

*This **document** is the European Union's (EU) proposal for a legal text on goods regulatory practices and regulatory cooperation in the EU-Japan FTA. It has been tabled for discussion with Japan. The actual text in the final agreement will be a result of negotiations between the EU and Japan.*

**DISCLAIMER:** *The EU reserves the right to make subsequent modifications to this text and to complement its proposals at a later stage, by modifying, supplementing or withdrawing all, or any part, at any time.*

## **EU proposal for Chapter on Good Regulatory Practices and Regulatory Cooperation**

### **EU-Japan FTA**

#### **Section A**

#### **General Provisions**

#### **Article 1**

#### **Objectives and General Principles**

1. The objectives of this Chapter are to promote good regulatory practices and regulatory cooperation between the Parties with the aim to enhance bilateral trade and investment by:
  - (a) discussing regulatory measures, practices or approaches of a Party which affect or may affect bilateral trade or investment;
  - (b) promoting an effective, transparent and predictable regulatory environment;
  - (c) promoting compatible regulatory approaches and reducing unnecessarily burdensome, duplicative or divergent regulatory requirements;
  - (d) reinforcing Parties' bilateral cooperation in international fora.
  
2. Nothing in this Chapter shall affect the right of either Party to define or regulate its own levels of protection in pursuit or furtherance of its public policy objectives in areas such as:
  - (a) public health; human, animal and plant life and health; health and safety; labour conditions; animal welfare;
  - (b) the environment;
  - (c) consumers;

- (d) social protection and social security;
  - (e) personal data and cybersecurity;
  - (f) cultural diversity;
  - (g) financial stability.
3. Nothing in this Chapter shall be construed as to hinder a Party to:
- a) adopt, maintain and apply regulatory measures in accordance with its legal framework, principles, in particular the precautionary principle, and deadlines, to achieve its public policy objectives at the level of protection it deems appropriate;
  - b) provide or support services of general interest, including those related to water, health, education or social services.
4. Regulatory measures shall not constitute a disguised barrier to trade.
5. This Chapter shall not be construed as obliging the Parties to achieve any particular regulatory outcome.
6. This Chapter does not apply to regulatory authorities and regulatory measures, practices or approaches of the Member States of the European Union.

## **Article 2**

### **Definitions**

For the purposes of this Chapter:

- (a) "regulatory authority" means:
- (i) for the European Union: the European Commission;
  - (ii) for Japan: [...].
- (b) "regulatory measures" means measures of general applicability, which are:
- (i) for the European Union:
    - (1) regulations and directives, as provided in Article 288 of the Treaty on the Functioning of the European Union (TFEU);
    - (2) implementing and delegated acts, as provided in Article 290 and Article 291 TFEU, respectively;
  - (ii) For Japan[...]

### **Article 3**

#### **Scope**

1. This Chapter shall apply to regulatory measures issued by regulatory authorities in respect to any matter that may affect trade or investment.
2. Section C {Regulatory Cooperation} and Section D {Institutional and Final Provisions} shall in addition apply to other measures of general application issued by regulatory authorities, which are relevant for the regulatory cooperation activities, such as guidelines, policy documents or recommendations, including measures which are not legally binding but have de facto an impact on rights and obligations of entities subject to regulation.

### **Section B**

#### **Good Regulatory Practices**

### **Article 4**

#### **Internal coordination**

Each Party shall maintain internal coordination processes or mechanisms to foster good regulatory practices, including those set forth in this Chapter.

### **Article 5**

#### **Regulatory Processes and Mechanisms**

Each Party shall make publicly available descriptions of its processes and mechanisms used by its regulatory authority to prepare, evaluate or review regulatory measures. These descriptions shall refer to relevant guidelines, rules or procedures, including those regarding opportunities for the public to provide input.

## **Article 6**

### **Early Information on Planned Regulatory Measures**

1. The regulatory authority of each Party shall make publicly available at least once per year a list of its planned major<sup>1</sup> regulatory measures, together with a brief description of their scope and objectives.
2. With respect to the major regulatory measures included in the list referred to in paragraph 1, the regulatory authority of each Party shall make publicly available, as early as possible, the estimated timing for their adoption, including opportunities for public consultations. It should also provide an indication whether the regulatory authority anticipates that these measures will have a significant impact on trade or investment and on small and medium sized enterprises (SMEs).

## **Article 7**

### **Public Consultations**

1. When preparing major regulatory measures, the regulatory authority of each Party shall, in accordance with its respective rules and procedures:
  - (a) publish either draft regulatory measures or consultation documents that provide sufficient details about a possible new regulatory measure to allow any person to assess whether and how his/her interests might be significantly affected;
  - (b) offer reasonable opportunities for any person, on a non-discriminatory basis, to provide input; and
  - (c) consider the input received.
2. The regulatory authority of each Party should make use of electronic means of communication and seek to maintain a dedicated single access web portal for the purposes of providing information and receiving input related to public consultations.
3. The regulatory authority of each Party shall make publicly available any input it receives, as well as a summary of the results of the consultations, except to the extent

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<sup>1</sup> The regulatory authority of each Party may determine what constitute "major" regulatory measures for the purposes of its obligations under this Chapter.

necessary to protect confidential information or withhold personal data or inappropriate content.

