

Initial Provisions for

CHAPTER []

**[EU: REGULATORY COOPERATION] [US: REGULATORY COHERENCE,
TRANSPARENCY, AND OTHER GOOD REGULATORY PRACTICES]**

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[EU: Section I: Objectives, Definitions and Scope]

[Article X.1:] [EU: 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, *inter alia*, the environment, consumers, working conditions, human, animal and plant life; health and safety, personal data, cybersecurity, cultural diversity, or 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;

(d) To further the development, adoption and strengthening of international instruments, and their timely implementation and application, as a means to 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 X.2:] Definitions

[EU: 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.

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for the US:

- i. Federal Statutes;
- ii. (A) Rules as defined in 5 USC § 551 (4);
(B) Orders, as defined in 5 USC § 551 (6); and
(C) Guidance documents. As defined in Executive Order 12,866 §3(g) issued by any federal agency, government corporation, government controlled corporation or establishment in the executive branch of government covered by 5 USC § 522 (f) (1) of the Administrative Procedures Act, as amended;
- iii. Executive Orders and {other executive documents that lay down general rules or mandate conduct by government bodies}.

(b) “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)}.

(c) {Placeholder: “regulatory acts, regulators and competent authorities at non-central level: means: “to be defined”}

(d) “**international instruments**” means document 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.]

[US: For Purpose of this Chapter: “ **final administration decision and regulation**” have the meaning assigned to those terms as set out in Annex X-A].

[Article X.3:] Scope

[EU: 1. The provisions of Section II apply to regulatory acts at central level which:

{a} determine requirements or related procedures for a supply, or use of a service in the territory of a Party, such as for example authorization, licensing; or qualification; 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

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2. The provisions of Section III apply to regulatory acts at central level that fulfill the criteria in paragraph 1 and that have or are likely to have a significant impact on trade or investment between the Parties.

3. Regulatory acts at 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.]

[US: This Chapter applies with respect to regulations (as defined in Annex X-A) and regulatory authorities of each Party (as specified in Annex X-B).]

[Article X.4:] [EU: 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....}.]

[EU: Section II: Good Regulatory Practices]

[Article X.5:] [US: Internal Coordination of Regulatory Development

Each Party shall maintain processes or mechanisms to facilitate internal coordination, consultation, and review of regulations being developed by its regulatory authorities to pursue the following objectives:

- (a) identifying and avoiding potential unnecessary duplication and potentially inconsistent requirements among the Party's regulatory authorities;
- (b) complying with the international trade and investment obligations;
- (c) considering the special concerns of small entities;
- (d) sharing relevant available scientific and technical information among regulatory authorities; and
- (e) fostering good regulatory practices, including with respect to the provisions of this Chapter.]

[EU: Subsection II.1. Transparency]

[Article X.6:] [EU: Early information on Planned Acts

1. Each Party shall make publicly available at least once a year a list of planned regulatory acts at

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central level, providing information on their respective scope and objectives.

2. For planned regulatory acts at 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 X.7:] [EU: Stakeholder Consultations

1. When preparing regulatory acts at central level that are undergoing impact assessment, the regulating Party shall offer a reasonable opportunity for any interested natural or legal person, on a non-discriminatory basis, to provide input through a public consultation process, and shall take into account the contributions received in the finalization of their regulatory acts. The regulating Party should make use of electronic means of communication and seek to use dedicated single access web portals, 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}*

[Article X.8:] [US: Transparent Development of Regulations

1. During the period described in paragraph 2, when a regulatory authority of a Party is developing a regulation, it shall, under normal circumstances, make publicly available:

- (a) the text of the regulation it is developing;
- (b) an explanation of the regulation, including its objectives, how the regulation achieves those objectives, the rationale for the material features of the regulation, and any major alternatives being considered;
- (c) data, other information, and scientific and technical analyses it relied upon in support of regulation, including any regulatory impact assessment, risk assessment or technical dossier, and explanation for how such data, other information and analyses support the regulation; and
- (d) the name and contact information of an individual official who may be contacted to address questions regarding the regulation.

