIPO context. The EU rejected any linkage between the review of Lisbon and TTIP negotiations. The EU side summarised its assessment of possible conflicts related to the EU's GI shortlist on the US territory (pre-screening), underlining that the large majority of names are not conflicting. Conversations on legal alternatives to the trademark (TM) system continued, with a focus on the

"distinctive products" avenue chosen by the U.S. in previous FTAs.

SMEs

The section on cooperation provisions has been fully un-bracketed subject to final review. Difficult exchanges took place on the core transparency/exchange of information provisions. The EU side presented further evidence of feasibility by presenting UNCTAD work on database of non-tariff measures, including US federal measures.

Energy and Raw Materials

Constructive and extensive discussion was held on the potential scope of energy and raw materials provisions and the application of horizontal or possible specific rules in TTIP. Discussions were without prejudice to the question of whether or not there should be an ERM chapter in TTIP or the context of such a chapter. It was agreed to intensify work, including intersessionally.

Customs and Trade Facilitation

The Customs and Trade Facilitation group had a productive meeting. Further progress was made on the consolidated text of the chapter and negotiators agreed to pursue discussions on matters that would benefit from enhanced customs cooperation between the EU and the US.

State to State Dispute Settlement

Constructive discussions continued once again on state-to-state dispute settlement advancing further towards establishing a joint text with limited brackets. With regard to the more contentious issues of the compliance phase, where the US proposal does not provide for a reasonable period of time for implementation and allows immediate move to the authorisation of sanctions, further progress was made in exploring possible elements for a compromise and in understanding each other's flexibilities.

- 2) DETAILED REPORT

2.1. MARKET ACCESS

2.1.1. TRADE IN GOODS AND MARKET ACCESS AGRICULTURE

2.1.1.1. Market Access Tariffs

Structures of the offer

In this joint session on agricultural and industrial tariffs, the U.S. side suggested amending the offer structure with a new liberalisation basket (named "T") in which the parties could put items destined

for full tariff dismantling but with liberalisation modalities to be determined at a later stage. The EU took note and raised clarification questions.

Parties also engaged in clarification of tariff treatment in previous FTAs to better understand the types of tariff concessions used by each side. The U.S. asked a series of technical questions about CETA.

The first tariffs offers were then reviewed, focusing on product sectors with sensitive items. Each side explained the nature of the sensitivity. All main sectors (industrial, agricultural and fisheries) were discussed, some detailed and some on a more general level given time constraints.

On NAMA products, the U.S. signalled readiness to improve their offer on textiles but mentioned that full liberalisation at entry into force was subject to rules of origin (US yarn forward vs. EU double transformation) and a removal of EU sanctions under the Byrd Amendment case (women's denim trousers). In regards to sensitive product groups the U.S. indicated that it would use longest possible staging for ceramic and glassware. On Footwear the U.S. was ready to consider improvements and indicated that sport shoes were sensitive. Ball bearings are also considered by the U.S. as sensitive along with Titanium –linked to defence and aerospace-applications.

Motor vehicles – the US did not give a clear indication but the most likely scenario is that it will move cars to the proposed "T" basket. The treatment of car parts is not yet clear.

The U.S. signalled canned Tuna as sensitive for which it envisaged temporary TRQs. No other fishery product was discussed this time.

EU gave an explanation to the conditions it has placed on the offer on energy intensive chemicals and responded to U.S request for improvements on products also considered in the ongoing ITA review.

The U.S. also proposed zero-for-zero treatment on all wood products. EU took note and agreed to consult with domestic industry.

On agricultural products, the U.S. indicated flexibility in the fruit and vegetable sector, peanuts, cotton, vegetable oils, some confectionery and part of the dairy sector. The U.S. also indicated offensive interests in tomato paste. In the dairy sector, the U.S. signaled sensitivity vis-à-vis the EU cheese, while noting that the reciprocity condition on the EU side encourages them to increase their level of ambition. The U.S. would seek full liberalization on milk protein products. On grains, the U.S. seeks a zero tariff and referred to preferences granted by the EU in CETA. In the meat sector, the U.S. reiterated its SPS concerns which they see as barriers to entry to the EU market. The U.S. explained that they would wish to see further progress or engagement on non-tariff issues before they could indicate their approach in this sector. On sugar, the U.S. took a defensive position, implying it will seek an alternative to full tariff elimination for this product.

The EU did not undertake any commitment as regards potential improvement of the EU offer in the

agricultural sector, and stressed its offensive interest on products on which it offered immediate tariff elimination subject to reciprocity. Both in respect of dairy and wine, the EU underscored the need to have a satisfactory outcome on GIs.

A further review of the offers can be expected in the next round, building upon this useful and constructive exchange.

2.1.1.2. Market Access Goods

The two sides continued discussions on the basis of the consolidated text with a view to further remove brackets. The details per article substantively discussed, are described below.

Article X.4 (classification of goods)

U.S. had not a new proposal as agreed last round but wondered if EU needs the article. EU will consider using just the normal reference to CN and HS in the annexed tariff schedule (which is identical to the U.S. proposal).

Article X.5 (Standstil)

Allowing for raising duties with GATT Art XXII reference already covered in DS chapter so this sub para (X.5.2. b) can now be deleted. This article is now complete except for the definition of originating goods (to be defined in RoO protocol).

Article X.6 (Waiver of customs duties)

EU does not usually use these provisions. For the US this is a standard provision that serves the purpose of subsidies agreement. The US sees the need to include disciplines on performance requirement in trade in goods that would match those related to investment. The EU will investigate how it defines "performance requirement" in this respect and if we have any system in place with performance requirements.

Article X.10 (Import and export restrictions)

The U.S. thinks the scope (X10.2) is too narrow. U.S. also worried that it would need to consult with EU on measures only affecting third parties. As the specific reference in the EU proposal to art. XI.2 (a) and (c) is relevant for agriculture, it is to be seen whether export and import restriction could be specifically addressed in the agricultural chapter.

