

# Chapter 4

# European Union (EU)/United Kingdom (UK)

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# 1. European Union (EU)

## NATIONAL TREATMENT

### CARBON BORDER ADJUSTMENT MEASURE

#### <OUTLINE OF THE MEASURES>

The EU operates the EU-ETS (Emission Trading System), the world's largest greenhouse gas emissions trading system. When measures to reduce greenhouse gas emissions under such a system are taken within the EU, the issue of so-called carbon leakage can become a problem. This entails a situation in which global greenhouse gas emissions are not reduced due to the substitution of domestic products by products imported from overseas that are not subject to such regulations, as well as due to the relocation of production facilities abroad. The EU announced the "European Green Deal" in December 2019 with the Carbon Border Adjustment Mechanism (CBAM) to prevent carbon leakage to be proposed in 2021. Subsequently, in July 2021, the European Commission published a draft regulation on the CBAM as part of Fit for 55, a package of policies aimed at reducing greenhouse gas emissions by at least 55% by 2030 compared to 1990 levels. After negotiations among the European Commission, the European Parliament, and the Council, the regulation was formally adopted in May 2023.

The regulation imposes levies on importers of goods into the EU in proportion to the embedded carbon emissions in such goods by obliging the importers to purchase CBAM certificates. The scope of the planned measures covers imports from all countries, with exclusions limited to a few countries with systems fully linked to the EU-ETS (i.e., Iceland, Liechtenstein, Norway, and Switzerland), and no developing country exceptions. The product scope is limited to steel, aluminum, cement, fertilizer, hydrogen, electricity, and some downstream products of steel and aluminum (screws and bolts, etc.), which are energy intensive and are traded intensively. However, as described below, the EU plans to consider the extension of the product scope based on the information collected through importers' reports during the transition period.

The specific calculation method of the levies is as follows:

Import Levies = CBAM Certificate Price (P/CO<sub>2</sub>-ton) x Emissions per Product Unit (CO<sub>2</sub>-ton/Q) x Product Imports (Q)

Among the factors necessary for the above calculation, with regard to emissions, the scope of emissions to be considered is direct emissions only for steel, aluminum, downstream products of these products, and hydrogen, while indirect emissions (emissions associated with electricity use) are included for other products.

In addition, if the authorities are unable to properly verify the actual emissions, they may set a default value for each exporting country and product (except for electricity) by adding a country-specific markup (the details of which are left to the Implementing Regulation) to the average emission intensity of each exporting country. In the absence of credible data on the average emission intensity of the exporting country, the default value is to be set based on the average emission intensity of the production site of the lower X% of the emissions of each production process in the EU for the product (where X is to be defined in the Implementing Regulation). The default value is planned to be adjusted in consideration of the specific circumstances of each producing country, such as energy consumption (Article 7 of the EU CBAM Regulation, Annex IV).

The CBAM certificate price is set on the basis of the average closing price of EU-ETS auctions in the previous week and is intended to be at the same level as the domestic regulatory carbon price. However, carbon prices paid outside the EU (taxes, levies, fees or emission allowances) can be deducted from the amount of import levies (i.e., the number of CBAM certificates to be surrendered) (Article 9 of the EU CBAM Regulation). That is, the carbon price paid in the country of origin is deducted from the import levies. With regard to the consideration of carbon prices paid in third countries (countries of origin), the EU may conclude an agreement with third countries to take into account the carbon pricing mechanism of such third country (Article 2, Paragraph 12 of the EU CBAM Regulation).

In addition, the CBAM is explained as an alternative measure to the free allowances and electricity cost compensation, which are existing measures to address the risk of carbon leakage under the EU-ETS. The amount of import levies (i.e., the number of CBAM certificates to be surrendered) is planned to be adjusted to reflect the availability of free allowances (Article 31, Paragraph 1 of the EU CBAM Regulation). The free allowances will be phased out from 2026 to 2034, during which time the CBAM will be phased in. Following comments that the reduction of the free allowances would disadvantage exports from the EU, the Regulation also contains a provision (Article 30, Paragraph 5 of the EU CBAM Regulation) requiring consideration of some WTO-consistent measures (implying some form of support for exports) in the future if exports to third countries that do not apply the EU-ETS or a similar carbon pricing mechanism are assessed as being subject to the risk of carbon leakage.

The CBAM will be implemented as a "transition period" from October 2023 to the end of 2025. During the transition period, importers will not be required to pay import levies but will be required to submit quarterly CBAM reports beginning in January 2024, describing the amount of the subject product imported, the emissions during product manufacture (direct and some indirect emissions), and the carbon price paid in the exporting country. The CBAM will be reviewed during the transition period, and the reported items will be used to consider expanding the product scope to other goods and services and to develop emission calculation methods in the post-transition system. In January 2026, imposition of levies through the purchase of CBAM certificates is expected to begin.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

There are a wide range of issues under WTO rules that may be relevant to the CBAM overall, but the relationship with national treatment obligations (Article III: 2 of GATT for domestic taxes, etc., and Article III: 4 of GATT for domestic regulations) may be the most salient issue. Article III:2 prohibits the imposition of domestic taxes and other charges on imported goods in excess of those applied on "like domestic products", and Article III:4 stipulates that imported products should be given "treatment no less favorable" than like domestic products under domestic regulations. The EU CBAM is based on the EU-ETS, and Article III:4 is likely to apply because the EU-ETS is likely to be considered as a domestic regulation and not a domestic tax on goods.

The EU CBAM refers to the EU-ETS and states that imports will be subject to the same level of burden as that of domestic products under the EU-ETS. However, since the CBAM which imports are subject to is not the same system as the EU-ETS, it can be assumed that imported products may be placed at a disadvantage compared to domestic products. As an example, there are a wide array of

options in which EU-ETS emission credits can be obtained by producers in the EU, including purchases in the EU-ETS market, over-the-counter trading, and the use of surpluses from past allowances, whereas CBAM certificates are only expected to be available for purchase at a single weekly price. In addition, although the details are not clear, as a matter of principle, the calculation method for carbon emissions in the manufacturing process of the eligible products will inevitably have to differ between the EU-ETS and the CBAM (in this context, it should be noted that the EU-ETS applies to facilities, while the CBAM will be applied to individual product imports), and it is difficult to deny the possibility that the imported products may be disadvantaged depending on the method used.

Even if the CBAM constitutes a violation of national treatment obligations, they may be justified under the general exceptions articulated in Article XX of GATT, in particular Article XX(g) on the conservation of exhaustible natural resources (in this case, an unpolluted atmosphere). In this case, however, the question is whether the CBAM is properly designed for the regulatory purpose of preventing carbon leakage for environmental protection. In the first instance, if the carbon intensity of imported products is equal to or lower than that of domestic products, there will be no carbon leakage associated with such imports, and thus no reason to impose a levy at the border in terms of environmental protection. Therefore, the relationship between the design and structure of the CBAM and its purpose, which is claimed to be environmental protection, can be questioned, as the design of the EU CBAM may require the purchase of CBAM certificates (provided, however, that as described above, the amount equivalent to the carbon price paid in the country of origin and the amount equivalent to the free allowances under the EU-ETS are deducted from the number of CBAM certificates to be surrendered) even if the carbon intensity of the imported product is lower than that of the domestic product in the EU, unless the carbon intensity of the imported product is equal to zero.

With regard to another issue, on the possibility of future support measures for exports from the EU, it is stipulated that if such measures are to be considered, consideration should be given to consistency with WTO rules, but in general, support contingent on the export of products is likely to fall under export subsidies prohibited by the Agreement on Subsidies and Countervailing Measures (the “ASCM”). Under the ASCM, it is clearly stated that refunds of indirect taxes at the time of export do not constitute export subsidies; however, since the EU-ETS is not a domestic tax imposed on goods and does not constitute an indirect tax, it will not be easy to ensure WTO consistency with regard to a mechanism for exempting export products from the burden of emission credits.

#### <RECENT DEVELOPMENTS>

The transition period for this Regulation has started in October 2023, and the mechanism is expected to be revised in the future, based on, among other things, information collected during the transition period. It is necessary to continue discussions with the EU, both bilaterally and through various forums such as the WTO, to ensure that imports are not disadvantaged under the specific design details of the CBAM, while also continuing to cooperate for the purposes of global environmental protection.

In addition, the UK conducted a public consultation on carbon leakage measures from March to June 2023, and announced in December of the same year that it would introduce its own CBAM by 2027. Including these trends, it is necessary to continue to consider how the international rules on the CBAM should be.

## TARIFFS

### TARIFF STRUCTURE

\* This particular case was included in light of the following concerns despite it being a trade or investment policy or measure that does not expressly violate the WTO Agreements or other international rules. Refer to Chapter 5, 1 of the 2020 Report on Compliance by Major Trading Partners with Trade Agreements - WTO, FTA/EPA and IIA- for definitions of tariffs, tariff rates, bound tariffs, and bound tariff rates.

