TTIP- EU proposal for Chapter: Regulatory Cooperation

Preamble to the TTIP:

The Parties, having regard to:

the importance of regulatory measures to achieve public policy objectives, and each Party's right to regulate and adopt measures in accordance with that Party's respective regulatory or administrative procedures to ensure that these objectives are achieved at the level that each Party considers appropriate and does not reduce, undermine or otherwise compromise the level of protection in the relevant public policy areas.

Article x1. Objectives and general principles:

1. The objectives of this Chapter are:

    a) To establish and reinforce bilateral regulatory cooperation in areas where the Parties identify common interests and where this cooperation would benefit citizens, entities subject to regulation, in particular small and medium sized enterprises, as well as the public interest;

    b) To contribute to the Parties' activities pursuing public policy objectives such as inter alia a high level of protection of:

        i) public health; human, animal and plant life and health; health and safety; working conditions; animal welfare;
        ii) the environment;
        iii) consumers;
        iv) social protection and social security;
        v) personal data and cybersecurity;
        vi) cultural diversity;
        vii) financial stability;

whilst facilitating trade and investment.

c) To promote an effective regulatory environment, which is transparent and predictable for citizens and economic operators;

d) To promote compatible regulatory approaches and reduce unnecessarily burdensome, duplicative or divergent regulatory requirements, including through recognition of equivalence, promotion of convergence and other methods, as appropriate;

e) To further the development and implementation of internationally agreed regulatory documents[1] in order to achieve consistent regulatory outcomes with each other and with third countries.

2. Regulatory co-operation activities shall aim at improving, and not reduce, undermine or otherwise compromise the level of protection in public policy areas such as those referred to under paragraph 1 a), as considered appropriate by either Party.

3. Nothing in this Chapter shall affect the ability of each Party to:

a) adopt, maintain and apply measures without delay, in accordance with deadlines under its respective regulatory or administrative procedures, to achieve its public policy objectives such as those referred to under paragraph 1 a) at the level of protection it considers appropriate, in accordance with its regulatory framework and principles;

b) provide or support services of general interest, including those related to water, health, education or social services;

c) apply its fundamental principles governing regulatory measures in its jurisdiction, for example in the areas of risk assessment and risk management[2].

4. The provisions of this Chapter shall not oblige the Parties to achieve any particular regulatory outcome.

[1]For greater certainty, only regulatory documents adopted by international bodies or fora in which both parties' regulatory authorities participate and to which they have agreed can be considered as "internationally agreed regulatory documents" for the purposes of this Chapter. Cooperation related to voluntary consensus standards developed by private standardization bodies is not covered by the provisions of this Chapter; reference is made to [Chapters on TBT, SPS and specific and sectoral provisions -to be identified].

[2] For the EU, such principles include those established in the Treaty on the Functioning of the European Union as well as in Regulations and Directives adopted pursuant to Article 289 of the Treaty on the Functioning of the European Union.

Article x2. Definitions

For the purposes of this Chapter

a. "regulatory authorities" means:

- For the EU: the European Commission
- For the US: any rule-making authority at the central level of government, including any Executive Branch or independent agency that develops regulatory measures.

b. "regulatory measures" means measures of general applicability[3] concerning specific goods or services prepared by the regulatory authorities, including:

For the EU:

i. proposed Regulations and Directives to be submitted for adoption pursuant to Article 289 of the Treaty on the functioning of the European Union;

ii. Delegated and Implementing acts pursuant to Articles 290 and 291, respectively of that Treaty;

iii. measures which are not legally binding but have a de facto impact on rights and obligations of entities subject to regulation[4].

For the US:

i. Draft bills proposed by the US Administration to Congress;

ii. agency statements of general and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency;

iii. measures which are not legally binding but have a de facto impact on rights and obligations of entities subject to regulation[5];

[3] For greater certainty, this does not include measures addressed to individual natural or legal persons.
[4] *NB Guidance documents related to requirements for the marketing/supply of individual goods/services in the EU or the US.*

in respect to any matter covered by this Agreement.

Article x3. Scope

1. The provisions of this Chapter shall apply to:

   a) Cooperation covered by specific or sectoral provisions concerning goods and services in this Agreement *[to be identified]*;

   b) Cooperation in any other areas or sectors covered by this Agreement that has or is likely to have a significant impact on trade or investment between the Parties, in relation to which regulatory authorities of both Parties have determined common interest[6].

2. This Chapter shall not apply to regulatory measures concerning those services to which Section 1 of Chapter II [Liberalisation of investment] and Chapter III [Cross border supply of services] of Title [Services & Investment] do not apply.

3. In case of any inconsistency between the provisions of this Chapter and the provisions laid down in specific or sectoral provisions concerning goods and services *[to be identified]*, the latter shall prevail.[7]

4. Regulatory cooperation in financial services shall follow specific provisions set out in [to be identified – *Financial Services chapter/section* …..].