X10.3 Exception introduced by US should be clarified. EU believes only SPS and TBT would be concerned and asked US to specify if they believed otherwise. X10.4. U.S. to redraft language that "affirms" rather than understands GATT rights and obligations. X10.5 references to U.S. exceptions (Jones Act and Logs). US still to verify if it needs the logs exception. X10.6 **Article X.11 (Remanufactured goods)**

Parties agree on the substance and need to make sure scope is acceptable to both parties.

Article X.12 (Import [and Export] Licensing)

EU: Not yet ready with a redrafted proposal. EU not against separating the article in one export and

one import article. US clearly defensive on export licensing for security measures. More work to be done by Eu on redrafting.

2.1.1.3. Market Access – Agriculture

The session focused on the following items: a) EU draft chapter on wine and spirits; b) regulatory provisions on spirits; c) non-tariff issues.

On the draft chapter on wine and spirits, the EU stressed the need to ensure progress on the draft text and invited the U.S. to be ready for such an exercise in the next round, where the U.S. relevant agency (TTB) is due to participate. The EU explained that a pre-screening of the 17 names of Annex II of the 2006 Wine Agreement showed the limited number of existing trademarks using these names.

The U.S. presented a textual proposal on regulatory commitments on spirits, in particular labelling. The EU raised clarification questions and the Parties will further review these matters in the next round.

The EU stressed the importance of finding solutions on non-tariff issues raised in earlier rounds: marketing order for table olives; dairy import assessment; direct shipping of wine; duty drawback on wine; support to small wine and beer producers; bottle size requirement. A useful exchange was held that can help the EU to move to textual proposals where and when appropriate.

Finally, the U.S. explained that it may cease a certificate requirement for EU export of pasta to the U.S., as part of a review conducted by U.S. Customs. The EU noted that such a suspension may be considered.

2.1.2. PUBLIC PROCUREMENT

Two days of technical discussions focusing on the text of the chapter (disciplines applicable to covered procurement) and clarifications of existing market access commitments. As for text, US presented its recent proposals which concern documentation requirements and the integrity of procurement process. Furthermore, the two sides exchanged views on some of the main remaining "bracketed" text provisions, although the discussions remained inconclusive. Topics covered included transparency, aggregated procurement, relationship between the services and procurement chapters, abnormally low tenders, social and environmental criteria.

On Public-Private Partnerships, the US considered that according to their interpretation Build-Operate-Transfer ("BOTs") are a form of procurement "by any contractual means" and already covered by US commitments. The EU reiterated that this issue had never been settled in GPA and it had taken a different approach and offered specific commitments to certain parties for works concessions in its market access schedules. The discussion will need to be continued as there is still no clarity on what the US could possibly cover on concessions.

In addition to text discussions, there was a discussion with a view to clarifying existing market access commitments under GPA and answering to the respective questions. The clarifications focused in particular on the scope of services commitments, funding for procurement purposes (such as the funds administered by the US Environmental Protection Agency ("EPA")) and US SME programs (set-asides and sub-contracting obligations relating to US SMEs). The US finally reiterated their interest towards market access commitments for specific EU agencies as well as a number of non-EU inter-governmental organizations, such as Eurocontrol.

2.2. REGULATORY COMPONENT

2.2.1. REGULATORY COHERENCE

On the first day of discussions, negotiators went through the consolidated version covering most of the provisions suggested by the EU and the US in relation to Good Regulatory Practices (GRPs) side by side. The EU side asked questions about the terminology used in the US draft and reiterated its overall concern –as expressed in previous rounds- in light of the asymmetry of acts covered by the US proposal. The EU side also explained that it welcomed US' intention to set standards for third countries as regards GRPs, but remained to be convinced on the usefulness on some of these very detailed principles. In any event, all principles would need to be phrased in a way compatible with both legal systems.

The US came back again on its core request with regard to stakeholder consultations on draft legal texts and draft impact assessments; the EU side – as done in previous rounds- offered explanations why this will not be possible. The EU side indicated that the EU Better Regulation Reform Package would be published in the second half of May and offered to provide explanations to the US side in the margins of the tenth negotiating round.

On the second day, the EU presented its revised text. The US side welcomed the presentation of the text and asked a number of detailed questions, in particular regarding the type of acts covered, and the interpretation of some of the general notes (in particular the significance of framework laws). The US side expressed disappointment in view of the fact that the EU text on GRPs did not include the EU Member States, since they will be Parties to TTIP. The US side also voiced concerns with regard to obligations that would bind Congress or US States directly, but was reassured by the EU side that this was not the case and that binding obligations were drafted in a manner consistent with US law and the US constitution.

Discussions took place in a constructive mood and covered a greater level of detail than in previous rounds, although the fact remains that the two texts have little overlap and are quite different in scope - in light of the objectives pursued. It is also apparent that there are different visions as to the institutional framework that would apply to the regulatory cooperation chapter and specific or sectoral provisions.

2.2.2. TECHNICAL BARRIERS TO TRADE

1. Conformity Assessment

a) US proposal on additional provisions on Conformity Assessment

Following a brief presentation by the US, both parties went through the additional textual proposal

on conformity assessment recently tabled by the US. The new text adds to Article 5 of the original US proposal for a TTIP TBT Chapter. The EU provided preliminary comments and indicated that it could come back later on with additional questions.

The US proposal is the legal translation of the well-known US positions on conformity assessment, as already discussed in previous rounds. Accordingly, the US text puts forward as a main request that US-domiciled conformity assessment bodies (CABs) be granted national treatment as compared with EU-domiciled CABs.

