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Unit E1, Trade relations with the United States and Canada

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Trade Policy Committee	
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LIMITED

NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE

SUBJECT: **Transatlantic Trade and Investment Partnership (TTIP*)***

***ORIGIN*:** **Commission, DG Trade, Unit E1**

Ignacio Garcia Bercero
Director Neighbouring countries, United States and Canada
+32 2 299 56 61
Ignacio.Garcia-Bercero@ec.europa.eu

Damien Levie
Head of Unit Trade Relations with the United States and Canada
+32 2 298 44 02
Damien.Levie@ec.europa.eu

Carsten Sorensen
Policy Coordinator Trade Relations with the United States
+32 2 295 77 21
Carsten.Sorensen@ec.europa.eu

OBJECTIVE: ***For information***

REMARKS: ***Please find attached the following papers that will be sent to the US side ahead of the first round. Additional papers could follow subsequently.***

Initial position papers on:	***Regulatory Issues - Cross-Cutting Disciplines and Institutional Provisions; Technical Barriers to Trade; Regulatory Cluster: automotive sector, chemicals, pharmaceuticals; Sanitary and Phytosanitary issues (SPS); Trade and Sustainable Development; Anti-Trust & Mergers, Government Influence and Subsidies; Trade and Investment in Raw Materials and Energy.***
Non-paper on:	***Public Procurement***

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Initial position paper

Limited

Without prejudice, 20 June 2013

Subject: TTIP; regulatory cluster; initial position papers for discussion at the first round

Please find enclosed in the annex three distinct sectoral initial position papers on the automotive sector, on chemicals and on pharmaceuticals, which we suggest to discuss at the first negotiating round, in addition to the ones on cross-cutting disciplines and TBT. These sectoral papers contain the Commission's initial reflections on a number of joint submissions received from stakeholders on both sides of the Atlantic in response to the public consultations on TTIP.

The Commission is still in the process of analysing these submissions and preserves the right to present, ahead of the next negotiating round, additional initial position papers in other goods and services' sectors, including in areas where there are no (joint) submissions.

Please note that the regulatory component of TTIP is meant to cover both goods and services. Regulatory issues pertaining to the financial services sector will be discussed within the services' cluster but this is without prejudice as to where the provisions covering these issues will ultimately be placed in the agreement.

Annex I

Initial position paper
Motor vehicles in TTIP

The purpose of this paper is to outline the main elements of a possible approach under the TTIP to promote regulatory compatibility/convergence and recognition in the motor vehicles sector, while achieving the levels of health, safety, and environmental protection that each side deems appropriate. These elements build on the ideas put forward jointly by the motor vehicles and parts and components industries from the EU and the US as well as the need and the duty of regulators to achieve the necessary health, environmental and safety protection levels.

1. Objectives

A high level of ambition in this sector is warranted not only by the expectations of the EU and US industries, but also by the very substantial efficiency gains and cost-savings that would arise from addressing regulatory divergences in addition to eliminating tariffs , without lowering safety, health or environmental protection levels. Furthermore, a joint EU-US approach would create a basis for genuine international leadership on motor vehicle standards and regulations.

Accordingly, the ultimate goal pursued in the TTIP negotiations would be twofold:

- firstly, the recognition of motor vehicles (and their parts and components, including tyres) manufactured in compliance with the technical requirements of one party as complying with the technical requirements of the other. Such an ultimate objective would be pursued in stages: it is expected that substantial results should already be reached at the time the negotiations are concluded (i.e. recognition of equivalence for regulations deemed to have similar test and in-use effects), and that a built-in agenda for further regulatory convergence would be defined with, insofar as possible, concrete timelines.

- secondly, a significant strengthening of EU-US cooperation also in the framework of UNECE 1998 Agreement, especially on new technologies. This process should lead in the near future to the adoption of Global Technical Regulations (with a limited number of options and modules) subsequently incorporated in the national legislations – see built-in agenda below.

2. Methodological approach

EU and US motor vehicle regulations, even though they contain diverging technical requirements, provide for a high level of safety and environmental protection. Overall, there is little doubt that the levels of safety required by both sides are broadly comparable. In fact, some motor vehicles manufactured according to the US specifications can already drive legally in the EU under the individual approval system.

Thus, in principle, the technical divergences between both regulations are not a sufficient reason to stand in the way of recognition of each other's regulations: equivalence of outcome is a more relevant consideration. Methods can be devised to make possible the assessment of equivalence, which would open the way to recognition. Assessing the equivalence of the environmental performance of certain motor vehicle categories may warrant adapted methods.

If the overall level of protection is comparable, the main concept and starting point in such a methodological approach – as proposed by ACEA and AAPC - could consist in a presumption that the regulations of one side should be considered as equivalent (i.e. having the same effect) to those of the other side, unless it can be established that the regulations of the other side do not offer a comparable/similar level of protection as that provided for by the domestic regulations. Such a presumption would not be a legal presumption – i.e. a legal requirement that equivalence exists unless proven otherwise -, but would form part of a methodological approach in order to facilitate the task of assessing equivalence of regulations, to be conducted by regulators.
Such an approach would require the contribution of industry and, as appropriate, of other relevant stakeholders. The EU and US industry would be requested to provide, as an input to the TTIP discussions, relevant information to help conduct such an assessment: this would include as much evidence and data as possible (including on the economic value of establishing the

equivalence) in support of the request for consideration of equivalence. Pending a more detailed data-driven analysis, the lists of matching regulations submitted by the industry in their joint contributions, already provide a valuable indication of industry's expectations for this negotiation. As a starting point, it would be appropriate to focus on a first batch of regulations on which work would begin immediately. This could concern regulations which have important economic value and indeed presumed similar effect, be it on safety or on the environment. This approach would allow the Commission and the US agencies to test and refine the methodology for the examination of equivalence in the remainder of the regulations. The data for these first cases should be provided in the shortest possible timeframe.

Importantly, as absence of recognition of any individual regulation could imply important additional costs, the examination of equivalence should be comprehensive and extend to all relevant technical regulations applicable to motor vehicles – going even beyond the list proposed by the industry so far. Other stakeholders would also be able to provide input.

Regulators would conduct such an equivalence assessment based on emission levels and data provided by the industry as well as on the data used in the legislative process (e.g. cost-benefit analysis and health data). If regulators establish that there is no equivalence, the reasons for this conclusion should be identified as well as the means that would enable recognition of equivalence for future standards.

It will be critical that such an evaluation focuses on the outcome of the regulations, i.e. their effects in terms of protection of safety and the environment. Therefore, differences in specific technical requirements or testing methods would not per se constitute a proof of absence of equivalence, unless it is determined that such differences have a significant material impact in terms of protection.

3. Possible deliverables during the negotiations

In the course of the negotiations, both sides would identify the areas where there could be recognition of equivalence between the EU/UNECE and FMVSS and other regulations relevant for safety and the protection of the environment. The objective would be to establish a list in the TTIP agreement

covering a high number of matching EU/UNECE-FMVSS and other regulations, both in the field of safety and the environment. For areas where there is recognition of equivalence, such recognition would mean in legal terms that compliance with the relevant regulations of the other TTIP partner would have the same legal effects as compliance with domestic regulations, and therefore be considered for all purposes (although with limitations with respect to conformity assessment, see below) as compliance with the relevant corresponding domestic regulations.

Such recognition would concern the technical requirements applicable to motor vehicles and their parts and components, and cover the technical specifications, how they are measured (i.e. tests carried out to assess compliance), and marking requirements. Such recognition could not be extended to conformity assessment, in view of the wide divergence between conformity assessment systems (prior type approval in the EU, in accordance with the UNECE system, and self-certification with market surveillance in the US). However, in order to facilitate trade and the recognition of the substantial technical requirements, EU type-approval authorities would be required to test US vehicles destined for the EU market against US regulations using US testing methods, while US bodies would, in their market surveillance activities, test EU vehicles against EU/UNECE regulations and their testing methods. The agreement would have to specify how to make the two systems work smoothly alongside each other, and reduce paperwork as much as possible, whilst respecting their integrity.

4. Built-in agenda

For cases where equivalence cannot be established during the negotiations because of important differences in the effects of technical requirements, the agreement should identify those areas where further convergence would be necessary. It should also define how and when to achieve it: the gaps should be specified and a clear process and timeline (in-built agenda) would be agreed. This should be complemented by a strengthening of EU-US cooperation in the framework of UNECE 1998 Agreement.

Reinforced cooperation in the context of the UNECE 1998 agreement would

also be the central element to cover new technologies and lead to the adoption of EU-US and ultimately of Global Technical Regulations, in areas such as hydrogen and electric vehicles, test-cycle on emissions, and advanced safety technologies. The objective would be for a quick incorporation of the resulting GTRs in national legislation, insofar as possible abstaining from options, exemptions and modules - or otherwise providing for recognition of the options that the other party may have chosen. Progress in this work would be regularly monitored under the relevant bodies of TTIP at the highest level.

Insofar as possible, some outcomes on these topics could be achieved during the timeframe of the negotiations and reflected in the resulting texts.

5. Future convergence

In addition to the areas identified for further work, there could also be a provision concerning other future regulations, according to which whenever either side considers that a new regulation is required they will consult the other and commit to work together in order to establish common rules, in principle in the framework of the 1998 Agreement.

6. Practical considerations – work organisation

The next step would be to agree on a work plan and concrete steps to be carried out during the negotiations, in particular during the course of 2013. Stakeholders would be invited to provide the necessary information to support the process. On the EU side, Member States (which are responsible for type-approval activities) will need to be consulted regularly.

Within the framework of the TTIP negotiations, regulators from both sides would develop the methodology and identify areas and questions requiring further work.

Annex II

Initial position paper

Chemicals in TTIP

The purpose of this paper is to outline the main elements of a possible approach under TTIP to promote regulatory convergence and recognition in the chemicals sector. These elements build on the ideas put forward jointly by Chemicals Industry Associations of the EU and US.

1. Overall objectives

Both industry associations and governments are aware that neither full harmonisation nor mutual recognition seem feasible on the basis of the existing framework legislations in the US and EU: REACH (Regulation (EC) 1907/2006) and TSCA (Toxic Substances Control Act) are too different with regard to some fundamental principles. The recently completed REACH Review concluded that REACH should not be amended, while in the US a bipartisan proposal to amend TSCA has been introduced into Congress in May 2013. However, the draft legislation does not foresee any general registration obligation for substances as a condition for their marketing (a fundamental requirement under REACH), nor elements comparable to authorisation, while it would give the EPA new and easier possibilities to conduct chemical assessments and adopt risk management measures such as restrictions. The objective of the negotiations, therefore, must be to find and agree on all possibilities for regulatory co-operation/convergence within the limits of the existing basic frameworks – details are set out below. Some of these objectives could already be achieved at the time the negotiations are concluded, while for others only adherence to certain regulatory principles and mechanisms for further work might be feasible.

2. Detailed objectives

Four main areas have been identified in which a higher degree of convergence may be sought to increase efficiency and reduce costs for economic operators:

2.1. ***Co-operation in prioritisation of chemicals for assessment and assessment methodologies:*** prioritisation happens in the US in the framework of the so-

called Chemicals Management Plans of the EPA as well as through the selection of chemicals for the so-called 'Reports on Carcinogens' by the National Toxicology Programme (NTP), and in the EU through (a) the establishment of the Community Rolling Action Plan (CoRAP) for Evaluation under REACH drawn up by ECHA (***to note***, though: evaluations under REACH are expected to be much more targeted and limited in scope than the full assessments made by the EPA under its chemicals management plans), as well as (b) in a much less formalised and purely voluntary risk management option analysis followed by proposals for restrictions, substances of very high concern (SVHC) identification (candidate list), authorisation and proposals for harmonised classification and labelling under Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP). None of these processes in the EU and US, respectively, currently foresees the consultation or involvement of authorities of the other, but TTIP could be an opportunity to develop relevant mechanisms. Methods for assessment/evaluation are also an area where EPA and ECHA already co-operate and this can be intensified – in particular in the development/integration of new scientific developments. The already existing Statement of Intent[1] signed between EPA and ECHA could be a good basis for developing further co-operation activities. The US Agencies should also accept to monitor the activities of individual States in this regard and inform the EU about all draft measures envisaged at sub-Federal level.