5. Regulatory cooperation in competition and subsidies as defined by [*to be identified* -Article x.2 of the *Competition chapter/section or Subsidies chapter/section respectively…*] shall follow specific provisions set out in that [*chapter/section*].

6. With the exception of Article x.7, this Chapter shall only impose obligations on the European Union and the United States.

[5]idem
[6]For greater certainty, it will be up to the relevant regulatory authorities of each Party to determine their interest in a particular cooperation.
[7]*NB: It remains open at this stage whether in some sectors, such as for example chemicals, such specific or sectoral provisions might have a comprehensive character*.

Article x.4 General provisions governing regulatory cooperation

1. The Parties shall pursue and keep under periodic review ongoing regulatory cooperation and, in this context, shall periodically update each other on any developments related to their upcoming regulatory measures. They agree to collaborate bilaterally and at international level with a view to identifying opportunities for cooperation and, where appropriate, aim at achieving common or compatible regulatory measures. To this end, regulatory authorities of either side will have the opportunity to propose to the regulatory authorities of the other side particular steps to deepen existing cooperation or to start new cooperation and will receive timely feed-back on their proposals. They shall incorporate in the Joint Annual Regulatory Cooperation Program referred to in Article x.6 paragraph 2 those cooperation initiatives,which they consider joint priorities and which have or are likely to have a significant impact on trade or investment between the parties.

2. When developing new or amending existing regulatory measures which will have or are likely to have an impact on cooperation:

   a) the Parties shall provide each other opportunities for cooperation and information exchange, at the earliest possible stage[8] to allow for the responsible regulatory authorities of both Parties to discuss regulatory objectives and options and any other related issue;

   b) without prejudice to the Parties' commitments under Article X.5 paragraph 3 and other international legal commitments, each Party shall take account of approaches by the other party[9], when the other Party has adopted or is planning to adopt regulatory measures on the same or a related matter.

Article x5. Specific activities promoting regulatory compatibility

[8] For greater certainty, US regulatory agencies shall provide cooperation opportunities before the launch of the (advanced) notice of proposed rulemaking or in a timely manner before adopting or consulting on a guidance document; the Commission shall provide cooperation opportunities before the Commission adopts a formal position. Such cooperation opportunities do not imply any commitment to share draft texts before they have been made public under the respective regulatory or administrative procedures.

[9]For greater certainty, this is an obligation for regulatory authorities to examine the regulatory approaches by the other party on their merits, but not to a particular result.

1. Cooperation activities towards furthering regulatory compatibility will be conducted by the relevant regulatory authorities of both Parties. These activities should promote regulatory compatibility through different means and approaches, *inter alia*:

   a) Common principles, guidelines, or codes of conduct;

   b) Mutual recognition of equivalence or harmonization of regulatory measures in whole or in part;

   c) Mutual recognition or reliance on each other's implementing tools, to avoid unnecessary duplication of regulatory requirements; such as testing, certification, qualifications, audits or inspections.

2. Natural or legal persons[10] of both parties may jointly submit to the Parties concrete and sufficiently substantiated proposals[11] for regulatory measures, which may *inter alia* include any of the means and approaches identified in paragraph 1. The Parties shall consult each other and, where they consider common approaches to be meritorious each Party shall provide timely feed-back on the submissions received and the Parties shall incorporate a cooperation initiative in the Joint Annual Regulatory Cooperation Program. Where the Parties have identified a common approach achieving further compatibility, each Party's relevant regulatory authorities shall launch the necessary regulatory procedures on this basis.

3. The Parties shall co-operate bilaterally and with third countries in international fora, with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed regulatory documents, where feasible, including through presentation of joint initiatives, proposals and approaches.

4. The Parties will promote cooperation at the stage preceding the regulatory process, including *on* research, where appropriate. This may include the exchange of any information relevant for this purpose.

[10] No class of stakeholders should be accorded privileged treatment. Particular effort should be made to seek input from small and medium sized enterprises and public interest groups.

[11] Each party should provide guidance to facilitate the submission of such proposals, taking into account in particular the needs of small and medium sized enterprises.

[Placeholder for Article on the exchange of confidential information between regulatory authorities][12]

Article x.6 Transparency and public participation

1. Regulatory cooperation shall be carried out in a transparent manner. To this effect, each Party shall:

   a) take appropriate measures to ensure that any natural or legal persons[13] are provided timely opportunities to present their views on the progress of existing regulatory cooperation, propose new initiatives and activities[14] and present their views on priority setting;

2. b) provide timely information on its assessment of any contributions received, and make the contributions publicly available, without undue delay, except to the extent necessary to protect confidential information or withhold personal data or inappropriate content.

2. A joint EU-US Annual Regulatory Cooperation Program providing an overview of ongoing and planned priority regulatory cooperation initiatives as referred to in Article x.3 paragraph 1, shall be published by each Party on a freely accessible website and shall be updated at least once a year. The initial Annual Regulatory Cooperation Program shall include, as a minimum, all activities related to future regulatory cooperation covered by specific or sectoral provisions concerning goods and services in this Agreement *[to be identified, see Article x.3 a]* and shall be published at the latest by the time of signature of this Agreement.