The EU explained that the US proposal, in its current terms, was not acceptable, not only because it would create an un-level playing field between CABs, but also because it would be against the principles established by EU conformity assessment legislation. The EU reiterated that a pre-requisite for US-domiciled CABs to be recognised in the EU would be for the US government to be involved and take direct responsibility for such CABs in order to mirror the role of Member States in the public supervision of notified bodies. However, the EU also noted that, should the Parties be able to agree on a mutually beneficial outcome on conformity assessment comprising as one of its elements, a framework for the mutual acceptance of conformity assessment results setting out criteria for the recognition of CABs meeting the requirements of EU law, some of the additional provisions contained in the US proposal could be used as basis for discussion, although they would require different degrees of adjustment.

b) OSHA NRTL Program Review

The Occupational Safety and Health Authority (OSHA) gave an update on the on-going revision of the Nationally Recognised Testing Laboratories (NRTL) Program. The revision is a long-term project, which will have deliverables at different stages.

In the shorter term (target: end 2015), OSHA is working on streamlining requirements for NRTLs, notably by providing a clear separation of testing and certification functions and aligning the qualifying criteria with the requirements set out in the ISO/IEC international accreditation standards for testing laboratories (17025) and certification bodies (17065). Further to a preliminary stakeholder consultation on a first draft published in September 2014, OSHA expects to publish a revised Draft Program Directive for formal Notice and Comments around June and then provide 60 days for comments. OSHA aims to adopt the final Program Directive before the end of 2015.

Longer-term issues, which would require formal rule-making, include for instance relying mainly or exclusively on external accreditation to qualify CABs, any possible changes to the product scope of the Program and to the applicable third-party conformity assessment procedure, including the issues of factory visits and factory surveillance, the possible introduction of a common NRTL mark in

addition to each NRTL's logo, etc.

Following questions from the EU on the operation of the current Program, OSHA explained that the accreditation process for NRTLs (wholly managed by OSHA directly and not relying on independent accreditation bodies) had recently been improved. Further improvements are expected from the revised Program Directive, which will formalise the passage from the obsolete ISO Guidelines 25 and 65 to their successors ISO/IEC accreditation standards 17025 (for laboratories) and 17065 (for certification bodies). For the time being OSHA will continue to accredit the laboratories, although applications backed by external accreditation will likely undergo a simplified procedure under the revised Program Directive. OSHA went on to explain how standards are referenced / recognised under the NRTL program. This is done following a request from any stakeholder. In practice most of the requests come from the NRTLs. At this moment there are around 300 standards referenced. OSHA explained that no case of request of recognition of foreign standards had been received so far.

OSHA said that such a request, in any case, would not be dealt by OSHA in the first place but by the American National Standards Institute (ANSI). In this context, consideration would be given not only to the relevance of the standard to the US market but also as to whether the standard has been developed following the principles of openness, transparency and consensus.

The discussion concluded with OSHA explaining how the NRTL Program is being used by other authorities in the US States for different purposes, usually concerning the use of product in specific situations. In this context, OSHA indicated that some States have introduced similar or more stringent requirements for certain types of products regulated by OSHA outside the NRTL Program.

c) US follow-up questions on the EU Notified Body system

The US presented several questions on the EU Notified Body System as described in Council and European Parliament Decision 768/2008 on a common framework for the marketing of product (commonly referred to as the "New Legislative Framework"). In particular, the US asked how the EU had departed from the principle that CABs need to be established under national law of a Member State in relation to the recognition of Canadian CABs under the future CETA Protocol on the Mutual Acceptance of the Results of Conformity Assessment. The EU explained that these are the general principles on which mutual recognition agreements (MRAs) are based, and this was not considered to be a different or wider interpretation of 'national law' but a specific situation under an international agreement. The EU clarified that, once recognised under the Protocol, a Canadian CAB would be treated for all intents and purposes as a notified body and registered in the appropriate database with the rest of EU notified bodies (this actually is not a new development in EU law and it is already the case for all CABs recognised under the existing MRAs, including the 1998 EU-US MRA).

2. Standards

a) US follow-up question on European Standardisation

The US asked for an update on the Annual Union Work Programme (AUWP), the Vademecum on European Standardisation and the Independent Review of the European Standardization System. The EU replied that the Vademecum will shortly be available online and that it was drafted after thorough public consultation in which US stakeholders were also participating. The US was most interested in the sections regarding international cooperation and consideration of standards developed outside the EU in the development of harmonised standards, and in particular the examination of standards produced by US-domiciled bodies.

b) Review of OMB Circular A-119

The EU requested an update on the on-going review of Office of Management and Budget (OMB) Circular A-119, the key policy guidance document on the use of standards in support of US federal regulations. The EU recalled its interest in having more transparency prior to the formal notice and comment carried out for the referencing of a standard. Appropriate early notice of the interest of any given agencies in the work of a particular standard development organization could facilitate the participation of interested stakeholders. The US indicated that the revised Circular was undergoing final inter-agency clearance.

3. Transparency

The EU asked for follow-up on two questions raised during the previous rounds. Recalling its concerns on the lack of notification of US Congress bills, the EU requested the US to identify an advanced appropriate step in the Congress legislative process which would then trigger a notification or at least some form of communication in the form of an early warning to the WTO or bilaterally enabling interested parties to submit input to Congress. The US remained non-committal. The second question was on the possibility of conducting bilateral dialogue after written comments have been sent on US TBT notifications, with the involvement of the competent US regulators. The EU at least expected to receive a written reply on how EU comments were taken into account no later than the adoption of the final regulation. The aggregate answers provided under the current format (Appendix to the adopted final rule) were not specific enough to identify how EU comments had been addressed.

- 2.2.3. SANITARY AND PHYTOSANITARY ISSUES

SPS Chapter TTIP

The Postdam Group Member States attended the meeting and the consolidated text of the SPS Chapter was projected on a screen as reference.

The US introduced the SPS session by reading out a statement urging the EU 'to take responsible action' in the GMO legislation review. The US chief negotiator also conveyed the US concern and described the timing of the announcement on Wednesday 22 April as 'unfortunate'.

The EU negotiators expressed disappointment about the absence of progress on consolidating the text between the 8 and 9 round and indicated appetite for intercessional DVC's before the next round.

