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.

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. 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. As regards the references to a "Party" or "the Parties", there may be a need to introduce some clarifications about the actors involved in the actual implementation of certain provisions –in principle, as a general rule, it is the authorities directly responsible for any given regulatory act that are expected to make the notifications or other steps in relation to that act (e.g. in the case of an EU Regulation, the EU authorities; in the case of an EU Member State regulation, the authorities of that Member State)

Preamble[1] to the TTIP: The Parties, having regard to:

- the importance of regulatory action to achieve public policy objectives, and their right to adopt measures to ensure that these objectives are protected at the level that each Party considers appropriate;

- 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……

[1] *NB: These considerations are of a broader nature and would fit best in the preamble to the TTIP Agreement*.

Section I: Objectives, definitions and scope

Article 1 - General Objectives and Principles

1. The general objectives of this Chapter 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 the environment, consumers, human, animal and plant life and health and safety working conditions, personal data, cultural diversity 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 a transparent and predictable regulatory environment for citizens and economic operators;

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 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 adopt and apply measures to achieve legitimate public policy objectives at the level of protection that it considers appropriate, in accordance with its regulatory framework and principles.

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:

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

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

for the US:

i. Statutes by the US Congress;

ii. Legislative rules, guidance and orders by Federal Agencies [as defined by the Administrative Procedures Act (APA); 5 U.S.C. Subchapter II; § 551 (Definitions) para. 4 and the FOIA].

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.

c) "regulators and competent authorities at central level" means:

i. for the EU, the European Commission;

ii. for the US, US Federal agencies [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.

e) "international instruments" 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.

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 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. 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.

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

Section II: Good Regulatory Practices

Sub-section II.1. Transparency

Article 5 – Early warning 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, providing information on their respective scope and objectives.

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 that may be potentially affected by a planned regulatory act to provide input through a public consultation process, and shall take into account the contributions received in the finalisation of their regulatory acts. The regulating Party should make use of electronic means of communication.

2. [Placeholder – a provision on the publication and entry into force of adopted regulatory acts may be envisaged, 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 regulatory acts falling under the scope of this Chapter as set out in Article 3.

2. Whenever carrying out impact assessments on regulatory acts at central level, the regulating Party shall, among other aspects, 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.

3. The following provisions shall apply with 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;

c) the Parties shall promote and exchange experience on ex-post evaluations and retrospective reviews.

4. For 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. 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.

2. Each Party shall designate an office in its central administration to act as a Focal Point responsible for providing and receiving information about envisaged and existing regulatory acts at central and non-central level, 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. Upon publication of the list of planned regulatory acts referred to in Article 5.1, each Party shall identify those that are likely to have a significant impact on international trade or investment, including trade or investment between the Parties, and shall inform the other Party through their respective Focal Points.

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

3. Regulatory exchanges shall be led by the regulators and competent authorities responsible for the regulatory acts concerned. When the exchanges concern an envisaged 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.]*

5. The Parties shall participate constructively in regulatory exchanges. In addition to the information made available in accordance with Article 5 a Party shall, if so requested, provide to the other Party 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]

6. The cooperation may take the form of meetings, written exchanges or any other appropriate means of direct communication.

7. 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.

Article 10 – Timing of Regulatory Exchanges

1. When a regulatory exchange on an envisaged or existing regulatory act is requested, it shall start promptly.

2. With regard to envisaged regulatory acts at central or non-central level, regulatory exchanges may take place at any stage of their preparation. They may continue until the adoption of the regulatory act.

3. Regulatory exchanges shall be without prejudice to the right to regulate in a timely manner, particularly in cases of urgency or in accordance with deadlines under domestic law.

Article 11 – Promoting regulatory compatibility

1. When a regulatory exchange has been initiated pursuant to Article 9 with regard to an 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 instrument; or

   ii. Approximation of rules and procedures on a bilateral basis.

2. 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 response should be substantiated.

3. In addition to regulatory exchanges pursuant to Article 9, the Parties agree to cooperate with respect to pre-normative research, and to exchange scientific and technical information relevant for this purpose.

Article 12 – 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 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 13- Establishment of the Regulatory Cooperation Body

1. The Parties hereby establish a Regulatory Cooperation Body (hereafter "RCB") in order to facilitate the implementation of the provisions set out in this Chapter and of the [specific or sectoral provisions – 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;

b) The monitoring of the implementation of this Chapter, as well as the [specific or sectoral provisions] of this Agreement, including progress in achieving agreed co-operation programmes;

c) The preparation of the decisions of the Joint Ministerial Body as far as they relate to this Chapter, or the [specific sectoral provisions in annexes X, Y, Z] of this Agreement; this includes any decisions to amend or extend [the specific sectoral provisions in Annexes X, Y, Z], or the addition of new Annexes concerning other goods or services' sectors, as the case may be; [*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 12 paragraph 1 lit. b);

f) Ensuring transparency in regulatory cooperation between the Parties;

g) 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]

Article 14 –Composition and Rules of Procedure

1. The RCB shall be co-chaired by representatives of each Party in charge of regulatory affairs, regulatory coordination activities and of international trade matters.

2. [Placeholder for more detailed provisions on the composition and Rules of Procedure of the RCB].

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 representatives of business, consumers, trade unions, environmental groups and other relevant public interest associations.

3. Each Party shall provide for means to allow stakeholders to present concrete suggestions for further regulatory co-operation. 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 suggestions without undue delay.

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