



Transatlantic Trade and Investment Partnership (TTIP)

Chapter on Regulatory Cooperation

**Detailed Explanation on the EU proposal<sup>1</sup> for a Chapter on  
Regulatory Cooperation**

(as per revised version made public on 4 May 2015)

**6 May 2015**

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<sup>1</sup> References to the “EU proposal” refer to the [EU Commission’s proposal on regulatory cooperation](#) submitted during the 9<sup>th</sup> round of TTIP negotiations, and made public on 4 May 2015

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## **1. Rationale: Why is regulatory cooperation important? What does it mean in practice? (General notes and Article 1)**

**Regulatory cooperation matters more than ever today.** In a **globalised economy** we cannot achieve our public policy goals in isolation. Indeed, the domestic mission of many regulators in the EU and the US nowadays is affected by developments on the other side of the Atlantic – and around the world. In a context of increasing cross-border trade in pharmaceuticals, food and many other products, ensuring consumer safety is very closely linked with the way these products are regulated in their countries of origin. We thus need to develop and promote internationally better and more effective regulations in areas ranging from product safety and consumer protection to protection of the environment or plant health. EU and the US are not only the world's largest trade and investment partners, but also the world's largest regulators, and are engaging in bilateral and international cooperation in many fora (i.e. WTO, UN or other international bodies). Strengthening this cooperation should permit to achieve better results.

Bilateral regulatory cooperation leading to **more compatible EU and US regulations** can lead to safer products and increased consumer choice. If the EU and the US were to develop a joint approach to further align procedures for the approval of certain medicines or medical devices, citizens would benefit from faster access to new pharmaceuticals and life-saving devices such as pace makers. The monitoring and tracking of these products would also be improved.

Regulatory cooperation could help reduce unnecessary burdens for business, thus creating potential for more growth and competition, lower prices, etc. This is of particular relevance to small and medium sized enterprises (SMEs) whose export competitiveness is disproportionately affected by regulatory costs. SMEs could benefit for instance from removal or reduction of duplicative testing, inspections or certification. Regulatory cooperation can lead to important savings and efficiency gains for business, regulators, governments and citizens alike.

The benefits of bilateral regulatory cooperation would be further multiplied if, for instance, the EU and the US rules were to **converge around international instruments**. These rules could then be applied at international level - beyond European and US borders – making products coming from other countries safer.

For example, the EU and the US are considering basing their national systems for identifying and tracing medical devices on the international *Unique Device Identification* (UDI) system. Or, say the EU and the US were to agree to jointly promote relevant international standards seeking a high level of protection, such as the UN Globally Harmonized System (GHS) for classifying and labelling chemical substances and mixtures. This would facilitate trade between them as the same rules would apply for providing information on hazardous chemicals. If more countries were to use these standards, then workers and consumers in these countries would be better protected.

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Closer EU-US regulatory cooperation could also play an important role in furthering the adoption of Global Technical Regulations ('GTRs') on safety of motor vehicles and their environmental performance. This would contribute to setting the highest standards of protection in a sector largely globalised.

The EU proposal makes clear that regulatory cooperation must be consistent with the objective of pursuing a high level of protection and in no way restrict the right of each side to maintain, adopt and apply timely measures to achieve legitimate public policy objectives (see in particular Articles 1 paragraph a) and paragraph 3 as well as Article 10 paragraph 1, Article 12 paragraph 3).

## **2. Scope of the EU's proposal**

*- Who would cooperate?*

**Regulators on both sides would be the driving force**, whether at central level (*see Article 2 subparagraph b*) - EU Commission and US federal regulatory agencies) or non-central level (*see Article 2 subparagraph c*) - US states and EU Member states central governments). Results will only materialize in areas where there is sufficient convergence of approaches, mutual interest, trust and the prospect of timely results.

