

**Initial Provisions for**  
**CHAPTER [ ]**  
**Regulatory Cooperation**

*General notes:*

1. As TTIP negotiations progress, the provisions in this Chapter may be reviewed in the light of developments in other Chapters, and vice versa, with a view to resolving possible duplications, overlaps or inconsistencies. In particular, there is a need to consider the relationship with the TBT and SPS chapters as well as with sectoral provisions, including those on Financial Services. Sectoral provisions are intended to respond to the specific needs of a sector, and it will be important to ensure that the approaches and solutions embodied in the sectoral provisions- are not duplicative or incoherent with other parts of TTIP, including this Chapter.

2. Given that the provisions of this Chapter concern predominantly procedures for cooperation, they may not lend themselves to the application of dispute settlement rules. Alternative mechanisms for ensuring proper application could be explored, such as regular monitoring and reporting, including to the political level (Joint Ministerial Body). As regards the sectoral provisions of the TTIP regulatory cluster, further reflection will be required as regards the most appropriate mechanisms of ensuring proper application. In respect of cooperation on financial services, the EU has expressed the view that provisions should not be subject to dispute settlement.

3. This draft covers regulatory acts at "central" level, understood as EU-level and US Federal acts. However, the draft also envisages the possibility to discuss, upon request, on other regulatory acts, in particular, those adopted by the central national authorities of EU Member States or by US States. Cooperation on those other regulatory acts may need to be addressed further, in order to achieve the objective of enhancing regulatory cooperation, including in light of the discussions in particular in sectors. The EU reserves the possibility of tabling specific proposals in this regard.

4. "Party" or "the Parties" in this draft refers to the EU, on one side, and the US, on the other, consistent with the focus on regulatory acts at "central" level. In terms of the practical application of the provisions, particularly as regards the possibility to discuss regulatory acts at "non-central" level, each side will take any necessary steps, including as regards the determination of the specific actors who will implement the agreed rules.

5. The institutional and decision-making modalities in the horizontal chapter regarding the update, modification or addition of sectoral provisions will need to be discussed as

[negotiations on the regulatory cluster and the general institutional provisions of TTIP proceed.](#)

Preamble<sup>1</sup> to the TTIP: The Parties, having regard to:

- the importance of regulation~~only action~~ to achieve public policy objectives, and their right to regulate and adopt measures to ensure that these objectives are protected at the level that each Party considers appropriate, in line with its respective principles;
- ~~their shared commitment to good regulatory principles and practices, such as those laid down in the OECD Recommendation of 22 March 2012 on Regulatory Policy and Governance.....~~

## **Section I: Objectives, definitions and scope**

### **Article 1 - General Objectives and Principles**

1. The general objectives of this Chapter<sup>2</sup> are:
  - a) To reinforce regulatory cooperation thereby facilitating trade and investment in a way that supports the Parties' efforts to stimulate growth and jobs, while pursuing a high level of protection of inter alia: the environment; consumers; human, animal and plant life, ~~and~~ health and safety ~~working conditions~~; personal data; cybersecurity; cultural diversity; or as well as preserving financial stability;
  - b) To reduce unnecessarily burdensome, duplicative or divergent regulatory requirements affecting trade or investment, particularly given their impact on small and medium sized enterprises, by promoting the compatibility of envisaged and existing EU and US regulatory acts;
  - c) To promote an effective, pro-competitive regulatory environment, which is transparent and predictable for citizens and economic operators;

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<sup>1</sup> NB: These considerations are of a broader nature and would fit best in the preamble to the TTIP Agreement.

2 NB: Accordingly, the provisions as set forth in this Chapter cannot be interpreted or applied as to oblige either Party to change its fundamental principles governing regulation in its jurisdiction, for example in the areas of risk assessment and risk management

d) To further the development, adoption and strengthening of international instruments, and their timely implementation and application, as a means to ~~more effectively~~ work together more effectively with each other and with third countries to strive toward consistent regulatory outcomes.

2. The provisions of this Chapter do not restrict the right of each Party to maintain, adopt and apply measures to achieve legitimate public policy objectives, such as those mentioned in paragraph 1, at the level of protection that it considers appropriate, in accordance with its regulatory framework and principles.