2. Each Party shall make publicly available the information described in paragraph 1:

- (a) after the regulatory authority of the Party has developed a text for the regulation that contains sufficient detail so as to allow persons to evaluate how the regulation, if adopted, would affect their interests; and
- (b) before the regulatory authority of the Party that is developing the regulation issues or submits any final administrative decision with respect to the regulation so that this authority may take into account comments it receives and, as appropriate, revise the regulation.

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3. Where regulatory authority of a Party is developing a regulation and makes publicly available the information described in paragraph 1, the Party shall ensure that any person regardless of domicile has an opportunity, on no less favorable terms than any person of the Party, to submit comments on the regulation, including by providing written comments and other input with respect to the information described in paragraph 1, to the regulatory authority.

4. Each Party should normally provide a time period to submit comments and other input on the information described in Paragraph 1 that is:

(a) not less than 60 days from the date the information described in paragraph 1 is made publicly available; or

(b) such longer period as is appropriate due to the nature and complexity of the regulation, to provide interested persons adequate opportunity to understand how the regulation may affect their interests.

Each Party shall consider reasonable requests to extend the comment period.

5. Each Party shall promptly make publicly available any comments it receives on the regulation, except to the extent necessary to protect confidential information or withhold personal identifying information or inappropriate content, in which case the Party shall ensure it makes publicly available a version that redacts such information, or a summary of the comment.

6. Where a regulatory authority of a Party issues or submits any final administrative decision with respect to a regulation, it shall promptly make publicly available:

(a) the text of the regulation;

(b) the regulatory authority's views on substantive issues raised in the comments; and

(c) an explanation of the nature and the reason for any significant revisions to the regulation since the Party made it available for public comment.

7. Each Party shall publish at least annually a plan that identifies the major regulations that it reasonably expects to make publicly available for comment, or on which it expects to issue or submit a final administrative decision, within a period of at least twelve months commencing on the date it makes the plan publicly available.

8. Each Party shall maintain a single, freely accessible Internet website¹ that, to an extent practicable, contains anything that it is required to make publicly available under this Chapter. Each Party shall also provide for the electronic submission of comments and other input on this website in accordance with paragraph 5. If it is impracticable to post on the Internet all comments that a Party is required to make publicly available under paragraph 5, the Party shall ensure that its regulatory authorities maintain freely accessible public dockets where comments that have not been

¹[US: A Party may comply with the obligation regarding a single Internet website by making publicly available information on, and providing for the submission of comments via, more than one website, provided the information can be accessed, and submissions can be made, from a single web domain (e.g., from one website via links to another website).]

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posted can be viewed.]

[Article X.9:] [US: Trade Effects

When developing a regulation, a regulatory authority of a Party shall evaluate any information provided in comments by the other Party or a person of the other Party regarding the potential trade effects of the regulation that it receives during the comment period and, in accordance with paragraph 6 of Article X.8, provide its views on substantive issues raised.]

[Article X.10:] [US: Access to Government Documents

1. Each Party shall make publicly available the following:

- (a) a description of each of its regulatory authorities' functions and organization, including the appropriate offices through which the public can obtain information, make submissions or requests, or obtain decisions; and
- (b) any rules of procedure or forms utilized or promulgated by any of its regulatory authorities, as well as any associated fees.

2. Each Party shall adopt or maintain laws or procedures that allow for persons to request access to documents from a regulatory authority of a Party. Such laws or procedures shall provide no less favorable treatment to persons of the other Party than it provides to persons of the Party.]

[Article X.11:] [US: Description of Regulatory Processes

Each Party shall make publicly available a detailed description of the processes and mechanisms employed by its regulatory authorities to develop regulations. The description shall identify:

- (a) the applicable guidelines or rules for providing the public with opportunities to participate in the development of regulations;
- (b) the procedures for ensuring that regulatory authorities have considered public input;
- (c) the judicial or administrative procedures available to challenge regulations or the procedures by which they were developed; and
- (d) the processes or mechanisms referred to in Article X.5.]

