European Commission

EU - US TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP

Technical barriers to trade

Initial EU position paper

Without prejudice

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 and conformity 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 regulations

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 US, and the EU Member States, or their respective national standardisation bodies, as the case may be, are 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 cooperation and 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 and, as a result, of accredited conformity assessment results.

7.5 Marking and labelling

Marking and labelling are mentioned briefly in the TBT Agreement, but it is suggested that some disciplines be added for trade between the Parties, so that compulsory marking requirements, while continuing to provide the necessary information to the user or consumer as well as to public authorities regarding compliance of products with specific requirements, are limited as far as possible to what is essential and the least trade restrictive to achieve the legitimate objective pursued. Where obligatory requirements are made for origin marking in the US it would be appropriate to enable EU manufacturers to mark their products either as originating in the EU or in the respective EU Member State of origin. Furthermore, consideration should be given to measures to inhibit the use of markings that may mislead users, consumers or public authorities, including possible sanctions against the use of such misleading markings by manufacturers and suppliers.

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.