2.2. ***Promoting alignment in classification and labelling of chemicals:*** this is an area with great potential, because an international standard exists, which is essentially a 'fusion' of the earlier EU and US systems. In the EU the CLP Regulation constitutes a comprehensive implementation of the UN GHS, whereas in the US, only OSHA has implemented the GHS for chemicals used at the workplace. EPA (and possibly also the Consumer Product Safety

[1] The European Chemicals Agency has already a cooperation agreement with the US EPA. This agreement on technical and scientific cooperation is underpinned by revolving work plans. The interaction with the peer organisation includes regular director level meetings and technical dialogue between experts when topics of mutual interest to share information and best practice on the regulatory science, IT tools and databases relevant for sound management of chemicals. The cooperation under the current agreement does not include the exchange of confidential business information.

Commission CSPC) would have to also implement the UN GHS for legislation under their responsibility if this objective were to be reached. The EU and US authorities could also commit to implement the regular updates of the GHS and, in areas, where a certain flexibility is allowed, to work towards convergence. ACC/CEFIC also called for a common list of chemicals with agreed classifications, which fits with an initiative in the UN GHS promoted by the US for a global list of agreed GHS classifications. The EU already maintains a list of binding harmonised classifications in Annex VI to the CLP Regulation, and an inventory of all existing industry self-classifications – which are not fully harmonised yet - has been established in the C&L Inventory maintained by ECHA. An enhanced EU-US co-operation on agreeing classifications for chemicals could become a good basis for a global list.

2.3. ***Co-operation on new and emerging issues:*** Co-operation on new and emerging issues in a forward looking manner has the greatest potential to avoid trade irritants in the future. Current topics of interest would be endocrine disruptors (where contacts between the Commission and EPA are already established), nanomaterials (contacts also already established) and mixture toxicity. Mutual consultation as of an early stage, whenever US agencies or the Commission start developing new criteria or new legislation, could relatively easily become part of the preparatory processes conducted by both.

2.4. ***Enhanced information sharing and protection of confidential business information (CBI):*** this has been proposed by ACC/CEFIC, including also a call to identify 'existing barriers for exchanging information'. The US EPA and OSHA (mainly to obtain full test study reports from the EU) as well as ECHA (mainly to receive full information about substance identities from the US authorities, e.g. in the Chemical Data Reporting scheme) have also expressed interest. In addition, several animal welfare organisations have called on the authorities to increase data exchange to avoid duplication of tests involving animals. While it is undoubtedly important that the EU and US authorities exchange information, both sides also make vast and increasing amounts of data publicly available. Therefore, several elements would require additional

consideration before deciding what further steps could be taken or what benefits an agreement on sharing CBI would bring. For example, the US EPA is content with working with robust summaries (and does not require full study reports) in the context of the OECD HPV Programme. Also, neither ECHA nor the Member States authorities do normally receive full study reports as part of REACH Registration or even evaluation – these are owned by the industry and shared between the registrants via Substance Information Exchange Fora (SIEFs) which could be approached directly by the EPA. It also has to be ascertained that information exchange would be mutual, which raises the question of the limits on the US authorities to give any confidential information to other authorities under Section 8 of TSCA. This analysis should also include to what extent the definitions of CBI is equivalent in the EU and in the US.

3. Possible deliverables during the negotiations

Realistically achievable deliverables during the course of the negotiations will differ for the specific objectives set out in section 2, as detailed in the following. It should also be noted that both for the negotiation and later implementation the relevant US agencies need to cooperate internally to avoid diverging developments on the US side, which would make convergence with developments in the EU impossible.

For objective 2.1: agreement on a mechanism for mutual consultation on prioritisation of chemicals for assessment/risk management and for co-operation in the development of assessment methodologies, which could be described in an article in the relevant sector annex for chemicals. commitment by both sides to inform about activities at sub-Federal level in the US and Member State activities in the EU, respectively.

For objective 2.2: commitment to implement the UN GHS for a broad range of chemicals by a certain date and to implement the regular updates of the GHS. There could also be agreement on a mechanism for mutual consultation and involvement in processes for classification and labelling of substances (i.e. harmonised classification in the EU under CLP – NTP reports on cancer in the US), or on other ways of establishing a common list of classifications for substances (e.g. reviewing existing lists and identifying commonalities, working through the OECD or others). These elements could be described in an article in

the relevant sector annex for chemicals

For objective 2.3: agreement on a mechanism to regularly consult with each other on all new and emerging issues – in particular those of regulatory relevance, which could be described in an article in the relevant sector annex for chemicals. Commitment to consult and respond to comments/questions from the other side and undertake efforts to work towards common criteria/principles/measures on such new and emerging issues, where feasible.

For objective 2.4: completion of a full analysis on the expectations of each side, possible obstacles to exchange of (confidential) data, possible benefits of such exchange and perspectives for reciprocity. If considered worthwhile, commitment to undertake negotiations on a relevant mechanism with an objective to conclude them within X years.

4. Built-in agenda

The sector annex could contain a provision to periodically review the functioning of the mechanisms developed for each of the above objectives and their revision as appropriate. Furthermore, both sides could commit to periodically examine whether additional and new objectives could be covered and the sector annex be amended accordingly.

5. Future convergence

The horizontal chapter of TTIP would have provisions concerning an effective bilateral cooperation/consultation mechanism and an improved feed-back mechanism, for both parties to get sufficient time to comment before a proposed regulation is adopted and to receive explanations as to how the comments have been taken into account. For the chemical sector, this would include in particular risk management proposals for prioritised substances at Federal/EU level and US State/Member State level.

6. Practical considerations – work organisation

The next step would be to establish a work plan and concrete steps to be carried out during the negotiations and in particular during the course of 2013. This would include in particular the identification of all relevant actors (i.e. agencies on the US Side, COM and ECHA on the EU side). Stakeholders would be invited to provide proposals to support the process.

Annex III

INITIAL POSITION PAPER

PHARMACEUTICALS IN TIIP

INTRODUCTION

The final report of the US - EU High Level Working Group on Jobs and Growth (February, 2013) highlights that as regards regulatory aspects TTIP should contain in addition to cross-cutting disciplines and TBT plus elements provisions concerning individual sectors.

The purpose of this paper is to present some possible elements for a TTIP annex on pharmaceutical products. It is based on ideas put forward by EU and US industry and builds on existing cooperation between EU and US regulators in this area. It is anticipated that stakeholders will continue to support the process and could play an active role towards the implementation of some of the identified objectives.

Regulatory cooperation between EU and US in the pharmaceutical area supported by existing confidentiality arrangements is very well established both at bilateral level as well as at multilateral level via ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use).

TTIP could reinforce existing collaborative processes on pharmaceuticals by:

- establishing bilateral commitments that would facilitate pharmaceutical products authorization processes and optimise agencies resources (notably with respect to reliance on each other's GMP inspections results and exchange of confidential information),

- fostering additional harmonization of technical requirements in new areas or in areas where the need to improve harmonization at bilateral or international level has been identified (e.g. biosimilars, paediatrics, generics, terminology),

- reinforcing joint approaches on scientific advice and evaluation of quality by design applications).

POSSIBLE ELEMENTS FOR A PHARMACEUTICALS ANNEX IN TTIP

GMP inspections

Both Parties could explore possibilities for the improvement of the recognition of each other's GMP inspections carried out in third countries and inspections carried out in EU and US territory.

An advantage of this approach would be that FDA and EU Member States would be able to focus their resources on inspecting high risk areas (which are located outside EU and US) instead of spending resources on inspecting third countries facilities and EU and US facilities which have been already inspected by one of the Parties. In addition, this approach would entail significant cost savings for the industry.

Although the EU has functional MRAs or equivalent in place with Canada, Japan, Switzerland, Australia, New Zealand and Israel, between the EU and US a more flexible approach could be taken.

Therefore, in TTIP, a system based on mutual reliance on each other's GMP inspections (instead of legally binding mutual recognition) could be envisaged. Such approach should include progressive targets that would contribute to confidence building.

Provisions on the exchange of confidential/trade secret information should be in place for such approach to function.

Exchange of confidential information and trade secret information

Both Parties should explore possibilities for allowing the exchange of confidential information and trade secret information between EU Member States/EU institutions and FDA. This approach would apply not only to GMP and other inspection reports but also to data and information on marketing authorizations applications.

TTIP could entail legal provisions allowing the exchange of confidential information in the horizontal chapter as well specific confidentiality provisions in the pharmaceuticals annex.

Innovative approaches from industry could greatly contribute to the realisation of this objective.

Establishing functioning systems for the authorisation of biosimilars

Both Parties could commit on establishing functioning systems for the authorisation of biosimilars. The FDA could benefit from the experience of EMA that has already completed opinions on 16 biosimilars. FDA and EMA are expected to pursue their scientific exchanges which contribute to the development or review of their respective guidelines. In particular, a formal acceptance of comparative clinical trials based on reference medicines sourced in the EU or US or in third countries should be envisaged.

An advantage of this approach would be the potential increase of approved biosimilars in both markets. In addition, US and EU could shape the international approach for the review/authorization of biosimilars.

Revising requirements for Paediatrics authorization

Both Parties could work towards the revision of ICH guidelines on paediatrics in particular by agreeing on clinical studies design (paediatric investigation plans) and by mutually accepting clinical studies. In addition, both Parties should agree on the timing for data submission.

Terminology for pharmaceutical products

Both Parties could work towards the implementation of a harmonized terminology for pharmaceutical products (unique identification of medicinal products and substances, pharmaceutical forms, routes of administration, etc.).

This approach would improve the information flow between enterprises and regulators and between regulators of both Parties.

Bilateral cooperation on joint assessment approaches

Both Parties could commit to continue existing cooperation on 'parallel scientific advice' (joint discussion between EMA, FDA and applicant/sponsor of scientific issues during the development phase of a new product) and existing cooperation on 'parallel evaluation on quality by design applications' (joint list of questions to the applicant and harmonized evaluation of the applicant's responses).

This approach would have the advantage of optimizing product development and avoiding unnecessary clinical trials/testing replication, optimising agencies

resources (sharing assessment reports/authorisation decisions) as well as important costs savings for industry.

Provisions on the exchange of confidential/trade secret information or industry readiness to allow such exchange should be in place to allow such approach to function.

NEXT STEPS

Taking into account that the objective of the current paper is to present a first analysis of possible elements for a TTIP annex on pharmaceutical products, the first negotiation meetings could aim at:

- discussing how to combine health regulators' agendas (focus on protecting human health) with more general competitiveness objectives (increased trade, growth and jobs);
- calling on stakeholders to see how they can best support these objectives;
- identifying common goals and possible scope of commitments;
- deciding on whether the identified goals should be achieved at bilateral level or at multilateral level (e.g. ICH) and within which time frame;
- discussing the best tools to achieve in a pragmatic way the goals (e.g. GMP recognition vs. reliance on GMP results);
- determining what type of deliverables can be expected within TTIP in the short and medium term;
- discussing implementing measures and what type of resources (financial, human, legal) will be necessary to put in practice TTIP commitments.

EU initial position paper on SPS matters for the TTIP negotiations – Without prejudice, 20.6.2013

In its Final Report, the High Level Working Group on Jobs and Growth (HLWG) recommended that the United States of America and the European Union (hereinafter "the Parties") should seek to negotiate an ambitious "SPS-plus" chapter. To this end a mechanism to maintain an improved dialogue and cooperation should be established to address bilateral sanitary and phytosanitary (SPS) issues. The chapter will seek to build upon the key principles of the World Trade Organization (WTO) SPS Agreement .

This chapter – as part of the FTA discussions within the TTIP - will seek to build upon the key principles of the World Trade Organization (WTO) SPS Agreement, including the requirements that each side's SPS measures be based on science and on international standards where these exist, while recognising the right of each Party to appraise and manage risk in accordance with the level of protection it deems appropriate and with the objective of minimising negative trade effects. Measures taken, in particular, when relevant scientific evidence is insufficient, must be applied only to the extent necessary to protect human, animal, or plant life or health, must developed in a transparent manner and must be reviewed within a reasonable period of time.

This chapter should seek to address market access issues and to facilitate the resolution of differences. It should be without prejudice to the right of the EU and Member States to adopt and enforce, within their respective competences, measures necessary to pursue legitimate public policy goals such as public health and safety in accordance with the WTO SPS Agreement.

The SPS chapter will form part of a broader move to also address regulatory issues and non-tariff barriers. In this context, the two sides should also seek to strengthen upstream cooperation by regulators and to increase their cooperation on standards setting at an international level. Regulatory convergence shall be without prejudice to the right to regulate in accordance with the level of health, safety, consumer and environmental protection that either Party deems appropriate, or to otherwise meet legitimate regulatory objectives.