Discussions were limited to questions about the Party's text proposals and identification of the individual articles which could be merged before next round. It was agreed to discuss how to proceed towards the consolidation phase and to share the work on drafting text of Annexes on equivalence (lead US), regionalisation (lead EU), audits (EU), and possibly certification (US, depending from available capacity).

Specific Trade Concerns

Open discussion about what the two sides will be able to identify as issues where both sides will aim to solve specific trade concerns in accordance with their respective legal framework. Further discussions will be taken up inter-sessionally.

- 2.2.4. SECTORS

- 2.2.4.1. PHARMACEUTICALS

1. Good Manufacturing Practice (GMP) inspections

Regulators from both sides (DG SANTE and Food and Drug Administration (FDA)) provided an update of the work carried out so far by the task force in charge of assessing the equivalence of EU and US GMP systems. Both sides acknowledged that intensive work took place since the last round.

System inspections: FDA provided positive feedback on the audit of Greece that took place in March 2015. This audit confirmed the positive experience of the audit of Sweden in 2014. Greece was the first of the 7 audits of Member States in the framework of the Joint Audit Programme (JAP) scheduled for 2015 (Greece, Germany, Croatia, UK, Czech Republic, Hungary and Italy). The audit of Germany will take place in April. After reception of the audit reports of these three first audits (Sweden, Greece and Germany), FDA will finalise the concept/template that it considers necessary for the evaluation of all Member States. FDA will benefit from the information collected during the audits of the JAP audit program (that FDA observers) and from the documentary information already provided by the EU.

The on-site audit of the US system by the EU team will take place in mid-September. In this respect, FDA has submitted the information requested by the EU (the audit reports of the US GMP system audits carried out in 2009 and 2010 in the context of PIC/S and answers to the preliminary questions from the EU).

Legal issues - Conflict of interest (CoI) rules: Although extensive information has already been provided in the previous round, FDA indicated that it will still request clarifications on the European Medicines Agency (EMA) rules on conflicts of interest. The finalisation of the FDA analysis of these rules and their equivalence to FDA rules is thus postponed. Regarding rules applied by Member States, FDA acknowledged reception of the information for most Member States. It was agreed that a template allowing to compare US rules with Member States rules will be used to complement the already provided information. This aspect is however no longer considered as a pre-requisite for starting the evaluation of Member States. It will thus be treated at the same time than the evaluation of each Member State.

2. Biosimilars

The EU welcomed the first authorisation of a biosimilar by FDA produced by Sandoz (filgrastim-sndz) but noted concerns as regards the fact that the name given to that biosimilar is different than the name adopted in the EU (filgrastim). FDA noted that the suffix "-sndz" was a placeholder and could not be considered as indicating the future US policy on naming that will be set out in the still to be defined draft guidance on naming of biosimilars.

In general the EU reiterated the interest to collaborate with FDA on biosimilars and noted that TTIP

remains important to support regulators to advance further collaboration on this matter. FDA indicated that they had the intention to issue final versions of draft guidelines including the one providing scientific requirements and guidance on the use of reference products that facilitates global development. The EU reiterated its expectations that these guidelines would be as much as possible harmonised with EU guidelines.

3. Exchange of confidential information between regulators

FDA indicated that analysis on the appropriate way to sharing inspection reports with foreign governments was ongoing.

The EU noted that the provisions on sharing confidential/trade secret information between regulators should go beyond inspection reports and cover other information relating to the marketing authorization files.

4. International Conference on Harmonisation (ICH) reform and guidelines on paediatrics

The EU and the US welcomed the ongoing work in ICH regarding paediatrics as well as the prospects to finalise the ICH reform in June 2015.

5. Common Standards for Unique Identifiers

The FDA indicated that it would provide written answers to EU questions on US rules on identifiers shortly after the round. As a consequence, no detailed discussions took place on this matter. The EU confirmed the information provided in the previous round regarding the adoption of the EU Delegated act: adoption is anticipated to take place in Summer 2015.

6. Transparency in Pricing and Reimbursement

The US reiterated its interest to include transparency provisions on pricing and reimbursement within the TTIP similar to the ones EU and U.S. have with Korea.

7. Generics

The EU and the US noted the joint submission by EU and US generics association (EGA and GPhA of 17 April 2015) calling for a single clinical development program for generics. While it was premature to express views on the content of the submission, both Parties indicated that they would analyse the matter in detail.

The EU committed to submit, ahead of next round, a non paper to explore opportunities for further collaboration on generics both at bilateral and at international level. The new contribution from industry will be duly considered for the preparation of the EU non-paper. FDA indicated that it would welcome the EU written submission in view of investigating further opportunities of collaboration.

- **2.2.4.2. CHEMICALS**

1. Review of follow-up items Round 8:

Both sides reviewed the implementation of the follow-up actions agreed at the 8th round. Most of the agreed follow-up actions had been delivered, including on the two pilot projects on priority chemicals as well as on classification and labelling. Cooperation on common priority chemicals, including state of play of pilot project

Some good progress was achieved on the co-operation on priority chemicals assessment. Overall, four Member States have confirmed their willingness to engage with the US EPA in the framework of the pilot project. The EU stressed that the evaluating Member States as well as actors on the EU side have to respect procedural deadlines under REACH. Classification and labelling including state of play of the pilot project

The EU informed that for one of the substances selected (*antraquinone)* the US NTP (National Toxicology Program) recently confirmed that they had reviewed the EU proposal and had concluded that the document was well-constructed and made appropriate use of available US-generated data. For the other substances of common interest (cobalt and certain cobalt compounds), which are already under review by NTP, a classification proposal is also expected on the EU side to be submitted.

2. Pilot project on Safety Data Sheets (SDS)

The US OSHA announced its intention to soon submit a first analysis on differences in governance, format and content of SDS, and described which items would be tackled in the analysis. The EU fully agreed with the suggested approach and requested the US' agreement to share the document, when available, with EU Member States and stakeholders for review. Co-operation on new and emerging issues

The US was interested to receive an update on the ongoing EU Impact Assessment for criteria to identify endocrine disruptors. The EU informed about a conference planned in June and invited U.S. to participate.

