

ARTICLE 17.6

Review and appeal

1. Each Party shall establish or maintain judicial, arbitral or administrative tribunals or procedures for the purpose of the prompt review or appeal and, where warranted, correction of administrative actions or, as provided for in its laws and regulations, of failures to act with respect to any matter covered by this Agreement. Those tribunals or procedures shall be impartial and independent of the office or authority entrusted with administrative enforcement of such actions and shall not have any substantial interest in the outcome of the matter.
2. Each Party shall ensure that the parties before the tribunals or involved in the procedures referred to in paragraph 1 are provided with the right to:
 - (a) a reasonable opportunity to support or defend their respective positions; and
 - (b) a decision based on the evidence and submissions of record.
3. Each Party shall ensure, subject to further review or appeal as provided for in its laws and regulations, that the decision referred to in subparagraph 2(b) is implemented by the relevant offices or authorities with respect to the administrative action concerned.

ARTICLE 17.7

Cooperation on the promotion of increased transparency

The Parties shall cooperate, where appropriate, in bilateral, regional and multilateral fora on ways to promote transparency in respect of international trade and investment.

ARTICLE 17.8

Relation to other Chapters

This Chapter applies without prejudice to any specific provisions in other Chapters of this Agreement.

CHAPTER 18

GOOD REGULATORY PRACTICES AND REGULATORY COOPERATION

SECTION A

Good regulatory practices and regulatory cooperation

SUB-SECTION 1

General provisions

ARTICLE 18.1

Objectives and general principles

1. The objectives of this Section are to promote good regulatory practices and regulatory cooperation between the Parties with the aim of enhancing bilateral trade and investment by:
 - (a) promoting an effective, transparent and predictable regulatory environment;
 - (b) promoting compatible regulatory approaches and reducing unnecessarily burdensome, duplicative or divergent regulatory requirements;

- (c) discussing regulatory measures, practices or approaches of a Party, including how to enhance their efficient application; and
 - (d) reinforcing bilateral cooperation between the Parties in international fora.
2. Nothing in this Section shall affect the right of a 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;
 - (b) human, animal and plant life and health;
 - (c) occupational health and safety;
 - (d) labour conditions;
 - (e) the environment including climate change;
 - (f) consumers;
 - (g) social protection and social security;
 - (h) personal data and cybersecurity;
 - (i) cultural diversity;
 - (j) financial stability; and
 - (k) energy security.
3. Nothing in this Section shall be construed to prevent a Party from:
- (a) adopting, maintaining and applying regulatory measures in accordance with its legal framework, principles ⁽¹⁾ and deadlines, in order to achieve its public policy objectives at the level of protection it deems appropriate; and
 - (b) providing and supporting 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. Nothing in this Section shall be construed as obliging the Parties to achieve any particular regulatory outcome.

ARTICLE 18.2

Definitions

For the purposes of this Section:

- (a) 'regulatory authority' means:
 - (i) the European Commission for the European Union; and
 - (ii) the Government of Japan for Japan; and
- (b) 'regulatory measures' means measures of general application, which are:
 - (i) for the European Union:
 - (A) regulations and directives, as provided for in Article 288 of the TFEU; and
 - (B) delegated and implementing acts, as provided for in Articles 290 and 291 of the TFEU, respectively; and
 - (ii) for Japan:
 - (A) laws;
 - (B) Cabinet Orders; and
 - (C) Ministerial Ordinances.

⁽¹⁾ For the European Union, such principles include those established in the TFEU as well as in regulations and directives adopted pursuant to Article 289 of the TFEU.

ARTICLE 18.3

Scope

1. This Section applies to regulatory measures issued by the regulatory authority of a Party in respect of any matter covered by this Agreement.
2. Sub-Sections 3 and 4 apply to other measures of general application issued by the regulatory authority of a Party which are relevant for regulatory cooperation activities, such as guidelines, policy documents or recommendations, in addition to the regulatory measures referred to in paragraph 1.

SUB-SECTION 2

Good regulatory practices

ARTICLE 18.4

Internal coordination

Each Party shall maintain internal coordination processes or mechanisms to foster good regulatory practices, including those provided for in this Section.

ARTICLE 18.5

Regulatory processes and mechanisms

Each Party shall make publicly available descriptions of the processes and mechanisms under which its regulatory authority prepares, evaluates and reviews its regulatory measures. Those descriptions shall refer to relevant guidelines, rules or procedures, including those regarding opportunities for the public to provide comments.

ARTICLE 18.6

Early information on planned regulatory measures

The regulatory authority of each Party shall make publicly available at least once a year a list of its planned major ⁽¹⁾ regulatory measures, together with a brief description of their scope and objectives, including, if available, the estimated timing for their adoption. Alternatively, if the regulatory authority of a Party does not make such a list publicly available, that Party shall provide annually, and as soon as possible, the Committee on Regulatory Cooperation established pursuant to Article 22.3 with the list together with the brief description. That list together with the brief description, with the exception of information designated as confidential, may be made publicly available by the regulatory authority of each Party.