At present, the 1999 *Agreement between the United States of America and the European Community on sanitary measures to protect public health and animal health in trade in live animals and animal products* (the so-called Veterinary

Equivalence Agreement or VEA) aims to facilitate trade in animals and animal products by offering a framework for establishing the equivalence of EU sanitary measures relative to the US level of protection and vice-versa, for US sanitary measures relative to the EU level of protection. The VEA also provides for recognition of the animal health status of the exporting Party, the recognition of the regionalisation, guidelines for border checks, procedures for the conduct of verification visits, improved information exchange and transparency, amongst other things.

The new SPS chapter should build upon the existing VEA and make it part of the overall architecture of any future comprehensive Free Trade Agreement. In particular it should take into account the experienced gained thus far, maintaining those elements of the VEA that have worked well and improving on those that have done less well.

Other existing forms of cooperation like the EU-US technical working groups on animal and plant health, or existing ad-hoc cooperation for example in multilateral fora or standard setting bodies, should be examined and updated in the same way, to reflect the overall experience gained to date.

Overall, the new SPS chapter should in particular seek to:

1. minimise the negative effects of SPS measures on trade through close regulatory, confidence building and technical cooperation,

2. respect legitimate objectives to safeguard human, animal and plant health measures applicable to trade in order to prevent and eliminate unnecessary barriers,

3. improve transparency by bringing certainty and consistency to the adoption and application of SPS measures.

To this end existing sanitary and phytosanitary measures should be revisited in a collaborative manner and with the aim to remove unnecessary barriers

Special focus should also be given to trade facilitation measures where a number of areas can be potentially benefit (e.g. approval and/or authorisation procedures where the administrative burden, redundancies, etc could be reduced).

In summary, the SPS component of the overall agreement should seek to achieve full transparency as regards sanitary and phytosanitary measures applicable to trade,

establish provisions for the recognition of equivalence, implement a 'pre-listing' approach for establishments, prevent implementation of pre-clearance, provide for the recognition of disease-free and pest-free health status for the Parties and recognise the principle of regionalisation for both animal diseases and plant pests.

In order to achieve these objectives, the EU proposes, *inter alia*, to cover the following elements:

- Scope and definition: the future chapter should apply to all SPS measures that directly or indirectly affect trade. It should complement and build upon the WTO SPS Agreement. To this end, the rights and obligations under the WTO SPS Agreement should be re-affirmed. The definitions established in the WTO SPS Agreements and by relevant international standard setting bodies should be used.

- Competent authorities: The chapter should be legally binding for both Parties and applicable to the Parties' territories at all administrative levels in order to ensure its maximum efficiency and effectiveness. It is paramount in this regard, that the Parties recognise each other as single entities for SPS purposes.

- Reducing administrative burdens, excessive bureaucracy or adherence to needless rules and formalities and replacing them by transparent, slim and predictable processes in order to allow real trade in due time: It is, in particular, essential to include predictability and transparency into the approval and/or authorisation procedures applicable to imported products, including risk assessments, timelines and technical consultations where necessary.

- Privileged Relationship - It should provide for the elements to set up a privileged relationship between the Parties, including e.g. a pragmatic and open approach for a more efficient recognition of equivalence. Consultations along the adoption of SPS measures or the import authorization process together with an early warning of upcoming legislative changes would also allow convergence among the two systems.

- Trade facilitation provisions: an ambitious set of trade facilitation measures should include, among other things, a clear and streamlined procedure for the listing of establishments based on an audit approach, whose frequency is risk- and performance-based. There should also be a procedure for the determination of equivalence. The EU is keen to discuss provisions on equivalence (comparability) assessments for systems or a certain category of goods, or alternative specific measures.

- Trade conditions: SPS related import requirements and certification conditions for all commodities should be available upfront, grounded in scientific evidence or the relevant international standards and apply to the entire territory of the exporting Party. Among other issues, it is paramount to set up a clear procedure which will include timelines for the recognition of animal health status, pest status and regional conditions, in line with international standards. Provisions on safeguard measures or emergency measures should ensure that trade is not unnecessarily or unjustifiably restricted. Pragmatic and open procedures should be established to recognise alternative measures.

- Fees and Charges: Among the trade facilitations measures, reciprocal treatment as regards fees and charges imposed for the procedures on imported products is of key importance. Both Parties commit to bear their own costs related to imports from the other Party namely with regard to the procedures of registration, approval authorisation, inspections or audits.

- Transparency and information exchange on key areas such on the verifications/audit activities, non-conformities at the border inspections post, new scientific developments, early consultation procedure of upcoming legislative changes and changes on the import conditions, etc.

- Enforcement: The establishment of a Committee with sufficient tools to monitor and ensure the implementation of the chapter.

- Cooperation: The SPS chapter should also include provisions to develop the cooperation on animal welfare aspects and to facilitate the exchange of information, expertise and experiences in this field. Cooperation in other areas of common interest, including in the WTO SPS Committee and in relevant international standards setting bodies should be also explored.

A possible skeleton of the Agreement related to the SPS+ issues should at least address the following points

The part of the agreement:

1. Objective;
2. Competent Authorities
3. EU and US as single entities for SPS purposes
4. Reaffirmation of multilateral obligations
5. Scope
6. Definitions
7. Trade facilitation
8. Animal Health
9. Plant health
10. Animal welfare
11. Equivalence
12. Verification (audit)

13. Export certification

14. Import checks/fees

15. Transparency/Information exchange

16. Notification/Consultation

17. Safeguard and emergency measures

18. Collaboration in international fora (multilateral and bilateral)

Transatlantic Trade and Investment Partnership
Without prejudice, 20 June 2013

EU INITIAL POSITION PAPER ON TRADE AND SUSTAINABLE DEVELOPMENT

I. Introduction

1. Sustainable development is an overarching policy objective of the international community. It stands for meeting the needs of present generations without jeopardising the needs of future generations. It offers a model of progress that reconciles immediate and longer-term needs. Social development, economic growth and environmental protection are inter-related and mutually reinforcing components of sustainable development. Sustainable development aims at bringing about economic prosperity through and with a high level of environmental protection and social equity and cohesion.

2. The EU is committed to furthering these objectives, both by an active engagement with its partners in the international arena and through the design, adoption, and implementation of its internal policies. The Treaty of Lisbon, establishing the core EU rules, enshrines sustainable development as a fundamental principle of the EU action, both domestically and in its relations with the wider world – be it political partnerships, trade relations, international cooperation, or external representation. Sustainable development therefore informs and guides the EU policy-making process and is high on the agenda of the EU institutions and key constituencies, including the European Parliament.

3. As part of this overall framework, maximising the important contribution that trade can make to sustainable development is a key objective that the EU consistently pursues both multilaterally and in all its bilateral and regional trade negotiations. In this context, the launch of the Transatlantic Trade and Investment Partnership (TTIP) negotiations presents opportunities and challenges in respect of sustainable development

4. The EU sets out on the path towards the TTIP with the US in the firm belief that our aspirations and objectives are based on a common overarching objective of sustainable development. Notably, the EU believes that, by building on the EU and the US commitment to high levels of protection for the environment and workers, including in their trade agreements, as also reflected in the HLWG's report, the TTIP negotiations will pave the way for a comprehensive and ambitious approach to trade and sustainable development issues – thereby responding to expectations on a true "21st century deal" in this area.

5. In addition to the recognition of sustainable development as a principle that should underlie the TTIP in all areas, we envisage an integrated chapter specifically devoted to aspects of sustainable development of importance in a trade context - more specifically, on labour and environmental, including climate change aspects, as well as their inter-linkages.

II. Trade and Sustainable Development (TSD) Chapter

6. The EU has developed a consistent practice of including chapters on Trade and Sustainable Development in its FTAs, aiming at ensuring that increased trade is mutually supporting environmental protection and social development, and does not comes at the expense of the environment or of labour rights. Building on this experience, the EU would consider the following areas as building blocks for the TTIP negotiations.

a. Internationally agreed sustainable development objectives and commitments

7. The EU believes that the TTIP should reflect the Parties' commitments regarding a set of internationally agreed principles and rules, as a basic framework underlying our economic and trade relations. In the labour domain, the starting point for discussions should be the Parties' existing commitments in relevant areas, including the ILO 1998 Declaration on Fundamental Rights and Principles at Work, as well as its follow-up, and the 2008 ILO Declaration on Social Justice for a Fair Globalization, which applies to all ILO members. In respect of environmental issues, the starting point should be the recognition of the importance of global environmental governance to tackle environmental challenges of common concern, whereby Multilateral Environmental Agreements (MEAs) are of critical importance to deliver global benefits.

8. On that basis, the TTIP negotiations should reflect the Parties' commitments in the labour area with respect to ILO principles and rules. In this regard, the EU considers that ILO core labour standards, enshrined in the core ILO Conventions and internationally recognised as the fundamental labour rights, are an essential element to be integrated in the context of a trade agreement, and could be further complemented by other ILO standards/conventions of interest, as well as by a resolve to promote the ILO Decent Work agenda. A similar approach should be followed regarding adherence to core MEAs and other environment-related bodies as internationally recognised instruments to deal with global and transboundary environmental challenges, including the fight against climate change. Due to their subject matter and cross linkages with trade aspects the EU considers the following MEAs to be of particular importance in trade negotiations: the Convention on International Trade in Endangered Species of Wild Fauna and Flora and its amendments, the Montreal Protocol on Substances that Deplete the Ozone Layer, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, the Convention on Biological Diversity and its Protocols, the United Nations Framework Convention on Climate Change, the Stockholm Convention on Persistent Organic Pollutants, and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

9. Our common commitment to the effective domestic implementation of these labour and environmental standards and agreements should also be an important element to emphasise.

b. Levels of labour and environmental protection

10. The integration of environmental and labour considerations in the TTIP is without prejudice to each Party's right to regulate in order to reflect its own sustainable development priorities. This means recognising in the TSD chapter each Party's right to define and regulate its own domestic levels of environmental and labour protection at the level deemed necessary, consistently with internationally agreed standards and agreements, as well as to modify its relevant laws and policies accordingly, while pursuing high levels of protection.

11. Furthermore, the overarching aim of the TSD chapter should be to ensure that trade and economic activity can expand without undermining the pursuit of social, and environmental policies. On the other hand, domestic labour and environmental standards should not be used as a form of disguised protectionism, nor lowered as a means of competing for trade or investment. Accordingly, the TSD chapter should expressly reflect the fact that the respective domestic authorities will not fail to enforce, and will not relax, domestic labour or environmental domestic laws as an encouragement of trade and investment.

c. Trade and investment as a means to support and pursue sustainable development objectives

12. In order to promote a greater contribution of trade and investment to sustainable development, it is important to discuss initiatives in areas of specific relevance. In this regard, the TSD chapter should promote, for instance:

- trade and investment in environmental goods and services and climate-friendly products and technologies. Moreover, further reflection could also be undertaken on other related trade actions which could be pursued under other chapters of the TTIP (e.g. frontloading liberalisation of such products, addressing NTBs in the renewable energy sector, consider environmental services);
- the use of sustainability assurance schemes, i.e. voluntary tools on environmental sustainability or fair and ethical trade initiatives;
- corporate social responsibility practices, further supporting relevant principles endorsed by both the EU and the US (e.g. international guidelines, bilateral joint statement of shared principles for international investment within the framework of the Transatlantic Economic Council).

