Section 5 Initiatives to create new rules

1. Global Trends in Regulatory Cooperation

(1) Background

Besides the reduction and abolition of tariffs, one of the key points in making international trade policy that attracts increasing interest amid the progressive globalization of the world economy and a growing awareness of the importance of global value chains is means to reduce costs arising from “behind-the-border issues” by eliminating or alleviating non-tariff measures. Moreover, global companies are cooperating with governments in “resolving global challenges” and “capturing markets” based on their strengths as medium- to long-term plans through the formulation of international standards and regulations.

As such trends and moves will lead to the future development of global rules governing non-tariff measures, discussions about “regulatory cooperation” are being held at various forums, including at bilateral and multilateral levels.

(2) Global trends

(A) U.S.-EU

Representatives of industry groups in Europe and the U.S. have already been lobbying their respective governments to introduce regulations in order to facilitate the introduction of their own products to markets five or even ten years hence.

Specifically, the Transatlantic Business Council has been held every year since 2005 as a public-private joint forum of dialogue on regulatory issues between the U.S. and the EU. At the EU Council’s meeting in April 2013, which was attended by representatives from more than 70 manufacturers and other businesses, proposals were presented with regard to the determination of specific fields of regulatory cooperation, inter alia, automobiles, the adoption of the principle of “tested once, tested in both markets” and the adoption of international standards. As part of this move, the U.S. Department of Energy (DOE) and the EU Joint Research Center (JRC) jointly established the Smart Grid Interoperability Center in order to promote cooperation in testing procedures and standards of electric vehicles.

“Regulatory cooperation” is being discussed in various sectors of industry in the negotiations between the U.S. and the EU concerning the Transatlantic Trade and Investment Partnership (TTIP), which began negotiation in July 2013. Representatives of industry in Europe and the U.S. are working together to verify the feasibility of putting such cooperation in place between the U.S. and the EU, and are actively making policy proposals to negotiators and regulatory authorities on both sides. In May 2014, the EU published a position paper concerning “regulatory cooperation” related to five fields (automobiles, chemicals, cosmetics, pharmaceuticals, and, textile and clothing), and discussions have also been held about medical equipment, agrochemicals, ICT, and engineering. In February 2015, the U.S. Chamber of Commerce published a document titled “Regulatory Coherence and Cooperation in the Transatlantic Trade and Investment Partnership” (TTIP), which proposed cooperation between the
U.S. and EU regulatory authorities through regulatory equivalence assessment, etc.

(B) EU-Canada

In accordance with the December 2002 EU-Canada Summit, a dialogue framework of “regulatory cooperation” was established in 2004. Discussions have been continued about various fields, including chemicals, electrical and electronics equipment, foods, automobiles, lumber products, and tobacco.

In addition, the chapter on regulatory cooperation of the EU-Canada FTA (CETA) (negotiations started in October 2009 and were concluded in September 2014), regarding which the procedures for ratification are underway, stipulates that a “Regulatory Cooperation Forum (RCF)” be established and that consultations may be held with private business operators, etc. as necessary.

(C) EU-ROK

Under the EU-ROK FTA, which entered into force in July 2011 on an “early harvest” basis, working groups were established with regard to three fields – automobiles, pharmaceuticals/medical equipment and chemicals, and the working groups have so far held two meetings (April 2012 and September 2013). Regarding automobiles, discussions were held about such matters as exhaust gas regulation and compatibility between the UNECE (Economic Commission for Europe) regulation and domestic regulation. In addition, discussions were held about quality tests of pharmaceuticals with regard to pharmaceuticals and medical equipment and about the REACH (Registration, Evaluation, Authorization and restriction of Chemicals) procedures of both sides with regard to chemicals.

Under the EU-Korea High-Level Industrial Policy Dialogue, which was established based on an agreement reached at the November 2013 EU-ROK Summit, discussions were held about such matters as regulatory cooperation, cooperation in support for small and medium-size enterprises, innovation and technical cooperation at the first meeting held in September 2014.