ARTICLE 18.7

Public consultations

1. When preparing major regulatory measures, the regulatory authority of each Party shall, where applicable, and in accordance with the relevant rules and procedures:
 - (a) publish either the draft regulatory measures or consultation documents providing sufficient details about regulatory measures under preparation to allow any person to assess whether and how the person's interests might be significantly affected;
 - (b) offer, on a non-discriminatory basis, reasonable opportunities for any person to provide comments; and
 - (c) consider the comments received.

⁽¹⁾ The regulatory authority of each Party may determine what constitutes 'major' regulatory measures for the purposes of its obligations under this Section.

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 comments related to public consultations.

3. The regulatory authority of each Party shall make publicly available any comment received or a summary of the results of the consultations. This obligation does not apply to the extent necessary for the protection of confidential information, for withholding personal data or inappropriate content or for other justified grounds such as the risk of harm to the interests of a third party.

ARTICLE 18.8

Impact assessment

1. The regulatory authority of each Party shall endeavour to systematically carry out, in accordance with the relevant rules and procedures, an impact assessment of major regulatory measures under preparation.

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 issue that the regulatory measure intends to address;
- (b) any feasible and appropriate regulatory or non-regulatory alternatives, including the option of not regulating, if available, that would achieve the Party's public policy objectives;
- (c) to the extent possible and relevant, the potential social, economic and environmental impact of those alternatives, including on trade and on small and medium-sized enterprises; and
- (d) where appropriate, how the options under consideration relate to relevant international standards, including the reason for any divergence.

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 18.9

Retrospective evaluation

1. The regulatory authority of each Party shall maintain processes or mechanisms to promote periodic retrospective evaluation of regulatory measures in force.

2. The regulatory authority of each Party shall make publicly available its plans for and the results of such retrospective evaluations to the extent consistent with the relevant rules and procedures.

ARTICLE 18.10

Opportunity to submit comments

The regulatory authority of each Party shall, without prejudice to the pursuit of each Party's public policy objectives, provide an opportunity for any person to submit comments for improvements of regulatory measures in force, including suggestions for simplification or reduction of unnecessary burdens.

ARTICLE 18.11

Exchange of information on good regulatory practices

The regulatory authorities shall endeavour to exchange information, including in the Committee on Regulatory Cooperation, on their good regulatory practices as referred to in this Sub-Section, such as practices regarding impact assessments, including the assessment of the effects on trade and investment, or those regarding retrospective evaluations.

SUB-SECTION 3

Regulatory cooperation

ARTICLE 18.12

Regulatory cooperation activities

1. Each Party may propose a regulatory cooperation activity to the other Party. It shall present that proposal via the contact point designated in accordance with Article 18.15.
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. On request of a Party, the Committee on Regulatory Cooperation shall discuss a proposal for regulatory cooperation activities referred to in paragraph 1.
4. In order to identify suitable activities for regulatory cooperation, each Party shall consider:
 - (a) the list provided for in Article 18.6; and
 - (b) proposals for regulatory cooperation activities submitted by persons of a Party that are substantiated and accompanied by relevant information.
5. If the Parties decide to engage in a regulatory cooperation activity, the regulatory authority of each Party shall:
 - (a) inform the regulatory authority of the other Party about the development of new or the revision of existing measures that are relevant for the regulatory cooperation activity;
 - (b) on request, provide information and discuss measures that are relevant for the regulatory cooperation activity; and
 - (c) when developing new or revising existing regulatory or other measures, consider, to the extent feasible, any regulatory approach by the other Party on the same or a related matter.
6. The Parties may engage in regulatory cooperation activities on a voluntary basis. A Party may refuse to engage in or withdraw from regulatory cooperation activities. A Party that refuses to engage in or withdraws from regulatory cooperation activities should explain the reasons for its decision to the other Party.
7. Where appropriate, the regulatory authorities may, by mutual consent, entrust the implementation of a regulatory cooperation activity to the relevant bodies in the Parties.

ARTICLE 18.13

Good practices to promote regulatory compatibility

The regulatory authority of each Party shall, in order to promote regulatory compatibility, consider, *inter alia*, the following:

