POSITION PAPER

28 November 2013

ADVANCING REGULATORY COOPERATION IN THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP

KEY MESSAGES

1 A key deliverable from the Transatlantic Trade and Investment Partnership (TTIP) will be a chapter on horizontal regulatory provisions. EU and U.S. regulators must commit to cooperate: the EU and the U.S. should establish a mechanism that will eliminate or reduce existing regulatory divergences in goods and services trade and prevent new ones from arising in the future. Tackling such regulatory divergences will benefit businesses of all sizes and increase transatlantic trade flows, spurring economic growth and job creation and contributing to closer economic integration between the EU and the U.S.

2 Regulatory cooperation is not about reducing health, safety or environmental standards. It accepts the principle of regulatory autonomy and the sovereign right to establish the level of health, safety and environment protection or other legitimate regulatory objectives deemed appropriate.

3 It is important that TTIP includes both horizontal regulatory provisions and sectoral annexes. Both components are important. The horizontal chapter must lay down general disciplines to achieve increased regulatory compatibility through effective upstream regulatory cooperation, transparency, accountability, and good regulatory practices, such as mandatory, early and meaningful consultations that allow sufficient time to comment and the use of impact assessments. Sectoral annexes would contain specific commitments for goods and services sectors. One-size-fits-all is not an available option: the exact content and shape of regulatory cooperation will be different from sector to sector and solutions to solve specific divergences will need to be identified. Negotiations should aim at achieving first results of reducing sectoral barriers to trade taking effect upon entry into force of TTIP.

4 To realize the economic potential of TTIP, meaningful EU-U.S. regulatory cooperation is a priority. A strong and sustained political support at the highest levels of governments and the relevant regulatory authorities is needed.

BUSINESSEUROPE a.i.s.b.l
AVENUE DE CORTENBERGH 168 – BE 1000 BRUSSELS – BELGIUM
TEL +32 (0)2 237 65 11 – FAX +32 (0)2 231 14 45 – E-MAIL MAIN@BUSINESSEUROPE.EU
WWW.BUSINESSEUROPE.EU
EU Transparency register 3978240953-79

BUSINESSEUROPE

POSITION PAPER

25 November 2013

ELEMENTS FOR A CROSS-SECTORAL REGULATORY COOPERATION CHAPTER IN THE TTIP

1. Introduction

Horizontal regulatory provisions are a priority issue for the European business community in the TTIP negotiations. Given the relative novelty of pursuing obligations with regard to regulatory cooperation, transparency, stakeholder involvement and good regulatory practices in the context of a trade agreement between two highly developed and regulated economies, BUSINESSEUROPE would like to put forward recommendations for an ambitious yet balanced approach to this issue.

Non-tariff barriers are a significant obstacle to a more integrated transatlantic economy. Such 'behind-the border-barriers' reduce European and American competitiveness in goods and services sectors on global markets and delay market entry of innovative products and services. From a regulatory perspective, divergent EU-US regulations tie up regulatory resources that could be used more efficiently. They also reduce the possibility for regulators to cooperate in reducing risks and ensuring fair competition across the Atlantic.

Regulatory cooperation needs to be dealt with realistically considering the complexities between two different regulatory systems that pursue similar high quality regulatory objectives. TTIP should develop the institutional framework to guide regulatory cooperation on both a horizontal and sector-specific basis. By directing regulators to consult each other on existing and future regulation, TTIP will help reduce unnecessary divergences. The underlying principle is an obligation to cooperate and consider trade impacts and impacts of future regulation on transatlantic regulatory compatibility, and not an obligation to achieve a determined result.

The horizontal regulatory provisions in TTIP will lay down cross-cutting principles for achieving increased regulatory compatibility. Sector-specific issues will then be addressed in sectoral annexes, that would contain commitments for specific goods and services sectors where there is or may be significant levels[1] of transatlantic trade and investment. Negotiations should aim at achieving results of reducing sectoral barriers to trade already when the TTIP enters into force.

However, regulatory cooperation is also an on-going task which will bear fruits even after the TTIP negotiations are concluded. The institutional mechanism incorporated in TTIP will enable it to be a "living agreement", by which more substantial sector specific commitments can be reached over time, allowing for additional gains beyond those achieved during the course of negotiations ("built-in agenda").

[1] Significant levels should not be read as to include only big industry sectors.

Businesses would like to reduce duplication of regulatory activity (e.g. double testing, double licensing, etc.) that add administrative burdens and are especially onerous for small and medium sized enterprises. BUSINESSEUROPE is working closely with companies and sector associations to identify the practices where such redundancies can be eliminated. Apart from the specific horizontal regulatory provisions, TTIP will also contain provisions on technical barriers to trade (TBT) and sanitary-phytosanitary measures (SPS) which are traditional chapters of trade agreements.