[Article X.12:] [US: Regulatory Compilation

1. Each Party shall ensure that its regulations that are in effect are published in a designated compilation. The compilation shall be organized logically to promote easy access to relevant regulations. To that end, the compilation should clearly identify regulations by the topic they address.

2. Each Party shall make its respective compilation publicly available on a single, freely accessible Internet website that is capable of performing searches for regulations by citation or by word search.

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3. Each Party shall ensure that its compilation is periodically updated.]

[EU. Subsection II.2: Regulatory Policy Instruments]

[Article X.13:] [EU: Analytical Tools] [US: Regulatory Impact Assessment]

[EU: 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 level.

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 international trade or investment.

3. 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;
- (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 the exchange of experience and share information on planned ex-post evaluations and retrospective reviews.]

[US: 1. Each Party shall maintain procedures that promote the consideration of the following factors when conducting a regulatory impact assessment (RIA) for a regulation:

- (a) the need for a proposed regulation, including the nature and the significance of the problem the regulation is intended to address;
- (b) the examination of reasonably feasible and appropriate regulatory and non-regulatory alternatives (including the option of not regulation), if any, that would achieve the objective of the regulation; and
- (c) the anticipated costs and benefits (quantitative, qualitative, or both) of such alternatives, including, as appropriate and to the extent information is available, potential social, economic, environmental, public health, safety, and distributive impacts, equity, and impacts on innovation (recognizing that some costs and benefits are difficult to quantify).

2. Where a regulatory authority concludes that the regulation would have a significant effect on a

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substantial number of small entities, it should consider the estimated adverse economic impacts on them and any steps taken by the regulatory authority to minimize such impacts.

3. With respect to any regulatory impact assessment it conducts for a regulation, each Party shall prepare and make publicly available for comment in accordance with Article X.8 a report detailing the factors it considered and how they support the assessment's conclusions.]

[Article X.14:] [US: Decision-Making Based on Evidence

1. Each Party recognizes the need for regulations to be based upon information that is reliable and of high quality. To that end, each Party should adopt or maintain publicly available guidance or mechanisms that encourage a regulatory authority when it is developing a regulation to:

(a) seek the best reasonably obtainable information, including scientific, economic, technical, or other information relevant to the regulation it is developing; and

(b) rely on information that is of high quality (including with respect to utility, objectivity, integrity, clarity and accuracy).

2. When publishing any final administrative decision with respect to a regulation, the Party shall make publicly available an explanation of:

(a) the regulation, including its objectives, how the regulation achieves those objectives, and the rationale for the material features of the regulation (to the extent different than the explanation provided in accordance with paragraph 1(b) of Article X.8); and

(b) the relationship between the regulation and the key evidence, data, and other information the regulatory authority considered in preparing the final administrative decision.

Such explanation should also identify any major alternatives that the regulatory authority considered in developing the regulation and provide an explanation supporting the alternative that is selected for the final administrative decision.

3. Each Party shall prepare, on an annual basis, a public report setting forth:

(a) an estimate, to the extent feasible, regarding the total annual costs and benefits of major final regulations issued in that period by its respective regulatory authorities;

(b) any proposals for systemic regulatory improvements; and

(c) any updates on changes to relevant processes and mechanisms.]

[Article X.15:] [US: Petitions

1. Each Party shall provide for any interested person to petition any regulatory authority of the Party for the issuance, amendment, or repeal of a regulation. The basis for such petitions may include, for

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example, that in the view of the person submitting the petition, the regulation has become ineffective at protecting health, welfare, or safety, has become more burdensome than necessary to achieve its objective (including with respect to its impact on trade), fails to take into account changed circumstances (such as fundamental changes in technology, or relevant scientific and technical developments), or relies on incorrect or outdated information.