13. Similarly, the TSD chapter should emphasize the Parties' commitment towards the conservation and sustainable management of biodiversity and ecosystems, the sustainable use and management of natural resources, and the role that trade could play in this regard. These considerations would apply to areas such as forests, fisheries, wildlife, and biological resources. The promotion of trade in legally obtained and sustainable products should thus be a key area to be covered, against the background of internationally recognised instruments, as well as the common determination of the EU and the US to address in their FTAs issues related to trade in such resources obtained or produced illegally.

d. Good administrative practices

i) Scientific information

14. The TSD chapter should recognise the importance of taking into account international guidelines and principles on the use of scientific and technical information as well as on risk management, when preparing and implementing measures aimed at protecting the environment or labour conditions which may have an impact on trade and investment.

ii) Transparency

15. Transparency is of particular relevance in the context of trade and sustainable development, in order to ensure that stakeholders, particularly non-state actors, can be informed about, and provide views and inputs on, the development, introduction, and application of measures related to labour or the environment. This also applies to measures concerning the implementation of the TSD chapter. Therefore, the TSD chapter should foresee appropriate channels for engaging with the public.

iii) Review and assessment

16. Appropriate recognition should also be given to the fact that, once the TTIP is in force, it will be important for the Parties to have an active policy of review and assessment of the effects of the agreement on sustainable development objectives.

e. Working together

17. The TTIP could also establish priority areas for share of information, dialogue, and joint initiatives on the trade-related aspects of sustainable development, such as:

    - Cooperation in international fora responsible for social or environmental aspects of trade, including in particular the WTO, ILO, MEAs and UNEP;

- Strategies and policies to promote trade contribution to green economy, including eco-innovation;

- Trade-related aspects of the ILO Decent Work agenda and, in particular, on the impact and inter-linkages of trade and full and productive employment, labour market adjustment, core labour standards, labour statistics, human resources development and lifelong learning, social protection floors and social inclusion, social dialogue and gender equality;

- Trade impacts of labour or environmental protection and, *vice versa*, the impacts of trade on labour or environmental protection;

- Trade-related aspects of natural resources and the protection and use of biological diversity, including ecosystems and their services, such as measures to enhance trade in legal and sustainable timber, fish, or wildlife products as well as other issues related to biodiversity and ecosystems;

- Trade-related aspects of the climate change strategy, including consideration of how trade liberalisation or trade-related regulatory cooperation can contribute to achieving climate change objectives and more generally to ensure increased production of renewable energy, implemented in a sustainable manner and increased energy efficiency.

f. Implementation, monitoring, and enforcement

18. In order to ensure an appropriate implementation of the TSD chapter, in the EU's view it is crucial to incorporate a strong monitoring and follow-up mechanism. The EU is convinced that an effective mechanism should be based on transparency, regular dialogue, and close cooperation between the Parties, and provide for effective channel of communications and means for reaching mutually agreed positions on any matter related to the TSD Chapter.

19. In this context, the EU sees an essential role for civil society, both domestically and on a bilateral basis, in ensuring that sustainable development considerations are brought to the attention of the Parties to the TTIP, as well as in providing advice and follow-up on the implementation of the TSD chapter and related matters.

20. Finally, it is important to ensure that there are channels for the Parties to deal effectively with disagreements on any matters which might arise under the TSD chapter, such as government consultations and independent and impartial third-party assessments to facilitate the search for and implementation of solutions.

Without prejudice, 20 June 2013

Initial position paper

Technical Barriers to Trade

1. Introduction

The final report of the HLWG refers to five basic components of TTIP provisions on regulatory issues, as follows: cross-cutting disciplines on regulatory coherence and transparency; provisions concerning technical barriers to trade (TBT) and sanitary and phytosanitary measures (SPS); provisions aimed at promoting (greater) regulatory compatibility in individual sectors; and a framework providing an institutional basis for future cooperation.

With respect to the horizontal TBT Chapter, the HLWG specifically recommends the following:

"An ambitious "TBT-plus" chapter, building on horizontal disciplines in the WTO Agreement on Technical Barriers to Trade (TBT), including establishing an ongoing mechanism for improved dialogue and cooperation for addressing bilateral TBT issues. The objectives of the chapter would be to yield greater openness, transparency, and convergence in regulatory approaches and requirements and related standards development processes, as well as, inter alia, to reduce redundant and burdensome testing and certification requirements, promote confidence in our respective conformity assessment bodies, and enhance cooperation on conformity assessment and standardization issues globally."

This draft presents some elements that could be contained in the horizontal TBT Chapter of the future TTIP.

In particular, this paper addresses general issues concerning technical regulations, standardization, conformity assessment and transparency. It is limited to aspects covered by the WTO TBT Agreement. It therefore does not cover issues related to services, public procurement, and aspects covered by the WTO SPS Agreement.

As indicated above, it is envisaged that separate provisions will be made for specific product sectors. Many technical sectors have regulatory peculiarities arising either from their nature, or for historical reasons, and where such peculiarities exist, or where the economic importance of a sector is such as to justify it, specific measures will be considered in a separate sectoral annex, limited to that set of products. It is the purpose of this discussion to address the general case, i.e., where sectoral measures are not, or not yet, envisaged for the TTIP as a whole, or where sectoral measures are intended to complement measures of general application.

2. Principles

The EU considers that transparency and predictability of the regulatory and standard-setting process is key to trade and growth in general. It has therefore been a strong advocate, both in the SPS and TBT Committees, for improving regulatory and standardization practices of WTO Members, in particular through the application of principles of transparency and good

regulatory practice at all stages of the regulatory and standard-setting process as well as convergence to international standards.

The EU views for the TBT component of the TTIP are based on a number of guiding principles.

First, as far as possible, measures should *aim at removal of unnecessary barriers to trade* arising from differences in the content and application of technical regulations, standards and conformity assessment procedures.

Second, although compatibility is important, it must be recognised that the systems of the two regions are different, both to meet the specific needs of their economies and for historical reasons, and *it is not possible for one side to impose its system on the other*; *nor can either side be expected to treat its partner more favourably than its own side*.

Third, while the need for a high level of protection remains, measures should aim for *methods* of regulation, standardisation andconformity assessment that are *not more trade-restrictive than necessary* to achieve the relevant public interest objective, while taking into account the need to give preference to internationally harmonized methods.

Fourth, closer co-operation between the EU and the US *should not result in new hindrances to their trade with the rest of the world*.

Finally, it should be recognised that there are existing voluntary instruments of transatlantic co-operation in or related to TBT matters, arising from earlier sectoral or general trans-Atlantic initiatives, *and that the results of such initiatives should not be compromised* in any new Agreement.

3. Understanding the functioning of the EU and US internal markets – Improving framework conditions for market access

As a scene-setter, it is proposed to gain a better understanding of the principles governing inter-State commerce in the US and free movement of products in the EU internal market, i.e. the conditions under which products lawfully placed on the market of any US State or EU Member State can benefit from free circulation within the respective internal markets.

A shared objective should be to look into ways to improve framework conditions for market access on both sides (for the benefit of products and suppliers of both Parties), regardless of the actual level of compatibility of the substantive regulatory requirements and standards.

This involves consideration of basic issues concerning the functioning of the EU and US internal markets and pertaining, *inter alia*, to:

(i) the overall predictability and transparency of the EU and US regulatory systems and whether the rulebook is easily accessible and understandable, having regard in particular to the needs of Small and Medium-Sized Enterprises (SMEs);

(ii) scope of sub-regional (in the EU) and sub-federal (in the US) TBT-related measures, and their relevance in connection with market access requirements;

(iii) available mechanisms in either system to prevent the erection of / eliminate barriers to trade as a result of sub-regional (EU) or sub-federal measures (US);

Any agreement must take account of any divergences with regard to the above aspects, with the aim of maintaining an overall balance of commitments in the TBT area. From an EU perspective, it would be important for such an overall balance that the commitments to be agreed in the TTIP apply also to both the sub-regional (in the EU) and the sub-federal level of regulation (in the US).

4. Transparency

The WTO Agreement on Technical Barriers to Trade (TBT) already provides for a system of notifications of new draft technical regulations and conformity assessment procedures, and the EU and the US both participate actively in this. The EU and US sides have in the past been working on a draft understanding aimed at improving transparency in the TBT (and SPS) notification procedures. The parties could not agree on a common approach as their notification practices differ significantly.

Although it is not proposed to duplicate notifications already made in the context of the WTO, there is an interest in providing for improved transparency through a dialogue of regulators with regard to notification of draft legislation and replies to written comments received from the other party. In this context, notification of all draft technical regulations and conformity assessment procedures (including proposed new legislation), regardless of the initiator of the proposal in compliance with Articles 2.9 and 5.6 of the TBT Agreement, as well as the possibility to receive feedback and discuss the written comments made to the notifying party in compliance with Articles 2.9.4 and 5.6.4 of the TBT Agreement shall be ensured. Of particular importance will be the possibility to receive written replies to comments and the ability of regulators to communicate with each other during the comments procedures.

The possibility to provide for an advanced information exchange between regulators, before the TBT notifications are carried out, may also be examined in this chapter or the context of cross-cutting disciplines. The Agreement might make it possible to identify sectors that would be of interest for such an exchange to take place at a preliminary stage.

5. Technical regulations

Divergent technical regulations act as barriers to transatlantic trade. Clearly, there is a gain from removing unnecessary duplicative compliance costs in the

transatlantic market. There is also a potential gain to be had through measures such as improvements in information transfer and regulatory co-operation, and where possible through measures towards convergence – or at least, compatibility - of the parties' regulations themselves. This Section outlines some mechanisms and tools that could contribute to achieving this goal

5.1 Harmonisation or acceptance of technical regulations

Addressing potential differences at the source is more effective than removing barriers that have found their way into our respective regulatory systems. Where neither side has regulations in place, the making of common – or at any rate coherent – technical regulations may be considered by the Parties. Wherever appropriate, consistent with Article 2.8 of the TBT Agreement, consideration should be given to basing such common / coherent regulations on product requirements in terms of performance rather than detailed design prescriptions. The EU's positive experience of the "New Approach" as a method of regulating based on setting "essential requirements" for health and safety without prescribing specific technical solutions, which themselves are laid down in supporting voluntary standards, shows that this is, for large industrial product sectors, a very efficient, flexible and innovation-friendly regulatory technique.

Wherever possible, global harmonization of technical requirements should be pursued in the framework of international agreements / organisations in which both the EU and the US participate. This would then allow both sides to recognise each other's technical regulations as equivalent, as was done for instance with the 2004 Mutual Recognition Agreement on marine safety equipment, where equivalence rests on the parties' legislations being aligned with certain International Maritime Organisation Conventions).

Another practical example is the area of electric vehicles (EVs) where EU and US collaborate closely in UNECE on global technical regulations (GTRs) relating to safety and environmental aspects. Such an approach is perhaps difficult to achieve in the general case; but there may be sectors – particularly related to the regulation of innovative technologies, or where international regulatory activity exists or is planned – where it might be found profitable. Provision for such a process might be included.

5.2 The reference to standards in technical regulation

Standards are often referenced in legislation, as a means of determining compliance with technical regulations. Such standards ought in principle to be left voluntary, in order to allow sufficient flexibility for industry to choose the technical solution that best fits its needs, thus also stimulating innovation. In general, consistent with Article 2.8 of the TBT Agreement, which favours the use of performance-based technical requirements, mandatory legislation should neither copy nor reference standards (thereby making them mandatory themselves); ideally, mandatory legislation should only set general requirements (e.g. health, safety, and the protection of the environment) and then leave flexibility to the market as to how compliance should be assured.

5.3 Sub-regional and sub-federal technical legislation

Both the EU and the US have decentralised structures in which the States or Member States have some freedom to regulate.

As regards placing of products on the market, the EU is a single entity: on the one hand, compliance with harmonised technical requirements at EU level gives full access the whole EU market while, on the other hand, for those products / risks where national requirements apply in the absence of EU legislation, effective circulation throughout the EU is ensured by the application of the principle of mutual recognition of national requirements derived from the case-law of the European Court of Justice interpreting the EU Treaty provisions on free movement of goods. Strict procedures safeguarding the rights of economic operators apply when EU Member States intend to restrict the free movement of products. In addition, Member States are not permitted to erect new national barriers to trade and a specific notification procedure for draft national technical regulations has been in place for almost 30 years, effectively preventing new intra-EU obstacles to trade as a result of national regulations.

It is understood that the scope of the federal US Government is analogously limited, insofar as some States are permitted to make autonomous technical regulations for application on their own territory. Several submissions received in response to the various public consultations on the TTIP report on EU exporters' difficulties with accessing and understanding the rules they have to comply with to gain access to the US market, in particular where multiple layers of regulation (federal/ state / municipality) coexist.

As stated under Section 3 above, while taking into account any divergences with regard to the above aspects, the EU considers that the aim of maintaining an overall balance of commitments in the TBT area can only be achieved if both the sub-regional (in the EU) and the sub-federal (in the US) regulations are covered.

5.4 The TBT Agreement

All of what is proposed here is considered to be consistent with, and supplementary to, the WTO TBT Agreement, to which both EU and US are signatories. Consideration should be given to incorporating the TBT Agreement into this agreement, in order to make its terms part of the agreement, and to allow disputes arising out of its terms to be dealt with bilaterally.

6. Standardisation

6.1 The EU and US approaches to standard setting and international standards

The convergence of standards and technical regulations on the basis of the use of international standards is one of the most significant tools to facilitate trade. This is acknowledged by the WTO, which puts significant emphasis on international standards (e.g. in the TBT or SPS Agreements). The EU is therefore a major supporter of the international standard-setting system. Agreeing on common standards at international level is the best way to avoid costs related to differences in product development and proliferation of different (often conflicting) technical requirements.