(D) Multilateral discussions

The OECD has been discussing regulatory cooperation at the Regulatory Policy Committee. Following the Workshop on Trade and International Regulatory Cooperation that was held in February 2014, the Trade Committee also launched earnest discussions about the benefits of international regulatory cooperation in the context of trade in October of that year.

Moreover, under the E15 framework, co-sponsored by the International Centre for Trade and Sustainable Development (ICTSD), which is based in Geneva, Switzerland, and the World Economic Forum (WEF), the Task Force on Regulatory Systems Coherence, comprised of trade negotiation experts, was established, with representatives from industry participating as observers. The goal is to present proposals concerning the global trading system in 2025 by the WTO Ministerial Conference at the end of 2015 and the Davos meeting at the beginning of 2016.

(3) Initiatives implemented by Japan

The Japan-EU EPA, which is now under negotiation, aims to promote the development of high-level trade and investment rules among advanced countries, and discussions on domestic measures are being held that may affect each other’s trade and investment, in addition to conventional
discussions such as the abolition and reduction of tariffs. An early conclusion of the Japan-EU EPA will contribute to regulatory cooperation between Japan and the EU.

As a pioneering case of “rule development strategy,” which will be explained later, Japan and the EU are discussing regulatory cooperation. More specifically, as an initiative to promote cooperation between the public and private sectors of Japan and the EU from the initial stage of policymaking in order to improve regulatory coherence and cooperation by dismantling unnecessary regulatory barriers between the two sides, the Ministry of Economy, Trade and Industry of Japan and the European Commission’s Directorate-General for the Internal Market, Industry, Entrepreneurship and SMEs agreed at the April 2014 Japan-EU Industrial Policy Dialogue to hold specific discussions about “Japan-EU Regulatory Cooperation.” In accordance with this agreement, discussions by experts from regulatory authorities proceeded in such fields as automobiles, chemicals, robots and conflict minerals, and the Regulatory Cooperation Joint Statement between Japan and the EU, which concerns 13 items in 12 fields, was adopted at the March 2015 Japan-EU Industrial Policy Dialogue31. In March of that year, the Japan Business Federation (Keidanren) published Recommendations for Japan-EU Regulatory Cooperation32. It will be important for the public and private sectors to work together to promote the regulatory cooperation initiative.

<table>
<thead>
<tr>
<th>Japan - EU Joint statement on Regulatory Cooperation (Outline)</th>
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<tbody>
<tr>
<td>○ Policy dialogues will be promoted in relation to the standardization of product certification practices for expanding the use of living assistance robots.</td>
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<tr>
<td>○ Exchanged views on risk assessment for chemical substances and Transferring information of chemical substances.</td>
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<tr>
<td>○ Exchanged views on the technical review of the classification of flammable gases under the UN GHS.</td>
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<tr>
<td>○ Held discussions on the amendment to UN-R110 (the UN regulation on natural gas vehicles) and on phase 2 of the GTR (Global Technical Regulation) concerning hydrogen-fueled vehicles at the Automobile Working Group under the EU-Japan Industrial Policy Dialogue. Sought possible cooperation in other fields.</td>
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<tr>
<td>○ Exchanged views on appropriate response to the EU regulation on conflict minerals.</td>
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<tr>
<td>○ In addition, deepened the cooperation in following areas, eco-design policy, improvement of construction products’ energy efficiency, resource efficiency policy, medical devices, FLMs (Forced Localization Measures), IT utilization and manufacturing industry, and personal data protection regulations.</td>
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2. Rule making strategy

Currently, the international community is witnessing two ongoing phenomena, namely (1) the rise

31 http://www.meti.go.jp/press/2014/03/20150317005/20150317005.html
32 https://www.keidanren.or.jp/policy/2015/024.html
of emerging economies and the decline of Western countries and (2) the relative decline of the importance of sovereign nations. In other words, while the influence of emerging countries such as China and India is growing against the backdrop of their rapid economic growth, the influence of developed countries in the international community has become relatively weak. At the same time, the influence of non-governmental entities, including multinational companies and non-governmental organizations (NGOs), in the international community is also growing, a situation which has had no small impact on the structure of the international political society, of which sovereign countries are basic elements.