*- How to identify 'candidates' for future regulatory cooperation?*

In certain sectors, objectives for future regulatory cooperation may be identified in TTIP when it will be concluded. But regulators need to have flexibility to identify new priorities for regulatory cooperation in these and other sectors. This needs to be done in a transparent manner including through stakeholder input. The EU proposal thus suggests reflecting priorities for cooperation in the Annual Regulatory Cooperation Programme of the Regulatory Cooperation Body (see in particular Articles 14 and 15 of the EU proposal).

*- What types of regulations does the EU proposal on regulatory cooperation seek to cover?*

Article 3 of the EU proposal determines the types of regulations that would be covered. In essence these are regulations:

- that contain precise requirements on how products should be designed to be marketed and used in the EU or the US;
- that provide specific conditions for the supply of services, including for example licenses or qualification of service providers.

By contrast, regulatory cooperation would typically not cover legislation that establishes a framework or principles, applicable generally and across sectors (such as in the area of company law, consumer protection or the protection of personal data, to name a few).

In addition, the EU proposal is only concerned with regulatory acts that **have or may have a significant effect on EU – US trade or investment**. For example, a purely domestic rule on emission limits for certain industrial plants in the EU or the US would not be covered.

### **3. Main elements of the EU proposal**

The EU's proposal consists of three main elements.

1) First, in section II, we reaffirm adherence to a number of **good regulatory practices** that both the EU and the US are promoting in international fora. These include transparency, stakeholder consultations and an assessment of impacts of regulation.

2) Second, section III delineates a mutual **agreement to accommodate regulatory exchanges** -upon reasoned request from the other side. Of course, transatlantic regulatory exchanges already take place today in many policy areas. But the provisions in Article 9 ('Information and Regulatory Exchanges at central level'), Article 11 ('Information and Regulatory Exchanges at non-central level') and Article 12 ('Timing of regulatory exchanges') would add value as they spell out clearly the steps each Party is expected to take when receiving a request. The proposal also suggests establishing contact points ('Focal points' as laid down in Article 8), which would act as facilitators in the process.

In certain cases where specific common interests have been identified, the cooperation process may bring regulators to jointly examine methods leading to more compatibility, for instance, through recognition of equivalence or harmonization of regulatory acts (see Article 10 'Promoting regulatory compatibility at central level'). For example, in the area of car safety, the EU and the US could decide to work closely together from the very beginning when improving existing or developing new rules on car lighting or emergency braking.

3) Third, still as part of section III, the EU proposes an **institutional mechanism** to frame this enhanced regulatory cooperation. TTIP would go beyond other trade and investment agreements in including a framework for promoting regulatory cooperation and compatibility through horizontal provisions complemented by a number of specific commitments in sectors.<sup>2</sup> These are distinct from and come in addition to commitments the EU and the US have taken in the World Trade Organisation (WTO) regarding technical barriers to trade (TBT) and sanitary and phytosanitary measures (SPS). These commitments focus largely on regulatory cooperation in areas of common interest. They require an institutional framework that identifies, facilitate and supports cooperative initiatives on new and existing regulations.

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<sup>2</sup> Nine sectors have been under discussion to date: Automotive, chemicals, cosmetics, pharmaceuticals, ICT, engineering, financial services, medical devices and textiles.

#### **4. Good regulatory practices in section II (Articles 5-7)**

Both the EU and the US already apply a number of good regulatory practices such as **transparency, effective stakeholder consultations and the prior assessment of impacts before regulating**. TTIP is meant to highlight these principles; and to build bridges between our systems to make these principles work better in relation to EU-US trade and investment.

These good regulatory practices and **principles would also facilitate regulatory cooperation**. For example, publication on both sides of regulatory agendas would help regulators to identify areas of interest they would like to cooperate on (see in particular Article 5, 'Early Information on planned acts').

Providing opportunities for stakeholder consultations (see Article 6 'Stakeholder Consultations') is particularly important when the impact of planned regulations is being assessed.

EU-US regulatory cooperation would also benefit from exchanging experiences on how regulators from each side assesses the potential impacts of a regulation (ex ante) as well as how it evaluates whether an existing regulation has delivered on its specific objectives (ex post) (see Article 7 'Analytical tools').