#### <OUTLINE OF THE MEASURES>

The Union Customs Code, duty exemption system, and related legislation provide for basic tariff rates, provisional tariff rates, and elastic tariff rates (e.g., anti-dumping duties, countervailing duties, retaliatory duties, emergency duties, seasonal duties, and international cooperation duties). MFN or the Japan-EU Economic Partnership Agreement (Japan-EU EPA) tariff rates, etc. are applied to products imported from Japan. In addition, tariff preferences (reduction, exemption, and refund) are applied to imports of goods, raw materials, etc., intended for re-export.

In 2022, the binding ratio and the simple average bound tariff rate for non-agricultural products in the EU are 100% and 4.1%, respectively. Items with high bound tariffs include power transmission equipment (maximum 22%), leather and footwear, etc. (maximum 17%), minerals and metals (maximum 12%), and passenger cars (maximum 10%). Moreover, in 2022, the simple average applied tariff rate for non-agricultural products is 4.1%; the tariff rates for electric machines (maximum 14% [televisions, cameras, radio receivers, etc.], simple average 2.4%) and textile products (maximum 12%, simple average 6.6%) are higher than those of other developed countries, rendering imported products at a severe competitive disadvantage in comparison with domestic products.

#### <CONCERNS>

As long as the high tariff itself does not exceed the bound rate, there is no problem in terms of the WTO Agreements, but in light of the spirit of the WTO Agreements that promotes free trade and enhances economic welfare, it is desirable to reduce tariffs as much as possible and eliminate the tariff peaks (see “Tariff Rates” in 1. (1) (iii) of Chapter 5, Part II) described above.

#### <RECENT DEVELOPMENTS>

With regard to the ITA expansion negotiations concluded in December 2015 to promote greater market access for IT products (see 2. (2) “Information Technology Agreement (ITA) Negotiation” in Chapter 5 of Part II for details), the EU began eliminating tariffs on 201 subject items in July 2016. For example, high tariff items include digital video cameras (14%), car audio devices (14%), television receivers (14%), etc. Tariffs on all the subject items including these were eliminated by 2023.

In addition, the Japan-EU EPA came into effect in February 2019, tariffs were eliminated immediately or gradually on items on all industrial products exported from Japan (passenger cars (eliminated in the eighth year), auto parts, general machinery, chemical products, electrical equipment, etc. and almost all agricultural, forestry and fishery products (beef, tea, marine products, etc.), and

market access has been improved.

In response to the spread of COVID-19, on April 3, 2020, the EU Government took measures to temporarily exempt from import tariffs and value-added taxes on certain items during the period from January 2020 to July 2020. The aim of these measures is to enable charitable organizations authorized by state agencies to distribute necessary items for free and to make them available to those who need them. In September 2022, the application of this measure was subsequently extended until December of the same year, following three extensions. Thereafter, this measure was terminated. The actual items subject to the measures and tariff rates were left up to each Member country.

## SAFEGUARDS

### STEEL SAFEGUARDS

#### <OUTLINE OF THE MEASURES>

In March 2018, the EU started a safeguard survey on imports of steel products. The EU implemented provisional measures on July, 19 of the same year, and final measures on February 2, 2019 (the initial period was until June 30, 2021 and extended until June 30, 2024). Based on the averaged import amounts over the past three years (2015-2017) for 26 categories of approximately 300 products with 8-digit HS code (72081000-73069000) (hot-rolled steel sheet, cold-rolled steel sheet, stainless steel sheet, etc.), the tariff rate quotas ((1) country quotas for countries with an export share of 5% or more, and (2) residual quotas for other countries collectively) have been prepared for each target item. An additional 25% tariff will be imposed when the import exhausts and exceeds the relevant tariff quota.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

As a background of the measures, the global steel overcapacity problem, import restrictions imposed by other countries and Section 232 measures implemented by the US were referred to. There is a room for debate on its consistency with “unforeseen developments” (generally interpreted as circumstances that could not be foreseen at the time of the tariff negotiation and that would cause changes in the competitive relationship between domestic and imported products, such as technological innovation and changes in consumers’ preference), which is one of the prerequisites of imposing a safeguard measure (Article XIX:1(a) of GATT). In addition, the panel in DS595 determined, as described below, that the EU’s finding of “threat of injury” was not based on objective evidence.

#### <RECENT DEVELOPMENTS>

EU’s regulation requires that of safeguard measures be reviewed annually. For the first review in May 2019, Japan submitted a government opinion, expressing its concerns about the method of determining injury and the operation of tariff quotas. Based on the review, on September 26, 2019, the EU announced its final decision to make partial changes to existing safeguard measures, such as the level and allocation of tariff quotas for each target item and updating the list of exclusions for developing countries. The decision came into effect on October 1, 2019.

The second review, launched in February 2020, solicited opinions on a proposal from the domestic industry (requesting a significant tightening of trade restrictions, including a 75%

reduction in tariff quotas, in consideration of the impact of the COVID-19 pandemic). Japan submitted a government opinion opposing the proposed tightening of the measure. On June 30 of the same year, the EU announced its final decision to shorten the period of country-based import quotas for some items (from every year to every quarter), and to strengthen the restrictions on the use of the residual quotas, which came into effect the following day, July 1. The industry’s proposals, such as reduction of tariff quotas, were not adopted.

In the third review, commenced in February 2021, it was decided that the measure itself would be extended until June 2024, while some modifications were made, including the additional review process of the whole measure in the event of changes in the trade effects of the US Section 232 measure. Most recently, in December 2022, the review process was commenced again to assess whether the measure was to be terminated earlier. However, as a result of the review, the measures were not terminated early and the safeguard measures were continued until June 30, 2024.

With regard to this safeguard measure, Turkey filed a dispute settlement procedure (DS595) with the WTO, claiming that it is inconsistent with the Safeguard Agreement, etc. The panel report released in April 2022 found that the logical connection between the above “unforeseen developments” and the increase in imports was not clearly presented, and that the finding of “threat of injury” was not based on objective evidence (the report was adopted next month). The EU announced its implementation method in December of the same year, but has indicated its intention to continue the measure itself.

Japan will closely monitor the trade diversions of the subject products to Asia, etc., and the risks of “rush” exports to the EU to quickly exhaust the tariff quotas, and reach out to the EU as necessary.

## STANDARDS AND CONFORMITY ASSESSMENT SYSTEMS

### (1) EU DIRECTIVE ESTABLISHING A FRAMEWORK FOR THE SETTING OF ECODESIGN REQUIREMENTS FOR ENERGY-RELATED PRODUCTS (ERP)

#### <OUTLINE OF THE MEASURES>

To establish a framework for designing environment-friendly products, the EU published the “Directive Establishing a Framework for the Setting of Ecodesign Requirements for Energy-Using Products” (EuP Directive) in 2005 and the “Directive Establishing a Framework for the Setting of Ecodesign Requirements for Energy-Related Products” (ErP Directive or Ecodesign Directive) in October 2009.

The Directives require subject business operators to design their products which would be placed on the EU market taking into consideration the environmental impact (e.g.: consumption of resources, emissions to air or water, noise, vibration, etc.) throughout the entire product life cycle, from procurement, manufacturing, and distribution to disposal (the general environmental consideration system requirements). Some products have specific numerical requirements on the volume of electricity consumption and standby electricity consumption (the specific environmental consideration system requirements). The requirements for each product type are specified in the

“Implementing Measures.”

#### <PROBLEMS UNDER INTERNATIONAL RULES>

The draft “Implementing Measures” notified to the TBT Committee had some issues: (1) part of the requirements were inconsistent with the existing regulations and their scientific basis and effects were unclear and (2) definitions of some requirement were not clear. If the Directive is regarded as trade-restrictive than necessary for the purpose of fulfilling legitimate policy objectives, it may violate Article 2.2 of the TBT Agreement.

#### <RECENT DEVELOPMENTS>

An amendment to the ErP Directive was proposed by the European Commission in March 2022, along with a draft Ecodesign for Sustainable Products Regulation (ESPR). The draft regulation would expand the scope of the ErP Directive to include a wider range of products. It also introduces circularity principles (such as product durability, resource efficiency, use of recycled material and recyclability), addresses the environmental impact (environmental footprints) throughout the product life cycle, and introduces a digital product passport to enable traceability of environmental information. In December 2023, the draft of this regulation was provisionally agreed upon by the European Parliament and the Council. As part of this agreement, the disposal of unused textile products will be prohibited. The regulation will be adopted by the Parliament and the Council and will enter into force 20 days after promulgation.

The new regulation itself will only establish a framework for sustainability requirements, but priority product fields will be defined in the later stage and the corresponding requirements will be set then after by the European Commission through delegated acts. The draft also proposes the disclosure of information regarding the disposal of unsold items for all products and the prohibition of disposing of unsold textiles and footwear.

It is necessary to closely monitor the developments in this case so that access to the EU market is not restricted by excessive requirements.