## **Article 8**

### **Impact Assessment**

1. The regulatory authority of each Party affirms its intention to carry out, in accordance with its respective rules and procedures, an impact assessment of major regulatory measures it is preparing.
2. When carrying out an impact assessment, the regulatory authority of each Party shall establish and maintain processes and mechanisms under which the following factors will be taken into consideration:
  - (a) the need for the regulatory measure, including the nature and the significance of the problem the regulatory measure intends to address;
  - (b) feasible and appropriate regulatory and non-regulatory alternatives (including the option of not regulating), if any, that would achieve the Party's public policy objective; and
  - (c) to the extent possible and relevant, the potential social, economic and environmental impact of those alternatives, including on trade and investment and on SMEs.
  - (d) how the options under consideration relate to relevant international standards, including the reason for any divergence, where appropriate.
3. The regulatory authority of each Party shall publish the findings of its impact assessments no later than the publication of the related proposed or final regulatory measure.

## **Article 9**

### **Retrospective Evaluation**

1. The regulatory authority of each Party shall maintain processes or mechanisms to promote periodic retrospective evaluation of regulatory measures put into effect.
2. The regulatory authority of each Party shall make publicly available its plans for and the results of such retrospective evaluations.
3. The regulatory authority of each Party shall provide the opportunity for any person to submit input on improvements to regulatory measures put into effect, including suggestions for simplification or for reduction of unnecessary burdens, while continuing to achieve the Party's public policy objectives<sup>2</sup>.

## **Article 10**

### **Exchange of Information on Good Regulatory Practices**

The regulatory authorities of the Parties shall endeavour to exchange information on their good regulatory practices as set out in this Section such as practices regarding impact assessments, including the assessment of the effect on trade and investment, or regarding retrospective evaluations.

## **Section C**

### **Regulatory Cooperation**

## **Article 11**

### **Regulatory Cooperation Activities**

1. Where a Party decides to propose a regulatory cooperation activity, it shall present a proposal to the other Party via the Contact Point designated under Article 14 of this Chapter.

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<sup>2</sup> No class of persons should be accorded privileged treatment. Particular effort should be made to seek input from small and medium sized enterprises and public interest groups.

2. The other Party shall review the proposal in due course and shall inform the proposing Party whether it considers the proposed activity suitable for regulatory cooperation.
3. Upon the request of either Party a proposal shall be discussed in the Regulatory Cooperation Committee established in Section D, Article 13.
4. In order to identify suitable opportunities for regulatory cooperation, each Party shall consider:
  - (a) the list that the other Party has published pursuant to Article 6 of Section B {Good Regulatory Practices};
  - (b) proposals for regulatory cooperation activities submitted by persons of either Party which are duly justified and accompanied by supporting evidence.
5. Where the Parties decide to engage in a regulatory cooperation activity, the relevant regulatory authorities of each Party shall:
  - (a) inform the relevant regulatory authorities of the other Party about the development of new or the revision of existing measures that are relevant for the regulatory cooperation activity;
  - (b) upon request, provide information and discuss measures relevant for the regulatory cooperation activity;
  - (c) when developing new regulatory or other measures or revising existing regulatory or other measures, consider, to the extent feasible, any regulatory approaches by the other Party on the same or a related matter.
6. The Parties may undertake regulatory cooperation activities on a voluntary basis. For greater certainty, a Party is not required to enter into any particular regulatory cooperation activity, and may refuse to cooperate or may withdraw from cooperation. However, if a Party refuses to engage in regulatory cooperation or withdraws from it, it should explain the reasons for its decision to the other Party.

## **Article 12**

### **Good Practices to Promote Regulatory Compatibility**

Each Party shall encourage its regulatory authorities to consider as appropriate, *inter alia*, the following mechanisms:

- (a) promotion of, *inter alia*, common principles, guidelines or codes of conduct, mutual recognition of equivalence and implementing tools to avoid unnecessary duplication of regulatory requirements such as testing, qualifications, audits or inspections;
- (b) cooperation, where feasible, bilaterally and with third countries in relevant international fora with a view to developing and promoting the adoption and implementation of international regulatory standards, guidelines or other approaches, including through joint initiatives and proposals.