3. The Parties reaffirm their shared commitment to good regulatory principles and practices, as laid down in the OECD Recommendation of 22 March 2012 on Regulatory Policy and Governance.

## Article 2- Definitions

1. For the purposes of this Chapter the following definitions shall apply:

a) “regulatory acts at central level” means:

for the EU:

i. Regulations and Directives within the meaning of Article 288 of the Treaty on the Functioning of the European Union, including:

ii. Regulations and Directives adopted under a legislative procedure in accordance with that Treaty;

iii. Delegated and Implementing acts adopted pursuant to Articles 290 and 291 of that Treaty.

for the US:

i. Federal Statutes ~~by the US Congress~~;

ii. Legislative rRules as defined in 5 USC § 551 (4), ~~guidance and orders as defined in 5 USC § 551 (6)~~, ~~–as well as guidance documents as defined in Executive Order 12,866; § 3(g)<sup>3</sup> adopted~~issued by Federal Agencies; [the latter as defined by the Administrative Procedures ActAdministrative Procedures Act (APA)APA); 5 U.S.C. Subchapter II; § 5512 (f) ~~(Definitions) para. 4 and the FOIA~~];

<sup>3</sup> 58 Fed. Reg. 51,735 (Sept. 30, 1993), as amended by Exec. Order No. 13,258, 67 Fed. Reg. 9385 (Feb. 26, 2002), as further amended by Exec. Order No. 13422 72 Fed. Reg. 2763 (Jan. 18, 2007).

iii Executive Orders [and other executive documents]-

~~b) “regulatory acts at non-central level” means:-~~

~~for the EU:-~~

~~–laws and regulations by the national authorities of an EU Member State;-~~

~~for the US:-~~

~~–laws and regulations by a US State.-~~

eb) “regulators and competent authorities at central level” means:

i. for the EU, the European Commission;

ii. for the US, US Federal agencies [defined by the Administrative Procedures Act (APA); 5 U.S.C. § 552 (f) as defined by the Administrative Procedures Act (APA); 5-U.S.C. Subchapter II; § 551 (Definitions) para. 1 ] .

~~d) “regulators and competent authorities at non-central level” means:-~~

~~i. For the EU, the national authorities of an EU Member State responsible for the preparation of regulatory acts at non-central level;~~

~~ii. For the US, the authorities at State level responsible for the preparation of regulatory acts at non-central level.~~

ec) “international instruments”<sup>4</sup> means documents adopted by international bodies or fora in which both Parties' regulators and competent authorities at central level participate, including as observers, and which provide requirements or related procedures, recommendations or guidelines on the supply or use of a service, such as for example authorization, licensing, qualification or on characteristics or related production methods, presentation or use of a product.

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4 NB: This definition captures documents produced by international bodies in which both the Commission and US federal government or one or more of its agencies participate, including for example bodies like the, UNECE, OECD, IMDRF, or the ICH; but the definition excludes bodies such as IEC, ISO, the ESOs, or US private standardisation bodies. The TBT Chapter is expected to cover cooperation in the area of product standards, generally; sectoral provisions in TTIP may also cover cooperation on standards.

### Article 3 – Scope

1. This Chapter applies to regulatory acts at central level ~~and at non-central level~~ which have or are likely to have a significant impact<sup>5</sup> on trade or investment between the Parties and:

- a) determine requirements or related procedures for the supply, or use of a service in the territory of a Party, such as for example authorization, licensing, or qualification; or
- b) determine requirements or related procedures applying to goods marketed in the territory of a Party concerning their characteristics or related production methods, their presentation or their use; and

2. Regulatory acts at central level ~~and at non-central level~~ concerning the matters covered by [specific or sectoral provisions concerning goods and services, to be identified] fall in any event within the scope of this Chapter.