## (2) REGULATIONS ON CHEMICALS (REACH/CLP)

#### <OUTLINE OF THE MEASURES>

In the EU, the REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) ((EC) No 1907/2006), which is a regulation concerning the registration, evaluation, authorization and restriction of chemicals, was enforced on June 1, 2007.

The characteristics of the regulation are as follows:

- (1) Any manufacturer or importer of chemical substances in the EU, in amounts greater or equal to 1 ton/year must be registered. In addition, a chemical safety report must be prepared by each registrant who manufactures or imports 10 tons or more quantities of chemical substance in a year.
- (2) The responsibility of the safety assessment of existing substances which was taken by the government so far is imposed on the companies.
- (3) Based on this regulation, the European Chemicals Agency (ECHA) and member countries will evaluate (examine) the registered substances. The ECHA and member countries will prioritize the evaluated target substances based on hazards information, exposure information and amount of usage, and publish them in CoRAP (Community Rolling Action Plan) list.

- (4) When an article contains intentionally released substances and the quantity placed on the market exceeds 1 ton in a year, the registration becomes mandatory under certain conditions.
- (5) If substances of very high concern (SVHC) exceed 0.1% concentration in an article and the quantity of that substance placed on the market exceeds 1 ton during a year, the notification and communication become mandatory. The manufacturers and importers of complex objects in the EU are obligated to calculate a concentration of SVHC in each component that construct complex objects, and this is burdensome especially for importers who must collect information from outside the EU, which is not covered by the REACH.
- (6) For chemical substances listed in Annex XIV as substances of very high concern, such as those that are carcinogenic, that are subject to authorization, market supply and usage is approved for each application.
- (7) In the case of unacceptable risks arising from the manufacture, use, or placing on the market of a substance, restrictions on its manufacture, use, or placing on the market are specified in Annex XVII.

In January 2009, the CLP (Regulation on Classification, Labelling and Packaging of substances and mixtures) ((EC) No 1272/2008) was enforced. This regulation classifies the hazardous properties of substances or mixtures in accordance with the hazard classification of the UN GHS, and requires warning labels for substances or mixtures that are determined to be hazardous.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

These regulations may violate Article 2.1 of the TBT Agreement when they bring disadvantages to non-EU companies compared to local companies. The REACH and CLP regulations aim to ensure a high level of protection of human health and the environment, to ensure the free movement of substances, mixtures and articles, and to ensure competitiveness and innovation, but if they are more trade-restrictive than necessary for the purpose of fulfilling the relevant policy objectives, they may be inconsistent with Article 2.2 of the TBT Agreement. In addition, if the CLP regulation is not based on the GHS, which is an international standard for labeling and classifying hazardous products, it may be inconsistent with Article 2.4 of the TBT Agreement.

#### <RECENT DEVELOPMENTS>

In October 2020, the EU also released the Chemicals Strategy for Sustainability (CSS), which aims to promote innovation regarding safe and sustainable chemicals and to strengthen health and environmental protection against hazardous chemicals. As part of this strategy, the EU is working on amending the 2021 REACH Regulation and the CLP Regulation. In the amendments to the REACH Regulation, registration of polymers and restrictions on the use of chemical substances based on the concept of “essential use” were considered, and public consultation was conducted from January 2022 to April of the same year. In the amendments to the CLP Regulation, a draft of the Delegated Regulation, which classifies and labels endocrine disrupting (ED), persistent, bioaccumulative, toxic (PBT/vPvB), persistent, mobile, and toxic (PMT/vPvM) as new hazards ahead of GHS, was announced on September 20, 2022, and the TBT committee was notified on the following day, September 21. The introduction of these new hazards is a proposal that undermines the harmonization with the

international GHS standards, and the Japanese domestic industry submitted comments, but the Regulation was promulgated as the Commission Delegated Regulation ((EC) 2023/707) on March 31, 2023. Furthermore, a draft amendment setting forth requirements for digital labels and online sales was published on December 19, 2022, notified to the TBT committee on April 17, 2023, and entered into force on April 20, 2023.

Based on the CSS, the new hazards will be included not only in chemicals management but also as in a standard for disclosure in the EU such as the Delegated Act on Taxonomy for Classifying Sustainable Business Activities and the Sustainability Reporting Directive.

On the other hand, the EU proposed at the UN GHS Sub-Committee meeting in December 2022 to introduce the new hazard classification introduced in the CLP Regulation into the UN GHS, and this proposal is now under consideration. Thus, as the effects of the REACH and CLP Regulations extend beyond the EU, developments in the regulation of chemicals in the EU need to be closely monitored.

Changes have also been seen in the application of REACH regulation restrictions, with proposals of restrictions in substance groups (bisphenols and PFASs (per- and polyfluoroalkyl substances)). In December 2022, the proposal for restriction on bisphenols with endocrine disrupting properties was made by Germany, but was temporarily withdrawn in August 2023.

With respect to PFASs, in January 2023, a comprehensive PFAS restriction proposal covering more than 10,000 PFASs was submitted by 5 Members: Denmark, Germany, the Netherlands, Norway and Sweden, and public consultation was conducted from March 2023 to September of the same year. In response, not only a number of Japanese companies and industry associations, but also the Materials Industry Division of the Ministry of Economy, Trade and Industry of Japan submitted comments pointing out the consistency with Article 2.2 of the TBT Agreement. At the WTO/TBT Committee meeting in June 2023, the Government of Japan made a statement together with South Korea regarding the proposed PFAS restrictions as a New Specific Trade Concern.

With respect to the REACH regulation, although not limited to the REACH regulation, the proposal to significantly lower the threshold for unintentional contamination of persistent organic chemicals regulated by the EU's Persistent Organic Pollutants (POPs) Regulation ((EU) 2019/1021) under the Stockholm Convention continues from 2023 and should be closely monitored.

### **(3) MEDICAL DEVICE REGULATION (MDR) AND IN VITRO DIAGNOSTIC MEDICAL DEVICE REGULATION (IVDR)**

#### **<OUTLINE OF THE MEASURES>**

The EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR) came into force in May 2017, and after a transition period, The MDR was scheduled to apply from May 2020, and the IVDR from May 2022. However, the number of Notified Bodies (NBs) designated by EU member states for MDR certification was insufficient even one year before the application of the MDR, and the accredited NBs had not yet started accepting new items for assessment in Japan, coupled with the delayed issuance of necessary guidance. Therefore, Japan has been expressing its concerns at the TBT Committee meetings since November 2019, and has been requesting actions such as postponement of the effective date. In this regard, in April 2020, the EU announced a one-year postponement of the application of the

MDR so that government agencies, research institutes, and the medical product manufacturing industry could focus on the response to the new coronavirus, and the postponed application was set to begin in May 2021. The MDR stipulates that MDD (Medical Device Directive) compliant products that have been placed on the market prior to or during the above period or during the validity period of the MDD certificate may continue to be made available on the market or put into service until May 2025. While the IVDR started to be applied in May 2022 as scheduled, the transition period for IVD devices requiring NB certification has been extended from 3 to 5 years depending on the class.

Restricted access to medical devices in the EU due to delays in MDR and IVDR certification was regarded as a problem. By (EU) 2023/607 of March 2023, the transitional measures were extended until the end of May 2026 for Class III implantable custom-made devices, until the end of December 2027 for other Class III devices and some Class IIb implantable devices, and until the end of December 2028 for other Class IIb devices, Class IIa devices, and Class I devices.

#### **<PROBLEMS UNDER INTERNATIONAL RULES>**

Requirements for clinical evaluation are excessive compared to Japan and the U.S., and may be more trade-restrictive than necessary to achieve legitimate objectives. In addition, there is an issue of no set transition period for guidance and harmonized standards.

#### **<RECENT DEVELOPMENTS>**

Japan has expressed concerns about the regulation to the EU with other countries at the TBT Committee, and also held discussions with policy makers at bilateral dialogues. In the past, at a meeting of the TBT Committee, Japan requested investigation into the cause of and improvement of the delay in assessments for MDR certification, and enhancement of NB and guidance documents for IVDR certification.

To ensure that Japanese companies are able to gain access to the medical device market in the EU, it is necessary to continue to request the EU to establish a system that allows a smooth transition to the new regulation.

## **(4) Rules for Batteries and Waste Batteries**

#### **<OUTLINE OF THE MEASURES>**

In December 2020, the EU published a new draft regulation on batteries and waste batteries, and notified the TBT committee of it in January 2021. In December 2022, an interim agreement was reached between the European Parliament and the Council of the European Union. On January 18, 2023, the draft amendment by the European Commission, the European Parliament, and the Council of the European Union was published. This regulation was adopted on July 12, 2023 and became effective on August 17, 2023. For the operation of this regulation, a sub-regulation is expected to be adopted between 2023 and 2028, and targets for recycling efficiency, material recovery rate, and recycling rate are expected to be phased in after 2025.