## **Section D**

### **Institutional and Final Provisions**

## **Article 13**

### **Regulatory Cooperation Committee**

1. A Regulatory Cooperation Committee is hereby established to enhance and promote good regulatory practices and regulatory cooperation between the Parties in accordance with this Chapter.
2. The Regulatory Cooperation Committee shall be co-chaired by a senior representative of the European Commission at the level of a Director General or by his or her designate, and a senior representative of Japan at the level of [...] or by his or her designate, and shall comprise officials of the relevant regulatory authorities of each Party. The Parties may, by mutual consent, invite interested persons to participate in the meetings of the Committee.
3. The Regulatory Cooperation Committee may, in particular:

- (a) discuss proposals for regulatory cooperation;
- (b) promote good regulatory practices;
- (c) recommend regulatory cooperation activities on matters of interest to both Parties, including on pre-regulatory research;
- (d) promote bilateral regulatory cooperation activities with the aim of facilitating compatible regulatory outcomes in each Party, in particular in areas where no regulatory measures exist or where their development is at an initial stage;
- (e) support the development of practical mechanisms, tools and best practices to promote regulatory cooperation and good regulatory practices;
- (f) encourage regulatory cooperation and coordination in international fora, including periodic bilateral exchange of information on relevant ongoing or planned activities;
- (g) identify and endorse periodically priority areas of regulatory cooperation;
- (h) provide guidelines, if necessary, to help streamlining the regulatory cooperation of the Specialised Committees referred to in Articles XX and of other bilateral regulatory cooperation *fora*;
- (i) consider the report on the outcome of the consultations referred to in Article 15 (7) and review the progress on the implementation of the satisfactory solution under Article 15 (5), if applicable; and
- (j) establish *ad hoc* working groups to pursue specific regulatory cooperation activities which shall report to the Regulatory Cooperation Committee.

4. The Regulatory Cooperation Committee shall:

- (a) meet within one year from the date of entry into force of this Agreement and at least once per year thereafter, unless the Parties decide otherwise;
- (b) adopt its rules of procedure at its first meeting after the entry into force of this Agreement; and
- (c) report to the Joint Committee on the implementation of this Chapter, as appropriate.

**Article 14**  
**Contact Points**

Upon entry into force of the Agreement, each Party shall designate a contact point for the implementation of this Chapter and for exchange of information under Article 15.

**Article 15**  
**Exchange of Information**

1. The contact point of each Party shall submit and respond to requests for information and clarifications regarding planned or existing regulatory measures that affect or may affect bilateral trade or investment. Each Party shall endeavour to provide the requested information promptly to the other Party as appropriate.
2. The contact point of each Party shall receive requests of a Party (hereinafter referred to as "requesting Party") to consider its concerns about a planned or existing regulatory measure of the other Party (hereinafter referred to as "responding Party") which affects or may affect bilateral trade or investment. In its request, the requesting Party shall identify the regulatory measure at issue, provide a description of its concerns and submit questions, where relevant.
3. The responding Party shall, within [xx] days after the receipt of the request by the contact point, provide written comments as regards the concerns raised by the requesting Party to the extent possible, including *inter alia* on the policy objective of the regulatory measure, its rationale, and, where relevant, an explanation as to the absence of a less trade or investment restrictive measure which could achieve the same policy objective with the same efficiency. The responding Party shall reply to any questions for clarification submitted by the requesting Party.
4. After the requesting Party has received the written comments provided by the responding Party or in case the responding Party does not reply within the time period referred to in paragraph 3, the requesting Party may request consultations, through meetings or via electronic means, with the responding Party. Each Party shall appoint an official responsible for conducting the meetings.

5. During the consultations the Parties shall explore in good faith a possible satisfactory solution to address the concerns of the requesting Party, including proposals for an adjustment of the measure at issue or for the adoption of a less trade or investment restrictive measure, where relevant.
6. The Parties shall not be required to disclose confidential or sensitive information or data.
7. A report on the outcome of the consultations shall be prepared by the requesting Party, in consultation with the responding Party. The contact point of the requesting Party shall send the report to the Regulatory Cooperation Committee for consideration.
9. The request referred to in paragraph 2 can be sent also in cases in which no satisfactory solution has been reached at the level of the relevant Specialised Committee and is without prejudice to the Parties' rights and obligations under Chapter X (Dispute Settlement) or under the dispute settlement procedure of any other applicable agreement.
10. The request referred to in paragraph 2 shall not require the responding Party to achieve a particular regulatory outcome and shall not delay the adoption of a regulatory measure.

## **Article 16**

### **Relation to other Chapters**

*[N.B. The possible exclusion of the application of the current chapter to other areas or chapters of this agreement will be reviewed after the finalisation of the negotiations of the other chapters to ensure a consistent approach. The chapter shall be without prejudice to any specific rules established under other Chapters of this agreement.]*

## **Article 17**

### **Dispute Settlement**

Chapter X (Dispute Settlement) shall not apply to this Chapter.

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