3. This Chapter also applies to regulatory acts by the central national authorities of EU Member States or by US States as provided in Article 12, provided that those acts meet the criteria laid down in paragraph 1.<sup>6</sup>

~~3. The Parties shall endeavor to ensure compliance with this Chapter by authorities at levels of government lower than EU Member State or US State level in respect of regulatory acts that would otherwise fall within the scope of this Chapter.~~

### Article 4 – Relationship with sectoral provisions

1. 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.<sup>7</sup>

2. Regulatory cooperation in financial services shall follow specific provisions set out in [to be identified – *FS chapter/section....*].

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5 NB: The regulators and competent authorities at central level of each Party ~~will identify regulatory acts that may have a significant impact on EU-US trade (see also Article 9 par. 1). Further discussion will be needed on how to identify these acts.~~

6 NB: Non-central acts are only covered by the cooperation provisions in Article 12 of this Chapter.

7 NB: The relationship of specific and sectoral provisions in TTIP and the Horizontal Chapter will need to be kept under review as both sets of provisions are taking shape.

## Section II: Good Regulatory Practices

### Sub-section II.1. Transparency

[Placeholder –measures or actions may be envisaged to facilitate the availability of information of planned acts at the level of the US States or the central national authorities of EU Member States]

#### Article 5 – Early **warning information** on planned acts

1. Each Party shall make publicly available at least once a year a list of ~~planned~~ regulatory acts at central ~~and non-central~~-level<sup>8</sup>, providing information on their respective scope and objectives.<sup>9</sup>
2. For planned regulatory acts at central ~~and non-central~~-level undergoing impact assessment each Party shall make publicly available, as early as possible, information on planning and timing leading to their adoption, including on planned stakeholder consultations and potential for significant impacts on trade or investment.

#### Article 6– Stakeholder Consultations

1. When preparing regulatory acts at central ~~and non-central~~-level undergoing impact assessment, the regulating Party shall offer a reasonable opportunity for any ~~domestic or foreign~~-natural or legal person whose interests that may be potentially affected by a planned regulatory act to provide input through a public consultation process, and shall take into account<sup>10</sup> the contributions received in the finalisation of their regulatory acts. The regulating

8 NB: For the sake of clarity, every time that one provision refers to "regulatory acts at central level" it covers only those acts that fall within the scope of the Chapter, as defined in Article 3 (i.e. acts which have or are likely to have a significant impact on trade or investment and fulfill requirements of paragraph 1 a) and b) of Article 3). Draft regulatory acts proposed by the US Administration to Congress are considered as "planned" acts, as are bills introduced by Congressmen.

9 NB: Parties can in practice comply with this provision by publishing a more comprehensive list of regulatory acts.

10 NB: This is an obligation for regulators to examine comments on their merits, but not to take on board include suggestions put forward by stakeholders. The language used ("take into account") is standard in international agreements dealing with regulatory matters and consultation: for instance, see Article 2.9.4 of the TBT Agreement.

Party should make use of electronic means of communication and seek to use dedicated single access webportals, where possible.

2. [Placeholder – a provision on the publication and entry into force of adopted regulatory acts may be envisaged in this Chapter, taking into account whether a horizontal provision is included elsewhere in the TTIP text]

## Sub-section II.2 Regulatory Policy Instruments

### Article 7- Analytical Tools

1. The Parties affirm their intention to carry out, in accordance with their respective rules and procedures, an impact assessment for planned regulatory acts at central and non-central level covered under Article 3.

2. Whenever carrying out impact assessments on regulatory acts at central level, the regulating Party shall, among other aspects,<sup>11</sup> assess how the options under consideration:

- a) relate to relevant international instruments;
- b) take account of the regulatory approaches of the other Party, when the other Party has adopted or is planning to adopt regulatory acts on the same matter;
- c) impact on international trade or investment;<sup>12</sup>

3. The following provisions shall applyW-withith regard to regulatory acts at central level:

- a) the findings of impact assessments shall be published no later than the proposed or final regulatory acts at central level;
- b) the Parties shall promote the exchange of information on available scientific and economic evidence and data as well as on the methodology and economic assumptions applied in regulatory policy analysis<sup>13</sup>;

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11 NB: These would include, for instance, relevant consumer or environmental protection impacts that Parties may assess in line with their respective frameworks.

