Chapter 4

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1. European Union (EU)

NATIONAL TREATMENT

CARBON BORDER ADJUSTMENT MEASURE [NEWLY ADDED]

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 a 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 a CBAM as part of Fit for 55, a package of policies aimed at reducing greenhouse gas emissions by at least 55% from 1990 levels by 2030. After negotiations among the European Commission, the European Parliament, and the Council, the final draft was officially approved in April 2023 and became a regulation in May of the same year.

The plan is to impose levies on importers of products into the EU in proportion to the embedded carbon emissions of such products by obliging the importers to purchase CBAM certificates. The scope of the planned measures covers imports from all countries, with exclusions limited to some 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, it is planned 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/CO2-ton) x Emissions per Product Unit (CO2-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 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 CBAM certificate price (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 submitted) is planned to be adjusted to reflect the availability of free allowances. 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 draft measures also contain 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 is scheduled to take effect from October 2023, but there is a transition period until the end of 2025. During the transition period, importers will not be required to pay import levies but will be required to report information such as emissions per product unit. Items to be reported include emissions per product unit (both direct and indirect) and carbon prices paid in exporting countries. The reported items could be used to consider expanding the product scope to other goods and services and to develop emission calculation methods for the operation of the system after the transition period.

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 3, Paragraph 2 of the GATT for domestic taxes, etc., and Article 3, Paragraph 4 of the GATT for domestic regulations) may be the most salient issue. Article 3, Paragraph 2 prohibits the imposition of domestic taxes and other charges on imported goods in excess of those applied on "like domestic products", and Article 3, Paragraph 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 3, Paragraph 4 is likely to apply because the EU-ETS is likely to be considered 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 to 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 20 of the GATT, in particular Article 20(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 still requires the purchase of CBAM certificates 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>

This measure will be effective from October 2023. 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 in the specific design details of the CBAM , while also continuing to cooperate for the purposes of global environmental protection.

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.

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 2021, 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 motor trucks (maximum 22%), footwear (maximum 17%), porcelain and ceramics (maximum 12%), glassware (maximum 11%), and passenger cars (maximum 10%). Moreover, in 2021, the simple average applied tariff rate for non-agricultural products is 4.1%; the tariff rates for electric appliances (maximum 14% [televisions, cameras, radio receivers, etc.], simple average 2.4%) and textiles (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 will be 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

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.

As a background of the measures, the global steel overcapacity problem, import restrictions imposed by other countries and Section 232 measures implemented by the4US 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 (GATT Article 19.1(a)). 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.

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 (scheduled to last until June 2023) to assess whether the measure was to be terminated earlier.

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)

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 Eco-design Directive) in October 2009.

The Directive requires to consider the environmental impact (e.g.: consumption of resources, emissions to air or water, noise, vibration, etc.) of products placed on the EU market in terms of their entire life cycle (during the period from procurement, manufacturing, and distribution to disposal) and demands to take action (the general environmental consideration system requirements). Some products are also required not to exceed a certain volume of electricity consumption and standby electricity consumption. (the specific environmental consideration system requirements). Requirements for each product are published in the "Implementing Measures."

The draft "Implementing Measures" notified to the TBT Committee had some problems: (1) part of requirements is inconsistent with the existing regulations and is unclear regarding the scientific basis and effects and (2) some wording regarding requirement is not clearly defined. If the Directive is more trade-restrictive than necessary for the purpose of fulfilling legitimate policy objectives, it may violate Article 2.2 of the TBT Agreement.

A draft Ecodesign for Sustainable Products Regulation (ESPR) amending the ErP Directive was proposed by the European Commission in March 2022, and is currently being discussed by the European Parliament and the Council. The draft regulation would expand the framework of ErP Directive and apply it to a wider range of products, as well as introduce circularity (such as product durability, resource efficiency, use of recycled material and recyclability), environmental impact (environmental and climate footprints) during the product life cycle, and a digital product passport to enable traceability of environmental information. In addition, the European Commission proposed implementing rules targeting smartphones in August 2022. The draft implementing rules include requirements for the design of certain parts in the device to be repairable and replaceable by the end user using common tools, obligations to provide spare parts for the device, requirements for durability such as scratch resistance and water and dust resistance, and requirements for OS updates.