#### **5. Regulatory cooperation mechanism in section III (Articles 8-13)**

*- What is the objective of the bilateral cooperation mechanism (Articles 8, 9, 11 and 12)?*

The cooperation mechanism offers a greater chance of **producing more compatible regulatory outcomes** that fulfill each side's public policy objectives. The provisions proposed by the EU (Articles 8, 9, 11 and 12) provide that regulators exchange information and answer questions. Regulators responsible for a particular regulatory act would lead the exchanges. The cooperation mechanism – while result oriented – does not prescribe a particular outcome. It would be up to the regulators, during their exchanges, to determine if and to what extent a particular joint outcome can or not be achieved.

*- What would be foreseen for EU Member States and US States (Article 11)?*

As regards cooperation on regulatory acts adopted by an EU Member State or a US State, Article 11 of the EU proposal ('*Information and Regulatory Exchanges on regulatory acts at non-central level*') provides for **voluntary cooperation based on common interest**. Article 11 is meant to facilitate the exchange of information on significant regulatory acts upon request by one side. The responsible regulators ultimately decide whether or not to enter into regulatory exchanges. This cooperation would only cover regulations adopted by the central national authorities of an EU Member State or the central authorities of a US State.

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There are some sectors of relevance to the EU-US trade and investment relationship, which are regulated at the non-central level by one side and on the central level by the other. This is for instance the case for the **liberal professions** in the US such as accountants, architects and lawyers, which are regulated by US States. The details and modalities of these and other areas may be determined in the specific or sector provisions of TTIP which are being negotiated in parallel to the regulatory cooperation chapter.

*- What could be the outcome of these regulatory exchanges?*

Regulatory exchanges would lead, at a minimum, to a better **mutual understanding** of the other side's approach and existing regulatory frameworks. It could help regulators to benefit from each other's experiences when developing new regulations (for instance in areas that only one side has addressed so far).

In some cases cooperation would go beyond this with the early dialogue helping to **avoid unnecessary barriers** to trade or help the development of international instruments, such as developed by international bodies such as UNECE or OECD.

In other cases there may be little or no room for regulatory compatibility; but the exchange may still result in clarifying the respective positions of regulators. Regulatory cooperation will not lead to greater compatibility in all cases – there will always be instances where each side will follow a different path due to the political sensitivities and specific needs of its domestic constituencies or because of differing policy objectives.

*- What would be the tools to promote regulatory compatibility (Article 10)?*

For regulatory acts at central level i.e. at the EU and US federal level, Article 10 ('Promoting regulatory compatibility') provides a **path for regulators to jointly assess appropriate means to promote compatibility**. For example, EU or US regulators could decide to cooperate and move forward jointly when developing new innovative regulations for hybrid cars or modern IT technologies that help cars communicate with each other.

EU and US regulators could also decide to work together on new areas related to modern information and communication technologies, which raise different kinds of challenges. For example, the EU and the US may jointly examine optimal standards for electronic labelling where this solution replaces traditional labels and stickers. The aim is to provide information to consumers, and to avoid duplicative or contradictory obligations.

Another potential area of common interest is e-accessibility, i.e. making ICT easy to use for people with disabilities. This would guarantee a high level of consumer protection and contribute to avoiding unnecessary differences in our rules. Such cooperation could put the EU and the US at the forefront when developing global standards in these innovative areas.

European and US small and medium sized firms would greatly benefit if regulators could find ways to facilitate acceptance of test results and certification in areas such as electrical

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and mechanical engineering or textiles and clothing. One way of doing so would be for regulators to talk to each other early in the process when they review their respective conformity assessment procedures. The aim of this collaboration should be to reduce unnecessary regulatory divergences between technical regulations and to introduce the least burdensome conformity assessment procedures possible while guaranteeing high levels of safety.

In sum, the EU proposal **opens up a process that could lead to greater convergence** - but **without predetermining any particular outcome**. The final decision and the conclusions drawn from the joint assessment would always be with the regulators concerned, taking into account input from stakeholders. The mechanism would mostly be used in areas where regulatory approaches are sufficiently similar and benefits can be expected in reasonable time.