12 NB: In this context, this will include EU-US trade and investment, which is understood to include the interests of investors of the other Party.

13 NB: Any exchange of scientific information needs to respect the rules to be agreed on the exchange of confidential information, see placeholder in Article 9, and needs to be consistent with each Party's legal framework as to information protected by intellectual property rights.

c) the Parties shall promote ~~and information the~~ exchange of experience ~~and share information~~ on planned ex-post evaluations and retrospective reviews

~~4. For planned regulatory acts at non-central level each Party will endeavor to comply with paragraphs 2 and 3 of this Article.~~

### Section III: Regulatory Cooperation

[NB: See general note on the relationship of this Chapter with other TTIP Chapters]

#### Article 8 – Bilateral cooperation mechanism

1. The Parties hereby establish a bilateral mechanism to support regulatory cooperation between their regulators and competent authorities at central ~~and non-central~~ level to foster information exchange and to seek increased compatibility between their respective regulatory frameworks, where appropriate.

2. The mechanism would further aim at identifying priority areas for regulatory cooperation to be reflected in the Annual Regulatory Cooperation Programme referred to paragraph 2(a) of Article 13.

23. Each Party shall designate an office in its central administration to act as a Focal Point responsible for ~~providing and receiving~~ exchanging information about envisaged and existing regulatory acts at central ~~and non-central~~ level. Those exchanges include submissions concerning acts that are being prepared or reviewed by each Party's legislative authorities.<sup>14</sup>

~~4. Focal points shall also provide and receive information including concerning such acts, which are being prepared or reviewed by each Party's legislative authorities.~~

[Placeholder for further details on the Focal Points.]

#### Article 9- Information and Regulatory Exchanges

1. ~~When a Party Upon publication of the publishes~~ a list of planned regulatory acts referred to in Article 5.1<sup>15</sup>, ~~each Party, it~~ shall identify those acts that are likely to have a significant

14 NB: Legislative authorities would include on the EU side the Council of the EU and the European Parliament and on the US side the US Congress.

15 NB: This obligation on the US side also covers US Federal Statutes.



impact on international trade or investment, including trade or investment between the Parties, if the list goes beyond the acts falling under the scope of this Chapter, and it shall inform the other Party through their respective Focal Points.

2. A Party shall also regularly inform the other Party about proposed regulatory acts that are likely to have a significant impact on international trade or investment, including trade or investment between the Parties, where those proposed acts do not originate from the executive branch and were not included in the most recent list published pursuant to Article 5.1.

23. Upon the request of a Party made via the respective Focal Points, the Parties shall enter into an exchange on ~~envisaged-planned~~ or existing regulatory acts at central ~~or non-central~~ level.

34. Regulatory exchanges shall be led by the regulators and competent authorities at central level responsible for the regulatory acts concerned. ~~When the exchanges concern an envisaged a planned or existing regulatory act at non-central level, regulators and competent authorities at central level shall be associated upon request.~~

~~4. [Placeholder concerning Focal Points taking the necessary steps to facilitate the exchanges at non-central level.]~~

55. The Parties shall participate constructively in regulatory exchanges. In addition to the information made available in accordance with Article 5 a Party shall provide to the other Party, if the other Party so requests, ~~any~~ complementary available information, including ~~any~~ available relevant scientific evidence and data related to the planned regulatory acts under discussion.

*[Placeholder for Article on exchange of confidential information between regulators and competent authorities at central ~~and non-central~~ level]—*

66. The cooperation may take the form of meetings, written exchanges or any other appropriate means of direct communication. Each point of substance raised by one Party shall be addressed and answered by the other Party.

77. Each Party shall communicate without delay to its legislative authorities and via its Focal point specific written comments or statements received from the other Party concerning regulatory acts at central level which are being prepared or reviewed by those bodies.<sup>16</sup>

## Article 10 – Timing of Regulatory Exchanges

<sup>16</sup> N.B.: Legislative bodies are under no obligation to include suggestions put forward by the other Party.