Probably, the major causes of these two phenomena are economic globalization and the deepening integration of the global market, for which the postwar GATT/IMF regime laid the foundation. Interconnectivity between economies around the world has increased remarkably through a succession of trade liberalization efforts under the GATT/IMF regime and under its successor the WTO. Negotiations on free trade agreements (FTAs) and economic partnership agreements (EPAs) have been actively conducted at regional and bilateral levels, and voluntary trade liberalization measures have been implemented by individual countries. Major developing countries that have effectively taken advantage of this new environment increased their economic and political power considerably. In addition, many developing countries succeeded in mitigating poverty. Meanwhile, the relative importance of issues other than economic growth, for example social problems such as the environment, human rights and labor, has grown, and as a result, the importance of “quality-oriented” economic development as exemplified by sustainability and inclusiveness of development, is starting to be emphasized. Examples include active discussions being held in the international community led by the United Nations, on such issues as the “Post-2015 Development Agenda” and “Business and Human Rights.” These social issues could undermine the sound management of highly globalized economies around the world if addressed in an inappropriate manner, making them economic issues as well.

It is necessary to adjust various policies concerning international political and economic issues in line with the concept of “quality-oriented” economic development, and trade policy is no exception. The rule making strategy is a new concept of trade policy that is designed and implemented in accordance with the abovementioned new international environment. This is a trade policy whereby Japan will do its utmost to enable global citizens to enjoy the fruits of globalization to the greatest extent possible, by developing various institutional programs and various rules in order to resolve global social issues and to achieve global “common goods.”

Japan, which already has experience resolving a variety of social challenges, such as environmental preservation and energy conservation, has a huge potential to adapt to such changes in the international situation. However, for Japanese products, technologies and services to come into widespread use, it is necessary that Japan’s social-problem-solving capability be appropriately evaluated. It is very important that in each country’s market an institutional framework for appropriate evaluation of such capability be established. However, in many cases international rule making starts
with the identification of various problems and the formulation of them through concepts and principles. If Japan fails to participate in discussions about such matters from the initial stage, it will be unable to take part in the process of rule making in an effective manner. In that case, even if Japan has technologies and products that may contribute to solving social problems, it may be unable to fully exercise its advantage because it has to follow existing rules. Therefore, in order to prevent such a situation, both the Japanese government and companies need to actively participate in the designing of institutional programs through discussion from the initial stage such as identifying problems and developing concepts so as to create institutional programs and mechanisms that appropriately evaluate Japanese products, technologies and services. From the above perspective, the rule making strategy requires Japan to more proactively participate in global rule-making in the initial stage of discussions about agenda setting and concept development in order to internationally establish institutional programs and mechanisms which appropriately evaluate the social-problem-solving capability of Japanese companies.

This perspective of rule making concerns various fields, various forms of rules and various occasions. Below are some examples in detail: 1. aging-related issues, 2-1. water-related issues, 2-2. combination type treatment and purification tanks, 3. food-related issues and 4. alternative chlorofluorocarbons.

(1) Aging-related issues

The proportion of elderly people in the overall Japanese population, which was 26.0% as of October 1, 2014, has continued to be the highest in the world since 2005. Japan will explore the possibility of offering new international cooperation to emerging countries where aging is proceeding as rapidly as or more rapidly than in Japan by taking advantage of the experience and knowledge gained through its initiative to deal with aging-related issues over many years.

In particular, Japan’s elderly care system has been developed based on an insurance system whereby society as a whole financially supports nursing care for elderly people. Japan will provide Asian countries with information concerning elderly care services and appliances/equipment that have been developed, and nursing care personnel that have been fostered, will encourage introducing various institutional programs, and will widely participate in discussions about standardization in fields related to nursing care and welfare (AAL: active assisted living), which are being discussed at ISO and IEC.