Article 48 of the regulation establishes the obligation for economic operators placing batteries on the market or using them to develop and implement a due diligence policy for raw materials and social and environmental risks. Article 77 of the regulation stipulates the creation of the "battery passport," and Annex XIII specifies the composition and structure of the battery materials as information that must be included in the battery passport. In

addition, the regulation includes new elements or concepts such as carbon footprint, inclusion of recycled materials, conformity assessment, and extended producer responsibility.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

Articles I and III of GATT prohibit discrimination between imported products and between imported products and domestic products, and Article XX of GATT allows measures for specific purposes under certain conditions, but prohibits the application of measures that would constitute arbitrary or unjustifiable discrimination. Article 2.1 of the TBT Agreement also prohibits discrimination. While each country has the right to determine its own domestic environmental protection policies and power source composition, when applying a measure, it is desirable to consider whether the regulation is appropriate in light of these non-discriminatory regulations and different circumstances in the exporting country and whether it has the flexibility to reflect the domestic circumstances of the exporting country. For example, an issue could be raised on whether the circumstances of the exporting country are taken into account in the way the carbon footprint is calculated, in the reporting format, and in the way due diligence is conducted. In addition, since Article 2.2 of the TBT Agreement requires that no more trade-restrictive measures be employed than are necessary to achieve legitimate objectives, it must be ensured that the procedures and requirements of this regulation are no more trade-restrictive than necessary to achieve the objectives of safe and sustainable production and recycling of batteries.

This regulation covers a wide range of battery types, from small portable batteries to automotive and industrial batteries. There are many points where it is not clear who in the supply chain is responsible for what obligations for the different sales channels of different types of batteries, and in addressing this issue, there is confusion and burden due to different interpretations by different companies. For example, if a final product into which a battery is incorporated outside the EU is imported into the EU and the battery to be incorporated is manufactured by an entity different from the manufacturer of the final product, it is not clear whether it is the manufacturer of the battery or the manufacturer of the final product that shall fulfill the obligation of “manufacturer” under the Regulation. There is a risk of violation of Article 2.1 of the TBT Agreement if imports from outside the EU are treated less favorably than goods produced within the EU. There is also a risk of violation of Article 2.2 of the TBT Agreement if it is more trade-restrictive than is necessary for achieving a legitimate purpose.

In addition, Article 77 of the proposed rules and Annex XIII described in <Outline of the Measures> require information such as the composition and structure of the battery materials to be included in the electronic switching system, which is often a trade secret for the business operator. There is a risk of a violation of Article 2.2 of the TBT Agreement if such trade secret request becomes more trade-restrictive than is necessary for achieving a legitimate purpose.

Furthermore, CHAPTER VII of the Regulation establishes the due diligence obligations of economic operators. Despite the fact that the requirements include time-consuming conformity requirements, such as the establishment of a management system that includes the appointment of top management and the requirement for third-party audits by certification bodies, the deadline for the preparation of guidelines that specify details is six months prior to the start date of application, and no date is specified for the adoption of relevant bylaws. It is impossible for business operators to foresee when the information necessary for conformity

will be collected and when they can begin to take action. If sufficient grace time is not given between publication and implementation of the regulations, Article 2.12 of the TBT Agreement may be violated.

Japan exchanged opinions on the proposed regulations at the Working Group on Automobiles under the EU-Japan Industrial Policy Dialogue held in December 2022, and requested the EU to provide information on the calculation method of carbon footprint, recycling, data handling, etc. Japan will continue discussions with the EU and urge the EU to ensure that these requirements and procedures are not more trade-restrictive than necessary to fulfill a legitimate objective.

## (5) F-gas Regulation

#### <OUTLINE OF THE MEASURES>

In the EU, greenhouse gas regulations have prohibited the use of certain CFCs (chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs)) since 2000 in order to protect the ozone layer and reduce global warming. In 2006, a regulation was implemented to control emissions of CFC substitutes (hydrofluorocarbons (HFCs)).

Subsequently, with the aim of reducing emissions of greenhouse gases containing fluorine (“F-Gases”) by two-thirds of the 2010 emissions by 2030, the regulation was newly revised in 2014 to require a reduction in the total amount of F-Gases used. It also prescribed a restriction on equipment using HFCs, stipulating that the global warming potential (GWP) of the refrigerant shall be less than 750 for split-type air conditioners with a refrigerant capacity of less than 3 kg starting 2025.

In order to further accelerate the reduction of HFC emissions, the European Commission submitted a new Commission proposal in April 2022, which was adopted by the European Council and the European Parliament in January 2023 (published in the Official Journal in February 2024) after trilogue discussions among the European Commission, the European Council, and the European Parliament in October 2023.

This revision includes provisions to prohibit the use of F-Gases in certain equipment such as air conditioners and heat pumps as follows: 1) in the case of split-type air conditioners (in which refrigerant circulates among both indoor and outdoor units), (i) for a capacity of 12 kW or less, the use of GWP 150 or more will be prohibited starting 2027 or 2029 (depending on the type of such products) and the use of F-Gases will be completely prohibited from 2035, and (ii) for a capacity greater than 12 kW, the use of GWP 150 or more will be prohibited starting 2033; and 2) in the case of self-contained ones (which contain refrigerant only in the outdoor unit), (i) for a capacity of 12 kW or less, the use of GWP 150 or more will be prohibited starting 2027 and the use of F-Gases will be completely prohibited starting 2032, and (ii) for a capacity greater than 12 kW, the use of GWP 150 or more will be prohibited sequentially depending on the equipment and capacity.

Japan has been developing next-generation refrigerants with GWP as low as natural refrigerants (e.g., hydrofluoro-olefins (HFOs), etc.) to reduce HFCs and mitigate climate change. The EU’s planned complete ban on F-Gases could obstruct such innovative solutions (innovations) and prevent access to safe, energy-efficient technologies and products. In addition, propane (R290), the leading alternative refrigerant under the EU’s F-Gases regulation, is highly flammable and raises safety concerns during installation, repair, and disposal.

### <PROBLEMS UNDER INTERNATIONAL RULES>

There are technological difficulties in using flammable natural refrigerants in light of safety risks, etc., especially for split-type air conditioners, which contain refrigerant in their indoor units. Thus, this revision, which prohibits all F-Gases including HFO refrigerants, will make it impossible to market “split-type air conditioners using F-Gases” manufactured outside Europe. Therefore, the F-gas Regulation is disadvantageous to such split-type air conditioners produced outside Europe compared to “monoblock air conditioners using natural refrigerants,” which are the mainstay like domestic products manufactured in the EU.

In addition, although the purpose of this Regulation is to reduce greenhouse gas emissions, it uniformly prohibits the use of low-GWP F-Gases (including HFO refrigerants) that would contribute to this purpose. Furthermore, no risk impact assessment of the safety risks associated with the use of highly flammable refrigerants or the greenhouse effects associated with the use of F-Gases with low GWP values has been conducted. Considering these aspects, it is doubtful that the Regulation has been designed to be sufficiently relevant to the said purpose. Therefore, the aforementioned disadvantages to split-type air conditioners, which are the mainstay products outside Europe, cannot be regarded as solely based on legitimate regulatory distinctions and may violate Article 2.1 of the TBT Agreement.

Further, the Regulation uniformly prohibits the use of F-Gases even in the case where there is no alternative refrigerant available to replace F-Gases. Moreover, as described above, the Regulation uniformly prohibits the use of low GWP F-Gases, which would contribute to the purpose of GHG reduction (in the preamble to the Regulation, there is a reference to the need to consider future PFAS regulations that take health and environmental impacts into account when considering alternative refrigerants). Thus, the Regulation may violate Article 2.2 of the TBT Agreement as a more trade-restrictive measure than necessary to fulfil a legitimate objective.

In the first place, the TBT notification under the TBT Agreement was implemented in November 2023 and comments on the notification were accepted for 60 days thereafter, but the Commission’s press release (dated October 2023) states that the regulation will enter into force upon adoption by the European Parliament and the Council of the EU, without expressing any intention to take comments from Members on the TBT notification into account. In addition, the part of the Regulation related to the complete prohibition of F-Gases, which was newly included by the October 2023 political agreement, was not reported in the said TBT notification. These points may violate Article 2.9 of the TBT Agreement, which establishes the obligation to notify Members of important information regarding the content of the proposed technical standards, to give them reasonable time to make comments in writing, and to take those comments into account.

### <RECENT DEVELOPMENTS>

In addition to submitting its opinion on the TBT notification, the Government of Japan has expressed its concern at bilateral consultations through the Japan-EU EPA Regulatory Cooperation Committee at the end of February 2024 and at the WTO TBT Committee (the “TBT Committee”) meeting in March 2024.

We will continue to closely monitor developments with regard to the revisions to the Regulation and work to ensure that the revised system strikes an appropriate balance among safety, energy efficiency, and other aspects.