3. EU draft outline on possible chemicals provisions in TTIP

For the first time, the US had accepted an agenda item to discuss the EU's proposal for an Outline on Possible Chemicals Provisions in TTIP. However, the US questions raised stayed very general. The EU invited the US side to provide further comments on the draft outline in writing or consider an inter-sessional phone conference ahead of the next TTIP round.

4. A.O.B.

The EU noted that given the very significant interest of stakeholders (notably on the NGO side) in the TTIP pilot projects, it should be considered to make more information public, notably with regard to the identity of the substances in the pilot projects. The US indicated this would require further discussions. The EU recalled that all substances covered by the pilot project are already included in publicly available lists on both sides; making more details public could create large benefits without risking the disclosure of any confidential information.

- 2.2.4.3. MEDICAL DEVICES

1. Discussion on the EU Position Paper on 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. In the US view, such an objective has not been explicitly discussed in the TTIP negotiations but rather the international Medical Devices Single Audit Programme (MDSAP). The EU noted that while committed to MDSAP work, a legal basis needs to be established for the EU to be able to accept audit reports carried out by US inspectors (TTIP could serve as legal basis).

2. Medical Device Single Audit Program (MDSAP)

The US welcomed the EU announcement of observer status in the pilot project at the MDSAP and active participation in relevant meetings in Tokyo in March 2015. Regarding future confidentiality arrangements, the US expects an answer from the EU on the FDA's proposal and formal signature at Commission level as soon as possible.

3) UDI

The EU thanked the US for having shared the technical dossier for the implementation of the UDI system/data base. EU's IT experts will study the dossier and will come back to the US FDA with questions if necessary. The EU is going to start preparatory technical work to avoid divergences of the two systems in the future. The EU asked the US for access to the US UDI data base.

4) RPS

EU informed that EU is in charge of coordinating the IMDRF global Table of Content (ToC) Pilot Project. In addition, EU will proceed with the implementation of the EU pilot.

5) AOB

The US raised the issue of transparency and pricing for medical devices which continues to be of concern for US industry. The EU asked more information about the 21 Century Cure Bill. US informed that the draft bill will be discussed in senate and is available on the Congress web site.

2.2.4.4. COSMETICS

1) Cooperation on risk assessment of cosmetics ingredients, in particular UV-filters

Both sides agreed to continue scientific exchanges between EU and US experts with the aim to understand better each other's approach for safety assessment of UV filters. A pilot project on safety assessment of UV filters was discussed. The objective is to compare the EU and U.S. requirements and the data that needs to be submitted for an ingredient approval in each jurisdiction. The pilot would take as a case study a concrete UV filter already approved in the EU (together with the data submitted). EU will provide terms of reference.

2) Labelling

Both sides noted that the issue of harmonization of labelling requirements is not a top priority of the EU and US cosmetics industry any longer. Practical solutions (such as labelling meeting both requirements) have been implemented by the industry.

3) Cooperation in ICCR

US presented the topics they wish to be dealt in ICCR, such as allergens, microbiolgical contaminants and in silico modelling to replace animal testing. US will submit a position paper on ICCR with the objectives on these three items in May ahead of the ICCR meeting 9November 2015).

4) Alternative methods to animal testing

The US informed about a link with guidance on animal testing on the FDA web site providing information to manufacturers on available alternative methods to animal testing.

- **2.2.4.5. MOTOR VEHICLES**

The following four items were discussed:

Concerning the 1998 Agreement, agreement has been achieved between US, JP and EU on a paper to be submitted to be discussed at the next WP.29 session at the UN in Geneva in June.

On equivalence, the parties first exchanged views on the methodology proposed by the US industry consultant UMTRI. Second, NHTSA provided a written reaction on the 2nd Test Case of the EC and noted that it used a pragmatic approach in its analysis. They identified in a first step 5 items where joint work was deemed possible, notably on harmonization rather that equivalence from the US point of view, but also hinting at the possibility of allowing alternatives to their domestic requirements.

With regard to bilateral 'expedited' harmonization, they provided an explanation of possible objectives and an update of current domestic work on the following three items: Advanced Emergency Braking, Adaptive Driving Beam, Seat Belt Reminders/Interlocks. In addition they submitted a proposal for a co-ordinated rulemaking process flowchart between US and EU, notably to align milestones and to benefit from common/shared input received from stakeholders at set times.

On research, the parties referred to the ongoing exchanges and positive contributions to the establishment of the respective research programmes.

- **2.2.4.6. TEXTILES**

1. Standards (ASTM/ISO)

In previous meetings there was interest to explore the possibility for closer cooperation on standards applicable to textile and clothing products (ISO/EN and ASTM). In this context, the US presented a draft table comparing ASTM and ISO standards. The table classifies the standards as: 1. technically equivalent, 2. technically similar or 3. not equivalent. Most of the standards are used on business to business relations (i.e. to demonstrate product quality) with no government intervention (e.g. standards not mentioned in regulations). Still business operators mention that tests have to be repeated to satisfy EU and US clients.EU will assess the contents of the table including the comparison classification

2. Fibre names

EU presented ideas on a possible coordinated way to deal with applications for the recognition and designation of new fibres submitted by economic operators to EU or US administration. The main

objective is that both administrations give the same name to the same fibre (useful for labelling purposes). Currently for a given fibre, sometimes the name used in the EU labels is different than the one used in the US (e.g. elastane in EU and spandex in the US). US gave a positive consideration to this proposal, subject to the opinion/detailed assessment by FTC (Federal Trade Commission).

In addition US would also like to open a debate on "eco-friendly certification" not just related to the final product but also taking into consideration all production steps.

3. Market Access

US noted interest for cooperation in certain areas (for instance test methods used in fire retardant apparel, water proof apparel and textiles used in medical devices). EU noted that more details would be needed to engage in a discussion and to assess whether US requests are feasible or not.