Furthermore, in January 2023, the European Commission began inviting comments on the consideration of horizontal measures for end products including textiles, furniture and toys; intermediate products including steel, chemicals and polymers; and durable, recyclable, and post-consumer recycled materials as priority products for future regulation under the ESPR. It is necessary to continue to monitor developments in this case closely so that access to the EU market is not restricted by unnecessarily excessive requirements.

(2) REGULATIONS ON CHEMICALS (REACH/CLP)

In the EU, the REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) (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 its quantity 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 exceeds 1 ton during a year, the notification and communication become mandatory. Regarding composite molded articles, the ECHA had interpreted that the concentration calculation matrix is the entire composite molded article. However, in September 2015, the European Court of Justice published their preliminary ruling that each component article that composes a complex object is the matrix. The manufacturers and importers of composite molded articles in the EU are obligated to calculate a concentration of high concern in each component that construct composite molded articles, 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 (supply to the market is prohibited unless it is verified that the risk is properly managed in the industry and permission is granted). When substances are to be listed for authorization in Annex XIV, it is stipulated that priority is given to substances that are widely distributed and used and with a high production volume, based on certain requirements, such as having characteristics of carcinogenicity, genotoxicity, and reproductive toxicity (CMR), persistent bioaccumulative, and toxic (PBT/vPvB), or other characteristics that might have the same extent of adverse effects as those characteristics (ELoC).

In January 2009, the CLP (Regulation on Classification, Labelling and Packaging of substances and mixtures) was enforced. Under the regulation, substances or mixtures classified as hazardous are required to be labelled with a hazard warning.

In December 2018, proposal of the CLP regulation for the EU's 14th Adaptation to Technical and scientific Progress (ATP) was notified to TBT committee. The proposed draft regulation classified the powder mixtures containing 1% or more of titanium dioxide as a carcinogen regardless of whether or not exposure of titanium dioxide by inhalation could occur. This could inappropriately broaden the scope of products to be regulated and may require warning labelling even for products distributed without being classified as carcinogenic under the GHS-compliant systems of other countries.

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.

The Japanese industry that manufactures products containing titanium dioxide submitted comments to the EU responding to TBT notification regarding the CLP regulation in December 2018, and Japan has also expressed its concerns to the EU since the TBT Committee in March 2019. In October 2019, however, the EU adopted the Commission Delegated Regulation (EU2020/217) regarding a proposal of the amendments to the CLP regulation for the EU's 14th Adaptation to Technical and scientific Progress (ATP), published in February 2020, and applied since October 2021.

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. There are 56 action plans in the annex of CSS, and these actions will be implemented in the future. The EU received feedback on the Inception Impact Assessment of the amendments to the REACH and CLP regulations from May 4, 2021 to June 1, 2021, after which the EU conducted a public consultation on the amendments to the CLP Regulation from August 9, 2021 to November 15, 2021, and on the REACH Regulation from January 20, 2022 to April 15, 2022. In the amendments to the REACH Regulation, restrictions on the use of chemical substances based on the concept of “essential use” were considered. The amendments to the CLP Regulation propose to classify and label endocrine disruption (ED), PBT/vPvB, and persistent, mobile, and toxic (PMT/vPvM) as new hazards ahead of GHS, and to promote only the introduction of new hazards by way of revision by the Commission Delegated Regulation. The draft of the Delegated Regulation was announced on September 20, 2022, public consultation started on the same day, 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 final draft of the Delegated Regulation was sent to Parliament and the Council on December 19, 2022.

Based on the CSS, the new hazards will be used not only for chemicals management but also as a standard for disclosure in the EU such as taxonomy and CSRD (Corporate Sustainability Reporting Directive). The EU will develop proposals for amendments to the REACH and CLP Regulations during 2023. As the effects of the REACH and CLP Regulations may 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 solicitation of opinions on the restriction proposal for bisphenols with endocrine disrupting properties commenced. 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. In addition, although not limited to the REACH regulation, in Europe, there is a tendency to propose extremely low regulatory concentrations (e.g., tolerable daily intake (TDI)) compared to the past, based on the non-monotonic dose response (NMDR) observed in endocrine disruption and the like.