33 Statistics Bureau, Ministry of Internal Affairs and Communications, Population estimates
34 In China, for example, the proportion of elderly people reached 9.4% as of the end of 2012, and since 2005, the proportion has been increasing by 0.2-0.4% annually (source: National Bureau of Statistics of China, Annual Statistics of China).  
35 ISO stands for the International Organization for Standardization. ISO is a private organization responsible for formulating international standards in industrial fields excluding the electrical field.  
36 IEC stands for the International Electrotechnical Commission. IEC is an international standardization organization that handles electrical and electronic engineering and related technologies.
(2-1) Water-related issues

In regions where water resources are scarce, securing drinking water for everyday life is a critical matter. In some regions, it is difficult to obtain clean water due to various factors, including the non-revenue water rate\(^\text{37}\), purification technology and the water pricing system. In this situation, there are moves among U.S. and European multinational companies and NGOs to make the water usage volume visible. In late July 2014, ISO formulated and published ISO14046, an international standard water footprint (WFP) that evaluates how much of an environmental impact a certain product, organization or business had on water.

(2-2) International expansion of Japanese domestic wastewater treatment systems

In emerging countries, water pollution is becoming an increasingly serious problem, and if the problem is to be resolved, it is essential to introduce appropriate domestic wastewater treatment systems. To contribute to the resolution of the problem, Japan has been implementing an initiative to promote international dissemination and standardization of domestic wastewater treatment systems that have been developed in Japan, including sewage systems and purification tanks. To further promote this initiative, the Japanese government will sponsor a public-private dialogue concerning water at the Asia-Pacific Economic Cooperation (APEC) Senior Officials Meeting scheduled to be held in Cebu City, the Philippines in August this year in order to ensure that the importance of

\(^{37}\) The ratio of water which is distributed from water purification plants but for which fees cannot be collected due to causes such as water leakage and theft.
initiatives to address the water pollution problem is shared within APEC. While Cebu City is a major resort region, water pollution is occurring there because the development of wastewater systems and local residents’ awareness about water quality have not kept up with the rapid economic development. In order to improve this situation, in 2012, Cebu City, together with Yokohama City, drew up a “Memorandum of Understanding on Technical Cooperation for Sustainable Urban Development”, and an initiative to resolve urban problems, including water-related ones, has already been launched. As described above, starting with the case of Cebu City, which is highly conscious about water pollution, Japan aims to promote the introduction in the APEC region of regulations and standards whereby superior Japanese wastewater treatment facilities and knowhow will be appropriately evaluated (Figure III-1-5-2-2 and Table III-1-5-2-3).

(3) Food-related issues

Around the world, approximately 1.3 billion tons of foods, a third of global production volume, are disposed of every year throughout the entire food value chain. On the other hand, there are over 805 million starving people, mainly in developing countries in Africa. Disposal of foods in specific regions may affect the availability and prices of the foods in other regions, in addition to causing economic losses and imposing an unnecessary burden on the environment, as exemplified by excessive consumption of water, energy and other resources, and emissions of greenhouse gases. In response to this situation, proactive initiatives have been conducted, mainly in European countries. For example, the EU has announced a plan to reduce food waste by 30% by 2025 while major European distributors started a program to reward companies contributing to reducing food waste. Japan will also promote rule making that ensures that superior Japanese products and technologies, such as food packaging technology and refrigerated logistics services that maintain food freshness, are appropriately evaluated, in addition to promoting such initiatives as changing consumers’ attitudes toward food waste reduction and easing the commercial practice called the “one-third rule”.