4. Silk flammability

The European Silk Association (AIUFASS) submitted a petition to CPSC (Consumer Product Safety Commission) requesting an amendment of the flammability test method (i.e. sampling conditioning) defined in the US *Standard for the Flammability of Clothing Textiles*, 16 CFR part 1610. In this context, CPSC issued a Notice of Petition for Rulemaking. Deadline for comments is June 8th.

5. Care labelling (FTC rule) and CPSC certificate of compliance rule

The EU asked for an update on the 2012 Federal Trade Commission (FTC) proposal on care labelling (that would allow manufacturers to be able to use either ASTM care symbols or, as an alternative, ISO care symbols).

The EU inquired about the state of play of CPSC certificates of compliance draft rule. US noted that the comments received are still being considered. Once that is done a recommendation will be prepared for the Commissioner but that will not happen during 2015 fiscal year. CPSC staff is preparing a notice to comments to call for volunteers to participate in a pilot of electronic filing for imported products.

- **2.2.4.7. ENGINEERING**

The EU started by recalling the proposals for co-operation that had already been presented, including those brought forward by industry recently which were already discussed during the previous rounds. In particular the EU recalled the proposal that was forwarded to the US on Road

Circulation of Self Propelled machinery, which it is aimed at regulating how that kind of equipment must meet the environmental requirements. The EU also noted that according to the feedback received from the industry, more joint proposals would be available soon.

The US started by noting that they had analysed the proposal on Self Propelled machinery that the EU had sent to them, and also other proposals that the EU had presented before. They noted, however, that this type of machinery is not regulated at a federal level. States regulate this area in a very light manner. Therefore at first sight it does not look like an area that would be suitable for cooperation. The US noted some industry interest in the LED lighting proposal issue - however this interest related to energy efficiency aspects. The US asked whether there is a willingness on EU side to look into these. The EU noted that there is a general willingness to address energy efficiency aspects under TTIP.

The US went on to explain that it is being difficult for them to identify areas for possible cooperation. The US regulatory framework in the sector differs greatly from the one in the EU. The US does not have any sort of wide scope legislation with essential requirements as in the EU. The US noted, however, that there could be some products covered by the Nationally Recognised Testing Laboratories (NRTL) scheme, and also some issues covered by the Consumer Product Safety Commission (CPSC) that maybe could be tackled. The US went on to note that in order to cooperate it would be necessary to identify specific areas which are economically significant and where there exists a similar framework of regulation on both sides. It would be possible to engage in discussions only if those products were regulated at federal level.

Both sides noted that joint industry submissions so far have mostly raised issues of a horizontal nature, normally addressed under the TBT chapter, like the use of ISO/IEC international standards. Both sides agreed to continue searching for possible examples with the assistance from industry.

- 2.2.4.5. ICT

E-health

The US started by presenting the state of play regarding the preparations for the US/EU e-health Riga event which will take place in May. This event will also provide the opportunity to have discussions with stakeholders on how the Roadmap has delivered so far and which objectives stakeholders think should be targeted next. Parties went on to discuss the possibility of bringing the standardization work into international fora involving other countries, which would be the ideal outcome, however as expressed by both parties this will depend on the different areas of activity being tackled.

Encryption

The issue of encryption was briefly discussed. The EU explained that Member State authorities were concerned about how this could affect their information security policies, but also about how it

would affect international standards.

On their side the U.S. noted that this is a third country issue. The U.S. further added that once TPP is finished they could present the text that has been agreed, but not before.

E-accessibility

The US made a brief description of the state of play. The Access Board has issued their Notice for Proposed Rulemaking on the e-accessibility standards for Section 508 of the Rehabilitation Act that they are also used for the update of the Section 255 of the Telecom Act.

The US and the EU agreed that this was a good opportunity to harmonize standards, always aiming at the highest possible levels of accessibility. The US standards are of compulsory regulatory nature while the EU standards are of voluntary character, hence objective is to make both documents compatible and coherent but not aiming both texts to be identical.

The parties concluded by discussing the possibility of the European standards being transformed into an ISO standard. The EU noted that there was not any formal decision on this yet. And that such initiative was in the hands of the European standardization bodies. In any case, it was agreed that the ideal situation would be an ISO standard that would be agreeable by both EU and US.

E-labelling

The Federal Communications Commission (FCC) provided an update on rule making process for allowing e-labelling for products under their jurisdiction having an integrated display. E-labelling is currently already allowed under guidance issued by FCC, the second step is now to formalise this through an official rule making process. FCC expects to have this rule published in summer 2015.

The EU provided update on e-compliance initiative. Currently all options are still under analysis taking into account feedback received from stakeholders. The Commission intends to decide on the way forward by end of 2015. US inquires whether e-labelling is part of e-compliance initiative and noted that e-compliance is much more wide. EU replied that currently all options are open.

Market surveillance

The parties agreed on need to decide whether and in which format cooperation should be part of TTIP. Both sides see it as an opportunity but it is necessary to further elaborate on the format.

Any other business

The parties briefly discussed other items of co-operation that had been suggested by the EU in the engineering paper: The common charger, Specific Absorption Rates (SAR) for mobile phones and software defined radio. The EU provided an update on state of play.

- **2.2.4.9. PESTICIDES**

The Parties had discussions to further explore the scope for collaboration, without duplicating work in other fora.

In the field of Maximum residue limits (MRLs) both sides had already exchanged information on

timelines and schedules for MRL reviews. Some dialogue is also ongoing with EFSA. To accommodate a joint submission and joint evaluation for an MRL or import tolerances, methodologies for the MRL evaluation would have to be aligned. As a first step, it was proposed to discuss methodological aspects at expert level. EU agreed to discuss methodological issues at technical level.It was agreed to organise a video conference with all the interested parties, ie Commission, Member States, EFSA and EPA.

From an EPA perspective, possible pilot subjects related to pesticide residues could include dimetylamine (apples), fosethyl (almonds), chlorothalonil (cranberries).

As regards collaboration in international fora including CODEX and OECD, both sides agreed that collaboration in these fora usually functions quite well. US would be interested to build on this positive experience.