## (6) Regulation on Trade in And Exports from the EU Market of Certain Products And Products Associated With Deforestation And Forest Degradation

### <OUTLINE OF THE MEASURES>

The Regulation on the making available and export of products associated with deforestation (Regulation (EU) 2023/1115) entered into force in June 2023. The Regulation covers cattle, cocoa, coffee, oil palm, rubber, soybeans, wood, and related products. This Regulation states that the covered products must not be imported into or sold within the EU unless they do not cause deforestation or forest degradation in the production process (i.e., “deforestation-free”) and are produced in accordance with the relevant laws and regulations in the country of production.

From December 30, 2024 (June 30, 2025 in the case of small or middle-size enterprises), before importing and selling the subject products in the EU internal market, business operators must conduct due diligence, including (i) information on the production process of the subject products (source, production area, production period, etc.), (ii) assessment of deforestation risk in the production process, and (iii) measures to mitigate deforestation risk.

The Regulation plans to set up a benchmarking system to classify deforestation risks in all countries or regions worldwide into “high risk,” “low risk,” and “standard risk,” which will be published by the end of 2024. It is planned that the content of obligations imposed on business operators will vary depending on the risk classification of the producing country or region. For example, (ii) risk assessment and (iii) risk mitigation measures will not be imposed on target products from “low risk” countries or regions.

### <PROBLEMS UNDER INTERNATIONAL RULES>

While the details of the above benchmarking system and business operators’ due diligence obligations are not yet clearly disclosed, there is concern that some of the targeted products may have complex supply chains that make it difficult to geographically identify and trace the production process of raw materials prior to processing. In such cases, depending on the content of the obligation, exports from “high risk” and “standard risk” countries/regions may be effectively difficult. If an EU Member were to be identified as “low risk,” it may not be consistent with Article III:4 of GATT (National Treatment Obligation).

Also, if a particular country is identified as a “high” or “standard” risk country, it may not be consistent with Article I of GATT (MFN Obligation), since the due diligence obligation on export of the subject product would be more onerous than for other non-EU “low” risk countries.

Although the objective of deterring deforestation itself may fall under Article XX: (b) and (g) of GATT, etc., it is not justified if the method is “a matter which would constitute a means of arbitrary or unjustifiable discrimination” under the chapeau of the same Article.

### <RECENT DEVELOPMENTS>

At the TBT Committee meeting in November 2023, in addition to Southeast Asian and Latin American countries with tropical rainforests, developed countries such as the United States, Canada, and Australia expressed concern about the risk classification in the benchmarking system to be announced and its trade restriction effects.

Japan will closely monitor the impact on Japanese industries and will continue to lobby the EU to ensure that the regulations enforced



do not become more trade-restrictive than necessary.

## (7) PACKAGING AND PACKAGING WASTE REGULATION

### <OUTLINE OF THE MEASURES>

On November 30, 2022, the European Commission published a draft Packaging and Packaging Waste Regulation, and reached a tentative political agreement with the European Parliament and the Council of the European Union in March 2024. It is expected to be adopted in the first half of 2024.

This Regulation is in line with the EU's environmental policy to promote the circular economy, which prioritizes plastic products and food waste, and will apply to all packaging placed on the market in the EU (such as cans, bottles, plastic bottles, and plastic packaging materials). The Regulation provides for the following: packaging must be recyclable in the EU; plastic packaging must contain a certain percentage of recycled materials; packaging must be designed to have the minimum necessary weight and volume; and packaging for transportation must be reusable and a system for reuse must be ensured. The various obligations for business operators will be applied gradually, starting 18 months after the implementation of the Regulation (or after January 1, 2030 for the recycling and reuse obligations).

### <PROBLEMS UNDER INTERNATIONAL RULES>

The obligations on business operators have not yet been enforced, and discussions are still ongoing on the details of the scope and content of the obligations, but there are concerns that the measure will place a heavy burden on business operators operating in the EU, particularly in the food and beverage industry, by requiring the establishment of an EU-wide recycling system for packaging materials in general.

On the other hand, there are criticisms that priority is being given to the impact on EU industries, such as the early exclusion of whiskey and wine, many of whose suppliers are based in the EU. As a result, if the obligation to recycle and reuse is imposed only on non-EU products that compete with EU products, they will be treated less favorably than EU products, which may not be consistent with the national treatment obligation.

### <RECENT DEVELOPMENTS>

The draft of the regulation tentatively agreed in March 2024 which specifies that the CN Code (Joint Customs Tariff Classification establishing the common customs duties outside the EU) 2206 00 (including *sake*) and 2208 (spirits; including plum wine, *yuzu-shu*, *shochu*, etc.) as excluded items. Then, it has been revealed that *sake* and *shochu*, the typical main exports of Japanese beverage manufacturers, have been excluded as products similar to wine.

We will continue to closely monitor the process of future rulemaking and to continuously lobby the EU to ensure that the regulations to be enforced do not become more trade-restrictive than necessary.

## TRADE IN SERVICES

### AUDIO-VISUAL SERVICE

\*This is a policy and measure related to trade and investment that cannot be said to be clearly problematic from the viewpoint of consistency with international rules, including the WTO Agreements. However, in view of the following concerns, we have decided to include this in this column.

### <OUTLINE OF THE MEASURES>

With the aim of protecting cultural values in the EU region, the EU had required Members to ensure, where practicable and by appropriate means, that broadcasters reserve a major proportion of their transmission time for European works, excluding the time appropriated to news, sporting events, games, advertising, and teletext services, under the EU Directive "Television without Frontiers" 89/552/EEC (amended Directive 97/36/EC). In accordance with this Directive, all Members have completed the preparation of national legislation. In France, for example, at least 60 percent of television broadcasts of films must feature European films; furthermore, at least 40 percent of all broadcasts must be in French (Government Statute No. 86-1067 of January 18, 1992). Subsequently, the Directive was reborn as the Audiovisual Media Services Directive, which entered into force on December 19, 2007. New disciplines have been added to the Directive for television advertising, video-on-demand, and the like.

In addition, on September 16, 2022, the EU adopted the discipline establishing a common framework for media services in the EU internal market (European Media Freedom Act) and a proposal to amend the Directive 2010/13/EU. Attached to this proposal was an EU Recommendation on internal safeguards for editorial independence and ownership transparency in the media sector. The objective of the European Media Freedom Act is to protect the pluralism and independence of the media in the EU and to allow the media to operate more easily across borders in the EU internal market without undue pressure and taking into account the digitalization of the media space, and this Act contains the following measures:

- A) Protection against political interference or surveillance of editorial decisions;
- B) Emphasis on independence and stable funding of public media and transparency in the allocation of media ownership and state advertising;
- C) Protection of the independence of editors and requisition of disclosure of conflicts of interest; and
- D) Creation of a new independent European Media Services Commission consisting of national media authorities.

The EU recognizes that the definition of "European works" contained in the Directive is in line with the "open and broad understanding of the concept of 'European audiovisual works'" established by the 1989 "Convention on Transnational Television" of the European Council.

### <CONCERNS>

In the WTO services negotiations, the EU has not made any commitments to the AV sector and has also registered a Most Favored Nation (MFN) exemption, so the above measures cannot be regarded as a violation of the WTO Agreement. However, since the General Agreement on Trade in Services (GATS) covers all services, efforts toward liberalization are desirable.

MFN is one of the most important pillars for achieving liberalization in the multilateral trading system and is a fundamental principle in the WTO Agreements. Since the MFN exemption measure is a deviation from its most important principle, it is

desirable to abolish such measure. The GATS also stipulates that the MFN exemption is temporary and must not exceed 10 years in principle. In this regard, it cannot be overlooked from the spirit of the WTO that the EU itself stated in its July 2009 “Staff Working Paper on External Aspects of Audio-Visual Policy” that it would encourage countries that intend to join the WTO in the future to refrain from undertaking audiovisual services and to register for MFN exemption in order to establish cultural cooperation with the EU.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

As mentioned above, the “Proposal for a Directive of the European Parliament and of the Council Amending Council Directive 89/552/EEC (EU Directive “Television without Frontiers”) on the coordination of certain provisions laid down by law, regulation or administrative action in Members concerning the pursuit of television broadcasting activities (Proposal for Audiovisual Media Services Directive)” [COM(2005)646] was adopted by the European Parliament in November 2007 and entered into force the following December. The deadline for transposing the Directive into national law was within 24 months (December 19, 2009) and all Members have already notified the European Commission of their legislation to transpose the Directive into national law.