2. Each Party should normally make such petitions it receives publicly available.]

[Article X.16:] [US: Retrospective Review of Regulations

1. Each Party shall maintain procedures or mechanisms to promote periodic reviews of regulations that are in effect in order to determine whether they are in need of revision or repeal, including on a regulatory authority's own initiative or in response to a petition filed pursuant to Article X.15.

2. Each Party shall make publicly available the results of any such retrospective reviews or analyses conducted by its regulatory authorities, including any supporting data whenever practicable.

3. Each Party shall include in procedures or mechanisms adopted pursuant to paragraph 1 provisions addressing regulations that it considers to have a significant economic impact on a substantial number of small entities.]

[Article X.17:] [US: Reducing Information Collection Burdens Associated with Regulation

Each Party shall provide that, to the extent regulatory authorities use surveys to request or compel information from the public in developing a regulation, these regulatory authorities should endeavor to do so in a manner that minimizes unnecessary burdens and avoids duplication.]

[EU: Section III: Regulatory Cooperation]

[Article X.18:] [EU: Bilateral Cooperation Mechanism

1. The Parties hereby establish a bilateral mechanism to support regulatory cooperation between their regulators and competent authorities at 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 Program referred to paragraph 2(a) of Article X.21.

3. Each Party shall designate an office in its central administration to act as a Focal Point responsible for exchanging information about envisaged and existing regulatory acts at central level. Those exchanges include submissions concerning acts that are being prepared or reviewed by each Party's legislative authorities.]

[Article X.19:] [EU: Information and Regulatory Exchanges

1. When a Party publishes a list of planned regulatory acts referred to in Article X.6.1, it shall identify those acts that are likely to have a significant impact on international trade or investment, including trade and investment between the Parties, and it shall inform the other Party through their

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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 X.6.1.

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

4. Regulatory exchanges shall be held by the regulators and competent authorities at central level responsible for the regulatory acts concerned.

5. The Parties shall participate constructively in regulatory exchanges. In addition to the information made available in accordance with Article X.6, a Party shall provide to the other Party, if the other Party so requests, any additional available information related to the planned regulatory acts under discussion.

6. *{Placeholder for Article on exchange of confidential information between regulators and competent authorities at central level}*

7. 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.

8. 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 X.20:] [EU: Timing of Regulatory Exchanges

1. When a regulatory exchange on a planned or existing regulatory act at central level is requested under Article X.19 paragraph 3, it shall start promptly.

2. With regard to planned regulatory acts at central level, regulatory exchanges may take place at any stage of their preparation². Exchanges may continue until the adoption of the regulatory act.

3. Regulatory exchanges shall not prejudice 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 envisaged under its domestic regulatory procedure.]

[Article X.21:] [EU: Promoting Regulatory Compatibility

1. This Article shall apply to areas of regulation where mutual benefits can be realized without

2 [EU: For a greater certainty, a dialogue may take place after the regulating Party has announced, through the publication of the list envisaged in Article 4.1, its intention to regulate, and: (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. This note is not applicable to the regulatory acts referred to in Article 17.2.]

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compromising the achievement of legitimate public policy objectives such as those covered by Article 1.

2. When a regulatory exchange has been initiated pursuant to Article X.19 with regard to a planned 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 fulfillment of the public policy goals pursued by both Parties;

(b) Harmonization of regulatory acts, or of the 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 new international instrument;

(ii) Approximation of rules and procedures on a bilateral basis or

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

3. 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. Every response should be substantiated.

4. In addition to regulatory exchanges pursuant to Article X.19, the Parties agree to cooperate, in areas of common interest, with respect to pre-normative research, and to exchange scientific and technical information relevant to this purpose.]

[Article X.22:] [EU: Promoting International Regulatory Cooperation

1. The Parties agree to cooperate between themselves, and with third countries, with a view to strengthening, developing and promoting the implementation of international instruments, inter alia, by 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 X.23:] [EU: Establishment of the Regulatory Cooperation Body

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.

