

*This **TEXTUAL PROPOSAL** is the European Union's proposal for legal text on "Good Regulatory Practices" in TTIP. It was tabled for discussion with the US and made public on 21 March 2016. The actual text in the final agreement will be a result of negotiations between the EU and US.*

## **TTIP- EU proposal for Chapter: Good Regulatory Practices**

### **Article 1 - General Provisions**

1. The Parties reaffirm their shared commitment to good regulatory principles and practices to achieve public policy objectives based on a high level of protection, while facilitating trade and investment.
2. Nothing in this Chapter shall affect the rights 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, in accordance with its regulatory framework and principles;
  - (b) apply its fundamental principles governing decision-making in its jurisdiction, for example in the areas of risk assessment and risk management.<sup>1</sup>
3. This Chapter shall only impose obligations on the European Union and the United States.

### **Article 2 - Definitions**

For the purposes of this Chapter:

- a) "regulatory acts" means acts of general applicability<sup>2</sup>:

for the EU:

- i. proposed Regulations and Directives 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.

for the US:

- i. Draft bills introduced by Members of Congress in Congress (with respect to Article 5 of this chapter)

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<sup>1</sup> 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.

<sup>2</sup> For greater certainty, this does not apply to measures addressed to individual natural or legal persons.

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ii. Draft bills proposed by the US Administration to Congress

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

in respect to any matter covered by this Agreement.

b) "regulatory authorities" means:

i. for the EU, the European Commission;

ii. for the US, any rule-making authority at the central level of government, including any Executive Branch or independent agency that develops regulatory acts.

### **Article 3 – Internal coordination**

Each Party shall maintain internal coordination processes or mechanisms in order to foster good regulatory practices, including transparent planning, stakeholder consultation, impact assessments and retrospective evaluations of regulatory acts.

### **Article 4 - Description of Regulatory Processes**

Each Party shall make publicly available a description of the processes and mechanisms employed by its regulatory authorities to develop and to review regulatory acts, including the applicable guidelines, rules or procedures which allow the public to provide input to the development of regulatory acts.

### **Article 5 – Early information**

1. Each Party shall make publicly available at least once a year a list of planned major<sup>3</sup> regulatory acts. Such list shall provide information on the scope and objectives of the regulatory acts.
2. For planned major regulatory acts 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, investment and on small and medium sized enterprises (SMEs).

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<sup>3</sup> Regulatory authorities of each Party define "major" regulatory acts.

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## **Article 6 – Stakeholder Consultations**

1. When preparing regulatory acts, each Party shall, in accordance with its respective rules and procedures:
  - a. offer a reasonable opportunity for any natural or legal person, on a non-discriminatory basis, to provide input;
  - b. publish either draft regulatory acts or consultation documents that provide sufficient details about a possible new regulatory act to allow natural or legal persons and the other Party to assess whether and how their interests might be significantly affected;
  - c. consider the contributions received.
2. Each Party should make use of electronic means of communication and seek to use dedicated single access web portals, where possible.
3. Each Party shall make publicly available any comments it receives, except to the extent necessary to protect confidential information or withhold personal data or inappropriate content.
4. In publishing a proposed or final regulatory act<sup>4</sup> each Party shall endeavor to provide a publicly available explanation of the results of the consultation process.

## **Article 7 - Feedback on the existing regulatory framework**

Each Party shall offer the opportunity for any natural or legal person to submit views to the relevant regulatory authority on improvements to existing regulatory frameworks, including whether a regulatory framework has become ineffective at protecting health, environment, welfare, safety or other public policy objectives, or suggestions for simplification and burden reduction.

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<sup>4</sup>For greater certainty, this obligation may be met by publication of a separate but contemporaneous document.

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## **Article 8 – Regulatory Impact Assessment**

1. Each Party affirms its intention to carry out, in accordance with its respective rules and procedures, a regulatory impact assessment for planned regulatory acts.
2. When carrying out a regulatory impact assessment in accordance with paragraph 1, each Party shall ensure that it:
  - a. considers the need for the proposed regulatory act and the nature and the significance of the problem the regulatory act is intended to address;
  - b. examines feasible regulatory and non-regulatory alternatives (including the option of not regulating), if any, that would achieve the objective of the regulatory act;
  - c. assesses potential short and long term social, economic, and environmental impacts of such alternatives and the anticipated costs and benefits (quantitative, qualitative, or both, recognising that some costs and benefits are difficult to quantify).
3. When carrying out a regulatory impact assessment in accordance with paragraph 1, special attention shall be given to the impact of the regulatory act in development on SMEs.
4. Within the overall framework of their regulatory impact assessments in accordance with paragraph 1, the regulatory authority shall, among other aspects, assess how the options under consideration:
  - a. relate to relevant internationally agreed regulatory documents<sup>5</sup>;
  - 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<sup>6</sup>;
  - c. have an impact on international trade or investment.
5. The findings of regulatory impact assessments shall be published no later than the proposed or final regulatory acts.
6. The Parties shall promote the exchange of information on available relevant evidence and data, on their practices in assessing impacts on international trade or

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<sup>5</sup> 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 provision.

<sup>6</sup> For greater certainty, this is an obligation for regulatory authorities to examine the approaches of the other Party on their merits, but not to a particular result.

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investment, as well as on the methodology and economic assumptions applied in regulatory policy analysis<sup>7</sup>.

#### **Article 9 – Retrospective Evaluation**

1. Each Party shall maintain procedures or mechanisms to promote periodic retrospective evaluations of regulatory frameworks.
2. The Parties shall promote the exchange of experience and share information on planned retrospective evaluations.
3. Each Party shall make publicly available the results of any such retrospective evaluations.

#### **[Article 10 Placeholder for a provision on Regulatory repository]**

#### **Article 11 – Non-application of dispute settlement**

Chapter XX (Dispute Settlement) does not apply to this Chapter.

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<sup>7</sup> Any exchange of information needs to respect the rules to be agreed on the exchange of confidential information and needs to be consistent with each Party's legal framework as to confidential information and information protected by intellectual property rights.