Without prejudice

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.

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.

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:

c. 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.

d. 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.

e. 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 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.
  - At the same time, an improved bilateral mechanism for comments and replies that would, in particular, enhance transparency under the WTO TBT Agreement notification procedure could be considered. This would be a means to further a dialogue between regulators, including with regard to draft measures notified under the WTO TBT Agreement, in line with the overall objectives of this chapter.

\(^3\) http://trade.ec.europa.eu/doclib/cfmr/doclib_section.cfm?order=abstract&sec=146&lev=2&sta=41&en=60&page=3
• **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 trans-Atlantic 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. There should also be regular monitoring of progress made, in order to identify priority actions and address obstacles.

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.