2. Regulatory Principles

The TTIP text should draw from the core regulatory best practices and build on regulatory principles that are embodied in U.S. and EU administrative law. It should enhance transparency, private sector engagement, and increase opportunities to provide timely inputs. The text could notably build upon bilateral principles already developed between the U.S. and EU, such as the Common Understanding on Regulatory Principles and Best Practices (June 2011) and the Guidelines on Regulatory Cooperation and Transparency (April 2002), and apply them, *mutatis mutandis*, at EU and U.S. federal and sub-federal levels covering services and sectors that are not included in those Guidelines.

Among other things, this section should emphasize the importance of:

- Sovereign right to regulate: regulatory cooperation shall not undermine or limit either side's responsibility to regulate for public purpose.
- Cooperation: this should lead to increased compatibility and, in areas where approaches are sufficiently aligned, eventually to more harmonisation, in particular when developing new regulations.
- Transparency and openness: this should allow for timely and meaningful participation by individuals, businesses and other stakeholders.
- Scientific, technical, economic, and other evidence.
- A risk-based approach: as elaborated in the Communication from the Commission COM(2000)1 of 2 February 2000 on how to apply the precautionary principle, which is an accepted EU principle enshrined in the EU Treaties.
- Analysis of relevant regulatory alternatives, including the possibility not to adopt regulation at all.
- Ex-post evaluation of the effectiveness of existing regulatory measures.
- Approaches that minimize burdens, are proportionate, aim for simplicity, including in the area of standards and conformity assessment.
- Reasonable time-limits and avoidance of undue delay; and
- Efficient administrative and/or judicial review of regulatory measures.

3. Good Regulatory Practice

TTIP should contain horizontal provisions on good regulatory practice.

Requirements for partners:

- Regular and timely information to the counterpart about upcoming legislation and regulations at an early stage[2] when comments and recommendations can still be taken into account.
- Address significant comments by the counterpart throughout the process, including explanations before the adoption of the final measure.

General requirements:

- Possibility for all relevant stakeholders concerned to provide input including through effective consultations. The process should be transparent and timely to allow for responses and their consideration before the final measure is adopted.
- (Draft) regulatory measures should be accompanied by a short, concise summary for general public awareness of the measure, the problem and the policy objective that the regulatory authority intends to address, including an assessment of the significance of the problem, its anticipated trade impacts and a description of the need for regulatory action evidence that supports the regulation and comments received from stakeholders.
- Regulatory authorities should provide appropriate public access to regulatory measures and their supporting documentation.
- Impact assessments.
  - Impact assessments should systematically analyse the impact of the draft legislation/regulation on the economy, the environment and the social realm as well as on transatlantic trade, investments and global supply chains. A common methodology to assess the transatlantic trade dimension should be developed.
  - Stakeholders should be closely involved and have the possibility to comment on draft impact assessments directly: the latter should be made public before the regulatory measure is adopted, including all the assumptions behind the calculations of costs and benefits.
  - On the EU side, changes to the legislative proposal through the co-decision process should be monitored in a transparent manner and their impact on transatlantic trade should be addressed. On the U.S. side, the administration should provide information on draft Congress bills with potential significant impact on transatlantic trade and facilitate comments by the Commission to the extent possible.
  - Accountability: regulatory authorities should indicate how information provided by stakeholders in the consultation process was reflected.
  - Ideally, impact assessments will contribute to increased compatibility and interoperability of EU and US regulation/legislation over time, thereby facilitating the development of common approaches in the transatlantic market.

[2] The terms timely and early stage may have to be defined differently for draft EU directives/regulations or delegated acts as well as for US executive regulations and relevant draft Congressional bills.

BUSINESSEUROPE would note that above priorities are consistent with its 20 September 2012 submission to the EU Commission on stakeholder consultation on smart regulation in the EU.

4. Obligation to cooperate

Increased regulatory compatibility can be achieved by authorising regulators to cooperate before they regulate and providing the necessary conditions to make this cooperation useful in practice. Such cooperation should explore inter alia:

- Common regulatory objectives;
- Assessments and analyses underpinning the regulation, including analytical assumptions and methodologies;
- Maximum uniformity of requirements and legislative instruments, as far as the legal systems allow.

The EU and the U.S. should seek to assess the transatlantic trade impact of a proposed regulatory measure, with the understanding that such an assessment will influence the final regulation with a view to minimise trade divergences.