2.3. RULES

2.3.1. TRADE IN ENERGY AND RAW MATERIALS

The EU and the US discussed energy and raw materials very extensively in this round. Parties examined the scope to be covered and reviewed the different areas of the energy and raw materials sector. In that context, negotiators assessed specific trade issues (bilateral and third country topics) that would need to be examined in TTIP. The US referred to clean coal technology and better extracting technology of coal, civil nuclear and renewable energy as potential areas of interest.

As to raw materials, the US mentioned that the definition should be more specific, this is it should be clear what raw materials should be covered. Parties also discussed in this context critical raw materials and conflict minerals.

Discussions took place on some horizontal and specific disciplines that should address the bilateral and third country trade issues. Parties reviewed horizontal disciplines in order to assess the adequacy or inadequacy to deal with the specific trade issues. Discussions took place on how the US Market Access/EU Trade in Goods Chapters tackles the trade in energy issues that were identified. In this context, there were discussions also on the dual pricing issue. Parties had another extensive discussion on export and import licensing. Discussions also started on the regulatory items, notably the licensing of hydrocarbon exploration and production.

As follow up EU and US agreed to exchange a series of documents and information and the EU and the US agreed to continue the discussions after this round by means of an inter-sessional (tentatively scheduled for the week of 2 June).

2.3.3. SME'S

On cooperation provisions, some compromise language was found on drafting issues. Both sides will work on a new consolidated version reflecting this.

On transparency/access to information, the EU presented UNCTAD work on a database of NTMs, searchable by HS code, which illustrates that our request is reasonable and can be delivered with minimal effort (estimated cost for UNCTAD to prepare the US database, only at federal level, is 100,000 USD).

The US was enthusiastic about the UNCTAD project but believed that in this context any work from their side not necessary – if UNCTAD does it the US government should not duplicate it, and EU stakeholders would already benefit from it.

The EU stressed that the scope of the UNCTAD project as too limited, and explained that it was indispensable to have a commitment from the US to deliver and maintain their own information

tool, so as to ensure that the database is updated over time (even if this does not necessitate a duplication of existing resources).

- 2.3.4. CUSTOMS AND TRADE FACILITATION

The Customs and Trade Facilitation group had a fruitful one and a half-day meeting, where incremental progress was made on the consolidated text of the chapter.

Discussions touched upon the following:

- A detailed presentation and discussion of EU customs clearance procedures, in particular simplified procedures, of relevance to several proposed articles in the chapter (release of goods, expedited shipments, facilitations/simplifications - *de minimis*).
- A review of the text on release of goods. Further exchanges will be needed on timelines and related information of traders.
- Presentations on advance rulings, with an emphasis on the respective approaches on the publication and related confidentiality aspects. Discussions continued on timelines for validity and issuance of rulings.
- An article on risk management was agreed.
- Further progress was made on data and documentation.
- a detailed discussion on penalties allowed for progress towards a common text. Outstanding issues include consideration of mitigating and aggravating factors (minor breaches / voluntary disclosure of breaches / records of compliance).
- On review and appeals, discussion will continue with a focus on the transparency of related decisions.
- Exchanges are to continue on fees and charges with consideration of existing waivers in other US free trade agreements.

Negotiators also agreed to continue to pursue discussions on topics that would benefit from a process of enhanced customs cooperation between the EU and US (data requirements, trusted trader programmes, single window systems), with reporting of practical related discussions between regulators.

- 2.3.5. INTELLECTUAL PROPERTY RIGHTS, INCLUDING GEOGRAPHICAL INDICATIONS

The IPR discussion took place over two days, including half a day dedicated to GIs. The discussion covered the areas of copyright, patents, plant varieties, trade secrets, customs enforcement, regulatory test data protection and cooperation (voluntary stakeholder initiatives and SMEs).

First, the EU presented its text proposal listing the international agreements to which both sides should commit in TTIP, and the U.S. gave preliminary reactions, largely positive. The list of treaties thus does not appear to be a contentious issue, although some of the treaties are difficult for either side (Rome Convention for the U.S., Cybercrime Convention and Brussels Convention for the EU). The US confirmed their continued preference for oral discussion and do not intend to present a counter-proposal in writing in the nearest future.

The EU also handed to the US and presented a new text proposal on IPR customs enforcement. The US gave a preliminary positive reaction since the draft proposal is along the lines of the concept paper presented to the US previously. Detailed discussion on substance is expected at the next round after the US has had a chance to consult internally.

On patents, both sides explored a range of technical questions in the areas of interest previously indicated by the US. The EU reiterated the difficulty of discussing these complex matters without concrete text proposals. The US stated that a number of their possible future requests can be found in the patent sections of their previous FTAs (ex; KORUS). The US inquired whether the EU's position on patent grace periods had evolved further: EU explained again the views of the stakeholder, remain predominantly negative and made reference to some of the most common concerns expressed against introducing grace periods on the EU side (ex increased legal uncertainty).

Both sides also worked through technical questions with regards to plant variety protection. The US raised a number of issues concerning implementation of Nagoya Protocol and the corresponding draft legislation in the EU. The EU signalled that the links with IPR were tenuous, but proposed to establish a contact between US and EU officials responsible for the file.

On cooperation activities, the US made some constructive suggestions on measures to improve SME access to IPRs. The Parties will come back to the issue in subsequent rounds. The US also gave a presentation about voluntary best practices to tackle counterfeiting (with focus on payment processing companies) and inquired about progress on similar initiatives in the EU (which have been announced in recent EU Communications). In addition, the US showed interest in addressing in the IPR Chapter the issue of facilitating research/finding treatment for rare diseases, namely through incentives related to test data.

Negotiators also provided updates on the development of their respective trade secrets legislative proposals and exchanged views on latest developments in the copyright review processes under way on both sides of the Atlantic.

GIs

The US side complained strongly about the proposed revision of the Lisbon Agreement for the protection of "appellations of origin". The U.S. argued that if it is not given full negotiating right at Lisbon, this would have disrupting effects on GI talks within TTIP.