*- Will a focus on bilateral cooperation not hamper efforts at international level?*

Enhanced EU-US regulatory **cooperation** has often been paramount to the establishment of international regulatory disciplines, provisions or guidelines, in many international regulatory fora. Also, successful TTIP negotiations may help reignite multilateral trade talks in the WTO, in areas such as non-tariff barriers to trade.

Seen from a regulatory cooperation perspective, increased bilateral cooperation and coherence between EU and US positions in international fora could speed up important initiatives. For example, if the EU and the US were to strengthen joint engagement for the development of Global Technical Regulations for cars in UNECE (United Nations Economic Commission for Europe) they could be at the forefront of developing regulatory approaches to cover new technologies, such as hydrogen and electric cars and advanced safety technologies for such vehicles.

*Article 13* of the EU proposal (*'Promoting International Regulatory Cooperation'*) foresees that the EU and the US would cooperate with each other and with other countries in international fora to develop and promote implementation of international instruments. This ranges from bodies like UNECE or OECD to specialized fora like the International Medical Device Regulators Forum (IMDRF). In effect, EU-US regulatory cooperation should not be exclusive of third countries, but instead contribute to reinforcing wider international regulatory cooperation and instruments with the involvement of third countries.

*- How does the EU Commission's proposal square with the sovereign right to regulate?*

The EU proposal **fully recognizes** the right of each Party to regulate at the level of protection it considers adequate (this is made clear in the article on objectives, Article 1 paragraph 3). This means that in areas where the EU and the US provide for different systems or levels of protection, such as in chemicals, each side would maintain their own distinct regulatory approaches. But even in areas where the EU and the US may decide to further seek greater compatibility between their regulations (e.g. mutual equivalence of car

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safety or mutual recognition or reliance on each other's inspections of manufacturing sites for pharmaceutical products) one side may decide to introduce stricter measures. In this case, regulators would be required to inform and consult each other – but each would take their own decisions on how best to protect their citizens.

*- Is there a risk that the regulatory chapter as proposed by the EU could slow down or delay important regulatory measures such as those needed to protect consumers or the environment?*

No. The EU proposal on regulatory cooperation would not hold up regulatory outcomes. On the contrary, **early cooperation and exchange of information can help regulators to be more effective** and efficient from the start in achieving their objectives. They can learn from each other's experiences, considering what has worked and what has not in a particular situation. They can also save up resources.

Furthermore, according to Article 1 paragraph 3 - in combination with Article 12 paragraph 3 - any regulatory exchanges shall *not* prejudice the right to regulate in a timely manner in accordance with deadlines under domestic law. Neither side would be required to suspend or delay its respective regulatory processes. For example the EU processes for regulating chemical substances under REACH would not change. There, cooperation at technical/scientific level may take place, but only with due respect to the procedures and within the deadlines provided for in the EU regulations.

*- How would stakeholders be involved (Articles 5, 6, 15)?*

Interaction with **stakeholders** is crucial to achieve the objectives pursued by the Regulatory Cooperation Chapter. Stakeholders and the general public would benefit from transparency provisions ensuring early publication of lists of planned regulations and consultations on significant measures (*Article 5 'Early Information on Planned Acts'*, and *Article 6 'Stakeholder Consultations'*). Under Article 15 (*'Participation of Stakeholders'*) all stakeholders would be offered a way to submit observations and concrete suggestions to regulators which would be carefully examined by the sectoral working group in charge or directly by the Regulatory Cooperation Body (RCB).

*- Would the regulatory cooperation mechanism lead to disproportionate influence by 'big business' to the detriment of smaller interest groups with lesser resources?*

The EU proposal on regulatory cooperation reflects EU policy and best practices with regard to stakeholder consultations, conflict of interest management and the need to support smaller interest groups as well as small and medium sized enterprises. This is to ensure that all interested stakeholders are heard and their views taken into account before a proposal is put forward or a final decision taken. The Commission is charged with engaging in a detailed mapping of stakeholders concerned before it starts a consultation.