5. Regulatory compatibility

Regulatory cooperation can result in different outcomes.

- Increased compatibility: a first step will be the avoidance of duplicative approbation requirements (e.g. inspections, testing, conformity assessments). For example, many regulations require the presentation of data and studies. Procedural convergence could be achieved by accepting each other´s data, methodologies to gather data, etc.
- Mutual recognition: in order to make mutual recognition a reality, both the U.S. and the EU should assess to what extent their existing regulations are comparable or equivalent in effectiveness.
- Uniformity of product requirements: new legislation should aim to minimize unnecessary differences.

6. Scope

Given the differences between the U.S. and EU legal structures, the question of scope raises complex questions for a treaty covering regulatory cooperation. Ideally all regulatory measures that have a significant impact on transatlantic trade should be covered.

Another important requirement is balance. The constitutional differences should not lead to unbalanced and one-sided obligations. Therefore a thoughtful and engaged commitment should be designed to establish a balanced sense of obligations on both sides of the Atlantic covering both the U.S. federal/EU and, mutatis mutandis the sub-federal/member states level.

The simplest approach for the EU would be to cover the Commission's role in proposing legislative measures (e.g. draft regulations and directives, and delegated or implementing acts). Given the comprehensive role of the Commission in EU legislation/regulation, it would not be sufficient to cover only the role of the U.S. Executive Branch as well as the regulatory activities of independent agencies. The legislative role of Congress needs to be covered in order to strike a balance.

As such, and without making any specific proposal, the scope for regulatory cooperation needs to be dealt with in TTIP. It should result in a balanced, reasonable and well defined coverage of legislative acts and regulatory measures on both sides of the Atlantic.

7. Central coordination and institutional framework

To reap the economic and regulatory benefits of such an agreement, the Commission and the U.S. Administration would need to invest in an effective central cooperation body. The main purpose of such a body would be to promote regulatory cooperation after the entry into force of TTIP and to ensure that increased regulatory compatibility be achieved.

The central cooperation body would be tasked with:

- monitoring implementation of existing commitments,
- providing regular information on relevant upcoming regulatory initiatives,
- assessing the potential for cooperation, prioritizing issues and defining roadmaps,
- providing a discussion platform for regulators from both jurisdictions,
- offering legal and technical advice on the different institutional and regulatory setting in both jurisdictions via e.g. model agreements,
- considering proposals from stakeholders from both sides of the Atlantic on how to make EU and US sectoral regulations more compatible,
- proposing how to implement these recommendations in its yearly work programmes, for endorsement at the political level by both parties.

The body should publish an annual report containing references to its achievements and to the work still to be done. Such stocktaking would allow stakeholders to assess the results and to comment on the future activities of the body. Processes must be transparent to ensure accountability.

The body should conduct its activities under the responsibility of a high level government official from both sides. This high level leadership would ensure the body's coordination of regulatory cooperation across a wide range of institutions responsible for regulatory rule making.

Many European non-member states that are strongly linked to the EU either through a customs union, the EEA or bilateral agreements have strong transatlantic business interests that are likely to be affected by the TTIP. It will be the responsibility of the Commission to take into account the close links these countries have with the EU when conducting transatlantic regulatory activities in the context of TTIP.

8. The role of agencies

EU and U.S. agencies have different roles in the rule-making process. EU agencies are consultative in nature; they do not have the right to issue regulations. The regulatory power, for example delegated acts, rests with the Commission. U.S. agencies however do have rule-making authority. The chapter on horizontal regulatory provisions has to take into account this fundamental difference.

First, the chapter should clarify how the rule-making and decision-making activities of U.S. independent agencies are covered.

Second, the cooperation among agencies (whether independent, regulatory, or advisory) involved in regulations with significant effects on transatlantic trade should be defined. The scope of these activities should range, inter alia, from data collection, mutual acceptance of data, methodologies for data assessment, testing requirements or conformity assessments to market authorizations.

The chapter should also clarify how sensitive data is to be shared between agencies or how requests for public disclosure are handled, to ensure protection of confidential business information and intellectual property rights.

Conclusion

To sum up, the chapter on horizontal regulatory provisions should address both a system to further regulatory compatibility in the development of new regulation/legislation as well as immediate results. The chapter should:

- enhance the opportunity for compatibility of high quality regulation in order to boost trade and investment opportunities;
- increase transparency and openness in the regulatory process to enable closer cooperation across the Atlantic;
- reduce unnecessary and disproportionate burden economic operators face in view of different regulatory requirements that harm trade and investment while enhancing regulatory efficiency and effectiveness;
- address the legal framework associated with regulatory compatibility, including product liability issues.