The EU side took note of this position, strongly rejected any linkage with TTIP and reaffirmed that the Lisbon review process was conducted in complete transparency and in full compliance with international law.

The EU side presented the methodology followed for pre-screening EU GI names against a set of criteria (such as registered TM from an EU GI holder or another operator, prior use, plant variety

name/animal breed name, alleged generic, in the original language of the GI and/or in translation) and made a non-name-specific summary of pre-screening outcome for instance number of conflicts per typology, without prejudice. It resulted that, out of the totality of names, the large majority do not present any conflict.

On potential alternatives to the TM system for providing GI protection to EU names, the EU raised a number of questions on the protection that U.S. have to distinctive products in other FTAs. The U.S partially answered those questions, making clear that they do not see that solution as part of an IP discussion.

- **2.3.6 STATE TO STATE DISPUTE SETTLEMENT**

Constructive discussions continued and good progress was made on developing further compromise language for those provisions where the EU and US proposal are fairly close on substance to make further progress on consolidated texts if still partially bracketed. Both sides seemed clearly committed to be constructive and flexible in order to advance as much as possible on issue where we share the same objective. The EU presented further proposals for provisions on panel composition, establishment of the roster and for the interim and final panel report which were largely accepted by the US. A compromise proposal for a provision on rules of procedure was proposed by the US and agreed with small changes. The compromise developed during the last round on consultations and panel establishment was confirmed by both sides with small changes. Discussions also reverted in more detail to the respective proposals for the compliance phase. Based on the discussions during the last round, the US presented further elements for a compromise on the issue of "sequencing" of the compliance and sanctions proceedings. The underlying rationale for the US proposal (no reasonable period of time and immediate sanctions request possible) is that the complaining party should be able exert pressure on the responding party (to implement faster) and to "rebalance" the rights and obligation under the agreement, this is to shift the "costs" of the breach to the party that had been found to be inconsistent with the agreement. The US suggested to provide for the possibility of merged compliance and sanctions proceedings (similar to what was agreed in CETA) if the complaining party wishes to proceed as quickly as possible to the authorisation of sanctions. However, in order to address the concerns expressed by the EU during the last round, the proposal also included an option of having compliance proceedings only without having to put forward a request for sanctions first. Both sides engaged constructively in bringing out the commonalities and trying to bridge the difference. While reserving our position and linking our potential flexibilities to the US position on including an RPT, we engaged constructively outlining further areas of improvement if a compromise was to be found. On the RPT, the EU proposed some elements for a possible compromise on the reasonable period of time for implementation: some

qualitative elements to provide guidance on the length of the RPT and information on the state of play of implementation during the RPT. While the US kept repeating that their position is to have no RPT, there seems reasonable scope for a possible opening if a broader compromise can be found including the sequencing issue. The US suggested to further look into the possibility of the original panel remaining on duty and deciding the RPT in a swift manner once the panel report has been issued (and incompliance with the Agreement was found). The EU referred to the importance of ensuring time for the responding party to consult internally on the possible approach to implementation and the necessary measures and to not foreclose the possibility of the parties agreeing on an RPT without arbitration, which in the WTO is the case for the majority of RPTs. Both sides agreed to explore further options and flexibilities for the next round.

LIST OF ABBREVIATIONS

APHIS: USDA Animal and Plant Health Inspection Service
ATA: Carnet System - Passport for Goods
ATMs: Alternative Test Methods
BOT: Build-Operate-Transfer
CABs: Conformity Assessment Bodies
CABs: Conformity Assessment Bodies
CARE: EU-level accidents database
CENELEC: European Committee for Electrotechnical Standardization
CI: Colour Index
CoI rules: Conflict of interest rules
CoRAP: Community Rolling Action Plan
CPC: Central Product Classification
CSR: Corporate Social Responsibility
EMA: European Medicines Agency
EPA: Environmental Protection Agency
EPA: United States Environmental Protection Agency's
ESOs : European Standardisation Organisations
ETSI: European Telecommunications Standards Institute
FACA: Federal Advisory Committee Act
FARS: database on automobile accidents on public US roads
FAS: USDA Foreign Agricultural Service
FCC: Federal Communications Commission
FDA: Food and Drug Administration
FERC: Federal Energy Regulatory Commission
FOIA: Freedom of Information Act
FSIS: USDA Food Safety and Inspection Service
GMP: Good Manufacturing Practices
GPA: Government Procurement Agreement
GTR: Global Technical Regulations
ICCR: International Cooperation on Cosmetics Regulation
ICH: International Conference on Harmonisation
IEC: The International Electrotechnical Commission
ILAC: International Laboratory Accreditation Cooperation

ILAF: International Accreditation Forum

IMDRF: International Medical Device Regulators Forum

ISO: The International Organisation for Standardisation

ITA: The Information Technology Agreement

JAP: Joint Audit Programme

MDSAP: Medical Device Single Audit Program

MEAs: Multilateral Environmental Agreement

MRA: Mutual Recognition Agreement

MRL: Maximum Residue Level

NHTSA: National Highway Traffic Safety Administration

NIST: National Institute of Standards and Technology

NRTL: Nationally Recognized Testing Laboratory

NTP: National Toxicology Program

OJEU: Official Journal of the European Union

OSHA: Occupational Safety and Health Administration

OTCs: Over the Counter Drugs Product Specific Rules (PSR)

PPPs: Public-Private Partnerships

PSR: Product Specific Rules

QMS: Quality Management System

RAC: Regulatory Authority Council

RPS: Regulated Product Submission

RPT: Reasonable Period of Time

RVC: Regional Value Content

SBA: Small Business Administration

SCCS: Scientific Committee on Consumer Safety

SDO: Standard Developing Organisation

SoI: Standards of Identity

UDI: Unique Device Identification

UII: Unique Identifiers

US Office of Management and Budget OMB

USDA: U.S. Department of Agriculture