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In addition, the EU Commission's proposal contains explicit language to ensure **broad participation of all interested stakeholders**, including business, consumers, public health groups, trade unions, environmental organisations and other public interest representatives. Article 15 (*'Participation of stakeholders'*) contains more details on how this could be ensured in practice (see further below).

*- Is there a risk that regulatory cooperation would lead to future reductions in levels of protection? Or that the precautionary principle would be undermined?*

The EU text clearly states that the two parties would continue to regulate in accordance with their regulatory framework, procedures and principles. This means that the well-established **precautionary approach to regulation** in the EU would not be affected by the provisions of the Regulatory Chapter. The EU would retain the ability to maintain and develop its own approach with respect to e.g. risk assessment or risk management.

## **6. Institutional framework in section III (Articles 14-16)**

*- What would be the role the Regulatory Cooperation Body (RCB) proposed by the EU Commission?*

The EU side has proposed to establish a “**Regulatory Cooperation Body**” but this name is just a place holder for any regulatory cooperation 'body' the EU and US would agree on in TIIP.

Its core functions would be to **monitor the work done in sectors** and to **identify new opportunities** for cooperation. It would be a platform where the parties would discuss and consider the priorities for transatlantic regulatory cooperation taking into account input from stakeholders and with the full involvement of regulators and competent authorities from both sides. The focus of work would be to identify priorities for regulatory cooperation. By contrast, the RCB would not be tasked to “screen” draft regulations being considered by either side.

*- What would be the added value of the Regulatory Cooperation Body (RCB)?*

Its main added value would be to provide guidance to the **process of on-going interactive cooperation** among US regulators and EU competent authorities with the aim of increasing the level of future regulatory compatibility and convergence, where feasible. As mentioned earlier, priorities would be developed bottom-up and flow from the successful cooperation between regulators in a given area, to be extended to related areas or new areas.

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*-Who would be the members of the RCB?*

The exact composition and terms of reference of the institutional body will require further reflection. In order to be effective, **participation of high level representatives** of the **regulators** and competent authorities from both sides of the Atlantic would be required as well as representatives of those bodies or departments with a general oversight role in regulatory policy and those agencies or departments in charge of the overall implementation of TTIP. The RCB would only be composed of representatives of public bodies, although joint meetings would be organised with stakeholders on the basis of a balanced representation (i.e. business, trade unions, NGOs, etc.). The modalities for interaction with legislative bodies also require further reflection.

*- Would the RCB interfere with established decision making processes at EU or Member States' level? Would it take decisions binding the EU co-legislators?*

No. This body would not have regulatory or rule-making competences, as also clarified in Article 14 paragraph 2 subparagraph c) of the EU proposal (Article 14 'Establishment of the Regulatory Cooperation Body'). The RCB would not be a joint decision-making body, but will have a consultative role. The adoption of regulations would remain in the hands of domestic regulatory and legislative bodies or institutions. Any future initiative to further regulatory compatibility would follow the democratic process of each side, in full respect on the European side of the role of EU Member States and the European Council and Parliament, respectively. Such activity will also be conducted with the necessary transparency.

The RCB will not interfere with internal regulatory decision making by each side as it will not have any role of prior vetting or examination of draft regulations.

*- How would the RCB carry out its work? How would it interact with stakeholders and the general public?*

The RCB would work closely with other institutional bodies and committees in TTIP and with sectoral work groups to avoid duplication and overlaps. The activities of the RCB or any similar body need to be **transparent**, and updates on its work would have to be regularly published. The RCB would adopt terms of reference and meet at regular intervals. The RCB should proactively interact with stakeholders, including businesses, consumers, NGOs and trade unions, in line with best practice.

The EU Commission intends to further develop its proposal on the institutional framework regarding regulatory cooperation and sectors, taking into account input from stakeholders, once negotiations have sufficiently advanced.