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2. The functions of the RCB shall be:

- (a) The preparation and publication of an Annual Regulatory Cooperation Program 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 time frames proposed in relation to these identified common priorities;
- (b) The monitoring of the implementation of the provisions of this Chapter, including the {specific or sectoral provisions concerning goods and services} of this Agreement, and reporting to the Joint Ministerial Body on the progress in achieving agreed cooperation programs;
- (c) {Placeholder on technical preparation of proposals for the update, modification or addition of sectoral provision. The RCB will not have the power to adopt legal acts}
- (d) The consideration of new initiatives for regulatory cooperation, 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 X.19;
- (e) The preparation of joint initiatives or proposals for international regulatory instruments in line with Article X.20, paragraph 1;
- (f) Ensuring transparency in regulatory cooperation between the Parties;
- (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.

3. In the domain of financial services as set out under paragraph 2 shall be performed by the {Joint EU/US Financial Regulatory Forum (FRF)}, which shall ensure that appropriate information is given 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 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 X.24:] [EU: 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 Cooperation Program.

2. The annual meeting shall be prepared jointly by the co-chairs of the RCB and shall involve the

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co-chairs of the Civil Society Contact Groups, including a balanced representation of business, consumer, trade unions, environmental groups and other relevant public interest associations {to be agreed in more detail in the Rules of Procedures of the RCB, see Article X.25 paragraph 3}. 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 cooperation 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. These written replies shall also be published as part of the Annual Regulatory Cooperation Program referred to in Article X.23, paragraph 2(a).]

[Article 25:] [EU: Composition and Rules of Procedures

1. The RCB shall be composed of representatives of both Parties. It shall be co-chaired by senior representatives of regulators and competent authorities, regulatory coordinating activities and international trade matters.

2. Each Party shall nominate their representatives to the RCB by (date) and provide relevant information and contact details.

3. {Placeholder for more detailed provisions on the composition and Rules of Procedure of the RCB}.]

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[US: Annex X-A

final administrative decision means:

- (a) for the United States, a final regulation (as defined below); and
- (b) for the EU Party:
 - (i) a European Commission proposal for a regulation (as defined below), including any submitted to the European Parliament, Council, or relevant committees of Member State representative; or
 - {(ii) a final regulation (a defined below) of an EU Member State; and}

regulation means:

- (a) for the United States, a rule of general applicability that prospectively prescribes legally enforceable requirements to an entire class or category of persons, entities, or things issued by a regulatory authority specified in paragraph 1(a) of Annex X-B; and
- (b) for the EU Party
 - (i) at the EU level, a regulation, directive, implementing act or delegated act, {within the meaning of Articles 288, 290 and 291 of the Treaty of the Functioning of the European Union) or other measure of general applicability that prospectively prescribes legally enforceable requirements to an entire class or category of persons, entities or things, developed by a regulatory authority specified in paragraph 1(b)(i) of Annex X-B, or
 - {(ii) at the EU Member state level, a measure of general applicability developed by a regulatory authority specified in paragraph 1(b)(ii) of Annex X-B that prospectively prescribes legally enforceable requirements to an entire class or category of persons, entities or things, be it a regulatory measure or a proposal for a legislative measure,}

other than a measure concerning (i) a military or foreign affairs function, (ii) agency management, personnel, or rules of organization, procedure or practices, (iii) public property, loans, grants, benefits or contracts, or (iv) financial services or anti-money laundering measures. For greater certainty, the term regulation does not include guidance or general statements of policy. Any reference to a regulation shall be understood to apply to amendments to a regulation.]

[US: Annex X-B

1. This Chapter applies to regulatory authorities of each Party as follows:

- (a) for the United States, any agency at central level of government, including any Executive Branch or independent agency, that develops regulations; and

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(b) for the EU Party:

(i) the European Commission (including any component thereof) and any independent agency at the EU level that develops regulations or provides data, other information or analysis relied upon in developing regulations;
and

{(ii) any agency or ministry at the central level of government of a Member State that develops regulations.}

2. This Chapter does not apply to any legislature of any Party.]