Although in some areas (such as electronics), the use of international standards is widespread in both Parties, there are a number of sectors where differences resulting from their different standard setting practices may create unnecessary barriers to trade. Efforts to reconcile these diverging views and systems have been high on the bilateral agenda for years. Further consideration should be given to improving links between the systems, while allowing each to maintain its distinctive character. This may offer an opportunity for progress in specific areas such as innovative products and technologies (e.g. electric vehicles, IT, green chemistry, bio-based products, cloud computing).

6.2 Implementing the "bridge-building" document

In a joint document adopted in November 2011, entitled “Building bridges between the US and EU standards systems”, the EU and the US agreed on specific actions to improve each side’s processes for the use of voluntary standards in regulation. Mechanisms should be created to promote cooperation and coherence in this area, in view of minimizing unnecessary regulatory divergences and better aligning the respective regulatory approaches.

The EU side has given a political commitment that in its standardisation requests to the three European Standardisation Organisations (ESOs) (European Committee for Standardization - CEN, European Committee for Electrotechnical Standardization - CENELEC and European Telecommunications Standards Institute - ETSI) the European Commission will instruct them to consider, as a basis for EU regional standards, "consensus standards developed through an open and transparent process and that are in use in the global marketplace".

The US side has given a political commitment to instruct federal agencies to consider international standards when developing regulatory measures, consistent with law and policy.

Furthermore, both sides gave a political commitment to encourage the ESOs and the American National Standardisation Institute (ANSI) to strengthen transparency and facilitate comments by stakeholders on draft standards.

6.3 Improving cooperation on common standards to further the development of international standards

Improved cooperation between US and EU standardisation bodies should be sought, including the development of joint programmes of work, and the use – or potential use – of the resulting common standards in connection with legislation. The results of bilateral cooperation should be also used to further global harmonization through the development of international standards.

There may be areas in which the development of common or technically equivalent standards could be considered. A mechanism by which the EU and

US standards systems could – by common agreement – work on common standards, for transposition in both economies, might be developed (maybe in the form of a common web-based standardisation platform).

Clearly the preference would be for such common standards to be developed by international standardisation organisations and such a bilateral approach could not apply in the general case, but the possibility should be considered in some areas of mutual interest. At any rate, exchange of technical information between expert committees in the development of standards, while leaving the possibility for each side to provide standards to the market later on, should be considered and encouraged.

6.4 Co-operation in international standards bodies

The Parties are both members of several international standardisation organisations, and as developed economies, share an interest in the development of coherent and advanced standards that are acceptable world-wide to their trade partners. Consideration could be given to systematic co-operation in the context of such bodies, possibly with exchange of technical data, common actions within such bodies, and commitment to transposing the results.

6.5 Specific technical areas

The above is intended to address the general case. There are a number of distinct technical areas in which the Parties already co-operate more closely, such as in motor vehicles, pharmaceuticals and medical devices. The Agreement should encourage the development of similar sectoral mechanisms, and be flexible enough to take into account the specific nature of the products, and the existing and planned standardizing and regulatory structures.

7. Conformity assessment

7.1 Similarities and divergences in the systems of the Parties

Although the desired level of consumer and other users' protection might be considered broadly similar in the parties, regulators on either side of the Atlantic have developed different approaches to the conformity assessment of specific products and risks. For example, the US requires third party testing or

certification for a number of products for which the EU requires only a suppliers' declaration of conformity (SDoC), e.g., safety of electrical products, and machinery. In other sectors, different conformity assessment requirements apply owing to the differences in the classification of the product; for example, in the EU there is a specific regulation for cosmetic products, while the US either does not specifically regulate them or classifies them as Over the Counter Drugs (OTCs), which sometimes implies a stricter regulatory regime.

While differences of this kind should of necessity be respected, some attempts to reduce the obstacles to trade arising from such differences between the respective systems should be considered.

7.2 The level of conformity assessment applied to products

The EU largely does not require mandatory third party certification for many products considered of low risk, and instead relies on more trade-facilitative solutions, such as manufacturers' self-declaration of conformity, with a freedom to perform any necessary testing in a laboratory of the manufacturer's choice.

Deeply rooted regulatory traditions may be difficult to change. While we should not abandon hopes to achieve greater compatibility of our conformity assessment regimes in those areas over time, we should pragmatically acknowledge that prospects for substantial convergence will generally be less promising than in new areas linked to innovative technologies or emerging risks.

However, as both the US and EU regularly re-evaluate the regulations applicable to different industrial sectors over time, some re-evaluation might be possible on a common basis when it is prompted by the same reasons (such as significant but similar market changes in both the EU and the US, changes in technology or supply chain management, or major safety issues such as the parallel substantial revision of both EU and US toy safety legislation triggered by similar concerns regarding gaps in legislation and supply chain control). These opportunities should not be missed to explore potential convergence not only as regards the technical product requirements but also in the level of certification required. Where there is demand in the market for such regulatory revision, it might be made a priority.

A future commitment might be explored by which regulators on both sides, when introducing new rules, agree in principle (as set out in the TBT agreement) to apply common criteria with a view to identifying the least trade restrictive means of conformity assessment, commensurate with the relevant risks..

In areas where registration / authorisation procedures and similar requirements apply in both Parties, approaches could be devised to make such procedures as compatible as possible and identify opportunities for administrative simplification that would alleviate burdens for manufacturers and facilitate their business under both systems.

7.3 Mutual recognition of conformity assessment

In situations where there is a valid case for mutual recognition (e.g., where the Parties both require third party conformity assessment), experience has shown that the application of mutual recognition is much more successful when based on similar requirements, usually based themselves on an international standard and/or an international agreement / scheme; furthermore, it is preferable from a trade-facilitation perspective if the agreement / scheme is not closed or applied bilaterally only, but open to several partners who apply the international standard and wish to be part of the agreement / scheme (e.g. the UN 1958 Agreement on harmonization of technical requirements for motor vehicles, the OECD Mutual Acceptance of Data system for chemicals, the IECEE CB scheme for electronics, etc.).

Usually, the concept of 'mutual recognition' is applicable to conformity assessment procedures (e.g. testing, certification). Mutual recognition of conformity assessment, in the absence of convergence of the substantive requirements underlying conformity assessment (i.e. similar technical requirements or standards) delivers limited market access benefits – such agreements are cumbersome and onerous to apply, and do not offer any incentive for the partners in question to bring their systems closer together. Furthermore, in cases where there may be differences between the level of development or regulatory rigour of the partners, there is also a basic issue of confidence in each other, undermining the commitment to mutual recognition.

The 1998 Mutual Recognition Agreement has been successful only in two areas: telecommunications, and electromagnetic compatibility (though in the

latter the EU no longer applies third party certification). It is therefore not proposed to consider extending the 1998 MRA in its present form to new areas. In the other areas that it nominally covers as well in any additional specific, mutually agreed sectors, other approaches to facilitate conformity assessment may be considered at a sectoral level.

7.4 Accreditation

Both the EU and the US rely to some extent on accreditation as a means of determining the competence of conformity assessment bodies, though their systems are different. Arrangements for mutual recognition between accreditation bodies exist through organisations such as the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF); there may be some merit in encouraging greater use of these agreements to facilitate the mutual recognition of accreditation certificates.

7.5 Marking and labelling

Marking and labelling are mentioned briefly in the TBT Agreement, but it is suggested hat some disciplines be added for trade between the Parties, so that compulsory marking requirements are limited as far as possible to what is essential and the least trade restrictive. This may include origin marking where obligatory requirements are made for such marking, in which case it would be appropriate to enable EU manufacturers to mark their products as originating in the EU. Furthermore, consideration should be given to measures to inhibit the use of markings that may mislead consumers.

8. Irritants

A mechanism to cover trade irritants arising from the application of technical regulations, standards and conformity assessment procedures should be included as part of a common system under the Agreement as a whole.

9. *Sectoral measures*

As indicated above, this outline is intended to cover only the general case. A number of sector specific initiatives are already in place, with the participation both of the EU and the US. These should not be affected, nor – as indicated above - should any new sectoral initiatives for enhanced co-operation be inhibited.

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Initial position paper

Limited

TTIP – Rules Group Without prejudice, 19 June 2013

Anti-Trust & Mergers, Government Influence and Subsidies

I. Anti-trust & mergers

Objectives

The report of the EU-US High Level Working Group on Jobs & Growth concludes that a "comprehensive and ambitious agreement that addresses a broad range of bilateral trade and investment policies, including regulatory issues" could generate substantial economic benefits on both sides of the Atlantic.

Trade liberalisation has led to the globalisation of the markets. In some instances, however, traditional tariff barriers have been replaced by behind-the-border barriers such as anti-competitive practices by private and public enterprises. Such practices may have serious adverse impacts on international trade and can often be addressed in an effective manner through a proactive enforcement of competition laws.

The EU considers competition policy an essential element to ensure well-functioning markets, both domestically and abroad, and an important part of its trade relations. Although the EU and US competition systems have developed at different times and under different conditions, both partners share a belief in the need for impartial and proactive competition enforcement, subject to the rule of law and the control of the courts. The shared objective of promoting open, fair and competitive international markets have allowed effective cooperation in practice, bilaterally and in the framework of multilateral forums such as the International Competition Network (ICN) and the OECD Competition Committee (OECD CC). The relationship between the EU and the US in competition matters is the bedrock on which global competition enforcement is based.

The TTIP therefore provides the parties with a unique opportunity to jointly articulate the shared values and affirm the existing practices and procedures which they adhere to. Both the EU and the US have consistently sought to include ambitious competition related provisions in their respective bilateral negotiations with other important trading partners. Drawing from the two partners' special relationship in the field of competition enforcement, the TTIP's competition provisions would set a benchmark and send a strong message to trading partners around the world for future negotiations.

Proposed content

In light of the global context and the objectives set out above, the TTIP should include provisions with anti-trust & merger disciplines. These provisions should reflect the shared global interests and concerns and thereby constitute a platform for further development of competition disciplines and cooperation of interest also for other economies and markets. In this context, the EU and the US may wish to address anti-competitive behaviour that should be disciplined, the legislative and institutional framework for the enforcement of these disciplines that contain provisions on cooperation and exchange of information. The TTIP could also address rules and principles aiming at ensuring competitive neutrality by envisaging enforcement of competition laws on all enterprises. More specifically, the provisions on antitrust and mergers could address the following issues:

- Recognition of the benefits of free and undistorted competition in the trade and investment relations;
- Consideration of best practices and of the possibility to consolidate some of them;
- A commitment to maintain an active enforcement of antitrust and merger laws, with a generally worded description of the types of anti-competitive behaviour it should cover;
- A commitment to ensure that competition policy is implemented in a transparent and non-discriminatory manner, in the respect of the principle of procedural fairness, irrespective of the ownership status or nationality of the companies concerned;
- Provisions regarding the application of antitrust and merger rules to state owned enterprises (SOEs) and enterprises granted special or exclusive rights or privileges (SERs), save for narrowly defined legitimate exceptions (e.g. "Services of General Economic Interest" in the EU);
- Moreover, to address specifically the bilateral cooperation aspects between the EU and the US, the TTIP could include provisions on cooperation between the competition agencies of the parties, reflecting and building on the current practice under the existing EU-US cooperation agreements. In addition, it could be explored whether the parties could address the possibility for a further deepening of the cooperation arrangements in case related work in the future, such as creating a framework allowing for the exchange of confidential information in the absence of confidentiality waivers between competition authorities when they are investigating the same or related cases (while barring the use of this information for criminal sanctions). The TTIP could include a basis for developing such arrangements in a separate arrangement.

- A commitment to cooperate in multilateral forums with the aim of promoting convergence of antitrust and merger rules at a global level.
- Provisions on antitrust/mergers shall not be subject to the general dispute settlement mechanism of the agreement.

II. Government influence and subsidies

II.1. *State-owned enterprises (SOEs) and enterprises granted special or exclusive rights or privileges (SERs)*

Objectives

The EU is increasingly concerned about the discriminatory behaviour and the subsidization of state owned, controlled and influenced companies around the world. Overall, state presence in the global economy remains significant and has even increased in recent years. State involvement and influence can extend to all levels of government and to different sectors of the economy.

Various types of advantages and privileges that governments grant to companies can in some cases unjustifiably disadvantage EU and US companies. The EU and the US could therefore identify and discuss the concerns they have in this respect and identify issues that should be tackled in a global context.