1. When a regulatory exchange on ~~an envisaged~~ a planned or existing regulatory act at central level is requested under Article 9 paragraph 2, it shall start promptly.
2. With regard to ~~envisaged~~ planned regulatory acts at central ~~or non-central~~ level, regulatory exchanges may take place at any stage of their preparation-<sup>17</sup>. ~~They~~ Exchanges may continue until the adoption of the regulatory act.-
3. Regulatory exchanges shall ~~be without~~ not prejudice ~~to~~ the right to regulate in a timely manner, particularly in cases of urgency or in accordance with deadlines under domestic law. Nothing in this Chapter obliges a Party to suspend or delay steps foreseen under its domestic regulatory procedure.

### **Article 11 – Promoting regulatory compatibility**

1. This Article shall apply to areas of regulation where mutual benefits can be realised without compromising the achievement of legitimate public policy objectives such as those mentioned in Article 1.
2. When a regulatory exchange has been initiated pursuant to Article 9 with regard to a ~~planned~~ ~~envisaged~~ or existing regulatory act at central level, a Party may propose to the other Party a joint examination of possible means to promote regulatory compatibility, including through the following methods:
  - a) Mutual recognition of equivalence of regulatory acts, in full or in part, based on evidence that the relevant regulatory acts achieve equivalent outcomes as regards the fulfilment of the public policy goals pursued by both Parties;
  - b) Harmonisation of regulatory acts, or of their essential elements, through:
    - i. Application of existing international instruments or, if relevant instruments do not exist, cooperation between the Parties to promote the development of a new international instrument; ~~or~~
    - ii. Approximation of rules and procedures on a bilateral basis; ~~or~~

e) Simplification of regulatory acts in line with shared legal or administrative principles and guidelines.

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<sup>17</sup> For greater certainty, a dialogue may take place: (a) in the case of the US, before the publication of a draft for consultation or (b) in the case of the EU, before the adoption of a Commission proposal.

23. A proposal under paragraph 1 shall be duly substantiated, including as regards the choice of the method. The Party receiving a proposal for a joint examination shall respond to the requesting Party without undue delay informing the latter of its decision. ~~The Every~~ response should be substantiated.

34. In addition to regulatory exchanges pursuant to Article 9, the Parties agree to cooperate, in areas of common interest with respect to pre-normative research, and to exchange scientific and technical information relevant for this purpose.<sup>18</sup>

#### Article 12 – Exchanges on regulatory acts at non-central level

1. The Parties agree to enter into regulatory exchanges, upon a substantiated request by a Party, with regard to a planned or existing regulatory act of US States or of the central national authorities of EU Member States which have or are likely to have a significant impact on trade and investment between the EU and the US.

2. Such regulatory exchanges should take place on the basis of the modalities laid down in paragraphs 2 to 7 of Article 9, paragraph 3 of Article 10, and Article 11, with the involvement of the regulators and competent authorities responsible for the regulatory acts and the regulators and competent authorities at central level.

#### **Article 13 – Promoting International Regulatory Cooperation**

1. The Parties agree to co-operate between themselves, and with third countries, with a view to strengthening, developing and promoting the implementation of international instruments *inter alia* by ~~examining the feasibility of~~ presenting joint initiatives, proposals and approaches in international bodies or fora, especially in areas where regulatory exchanges have been initiated or concluded pursuant to this Chapter and in areas covered by [specific or sectoral provisions – to be identified] of this Agreement.

2. The Parties reaffirm their intention to implement within their respective domestic systems those international instruments they have contributed to, as provided for in those international instruments

#### **Article 14- Establishment of the Regulatory Cooperation Body**

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18 NB: See Footnote 13.

1. The Parties hereby establish a Regulatory Cooperation Body (hereafter "RCB") in order to monitor and facilitate the implementation of the provisions set out in this Chapter and of the [specific or sectoral provisions concerning goods and services – to be identified] of this Agreement.