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

The EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR) came into force on May 25, 2017, and after a transition period, The MDR was scheduled to apply from May 26, 2020, and the IVDR from May 26, 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, on April 24, 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 on May 26, 2021. The MDR stipulates that

MDD (Medical Device Directive) compliant products that have been placed on the market prior to or on the above application date or during the validity period of the MDD certificate may continue to be made available on the market or put into service until May 27, 2025. While the IVDR started to be applied on May 26, 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. On December 9, 2022, at the EPSCO (in charge of employment and social policy) meeting, a proposal to extend the transitional measures for European MDR and IVDR was presented. Subsequently, on January 6, 2023, the European Commission adopted a revised bill that includes, among other things, extending the MDR transition measures according to a device's risk class if certain conditions were met and removing the marketing deadline for MDD-compliant and IVDD (In Vitro Diagnostic Medical Device Directive)-compliant products. In order for the revised bill to become law, it will now need to be adopted by the European Parliament and the Council through an accelerated codetermination procedure.

The delay in establishing a system to adapt to the new EU regulation and the failure of smooth operation of the new regulation could stagnate the export of medical devices to the EU, which could practically be a trade-restrictive measure.

Japan has expressed concerns about the regulation to the EU at the TBT Committee with other countries, 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

On January 26, 2021, the EU notified the TBT committee of a new draft regulation on batteries and waste batteries. On December 9, 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. It is expected that a sub-regulation will be adopted between 2023 and 2028 for the operation of this regulation once it is established and comes into force in 2023.

Article 46, Paragraph 2 of the proposed regulation requires a battery supplier to be registered in each Member state and stipulates that if the supplier has designated an authorized agent, the authorized agent shall be responsible for registration. Article 65 of the proposed 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 proposed regulation includes new elements or concepts such as carbon footprint, inclusion of recycled materials, conformity assessment, due diligence, and extended producer responsibility.

Since Article 2.2 of the TBT Agreement requires that not more trade-restrictive measures be employed than are necessary to fulfill legitimate objectives, it must be ensured that the procedures and requirements of the proposed regulations are not more trade-restrictive than are necessary to achieve the objectives of safe and sustainable production and recycling of batteries. GATT Articles I and III prohibit discrimination between imported products and between imported products and domestic products, and GATT Article XX 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. In addition, Article 65 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.

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.

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.

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.

<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.

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.

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)

The regulation 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 market "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.

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 proposed 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).

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

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 28, Paragraph 1 of the 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 bind 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.

Unilateral tariff increases associated with EU enlargement are not consistent with Article 24, Paragraph 6 of the GATT, which requires compensatory adjustments in accordance with the procedures set out in Article 28 of the GATT in the case of an increase in bound tariff rates.

In July 2013, Japan notified the EU in writing that it intended to commence negotiations under Article 24, Paragraph 6 of the GATT in connection with Croatia's accession to the EU, and held discussions with the EU on this matter. In the negotiations under Article 24, Paragraph 6 of the 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 bind 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

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 TRIPS 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 TRIPS.

<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. Subsequently, 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 Design Directive, and began inviting comments. The proposed regulation and directive include the introduction of an EU-wide "repair clause."

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.

Developments in these major European countries may influence the recent discussions on the revision of the Design Directive, etc., and future developments should be closely watched.

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 discussion and urge abolition of the "repair clause" from the design system of each EU Member State and the Community design system.

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.

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 Members 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 Members 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 will be 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, and is continuing negotiations for accession to the CPTPP.

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 announced that it would continue 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.

Furthermore, 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.

<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 (GATT Article XIX: 1(a)).

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.

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. Currently, there are no major differences in requirements and procedures for REACH regulations in the EU and the UK, but their regulations may gradually diverge in the future. In this case, businesses may be required to respond differently in order to comply with regulations in the EU and the UK, which may increase the burden on businesses.

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. Therefore, in order to maintain status under the EU REACH regulation, it was necessary to switch to registration in an EU member state or appoint an Only Representative in an EU member state before the end of the withdrawal transition period. It should be noted that if such procedures have not been taken, the status of the business may have changed under the EU REACH regulation. In addition, 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. It remains to be seen how these powers granted to the Secretary of State will be exercised in practice.

For eight weeks from July 5, 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. The current deadlines are in three stages: October 27, 2023, October 27, 2025, and October 27, 2027, depending on the tonnage and hazard of the substance. As a result of the consultation, the government will introduce legislation extending the deadlines by three years for all stages.