On March 29, 2011, the European Commission asked 16 Members to provide information on the application of the “Audiovisual Media Services Directive (AVMSD).” It analyzed the national legislation adopted by the Members and communicated with the European Commission to ensure that the content of the Directive was properly reflected in the national legislation. From July to September 2015, a public consultation was held for stakeholders and users to obtain feedback on the Audiovisual Media Services Directive. On May 25, 2016, a proposed amendment to the Directive was submitted by the European Commission to the European Parliament. On April 25, 2017, the European Parliament’s Committee on Culture and Education agreed on this proposed amendment. Subsequently, the European Parliament approved a proposed amendment to the Directive on October 2, 2018, after tripartite consultations between the European Commission, the European Parliament, and the European Council, and the European Council adopted the proposed amendment on November 6 of the same year. This proposed amendment revises the regulations on audiovisual service providers from the viewpoint of consumer protection at a time when viewing methods of audiovisual services are changing from traditional TV to online media. In particular, it is noteworthy that on demand services are also subject to quota regulations that require the distribution of a certain amount of European works. In November 2020, the European Commission sent formal notifications to 23 Members for failing to transpose AVMSD into national law. On September 23, 2021, the European Commission also sent opinions to the Czech Republic, Estonia, Ireland, Spain, Croatia, Italy, Cyprus, Slovenia, and Slovakia for failing to fully develop national legislation addressing AVMSD. On May 19, 2022, the European Commission decided to request the Court of Justice of the European Union to impose sanctions pursuant to Article 260, Paragraph 3 of the Treaty on the Functioning of the European Union in respect of Czech Republic, Ireland, Romania, Slovakia, and Spain. Subsequently, the Court of Justice of the European Union ruled against Ireland on February 29, 2024, finding a breach of its obligations (Case C-679/22).

In 2023, the EU adopted a report on the implementation of the AVNSD. The report, which examines the implementation of the

Directive to date, criticizes the “insufficient willingness” of some Members to implement the new Directive on time and the EU’s “general reluctance” to initiate infringement proceedings, and calls on governments to implement the Directive without delay. According to the report, the lack of transfer by some Members has affected the ability of legislators to make a full-fledged assessment of the implementation of the Directive.

While cultural protection policies in the EU continue to be strictly enforced, Japan urges the EU to improve its liberalization commitments in the WTO services negotiations, etc.

## GOVERNMENT PROCUREMENT

### NEW REGULATION ON PUBLIC PROCUREMENT (INTERNATIONAL PROCUREMENT INSTRUMENTS)

#### <OUTLINE OF THE MEASURES>

The IPI Regulation 2022/1031 established a scheme where the European Commission will conduct a survey on a foreign procurement market and in the case where the Commission determines that the country “adopts or maintains a restrictive or discriminatory procurement measure or practice,” the Commission will consult with the country to resolve the problem. If the consultation fails, the Commission will take price adjustment measures for procurement from the country.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

Under this regulation, if the European Commission determines that it is in the interest of the EU, on its initiative or upon a substantiated complaint of Union interested party or a Member State, the European Commission may initiate an investigation into a suspicious measure or practice of a third country (Article 5, Paragraph 1). After the European Commission publishes a notice containing its preliminary assessment of the third-country measure or practice, it requests views and information from such third country and enters into consultations (Article 5, Paragraph 2). The investigations and consultations must end within 9 months from the date of their initiation. This period may be extended for a period of 5 months in duly justified cases (Article 5, Paragraph 3). If, after the conclusion of the investigations and consultations, the European Commission finds that the alleged measures or practices of the third country exist, it shall adopt IPI measures if it determines that they are in the interest of the EU (Article 6, Paragraph 1).

This regulation is applied only to the procurement of goods and services that are not covered by an international agreement (non-covered goods and services). In other words, this proposed regulation is applied to (1) goods and services of the third country that has not signed an international agreement with the EU, and (2) non-covered goods and services of the third country that has signed an international agreement with the EU.

Thus, under the basic scheme of this regulation, procurement for which the EU commits national treatment under an international agreement is said to be not applicable to the above regulation. However, for instance, when, in the case of bidding by a supplier from a third country where an alleged procurement measure or practice is identified, the total amount of goods from the country exceeds 50% of the bidding amount and a considerable quantity of Japanese goods are also included, Japanese goods may be subject

to the price adjustment measures under this regulation, and it cannot be denied that the regulation may violate the non-discrimination principle (Paragraph 1 of Article 4 of the WTO Agreement on Government Procurement).

#### <RECENT DEVELOPMENTS>

In March 2012, for the purpose of giving more incentives for trade partners to open their public procurement markets that are not sufficiently accessible, the European Commission proposed a new regulation on public procurement (COM (2012)124). In January 2016, the European Commission published an amendment to the proposed regulation (COM (2016)34). The latest amendment, which further amends the European Commission's 2016 amendment, was submitted by Portugal (President of the European Council for the first half of 2021) in 2021. The proposed amended regulation was adopted on June 23, 2022 by the Council of the European Union and the European Parliament through the ordinary legislative procedure provided for in Article 294 of the EU Treaty, using Article 207 of the EU Treaty as the legal basis. It was published in the official gazette, enacted and issued on June 30, 2022. It came into force on August 29, 2022, i.e., 60 days after its publication in the official gazette.

## REGIONAL INTEGRATION

### INCREASING BOUND TARIFF RATES

#### <OUTLINE OF THE MEASURES>

Croatia joined the EU in July 2013. As in the case of the successive EU enlargement since 1973, the EU Common Customs Tariff replaced tariffs imposed by the new Member, resulting in higher tariffs (bound tariff rates) on some products. According to Article XXVIII: 1 of GATT, the bound tariff rates may be increased by prior negotiation and agreement with the relevant countries. However, the EU did not terminate negotiations with Japan and other relevant countries, and the tariff rate was increased in the new Member. Unilateral increases in the bound tariff rates by the EU were also made when Bulgaria and Romania joined the EU in January 2007, when the EU expanded with the accession of 10 new Member States in May 2004, and even before that. At the time of EU enlargement in 2004, Japan urged the EU to conclude negotiations before the EU enlargement, but the EU raised tariffs in the new Members without conducting any prior negotiations with the relevant countries including Japan. It took about one year and eight months after the EU enlargement for the compensation measures agreed upon through negotiations with Japan to take effect, and during that period, some exporting companies to the EU suffered losses resulting from the collection of unilaterally increased tariffs.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

Unilateral tariff increases associated with EU enlargement are not consistent with GATT Article 24: 6, which requires compensatory adjustments in accordance with the procedures set out in Article XXVIII of GATT in the case of an increase in bound tariff rates.

#### <RECENT DEVELOPMENTS>

In July 2013, Japan notified the EU in writing that it intended to commence negotiations under Article XXIV: 6 of GATT in connection with Croatia's accession to the EU, and held discussions

with the EU on this matter. In the negotiations under Article XXIV: 6 of GATT in connection with the accession of Bulgaria and Romania to the EU in 2007, the differences between Japan's claim that the amount of damage is accumulated damages resulting from the tariff rate increase, and the EU's claim that even if the tariff rate is increased in one new Member, the benefit should be taken into consideration if the tariff rate is reduced in another new Member, and that compensation is unnecessary if the benefit of the tariff rate reduction is also taken into consideration, were not closed, and the negotiations were concluded without obtaining any compensation measures.

Turkey, North Macedonia, Montenegro, Serbia, and Albania are negotiating accession to the EU, and Ukraine, Moldova, and Bosnia and Herzegovina are also recognized as candidate countries. In the future, if these countries become Members, there is a risk that the bound tariff rates will be raised, and it is necessary to continue to closely monitor the situation.

## PROTECTION OF INTELLECTUAL PROPERTY

### DESIGN RIGHT ENFORCEMENT ISSUES FOR SPARE PARTS

#### <OUTLINE OF THE MEASURES>

In the EU, there has been much debate over how to protect replacement component parts (spare parts) of complex products by design rights.

As a result, Article 110 of the Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs (hereinafter, "Community Design Regulation"), entitled "Transitional provision" provides the so-called "repair" clause stipulating that even if a right holder has the design right of a spare part for a complex product, he/she is not permitted to enforce the right if the spare part is used for the purpose of the repair of that complex product so as to restore its original appearance. In addition, regarding the above "repair clause", Article 14 of the Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs (hereinafter, "Design Directive"), which aims to harmonize the design systems across the EU Member States stipulates that Member States shall retain the legal status quo on spare parts design protection and introduce changes to those provisions only if the purpose is to liberalize the market for such parts. There is no unification in protection of spare parts by design right among EU countries.

According to the report published by the European Commission in 2020, "Evaluation of EU legislation on design protection", a "repair clause" has not been introduced in Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Lithuania, Malta, Portugal, Romania, Slovenia and Slovakia, while it has been introduced in Belgium, Hungary, Ireland, Italy, Latvia, Luxembourg, the Netherlands, Poland, and Spain. Denmark, Sweden and Greece are reported to have different systems in place, e.g., with different protection periods, for restricting design rights for spare parts (as discussed below, Germany and France have since passed amendments to their design laws to add a "repair clause").