3. Each Party shall consult on the Joint Annual Regulatory Cooperation Program with a domestic Advisory Group composed by business including small and medium sized enterprises, trade unions and public interest groups, ensuring a balanced representation of all interests concerned.

[12] NB: Information exchanged in the course of regulatory cooperation shall only be used to further the objectives of the particular cooperation initiatives.

[13] See footnote 10.

[14] NB: idem

Article x.7 Regulatory cooperation at the non-central level[15]

1. For the purpose of this Article, "regulatory measures at non-central level" refers to regulatory measures of general applicability to be adopted by the central authorities of a State of the United States and regulatory measures of general applicability to be adopted by the central authorities of a Member State of the European Union, except those that implement acts of the European Union institutions into Member States laws.

2. The Parties agree to encourage and facilitate regulatory cooperation on regulatory measures at non-central level in accordance with the provisions of this Chapter in areas or sectors where the relevant regulatory authorities of both Parties concerned[16] responsible for the development and adoption of these measures have identified a common interest. Regulatory authorities concerned will determine the modalities of the cooperation.

3. This Article is without prejudice to more detailed specific or sectoral provisions concerning goods and services in this Agreement *[to be identified]*. [16]

Article x.8 Legislative proposals

1. This Article applies to proposed Regulations and Directives adopted by the European Commission, and to Congress bills introduced in Congress by Members of Congress.

2. The Parties shall keep each other informed in a timely manner on any legislative proposals that have or are likely to have an impact on activities covered by Article x.3 paragraph 1.

3. Each Party shall provide an opportunity within its respective regulatory or administrative procedures for the other Party to present its views on a legislative proposal.

Article x.9 Non-application of dispute settlement

The provisions of dispute settlement under Chapter XX (Dispute Settlement) do not apply to any matter arising under this Chapter.

[15] For greater certainty, this Article refers to a situation where cooperation concerns a measure at non-central level on either side.

[16] For greater certainty, the relevant regulatory authorities concerned could be the regulatory authorities as defined in Article x.2 b) of either Party on the one hand and the central authority of a State of the United States of or the central authorities of a Member State of the European Union, on the other hand, as the case may be.

[16] NB: For example, provisions in TTIP that may relate to the mutual recognition of professional qualifications that should be part of the chapter on services.

Annex

[Placeholder for provisions on the institutional set up for regulatory cooperation under TTIP]

Institutional set up for Implementation

The EU intends to submit after the February round detailed provisions on the institutional set-up to support regulatory cooperation under TTIP with a view to:

i. monitor and facilitate the application of this Chapter;
ii. ensure that proper priority is given to the implementation of specific or sectoral provisions in TTIP to pursue the cooperation initiatives agreed when TTIP is concluded;
iii. support and facilitate the determination of areas of common interest.

Below are some of the essential elements that will be required for the set-up of such an institutional mechanism for cooperation in areas considered joint priorities. These elements are meant to form the basis for formulating legal text:

- Political Accountability: Progress on regulatory cooperation needs to be regularly reviewed at Ministerial level with full participation by the relevant regulatory authorities concerned. At least once every two years a report will have to be presented by the latter to the EU-US Summit and to legislators highlighting the progress achieved in terms of specific regulatory cooperation initiatives. Such reports have to be made available to the public. Ministerial meetings will be prepared through a process that ensures full participation and involvement by the relevant regulatory authorities concerned, senior officials responsible for the implementation of TTIP and the authorities responsible for coordination of regulatory policies in both parties. In this context, particular attention should also be given by either side to ensuring proper involvement to legislators (NB: for the EU side the European Council and the European Parliament) on regulatory cooperation initiatives.

- Effective Coordination: An effective coordination structure will have to be set up to monitor and enhance progress in ongoing co-operation activities and to help to identify those initiatives that would benefit from a discussion at Ministerial meetings. Any such coordination structure requires the full involvement of the relevant regulatory authorities.

- Transparency: Stakeholder involvement is critical for the success of regulatory cooperation activities. All natural and legal persons need to be given the opportunity to provide input to ongoing regulatory cooperation initiatives and suggest new initiatives. Appropriate modalities will need to be established for a transparent dialogue with interested natural and legal persons, both at the Ministerial and working levels.

Completion of domestic regulatory or administrative procedures:

The institutional structure will provide support and advise to decision makers. It will not have the power to adopt legal acts neither will it replace any domestic EU nor US regulatory procedures which will be needed to implement regulatory cooperation initiatives. All provisions of the Regulatory Cooperation Chapter will be applied in full respect of the right to regulate to achieve public policy objectives – decisions on regulations will be made by regulatory and legislative bodies or institutions. Each side will remain fully sovereign in setting the levels of protection it deems appropriate.

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