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

SUB-SECTION 4

Institutional provisions

ARTICLE 18.14

Committee on Regulatory Cooperation

1. The Committee on Regulatory Cooperation established pursuant to Article 22.3 shall enhance and promote good regulatory practices and regulatory cooperation between the Parties in accordance with the provisions of this Section.
2. The Committee on Regulatory Cooperation may invite interested persons to participate in its meetings.
3. The Committee on Regulatory Cooperation may, in particular:
 - (a) discuss proposals for regulatory cooperation activities;
 - (b) exchange information on, and promote, good regulatory practices;
 - (c) recommend regulatory cooperation activities on matters of common interest to the Parties, including those 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 developments are at an initial stage;
 - (e) support the development of practical mechanisms, implementing tools and best practices to promote good regulatory practices and regulatory cooperation;
 - (f) encourage regulatory cooperation and coordination in international fora, including periodic bilateral exchanges of information on relevant ongoing or planned activities;
 - (g) periodically identify and endorse priority areas of regulatory cooperation;
 - (h) provide guidelines, if necessary, to help streamline the regulatory cooperation of other specialised committees referred to in Article 22.3 and of other bilateral regulatory cooperation fora;
 - (i) consider the report on the outcome of the consultations referred to in paragraph 8 of Article 18.16 and review the progress on the implementation of the satisfactory solution referred to in paragraph 6 of Article 18.16, if applicable; and
 - (j) establish, as necessary, *ad hoc* working groups to pursue specific regulatory cooperation activities, which shall report to the Committee on Regulatory Cooperation.
4. The Committee on Regulatory Cooperation shall:
 - (a) meet within one year of the date of entry into force of this Agreement and at least once a year thereafter, unless the representatives of the Parties decide otherwise; and
 - (b) adopt its rules of procedure at its first meeting after the entry into force of this Agreement.

ARTICLE 18.15

Contact points

Each Party shall, upon the entry into force of this Agreement, designate a contact point for the implementation of this Section and for exchange of information in accordance with Article 18.16 and notify the other Party of the contact details including information regarding the relevant officials. The Parties shall promptly notify each other of any change of those contact details.

ARTICLE 18.16

Exchange of information on planned or existing regulatory measures

1. A Party may submit to the other Party a request for information and clarifications regarding planned or existing regulatory measures of the other Party. The Party to whom the request is addressed shall endeavour to respond promptly.
2. A Party may submit to the other Party a request to consider its concerns about a planned or existing regulatory measure of the other Party. In its request, the requesting Party shall identify the regulatory measure at issue, provide a description of its concerns and, where relevant, submit questions.
3. The responding Party shall, as soon as possible but, unless justified, no later than 60 days after the receipt of the request, provide written comments as regards the concerns raised by the requesting Party pursuant to paragraph 2. Those comments shall, to the extent possible, include *inter alia* the policy objective and rationale of the regulatory measure and, where applicable, 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. The requesting Party may request consultations with the responding Party:
 - (a) after the receipt of the written comments referred to in paragraph 3; or
 - (b) after the expiration of the time period referred to in paragraph 3, if the responding Party does not provide written comments within that period.
5. The consultations may be held through meetings in person or by electronic means. Each Party shall appoint an official responsible for conducting the meetings.
6. 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 regulatory measure at issue or for the adoption of a less trade or investment restrictive regulatory measure, where relevant.
7. The Parties shall not be required to disclose confidential or sensitive information or data.
8. 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 Committee on Regulatory Cooperation for its consideration.
9. The request referred to in paragraph 2 may also be submitted in cases where 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 21 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.

SECTION B

Animal welfare

ARTICLE 18.17

Animal welfare

1. The Parties will cooperate for their mutual benefit on matters of animal welfare with a focus on farmed animals with a view to improving the mutual understanding of their respective laws and regulations.

2. For that purpose, the Parties may adopt by mutual consent a working plan defining the priorities and categories of animals to be dealt with under this Article, and establish an Animal Welfare Technical Working Group to exchange information, expertise and experiences in the field of animal welfare and to explore the possibility of promoting further cooperation.

SECTION C

Final provisions

ARTICLE 18.18

Application of Section A

1. The provisions of Section A do not apply to Section B and to the regulatory cooperation on financial regulation provided for in Sub-Section 5 of Section E of Chapter 8.
2. Notwithstanding Article 18.3, any specific provisions in other Chapters of this Agreement shall prevail over the provisions of Section A to the extent necessary for the application of the specific provisions.

ARTICLE 18.19

Dispute settlement

The provisions of this Chapter shall not be subject to dispute settlement under Chapter 21.

CHAPTER 19

COOPERATION IN THE FIELD OF AGRICULTURE

ARTICLE 19.1

Objectives

The Parties recognise that promoting trade in agricultural products ⁽¹⁾ and foods between them is in their mutual interest, and aim at promoting cooperation on sustainable agriculture, including rural development and the exchange of technical information and best practices for providing safe and high quality foods for consumers in the European Union and Japan.

ARTICLE 19.2

Scope

1. The Parties shall cooperate in the areas referred to in Article 19.1 in accordance with their respective laws and regulations. The Parties shall encourage and facilitate cooperation among relevant groups, entities, competent authorities and other organisations of the Parties.
2. The scope of cooperation referred to in paragraph 1 shall cover:
 - (a) the promotion of trade in agricultural products and foods, including a dialogue on the relevant regulation;
 - (b) cooperation with a view to improving farm management, productivity and competitiveness, including the exchange of best practices regarding sustainable agriculture, as well as the use of technology and innovation;
 - (c) cooperation on production and technology in agriculture and foods;

⁽¹⁾ For the purposes of this Chapter, 'agricultural products' does not include forestry or fishery products.