The EU concerns regarding state ownership or influence extend to enterprises granted special and exclusive rights or privileges (SERs). State ownership, control and influence can take various forms, ranging from designating monopolies to SOEs but also include companies that have been granted special rights or privileges, regardless of ownership. The EU considers that it is important to cover those companies that can otherwise escape competitive pressures of the market as a result of government action, save for narrowly defined legitimate exceptions (e.g. "Services of General Economic Interest" in the EU).

The EU Treaties are neutral as to the ownership of companies and competitive neutrality between public and private actors is ensured in the EU legislation. Therefore, the EU is not against public ownership in itself, provided that publicly owned or controlled enterprises are not granted a competitive advantage in law or in fact. In certain circumstances, however, advantages that SOEs/SERs enjoy may hinder market access, distort market conditions and affect export competition. Governments may interfere with the competitive process by

inducing or ordering SOEs/SERs to engage in anti-competitive behaviour, by taking regulatory measures favouring these companies, or by granting subsidies (or measures which have similar effects) to them. The same could apply to some formally private sector companies.

SOEs/SERs may therefore enjoy privileges and immunities that are not available to their competitors, thereby giving them a competitive advantage over their rivals. In the absence of a framework to ensure that such instances occur only under strict conditions, such state intervention can distort the level playing field between SOEs/SERs and companies which do not benefit from the same privileges and immunities. This may even have negative effects on global markets. For these reasons, the EU considers that rules should be developed to ensure a level playing field between state-owned or influenced companies and their competitors at all levels of government.

The TTIP should therefore serve as a platform to address issues where government interference is distorting markets, both at home and in third countries at all levels of government. The objective of the EU is to create an ambitious and comprehensive global standard to discipline state involvement and influence in private and public enterprises, building and expanding on the existing WTO rules. This could pave the way for other bilateral agreements to follow a similar approach and eventually contribute to a future multilateral engagement.

Proposed content

The parties should jointly seek to identify the types of companies and behaviour that need to be addressed with a view to creating fair market conditions between private and public companies.

This could cover monopolies and state enterprises but also address enterprises granted special rights or privileges (SERs). Definitions should be sufficiently broad to catch all the relevant market players and to ensure that rules are comprehensive and not easily circumvented. In the case of state enterprises, the parties could consider a definition which rests both on ownership but, alternatively, also on effective control, aiming at capturing the possibility of the state to exercise decisive influence over the strategic decision making of the enterprise.

The distinction should effectively be made between those companies (public or private), which have been afforded a special or exclusive right or privilege, and those where the government has a controlling interest but which compete on the market. Provisions would cover all levels of government in order to catch the important SOEs/SERs that might exist at sub-central levels. Both existing and designated enterprises should be covered.

In view of the above, the following provisions on SOEs/SERs could be considered:

- Rules that address discriminatory practices of SOEs/SERs when selling and purchasing (while leaving government procurement issues to be addressed in the relevant chapter of the TTIP). SOEs/SERs which provide a distribution/transmission network to competitors should also follow these rules.

- An obligation for SOEs/SERs to act according to commercial considerations. However, enterprises would not necessarily need to meet the obligation to act according to commercial considerations when fulfilling the specific purpose (e.g. universal service obligation) for which they have been granted a special or exclusive right or privilege.

- A prohibition to cross-subsidise a non-monopolised market, similar to that contained in GATS Article VIII, should be considered also for goods.

- Transparency is the starting point for levelling the playing field between private and public enterprises. This calls for rules based on the relevant international best practices. These rules could aim at fostering transparency related to e.g. ownership and decision making structures, links with other companies, financial assistance received from the state, and regulatory advantages such as exemptions, immunities and non-conforming measures.

II.2 *Subsidies*

Subsidies may distort competition and may contribute to disruption in global markets and the terms of trade. Subsidization can artificially shift competitive advantage to the subsidizing countries. Subsidies to SOEs/SERs may further distort the level playing field between these enterprises and companies that do not benefit from such subsidies. The EU is concerned about the subsidization not only of SOEs/SERs but also of the private sector in some situations, e.g. by direct grants, below-market interest rates on loans or unlimited guarantees.

The WTO Agreement on Subsidies and Countervailing Measures (ASCM) disciplines the use of subsidies, and regulates the actions countries can take to counter the effects of subsidies. Also GATS stipulates that negotiations will be held with a view to developing necessary disciplines to avoid the trade-distortive effects of subsidies that may arise in certain circumstances and to address the appropriateness of countervailing procedures. It also requires members to exchange information concerning all subsidies related to trade in services that they provide to their domestic service suppliers.

Subsidy disciplines in a bilateral context are aimed at preventing trade distortions and nullification of the commitments negotiated in the agreement. The TTIP would provide an important opportunity to explore the shared concerns in this area, taking the already binding WTO disciplines, in particular those foreseen in the ASCM, as a starting point to improve the global approach.

Improved transparency and cooperation, in line with but not necessarily limited to the existing requirements of the WTO regarding subsidies, could be a first step. Such combined efforts could have a demonstration effect on other WTO members subject to the same WTO transparency requirements. The TTIP also provides an opportunity to develop consultation mechanisms related to subsidies affecting trade between the EU and the US.

In view of the fact that services form an important part of trade between the EU and the US, the parties could analyse the impact of related subsidies and consider if there could be a shared interest in addressing them. In general, disciplining the most important and distortive types of subsidies could contribute to meeting the objective of the TTIP to reach a more ambitious level of trade and economic integration between the EU and the US.

Proposed content

In the context of the TTIP, which aims at creating a more integrated EU-US market, the EU considers it appropriate to include provisions on subsidies, including subsidies to SOEs/SERs and financing to and from SOEs/SERs, and subsidies to services.

More specifically, the following provisions on subsidies could be considered:

- Mechanisms to provide improved transparency (subsidies to goods and services).
- Consultation mechanisms to allow for an exchange of information on subsidies to goods and services that may harm the other party's trade interests, with the view of finding a mutually acceptable solution.
- Addressing the most distortive forms of subsidies.

Without prejudice, 20 June 2013

TTIP: Cross-cutting disciplines and institutional provisions

INITIAL POSITION PAPER

I. Introduction

A. The five regulatory components of TTIP and purpose of this paper

The final report of the High Level Working Group on Jobs and Growth of 11 February 2013[1] refers to **five basic components of TTIP provisions on regulatory issues**: the SPS plus component would build upon the key principles of the WTO SPS Agreement, and provide for improved dialogue and cooperation on addressing bilateral SPS issues; the TBT plus component would build on provisions contained in the WTO TBT Agreement as regards technical regulations, conformity assessment and standards; sectoral annexes would contain commitments for specific goods and services sectors.

The other two components, which are the focus of this paper, consist in:

i. "Cross-cutting disciplines on regulatory coherence and transparency for the development and implementation of efficient, cost-effective, and more compatible regulations for goods and services, including early consultations on significant regulations, use of impact assessments, periodic review of existing regulatory measures, and application of good regulatory practices."

ii. "A framework for identifying opportunities for and guiding future regulatory cooperation, including provisions that provide an institutional basis for future progress."

This paper is meant to provide elements for a reflection on component i) which would be part of a horizontal chapter, as well as on component ii). In line with the usual practice for trade agreements, the main provisions pertaining to component ii), e. g the substantial tasks and competences of the regulatory cooperation body or committee, would be outlined in the horizontal chapter, while the procedural rules (e.g. how this body operates, and its composition, terms of reference, etc.) would be placed in the institutional chapter of TTIP (see further section II C point 4). Although the horizontal chapter would apply to all goods and services sectors, specific adaptations for certain sectors (e.g. financial services) could be envisaged.

[1] http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf

B. Rationale for an ambitious approach

Elimination, reduction and prevention of unnecessary regulatory barriers are expected to provide the biggest benefit of the TTIP[2]. But far beyond the positive effects on bilateral trade the TTIP offers a unique chance to give new momentum to the development and implementation of international regulations and standards (multilateral or otherwise plurilateral). This should reduce the risk of countries resorting to unilateral and purely national solutions, leading to regulatory segmentation that could have an adverse effect on international trade and investment. Joint EU and US leadership can contribute to such an objective.

New and innovative approaches will be needed in order to make progress in removing unnecessary regulatory complexity and reducing costs caused by unnecessary regulatory differences, while at the same time ensuring that public policy objectives are reached.

C. Scope of the horizontal chapter

The ultimate scope of the TTIP regulatory provisions – i.e. the precise definition of the regulations/regulators to which TTIP will apply - will need to be determined in the course of the negotiations in the light of the interests and priorities of both parties. In principle, the TTIP regulatory provisions would apply to regulation defined in a broad sense, i.e. covering all measures of general application, including both legislation and implementing acts, regardless of the level at which they are adopted and of the body which adopts them. A primary concern when defining the scope will be to secure a ***balance in the commitments made by both parties***.

Disciplines envisaged

The horizontal chapter would contain principles and procedures including on consultation, transparency, impact assessment and a framework for future cooperation. It would be a "gateway" for handling sectoral regulatory issues between the EU and the US but could in principle also be applied to tackle more cross-cutting issues, e.g. when non-sector specific regulation is found to have a significant impact on transatlantic trade and investment flows. Further commitments pertaining specifically to TBT, SPS or various product or services sectors (e.g. automotive, chemicals, pharmaceuticals, ICT, financial services etc.) would be included respectively in the TBT and SPS chapters and sectoral annexes/provisions. Disciplines envisaged should not duplicate any already existing procedures under the TBT and SPS Agreements.

[2] According to the study "Reducing Transatlantic Barriers to Trade and Investment" (http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf, Table 17), reduction of non-tariff measures under an ambitious scenario would provide for ***two thirds of the total GDP gains of TTIP*** (56 % coming from addressing NTBs in trade in goods and 10 % in trade in services).

Coverage of products/services

The rules and disciplines of the horizontal chapter would in principle apply to regulations and regulatory initiatives pertaining to areas covered by the TTIP and which concern product or service requirements. The objective should be to go beyond the regulations and aspects covered by the WTO TBT and SPS Agreements. The precise elements determining coverage will need to be discussed, but it is understood that there will be a criterion related to the significant impact of covered regulations on transatlantic trade and investment flows. To the extent necessary, some specific aspects may be addressed in other chapters (e.g. trade facilitation, competition).

II. Possible outline and structure of a horizontal chapter

A. Underlying principles

Certain basic principles underlying the regulatory provisions of TTIP need to be highlighted, including the following:

a) The ***importance of regulatory action to achieve public policy objectives***, including the protection of safety, public health, the environment, consumers and investors, at a level that each party considers appropriate. TTIP provisions should contribute to such protection through more effective and efficient regulation by the application of best regulatory practices and improved cooperation among EU and US regulators. Insofar as possible, priority should be given to approaches and solutions relying on international (multilateral or plurilateral) disciplines whose adoption and application by the EU and the US would encourage other countries to join in.

b) TTIP provisions shall ***not affect the ultimate sovereign right of either party to regulate*** in pursuit of its public policy objectives and shall not be used as a means of lowering the levels of protection provided by either party.

c) ***The tools used to achieve the regulatory objectives of TTIP will depend*** on the issues and the specificities of each sector. The general instruments available include consultations and impact assessment. Other instruments may be developed in the context of sector specific regulatory cooperation.

B. Overall objectives

The overall objective of the regulatory provisions of the TTIP will be to **eliminate, reduce or prevent unnecessary "behind the border" obstacles to trade and investment**. In general terms (although this may not be applicable in all cases), the ultimate goal would be a more integrated transatlantic market where goods produced and services originating in one party in accordance with its regulatory requirements could be marketed in the other without adaptations or requirements. Achieving this long-term goal will entail:

- **Promoting cooperation between regulators** from both sides at an early stage when

preparing regulatory initiatives, including regular dialogue and exchange of information and supporting analysis as appropriate.

- **Promoting the adoption of compatible regulations** through prior examination of the impact on international trade and investment flows of proposed regulations, and consideration of common/convergent or compatible regulatory approaches where appropriate and feasible.
- **Achieving increased compatibility/convergence in specific sectors, including through recognition of equivalence, mutual recognition or other means as appropriate.**
- **Affirming the particular importance and role of international disciplines** (regulations, standards, guidelines and recommendations) as a means to achieve increased compatibility/convergence of regulations.