2. The RCB's functions shall be:

- a) The preparation and publication of an Annual Regulatory Co-operation Programme reflecting common priorities of the Parties and the outcomes of past or ongoing regulatory cooperation initiatives under section III of this Chapter, including information on the follow-up, the steps envisaged and timeframes proposed in relation to these identified common priorities;
- b) The monitoring of the implementation of the provisions of this Chapter, ~~as well as the~~ including the [specific or sectoral provisions concerning goods and services<sup>19</sup>] of this Agreement, and reporting to the Joint Ministerial Body on the progress in achieving agreed co-operation programmes;
- c) [Placeholder on technical preparation of proposals for the update, modification or addition of sectoral provisions. The RCB will not have the power to adopt legal acts]  
~~The preparation of the decisions of the Joint Ministerial Body as far as they relate to this Chapter, or the [specific or sectoral provisions in annexes X, Y, Z concerning goods and services to be identified] of this Agreement; this includes any technical updating of these provisions, where expressly foreseen by individual provisions of the Agreement decisions to amend or extend [the specific sectoral provisions in Annexes X, Y, Z], or and the preparation of proposals for amending these provisions, or the addition of new Annexes concerning other goods or services' sectors, as the case may be, in line with the respective domestic procedures applied by each Party; [NB: there should be a parallel provision in the institutional chapter empowering the joint ministerial body]~~
- d) The consideration of new initiatives for regulatory co-operation, on the basis of input from either Party or its stakeholders, as the case may be, including of proposals for increased regulatory compatibility in accordance with Article 11;
- e) The preparation of joint initiatives or proposals for international regulatory instruments in line with Article 13.2 paragraph 1 ~~lit. b)~~;
- f) Ensuring transparency in regulatory cooperation between the Parties;

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<sup>19</sup> NB: This is without prejudice to the specific mechanisms foreseen in the specific or sectoral provisions of TTIP to ensure their proper application and implementation.

- g) The examination of any other issue concerning the application of this Chapter or of [specific or sectoral provisions concerning goods and services] raised by a Party.

~~Any other functions that the Joint Ministerial Body may decide.~~

3. In the domain of financial services the functions as set out under in paragraph 2 shall be performed by the [Joint EU/US Financial Regulatory Forum (FRF)], which shall ensure appropriate information to the RCB. Any decisions concerning financial services should be taken by the competent authorities acting within the framework of the FRF.

4. The RCB may create sectoral working groups [as defined in annex x] and delegate certain tasks to them or to such other working groups that may be set up by the Joint Ministerial body.

5. The agenda and the minutes of the meetings of the RCB shall be made public.

*[6. Placeholder – provisions on the interaction of the RCB with legislative bodies ~~and non-central authorities~~]*

#### **Article 15- Participation of stakeholders**

1. The RCB shall hold, at least once a year, a meeting open to the participation of stakeholders to exchange views on the Annual Regulatory Co-operation Programme.

2. The annual meeting shall be prepared jointly by the co-chairs of the RCB and shall involve *[NB: depending on whether these groups are established]* the co-chairs of the Civil Society Contact Groups, including a balanced representation of business, consumers, trade unions, environmental groups and other relevant public interest associations *[to be agreed in more detail in the Rules of Procedures of the RBC, see Article 15 par. 2]. Participation of stakeholders –shall not be conditional on them being directly affected by the items on the agenda of each meeting.*

3. Each Party shall provide for means to allow stakeholders to submit their general views and observations or to present to the RCB concrete suggestions for further regulatory co-operation between the Parties. Any concrete suggestion received from stakeholders by one Party shall be referred to the other Party and shall be given careful consideration by the relevant sectoral working group that shall present recommendations to the RCB. If a relevant sectoral working group does not exist, the suggestion shall be discussed directly by the RCB. A written reply shall be provided to stakeholders who presented their general views and observations or concrete suggestions without undue delay.

#### **Article 16 –Composition and Rules of Procedure**

1. The RCB shall be composed of representatives of both Parties. It shall be co-chaired by senior representatives of each Party of regulators and competent authorities, in charge of regulatory affairs, regulatory coordination activities and international trade matters.
2. Each Party shall nominate their representatives in the RBC by (date) and provide relevant information and contact details.
- ~~23.~~ *[Placeholder for more detailed provisions on the composition and Rules of Procedure of the RCB].*