By all rights, if a right holder has the design rights of a spare part itself, it means that he/she has the exclusive right to the design of the spare part. Therefore, the right holder should be able to eliminate any counterfeit of the spare part, regardless of whether it

is for the purpose of repairing so as to restore the original appearance of a complex product. However, the introduction of the “repair clause” excludes these spare parts from design protection, which could cripple innovations especially in the automobile industry.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

Article 26(2) of the TRIPS Agreement stipulates that Member States may provide limited exceptions to the protection of industrial designs, and the three cumulative conditions (three-step test) must be fulfilled for the exceptions to be approved, which are (1) confined to certain special cases; (2) no conflict with a normal exploitation; (3) no reasonable prejudice to the legitimate interests of the owners of rights, taking account of the legitimate interests of third parties. Therefore, it is still debatable regarding whether the exception of design right protection for spare parts used for the purpose of repair in Community designs and EU Member States is consistent with Article 26(2) of the TRIPS Agreement.

#### <RECENT DEVELOPMENTS>

The debate in the EU over how to protect design rights of spare parts used for the purpose of repair has not yet been settled, and both Article 110 of the Community Design Regulation and Article 14 of the Design Directive stipulate the matter as a transitional provision. In 2004, the European Commission brought forward a proposal to include the “repair clause” in the Design Directive, but it was withdrawn in 2014 after no agreement was reached. Subsequently, the Circular Economy Action Plan published by the European Commission in March 2020 also mentioned the introduction of a “right to repair” as a measure to ensure the sustainability of products, and the “Intellectual Property Action Plan” published by the European Commission in November 2020 also proposed the modernization of design protection in the EU, including the harmonization of the EU system for the protection of spare parts. The European Commission conducted a public consultation on the modernization of EU design protection from April to July 2021, including the question “Should design protection for spare parts be reviewed?” and published its summary report on its webpage in September 2021. The European Commission announced in November 2022 that it had adopted a proposal for a regulation amending the Community Design Regulation and a proposal for a directive on the legal protection of designs, and began inviting comments. The proposed amendment includes the introduction of “repair clause” throughout the EU. The Council of the European Union subsequently proposed amendments to the draft of the Regulation as above and the draft of the Directive as above, but retained the concept of “repair clause”. The Council then announced in December 2023 that it had reached a tentative agreement on the draft of the Regulation and that of the Directive.

Meanwhile, in Germany, the introduction of a “repair clause” in the Design Law, which was positioned as one of the main measures for consumer protection by the Social Democratic Party of Germany, was included in the agreement document of the coalition government formed in March 2018, and the federal government approved the introduction of the “repair clause” in the Design Law by the Cabinet decision in May 2019. In September and October 2020, the Bundestag (equivalent to the House of Representatives) and the Bundesrat (equivalent to the Senate) passed an amendment to the Design Act to add the “repair clause”, and the amendment to the Design Law was passed on October 9, 2020, and promulgated and enforced on December 2, 2020. As a result, in Germany, design

right protection no longer extends to spare parts for repair purposes.

In France, a repair clause had not been introduced in the past due to unconstitutional decisions by the Constitutional Council on procedural grounds, etc., despite its adoption by the French Parliament, but in accordance with Article 32 of the “Law on combating climate change and strengthening resilience to its effects,” passed on August 22, 2021, a new repair clause was established in the Intellectual Property Law, limited to certain spare parts related to automobiles, and an amendment was made to shorten the term of protection for other spare parts as well, and the amended law entered into effect on January 1, 2023.

Japan has continuously requested the EU to abolish the “repair clause”. In November 2019, at the 1st Meeting of the Committee on Intellectual Property under the Agreement between the European Union and Japan for an Economic Partnership, Japan took up the protection of the design rights of spare parts as one of the agenda and requested the EU to abolish the “repair clause”.

In the future, Japan needs to continue to pay close attention to the legislative and operational status of the design system and the Community design system in each EU Member State, keeping in mind that it is not appropriate for the efficacy of design rights to be unduly restricted

## SUBSIDIES AND COUNTERVAILING MEASURES

### REVISION OF ELIGIBILITY REQUIREMENTS FOR EV SUBSIDIES IN FRANCE

#### <OUTLINE OF THE MEASURES>

In July 2023, the French government announced a proposed amendment to the eligibility requirements for its subsidy program for the purchase of electric vehicles (EVs) to take into account CO<sub>2</sub> emissions from the manufacturing and transportation of the vehicles, and solicited public comments until August. In September, regulations implementing this amendment were promulgated and went into effect in October of the same year. The amendment sets an environmental score to be set from the CO<sub>2</sub> emissions of EVs during their manufacturing and transportation processes, and vehicles with an environmental score of 60 or higher will be eligible for subsidies. For the purchase of a passenger car, 27 % of the purchase price will be subsidized (up to 5,000 euros for individuals, 3,000 euros for corporations, and 7,000 euros for low-income individuals).

The environmental score is calculated based on the sum of CO<sub>2</sub> emissions calculated by multiplying the emission factor and the amount used for each of the following items: (i) emissions from the manufacturing of steel, aluminum, and other materials, (ii) emissions from battery manufacturing, (iii) emissions from intermediate assembly, etc. excluding batteries, and (iv) emissions from transportation. Emission factors for (i) through (iii) are set for each country or region, and emission factors for (iv) are set uniformly for each country or region in the case of land transport (rail and road) and determined based on distance in the case of maritime transport. If there are objections to the calculation of the environmental score, there is a provision that allows recalculation and reapplication of CO<sub>2</sub> emissions based on actual measured values. In December 2023, the French government published the list of vehicle models eligible for this subsidy program.

**<PROBLEMS UNDER INTERNATIONAL RULES>**

The calculation of the environmental score, which determines the eligibility for this subsidy program, takes emissions from transportation into account. In the case of maritime transport, emissions from transportation are calculated by multiplying the transportation distance by a uniform factor. In addition, in the case of land transport, emission factors for rail and road transportation in Asian countries are set higher than those for European countries. Due to these designs, imported vehicles are treated differently depending on the length of transportation distance and the method of transportation, which may violate Articles I:1 (MFN Obligation) and III:4 (National Treatment Obligation) of GATT. Moreover, CO<sub>2</sub> emission factors for steel, battery production, etc., used to calculate environmental scores are set uniformly for each country/region, with European countries/regions, including France, being assigned with better factors than other countries/regions, making imported cars harder to make a better score and less likely to be eligible for subsidies than French or European-made cars. Therefore, there is a possibility that this eligibility requirement violates Articles I:1 (MFN Obligation) and III:4 (National Treatment Obligation) of GATT as a requirement that accords some imported vehicles less favorable treatment.

**<RECENT DEVELOPMENTS>**

The Ministry of Economy, Trade and Industry of Japan submitted a public comment in August 2023, expressing its concern from the perspective of consistency with the WTO Agreements. It has expressed its concerns to the French government through various opportunities and to the EU through various meetings, expressing its concerns about the spread of this measure and similar measures to other countries and other sectors. It is necessary to closely monitor the situation in cooperation with industry and other countries in order to ensure that measures of questionable consistency are corrected and that similar measures do not spread to other sectors or countries.

## 2. The UK

### TARIFFS

**TARIFF STRUCTURE**

\* This particular case was included in light of the following concerns despite it being a trade or investment policy or measure that does not expressly violate the WTO Agreements or other international rules. Refer to Chapter 5, 1 of the 2020 Report on Compliance by Major Trading Partners with Trade Agreements - WTO, FTA/EPA and IIA- for definitions of tariffs, tariff rates, bound tariffs, and bound tariff rates.

**<OUTLINE OF THE MEASURES>**

The Customs and Excise Management Act, the Taxation (Cross-Border Trade) Act 2018, the European Union (Withdrawal) Act 2018, the Taxation (Post-transitional Period) Act 2020 and related legislation provide for various provisions on the import and export controls and customs, and the customs regime for the import and export of UK goods after leaving the EU. MFN or the Japan-UK Comprehensive Economic Partnership Agreement (Japan-UK EPA) tariff rates, etc. are applied to imports from Japan. In addition,

there are special measures related to customs declarations following the end of the transitional period for leaving the EU as well as tariff incentives (tariff exemptions) for temporary admission, re-import/re-export, processing treatment, and goods imported for special use.

The UK officially left the EU in January 2020 under the EU-UK Withdrawal Agreement, and the withdrawal transition period ended in December 2020. During the withdrawal transition period, the UK was effectively part of the EU customs union, so the EU MFN rates and preferential rates were applied until December 2020 and since January 2021, the UK Global Tariff (UKGT) has been applied. By introducing UKGT, the nuisance tariff (tariff below 2.0%) and tariffs on items that have no or limited domestic production were eliminated, and tariff rates are simplified by removing the number after the decimal point. As an exception, the EU Common Customs Tariff rate will continue to be applied in Northern Ireland in accordance with the Northern Ireland Protocol to the EU-UK Withdrawal Agreement.

In addition, the applied tariff rates and bound tariff rates for high tariff items are treated almost the same as those in the EU.