C. Substantial elements

Cross-cutting regulatory disciplines would concentrate on three main areas: first, regulatory principles, best practices and transparency; second, assessment of the impact of draft regulations or regulatory initiatives on international trade and investment flows; and third, cooperation towards increased compatibility/convergence of regulations. Some institutional mechanisms will also be necessary to provide a framework for delivery of results and enable for necessary adjustments to ensure the effectiveness of the agreement in practice (see section II C point 4).

1. Regulatory principles, best practices and transparency

The TTIP could take as a starting point the 2011 Common Understanding on Regulatory Principles and Best Practices endorsed by the US government and the European Commission at the June 2011 meeting of the HLRCF[3]. The TTIP would incorporate the basic principles and main elements. The outcome should be a comparable level of transparency applicable on both sides along the process of regulation.

The main provisions would include:

- An effective bilateral cooperation/consultation mechanism. A commitment of both sides to keep each other informed in a timely manner on the main elements of any forthcoming regulatory initiatives covered by this chapter. This could be complemented with a strengthening of contacts, in any format, between both sides' regulators, so that each side can have a good understanding of the regulations or regulatory initiatives being considered or prepared by the other, in a way that they can share with the other side any relevant considerations (see next point). Note that early consultations may not be feasible where urgent problems of health protection arise or threaten to arise.

- An improved feedback mechanism:

    - Both parties should have the opportunity to provide comments before a

[3] http://trade.ec.europa.eu/doclib/cfm/doclib_section.cfm?order=abstract&sec=146&lev=2&sta=41&en=60&page=3

proposed regulation is adopted in accordance with the respective decision-making processes and should be given sufficient time for doing so. They should also receive explanations within a reasonable timeline as to how these comments have been taken into account.

- This should be done without duplicating the activities under the WTO TBT and SPS Agreements in a manner consistent with the parties' respective decision-making processes.
- For example, the TBT Agreement already introduces a system of notification of new draft technical regulations and conformity assessment procedures, in which the EU and the US actively participate. An improved bilateral mechanism for comments and replies in the context of the WTO TBT Agreement would provide for enhanced transparency and would allow for a dialogue between regulators with regard to the notified draft measure. Consistent with Article 2.9.4 and 5.6.4 of the TBT Agreement, this should enable both parties to provide feedback to each other, regardless of the initiator of the proposal. Of particular importance will be the possibility to receive replies to comments and to have a bilateral exchange on notified draft measures with the ability for regulators to communicate with each other during the comments procedures. As for the SPS Agreement, there is a mirroring notification system in place consistent with article 7 on Transparency and Annex B of the WTO SPS Agreement.

- Cooperation in collecting evidence and data. Regulatory compatibility and convergence of regulations could be enhanced through the collection and use by the parties, to the extent possible, of the same or similar data and of similar assumptions and methodology for analysing the data and determining the magnitude and causes of specific problems potentially warranting regulatory action. Such exchange would be of particular interest regarding best available techniques and could lead to convergence of requirements and provide inspiration to third countries.
- Exchange of data/information: Effective cooperation requires regulators to exchange information, which may be protected and subject to different and sometimes conflicting legal requirements. While multiple approaches will continue to exist in areas such as data protection and privacy, a process could be put in place to facilitate data exchange, without prejudice to any sector-specific provisions.

2. Assessment of the impact of draft regulations or regulatory initiatives on international trade and investment

Both the Commission and the US Administration have different systems in place to assess the impacts of regulations and regulatory initiatives. As part of the TTIP both sides should agree to strengthen the assessment of impacts of regulations and regulatory initiatives on international trade and investment flows on the basis of common or similar criteria and methods and by way of closer collaboration. In their assessment of options, regulators from each side would for example be invited to examine impacts on international trade and

investment flows, including on EU-US trade as well as on increased compatibility/convergence.

TTIP could also include provisions furthering transatlantic cooperation on ex-post analysis of existing regulations that come up for review with a view to examining whether there is scope for moving toward more compatibility and coherence including towards international standards/regulations and removing unnecessary regulatory complexity.

3. Regulatory cooperation towards increased compatibility/convergence in specific sectors

Preparatory work on sectors has started with strong support from stakeholders on both sides of the Atlantic. Many organisations contributed to the Joint EU-US Solicitation on regulatory issues of September 2012 and explained their suggestions to EU and US regulators at the stakeholder meeting of the April 2013 EU-US High Level Regulatory Cooperation Forum. These suggestions form an important input into TTIP regulatory work on sectors.

By the time the TTIP is concluded, it is expected that a number of specific provisions will have been agreed as part of various sector annexes, the TBT or the SPS chapters and other parts of the agreement. Some of these provisions will be implemented either upon entry into force or, as necessary, at a later fixed date. Other issues will have been identified on which the parties will continue to work with the aim of achieving increased compatibility/convergence, including by way of recognition of equivalence, , mutual recognition, or other means as appropriate, and with fixed objectives and timetables where possible. Other provisions will strengthen EU-US cooperation and coordination in multilateral and plurilateral fora in order to further international harmonisation. As regards future regulations, there should also be provisions and mechanisms to promote increased compatibility/convergence and avoid unnecessary costs and complexities wherever possible.

However, there will remain a number of areas warranting further work, which will be either identified when the TTIP negotiations are finalized or subsequently ("inbuilt agenda"). For those areas the TTIP should provide regulators with the means and support they need to progressively move towards greater regulatory compatibility/convergence and make TTIP a dynamic, 'living' agreement sufficiently flexible to incorporate new areas over time. Regulators need to have clear authorization and motivation to make use of international cooperation in order to increase efficiency and effectiveness when fulfilling their domestic mandate and TTIP objectives.

From this perspective the TTIP could include:

- Provision of a general mandate (understood as a legal authorization and commitment) for regulators to engage in international regulatory cooperation, bilaterally or as appropriate in other fora, as a means to achieve their domestic policy objectives and the objectives of TTIP.
- Provision to launch, upon the request of either party, discussions on regulatory differences with a view to moving toward greater compatibility which would enable the

parties to consider recognition of equivalence in certain sectors, where appropriate. The request could be based on substantiated proposals from EU and US stakeholders.

Flexible guidance could be provided for the examination of these proposals, including on the criteria for the assessment for functional equivalence or other concepts and scheduling of progress towards regulatory greater compatibility/convergence.

4. Framework and institutional mechanisms for future cooperation

An institutional framework will be needed to facilitate the application of the principles of the five regulatory components as described under I. A, including the provisions of the horizontal chapter laid out in section II C 1, 2 and 3.

Essential components of such a framework include:

- A **consultation procedure** to discuss and address issues arising with respect to EU or US regulations or regulatory initiatives, at the request of either party.
- A **streamlined procedure to amend the sectoral annexes** of TTIP or to add new ones, through a simplified mechanism not entailing domestic ratification procedures.
- A **body with regulatory competences** (a regulatory cooperation council or committee), assisted by sectoral working groups, as appropriate, which could be charged with overseeing the implementation of the regulatory provisions of the TTIP and make recommendations to the body with decision-making power under TTIP. This regulatory cooperation body would for example examine concrete proposals on how to enhance greater compatibility/convergence, including through recognition of equivalence of regulations, mutual recognition, etc. It would also consider amendments to sectoral annexes and the addition of new ones and encourage new regulatory cooperation initiatives. Sectoral regulatory cooperation working groups chaired by the competent regulatory authorities would be established to report to report to the regulatory cooperation council or committee. The competences of the regulatory cooperation council or committee will be without prejudice to the role of committees with specific responsibility on issue areas such as SPS.

Non-Paper

Limited

Without Prejudice

20 June 2013

EU-US FTA negotiations

Non paper on Public Procurement

1 Preliminary remarks

The EU suggests devoting the discussions in the first meeting/round to operational issues related to the negotiations on Public Procurement (PP). This implies that the discussion would focus on seeking a common view both on the overall substantive approach and the concrete organisation and sequencing of the negotiations.

In this initial process, the EU would like to emphasize the particular weight to be given to the understanding reached in the context of the High Level Working Group on Jobs and Growth with a view to achieving the goal of enhancing business opportunities through substantially improved access to government procurement opportunities at all levels of government on the basis of national treatment.

It is of utmost importance to make sure that both rules and market access issues are thoroughly dealt with in the course of the negotiations, with a view to reach as substantial result bilaterally as possible.

This approach does not preclude that the Parties would discuss issues in the course of the negotiations that prove relevant for the overall objective of further global liberalisation of trade in procurement.

First section: Substantive approach proposed by the EU

2 Overall architecture and scope of application of the PP chapter

2.1 Text structure

This negotiation would present an important opportunity for the EU and the U.S. to develop together some useful "GPA plus" elements to complement the revised GPA disciplines, with a view to improve bilaterally the regulatory disciplines. A model text agreed between the EU and the U.S., being the two largest trading partners in the world, could thus possibly set a

higher standard that could inspire a future GPA revision and where appropriate serve as a basis for the works conducted under the work program outlined in the WTO GP committee's decisions adopted on the 31st of March 2012. Beside this aspect the main focus of these negotiations will be to ensure better market access terms for EU and U.S. companies.

Two drafting options could be considered for the text of the PP Chapter:

- A PP Chapter comprising only "GPA plus" rules but which will incorporate the revised GPA text by reference, or
- A PP Chapter directly taking over the revised GPA text, including the amendments required to achieve the "GPA plus" outcome targeted.

The extent to which improved rules compared to the revised GPA text are required, should be an important factor in deciding whether the second option (improved revised GPA text as a whole) would be necessary to bring sufficient clarity and legal certainty to the agreed provisions of the PP Chapter.

It would be useful if the PP Chapter would also include rules allowing the Parties to take into account possible changes in the GPA disciplines, including, if appropriate, the outcome of the works conducted under the Work Program outlined in the WTO GP committee's decisions adopted on the 31st of March 2012.

2.2 Scope of application

The EU proposes that, to the extent possible, the improved rules negotiated bilaterally would apply to the entire scope of the GPA commitments undertaken by both Parties, as well as to additional market access commitments undertaken under the bilateral FTA, at federal as well as at state level.

3 Improved rules to be developed in the PP Chapter

3.1 Remedies to address existing trade barriers linked to the existing domestic regulations or domestic practices at central as well as at sub-central levels

The EU would suggest to include the following topics for negotiations – without prejudice to others that may be deemed relevant to address at a later stage:

- Definitions
- Removal of barriers to cross-border procurement and to procurement via established companies

- Consolidate and further improve the level of access to procurement-related information (transparency)
- Alleviate administrative constraints
- Make sure that the practical application of the e-procurement rules in the EU and the U.S. are not creating additional barriers to trade
- Make sure that the size of procurement contract is not used with a view to circumvent the market access commitments under the Chapter
- Ensure that technical specifications do not constitute an artificial barrier to trade.
- Provisions relating to qualitative award criteria
- The domestic challenge mechanisms

In addition, in certain other areas such as green procurement, rules could be examined and if need be improved.

3.2 Coverage-related disciplines

Besides the removal of the notes describing carve-outs in the Parties' schedules, we would propose to also make adequate provisions on coverage in the text. The EU would suggest to include the following topics for the negotiations for coverage–related disciplines - without prejudice to other topics that may be deemed relevant to address at a later stage:

- Ensure that rules on off-sets/set asides or domestic preferences such as, but not limited to, Buy America(n) and SME policies, do not restrict procurement opportunities between the EU and the U.S.
- Ensure committed coverage at federal level extends to cover also federal funding spent at the State level.
- Ensure the removal of possible discriminatory elements for example related to procurement by public authorities and public benefit corporations with multi-state mandates, interagency acquisitions, task and delivery order and in the field of taxation.

Moreover, discussions on additional elements of coverage, such as state-owned enterprises, public undertakings and private companies with exclusive rights may require the introduction of additional definitions and related rules.

Provisions should also be made for a mechanism for adjustments related to modifications and rectifications to coverage.

3.3 Horizontal disciplines

In the EU's views, the PP Chapter should as noted above under 2.2. also include rules allowing the Parties to take into account possible changes in the GPA disciplines.

4 Market Access discussions

4.1 Scope of market access discussions

4.1.1 Improvement of GPA market access schedules

Both Parties have accepted to enter into discussions affecting all the elements of their schedules at central as well as sub-central levels.

This implies that the negotiations should look for an expansion of coverage, to the extent possible, for all these schedules, by the removal of existing carve-out and by the offer of additional commitments.