**<CONCERNS>**

In preparation for leaving the EU, the UK prepared a new concession schedule and submitted it to the WTO in July 2018. It largely followed the EU annex table except for tariff quotas, and technical amendments were made in May 2020 and December 2020. Meanwhile, in January 2021, the UK submitted a communication to WTO member countries clarifying the UK's position in the WTO after the withdrawal transition period. It stated that the UK would apply the concession schedule, although it has not yet been approved. Therefore, there is a possibility that WTO member countries may appeal or take retaliatory measures against the UK for currently applying this unapproved concession schedule. In addition, in December 2020, the UK notified that it would continue to implement the ITA and the expanded ITA, so under the concession schedule, tariffs on 201 subject items were eliminated by 2023.

As long as the high tariff itself does not exceed the bound rate, there is no problem in terms of the WTO Agreements, but in light of the spirit of the WTO Agreements that promotes free trade and enhances economic welfare, it is desirable to reduce tariffs as much as possible.

**<RECENT DEVELOPMENTS>**

Aiming to avoid any disruption to trade continuity, the UK negotiated the continuation of trade agreements with third countries concluded by the EU, during the withdrawal transition period, and many trade agreements continue to be applied in the UK after Brexit. With Japan too, the UK had government-level negotiations during the withdrawal transition period, and after the approval process completed in each country in December 2020, the Japan-UK EPA entered into force in January 2021. This agreement basically follows the EU-Japan EPA. It maintains a business environment for Japanese companies to continue doing business with the UK, by providing catch-up provisions that apply the same reduced tariff rates as in the EU-Japan EPA from its effective date and cumulative and extended cumulative provisions that deem the use of EU materials and value-adding and machining processes in the EU region as those in the UK and Japan. In addition, the UK officially applied to join the Comprehensive and Progressive Agreement on Trans-Pacific Partnership (CPTPP) in February 2021. On March 31,

2023, the UK concluded its negotiations for accession to the CPTPP, and signed Protocol on the Accession on July 16, 2023. The entry into force of the Agreement will take place after the legislative process between the UK and the CPTPP parties is completed. The entry into force is expected in late 2024.

In response to the spread of COVID-19, in January 2021, the UK government granted tariff exemptions on medical supplies (i.e., personal protective equipment, medical equipment, and disinfectants), which it said were important in responding to the COVID-19 pandemic, and in October of the same year, it took additional measures to grant tariff exemption for key components of vaccine production. In December 2022, the government continued to grant the said tariff exemptions until December 2023, except for those for three items that had not been imported.

## SAFEGUARDS

### SAFEGUARD MEASURES ON IMPORTS OF STEEL PRODUCTS

#### <OUTLINE OF THE MEASURES>

On October 1, 2020, the UK announced that it would “transit” the EU’s steel safeguard measures after leaving the EU, imposing an additional tariff of 25% on 19 of the 26 steel products subject to the EU safeguard measures if they exceed tariff quotas (from January 1, 2021 to June 30, 2021). At the same time, a Transition Review was initiated to determine the course of action after July. As soon as the UK left the EU in January 2021, it invoked the safeguard measures “transited” from the EU.

In May 2021, injury was determined and a recommendation was made to extend the measure on 10 items, and in June, a notification of extension of the measure was made. However, the measure taken the following July was applied to items different from the 10 items subject to the TRA recommendation. In particular, five more items were added by the decision of Secretary of State Truss. The duration of the measure is for three years in principle, but tentatively only for one year for the additional five items.

In June 2022, as a result of the process of “Reconsideration” of the measures ongoing, the measures on the above additional five items were determined to be extended for further two years.

Furthermore, the UK started an extension review on September 4, 2023, and decided that it would consider whether or not to extend the measure by June 30, 2024.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

Under the WTO Agreement, there is no basis to legitimize “transiting” other countries’ safeguard measures. In essence, the UK, as an individual country after leaving the EU, invoked the safeguard measures without conducting investigation procedures regarding the prerequisites, which is inconsistent with the WTO agreement on safeguard investigation procedures.

Although the May 2021 TRA recommendation included a quantitative analysis of increased imports, injury to the domestic industry, etc., it was questionable whether the finding was sufficient to provide a basis for an extension of the safeguard. In addition, as a background of the measures, the global steel overcapacity problem, import restrictions imposed by other countries and Section 232 measures implemented by the US were referred to, but there

are concerns about the consistency of these factors with the concept of “unforeseen developments” as a prerequisite for imposing a safeguard measure (Article XIX: 1(a) of GATT).

Further, there are products that were not included in the TRA’s recommendation for extension in May, including the five products that were newly added by decision of the Secretary of State in July. The measures on these products are inconsistent with the WTO Agreement, as they have been extended without finding whether the various requirements for extension (continued necessity for prevention of injury, Article 7.2 of the Safeguard Agreement, etc.) are met.

#### <RECENT DEVELOPMENTS>

At the Safeguard Committee, etc., Japan has expressed regret that the measures were invoked without any investigation of the requirements under the Safeguard Agreement, such as injury to the domestic industry, and urged the UK to terminate the measures as soon as possible. In addition, the Japanese government will register its interest in the investigation of the extension of safeguard measures and will closely monitor the developments of the investigation.

## STANDARDS AND CONFORMITY ASSESSMENT SYSTEMS

### REGULATIONS ON CHEMICALS (REACH/CLP)

#### <OUTLINE OF THE MEASURE>

With the end of the withdrawal transition period on December 31, 2020, many of the EU regulations that directly applied to the UK prior to Brexit have been transposed into UK domestic law with the necessary amendments made in accordance with UK domestic law. The EU REACH regulation and CLP regulation also continue to apply to the UK after the withdrawal transition period as one of the “retained EU laws” that have been transposed into UK domestic law. As a result of the Northern Ireland Protocol, the UK REACH regulation and GB CLP regulation apply only to the island of Great Britain, while the EU REACH regulation continues to apply to Northern Ireland as part of the EU single market. Therefore, businesses in Northern Ireland will retain their status under the EU REACH Regulation after the end of the withdrawal transition period.

After the withdrawal transition period, in order to sell products on the market in the EU and the UK, chemical substances will need to be registered in both the EU and the UK.

As a result of Brexit, the UK is a third country from the perspective of the EU, and therefore, registrants located in the UK (manufacturers, producers, importers or Only Representatives) are not considered to be registrants in the EU. Businesses registered under the EU REACH regulation located in the UK will need to apply for registration again after a grace period determined by the volume of production and imports, etc., obtained through Grandfathering. Even if they use safety data that they have already paid for in their registration under the EU REACH regulation, if they want to use the safety data pursuant to the UK REACH regulation, they may have to pay for the use of the safety data again.

As one of the “retained EU laws,” the EU CLP regulation was also transposed into UK domestic law. In addition, the EU harmonized classification and labelling standards made on

December 31, 2020 were retained as GB mandatory classification and labelling standards (GB MCL). The role played by the European Chemicals Agency (ECHA) under the EU CLP regulation before Brexit will be taken over by the Health and Safety Executive as the supervisory authority under the GB CLP regulation in the post-Brexit UK. Currently, rules under the GB CLP regulation are not significantly different from those under the EU CLP regulation, but they may gradually diverge between the EU and the UK in the future.

#### <PROBLEMS UNDER INTERNATIONAL RULES>

These regulations may violate Article 2.1 of the TBT Agreement when they bring disadvantages to non-UK companies compared to local companies. The REACH and CLP regulations aim to protect human health, but if they are more trade-restrictive than necessary for the purpose of fulfilling the relevant policy objectives, they may be inconsistent with Article 2.2 of the TBT Agreement. In addition, if the CLP regulation is not based on the GHS, which is an international standard for labeling and classifying hazardous products, it may be inconsistent with Article 2.4 of the TBT Agreement.

#### <RECENT DEVELOPMENTS>

On November 9, 2021, the Environment Act 2021 was passed. Section 140 of the Act authorizes the Secretary of State to amend the UK REACH regulation to update the regulation of chemicals in the post-Brexit UK, in accordance with Schedule 21. In addition, the Secretary of State is empowered to extend the scope of criminal penalties for enforcing the UK REACH regulation and to specify the criminal penalties to be applied. It is stated that the Secretary of State may exercise these powers as he or she considers it necessary and appropriate.

In July 2022, Defra (Department for Environment, Food and Rural Affairs) conducted a public consultation on the extension of the transitional registration deadline for the UK REACH regulation. Based on the results, the registration period was extended to three stages: October 27, 2026, October 27, 2028, and October 27, 2030, depending on the tonnage and hazardousness of the substance.

The “Retained EU Law (Revocation and Reform) Act 2023” promulgated on June 29, 2023 revoked Annex VIII in the GB CLP Regulation as of December 31, 2023, making notification to the Poison Center unnecessary. The divergence with the EU CLP is occurring and the situation of both sides need to be monitored.