In concrete terms, Parties should seek to improve access to and/or expand the coverage of:

- Central Government entities
- Sub-central entities
- Other entities with a view to specific sectors*
- Services
- Construction services
- Information society services, in particular cloud-based services

**including market access negotiations on transit/railways, urban railways and urban transport.*

The EU suggests - without prejudice - that the discussions on coverage would include:

For Annex 1, all central government entities and any other central public entities, including subordinated entities of central government.

For Annex 2, all sub-central government entities, including those operating at the local, regional or municipal level as well as any other entities whose procurement policies are substantially controlled by, dependent on, or influenced by sub-central, regional or local government and which are engaged in non-commercial or non-industrial activities.

For Annex 3, all entities governed by public law, state owned companies and similar operating in particular in the field of utilities.

The elements required are here presented in the form of positive lists, but for the actual commitment the EU expects this to be done in the form of negative lists. It would also include procurement currently subject to restrictions related to domestic preferences programmes for example linked to federal funding or procurement pursuant to multi-jurisdictional agreement.

For the US system this would imply:

Annex 1 For example entities not yet covered such as the Federal Aviation Administration. It would also cover procurement currently subject to restrictions or domestic preferences related to federal funding as well as procurement regulated by specific policies and rules, such as those related to Buy America(n) provisions as well as those related to SMEs. The coverage would follow the projects funded by FAA even if they were channelled to a sub-federal level for actual spending.

Annex 2 It would concern all those States that are neither covered by the GPA nor by our bilateral agreement, such as Alabama, Alaska, Georgia, Indiana, Nevada, New Jersey, New Mexico, North Carolina, Ohio, South Carolina, and Virginia. It would also imply an upgrading to GPA standard of the access to North Dakota and West Virginia. Furthermore, it would imply a substantial upgrading of the coverage in the States currently covered in general by way of addressing current derogations as well as to include for example also larger cities and metropolitan areas such as New York, Los Angeles, Houston, Philadelphia, Phoenix, San Diego, San Jose, Jacksonville, Austin, San Francisco, Columbus, Fort Worth, Charlotte, El Paso, Memphis, Seattle, Denver, Baltimore, Washington, Louisville, Milwaukee, Portland and Oklahoma City.

Annex 3 For example entities not yet covered by neither the GPA nor by our bilateral agreement, such as procurement currently subject to restrictions or domestic preferences related to federal funding or procurement currently restricted by requirements for example decided by the Board of Directors of the Ports of New York and New Jersey.

Annex 4 All related **goods** not yet covered by the GPA or our bilateral agreement.

Annex 5 All **services** procured by entities listed in Annexes 1 through 3 in the coming

EU/US agreement.

Annex 6 All **construction services** not yet covered by the GPA or our bilateral agreement, including for example transportation services that are incidental to a procurement contract.

The above given examples are indicative – the EU reserves the right to revise the list and any listing would be for illustrative purposes only.

To ensure a uniform and extensive coverage:

- all entities falling under the "catch-all-clauses" as defined in Annex 1 to 3 would be covered by the Agreement.
- a system based on definition: an entity will be captured by the criteria laid down in the definitions.

4.2 Coverage related approach

For the purpose of these negotiations on improved schedules, the Parties will discuss the potential inclusion of new entities and sectors plus revised thresholds.

The EU suggests enlarging this approach to the expansion of coverage via discussions on **public private partnerships** (PPP). It is worth exploring what can be achieved in this domain to obtain a more comprehensive coverage of PPPs/and or a better clarification on the rules to be applied to such contracts, including contracts related to BOTs and similar set ups.

4.2.1 Systemic linkages with other FTA chapters

As made clear by several GPA parties under their respective schedules for services, market access commitments on services under the GPA do not concern the modes of supply of the services offered. Therefore, in the FTA context, it important to establish a proper linkage between the schedules in the Services Chapter or the Investment Chapter and the schedules of the PP Chapter, to ensure, that economic operators can actually benefit in practice from concessions made in another Chapter.

Both parties should also explore how to bridge the PP Chapter with the Competition Chapter when dealing with the categories of SOEs, public undertakings and private companies with

exclusive rights. Issues relevant to investment in goods may also require similar considerations.

Second section: Organisation and sequencing of the negotiations

5 Organisation of the negotiations

5.1 Text proposals for the PP chapter as a whole

Subject to the decision at the Chief Negotiator level, the EU is willing to submit text proposals on the PP Chapter, in parallel or not to a submission by the U.S. Texts could for example be exchanged at the second round.

5.2 Market access discussions

As for other Chapters, market access discussions should at points in time to be determined result in formal exchanges of requests and offers.

5.4 Organisation of intersessional discussions

The EU is open to the possibility of intersessional discussions.

Initial position paper

Limited

Without prejudice, 17.06.2013

INITIAL POSITION PAPER ON TRADE AND INVESTMENT IN RAW MATERIALS AND ENERGY FOR THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP) NEGOTIATIONS BETWEEN THE EU AND THE US

Introduction

This paper aims to identify common ground between the EU and the US regarding the treatment of raw materials and energy in the context of the EU–US Transatlantic Trade and Investment Partnership (TTIP) negotiations.

Non-discriminatory access to raw materials and energy and their subsequent trade across borders has remained at the margins of international trade and investment rules over the last decades. Yet forecasts suggest demand will continue to grow across sectors and countries as the world population grows and living standards improve. In parallel, efficient distribution has also become more pressing in particular for EU and US companies as production processes rely on a wider variety of critical inputs, some of which can be found only in a limited number of locations.

Although the US's energy landscape is changing, US and EU companies will remain dependent on open markets to source significant parts of their raw material and energy needs far into the future. Our companies operate complex raw material and energy supply chains, with varying dependences as processors, suppliers, importers and exporters, and as consumers too. Downstream companies depend on inputs of energy and raw materials from third countries, while upstream companies compete for access to resources abroad.

World Trade Organisation (WTO) rules have largely remained at the margins of international production and trade in raw materials and energy, as reflected in the WTOs 2010 annual report which was devoted to this issue. The WTO rulebook contains tough rules to tackle import barriers, and weaker concomitant rules to address export barriers. This has affected energy and raw materials disproportionately, insofar trade restrictions in this area are more pertinent on the export side. Other examples are the lack of definition of energy services in GATS, an absence of effective rules on international transit of energy goods transported by pipeline, prevalent trade and distribution monopolies in countries where domestic production is not monopolised, widespread use of local content requirements imposed on the equipment of foreign companies when they operate large scale projects in third countries, and insufficient transparency in regulatory processes pertaining to the granting of licenses for exploitation or trade in energy products.

The EU and the US have worked closely together over the past years and sent a strong signal in support of open trade and non-discriminatory access for raw materials and energy. Some of the above shortcomings have been partially addressed in the WTO accession protocols of countries like China or Russia, and in FTAs negotiated by the EU and the US. Some progress has also been achieved through the dispute settlement process. The multilateral trade system would however benefit from a stronger set of rules in the area of energy and raw materials. Indeed, international trade agreements have made only a modest contribution to promoting the application of market principles in this area regarding access, distribution, trade and sale.

The TTIP could therefore make an important contribution to the development of that process, within limits agreed by both sides. It could provide a basis to take the issues forward in a more comprehensive manner by providing an open, stable, predictable, sustainable, transparent and non-discriminatory framework for traders and investors in raw materials and energy, in a way that also serves our wider shared geo-strategic and political objectives for the longer term.

Disciplines agreed in the transatlantic context could serve as a model for subsequent negotiations involving third countries. It also sends a powerful signal to other countries that trade in raw materials and energy can be and will be subject to global governance, including the fundamental principles of transparency, market access and non-discrimination. In addition, agreed rules on trade and investment in raw materials and energy would also contribute to developing and promoting sustainability.

Approach

It is understood that general disciplines and commitments concerning trade in goods and services, and investment, negotiated in the TTIP will apply to raw materials and energy, including e.g. non-discrimination, the elimination of import and export duties and other restrictions relating to import or exports.

It is also understood that where the general rules do not address certain energy and raw materials related issues, these should be covered by energy and raw materials specific rules. Such rules would go beyond existing WTO provisions and in particular beyond the provisions in GATT and GATS. There are precedents as both the EU and the US have negotiated such specific rules with third countries.

Disciplines for the template

Scope

In principle, the scope of the specific rules could include measures related to trade and investment in raw materials i.e. raw materials used in the manufacture of industrial products and excluding e.g. (processed) fishery products or agricultural products, and energy products, i.e. crude oil, natural gas electrical energy and renewable energy.

The following areas have been identified around which specific raw material and energy provisions could be developed.

Transparency

Increasing transparency and predictability is the first and most important step towards a better (global) governance of trade in raw materials and energy. Transparency improves investment opportunities, facilitates continued production, and improves the functioning and expansion of infrastructure, including for transportation. The agreement should encourage **transparency** in the process of licensing and allocation conditions of licences that could be required for trade and investment activities in this area.

Market access and non-discrimination

In line with this objective, the elimination of export restrictions, including duties or any measure that have a similar effect should be ensured.

As regards exploration and production of raw materials and energy, it is important to confirm that the parties should remain fully sovereign regarding decisions on whether or not to allow the exploitation of their natural resources. Once exploitation is permitted **non-discriminatory** access for exploitation, including for corresponding trade and investment related opportunities, should be guaranteed by regulatory commitments. In terms of regulatory commitments related to exploration and production of energy, the US and EU should also have an interest in developing further common standards as regards off shore safety, on the basis of their respective domestic legislation. Additionally, it should be assessed how to incorporate elements related to the Extractive Industry Transparency Initiative (EITI), which reflects both the EU and US domestic legislation.

The EU and the US should consider rules on transport of energy goods by natural gas pipelines or electricity grids, which would be particularly relevant in countries with monopolized pipelines. In this context, there should be regulation of transport and transit. The agreement could provide that if private construction of infrastructure is not allowed or not economically viable, Third Party Access (TPA) should be mandatory, subject to regulatory control by an independent regulator vested with the legal powers and capacity to fulfil this function. Transit rules should be compatible with - and at least as favourable as - the transit rules defined in the Energy Charter Treaty. They should be established in a manner to avoid or mitigate an interruption of energy flows.

Competitiveness

There are at least two different areas where **competiveness** in the raw materials and energy markets can be improved.

Government intervention in the price setting of energy goods on both the domestic market and of energy goods destined for export purposes should be limited. A prohibition on dual pricing should further limit the possibility for resource rich countries to distort the market and subsidize sales to industrial users thus penalising foreign buyers and exports. Whereas further reflection is needed, precedents like WTO Accession commitments (by Russia and Saudi Arabia) or relevant provisions from the NAFTA Agreement (Article 605(b)) could possibly be used to explore possible avenues in this respect.

As regards State Owned Enterprise (SOE) and enterprises granted Special or Exclusive Rights (SER) specific rules for raw materials and energy could be discussed. Although these rules should in principle be of a general nature, it could appear necessary during the negotiation process to agree on rules specifically for companies active in the raw materials and energy sector, especially in so far as they benefit from special or exclusive rights, in coordination with the horizontal rules.

Trade in sustainable energy

The EU and the US have a shared interest in improving global governance in the area of renewable energy. Liberalisation of trade in green goods and services would bring considerable environmental, social, economic and commercial benefits to the US and the EU. A rules-based, open international market would promote more cost-efficient and more widely available green goods and services (including green technologies). It would also foster innovation as well as create jobs and bring an important contribution to the achievement of environmental objectives and the fight against climate change.

The TTIP could build on the APEC agreement on environmental goods. The parties could agree on commitments to address non-tariff barriers which cause specifically in this area many trade irritants. In terms of concrete provisions, a confirmation of prohibition of local content requirements for goods, services and investments could be introduced. Commitments related to subsidies contingent on local content requirements and prohibitions on forced transfer of technology or set offs could also be included.

Energy efficiency and the promotion of renewable energies are a fundamental aspect of the energy policy of the EU and the US. They are being promoted through various policy measures, for instance regulatory measures, standards and incentive programmes. The TTIP should promote the objective of renewable energy and energy efficiency and should guarantee the right for each party to maintain or establish standards and regulation concerning e.g. energy performance of products, appliances and processes, while working, as far as possible, towards a convergence of domestic EU and US standards or the use of international standards where these exist.

Security of energy supply

The secure and reliable supply of energy is of crucial importance for any country. Consideration could be given to developing provisions on the security of energy supply designed, inter alia, to identify existing and upcoming supply and infrastructure bottlenecks that may affect energy trade, as well as mechanisms to handle supply crises and disruptions, taking into account and promoting multilateral obligations in this field (notably in the context of the International Energy Agency).