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38 FAO, What Causes Hunger?
39 FAO, The State of Food Insecurity in the World
41 The one-third rule is a commercial practice in the food industry that divides the period from the production date to the best-by date into three equal parts and sets the end of the first third as the deliver-by date and the end of the second third as the sell-by date. For example, in the case of a product with a best-by period of six months, a manufacturer or a wholesaler has to deliver the product by the second month from the production date and a retailer has to sell it by the fourth month.
Example of the structure of a combined type treatment and purification tank

- Inlet
- Sedimentation Chamber (sludge separation)
- Sedimentation Chamber (sludge storage)
- Anaerobic Filtration Chamber
- Storage Chamber
- Aerobic Contact Filtration Chamber (biofiltration)
- Aerobic Contact Filtration Chamber (contact aeration)
- Disinfection Chamber
- Outlet

Source: Created by the Ministry of Economy, Trade and Industry based on a document by Fuji Clean, Co. LTD.
Table III-1-5-2-3 Regulations on domestic wastewater quality (Viet Nam and Indonesia) (as of August 2011)

<table>
<thead>
<tr>
<th></th>
<th>Viet Nam Regulation on domestic wastewater (QCVN14:2008/BTNMT)</th>
<th>Indonesia (Regulation of Governor of DKI Jakarta Number 122 Year 2005)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A (Source of domestic water)</td>
<td>B (Others)</td>
</tr>
<tr>
<td>BOD (biochemical oxygen demand)</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td>CODcr (chemical oxygen demand)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>TSS (total suspended solids)</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>NH4-N (ammonia nitrogen)</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>NO3-N (nitrate nitrogen)</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td>T-N (total nitrogen)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>T-P (total phosphorus)</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Oil extracted from animals and plants</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Number of coliform bacilli</td>
<td>3000</td>
<td>5000</td>
</tr>
<tr>
<td>pH</td>
<td>5.0–9.0</td>
<td>5.0–9.0</td>
</tr>
</tbody>
</table>

Source: Created by the Ministry of Economy, Trade and Industry based on the website of the Jokaso System Association.

(4) Alternative fluorocarbons

Following the international discussions under the Montreal Protocol, it is necessary to shift standard industrial practices from the use of CFCs and HCFCs to HFCs. There are a variety of alternative fluorocarbons, and it is necessary to use policy initiatives to promote the use of

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42 The Montreal Protocol was adopted in 1987 in Canada in order to designate substances that may destroy the ozone layer and regulate the production, consumption and trade of such substances based on the Vienna Convention (Vienna Convention for the Protection of the Ozone Layer). The Protocol required developed countries to totally abolish specified chlorofluorocarbons, halons and carbon tetrachlorides by 1996 (the abolition deadline for developing countries is 2015) and alternative fluorocarbons by 2020 (the abolition deadline for developing countries is 2030 in principle).

43 CFC stands for chlorofluorocarbon, which is a specified fluorocarbon. The Montreal Protocol required developed countries to totally abolish CFCs by 1996 and developing countries to do so by 2015.

44 HCFC stands for hydrochlorofluorocarbon. The Montreal Protocol required developed countries to halt production of HCFCs by 2020 and developing countries to do so by 2030.

45 HFC stands for hydrofluorocarbon. HFCs are designated under the Kyoto Protocol as substances subject to reduction (greenhouse gases).
fluorocarbons with low global warming potential (GWP)\textsuperscript{46}. However, it seems that the combustible gas classification system has excessively labeled potential alternative gases as “highly inflammable.” Because the classification for “highly inflammable” gases is based on ignition concentration alone, it does not take into account how chemical products like GHS\textsuperscript{47} and TDG\textsuperscript{48}, with low GWP, do not spread flames and are in practice low risk. Therefore, the safety standards for transport and storage in countries which look to the classification as a reference represent excessive regulation. ISO has already published a safety classification regarding the combustion speed of air conditioner coolants. Therefore, Japan will promote appropriate dissemination of coolant gases with a low GWP by revising the combustion standards under the GHS so that the classification takes into consideration the combustion speed in addition to the combustion concentration and by appropriately reclassifying gases with a low GWP as “inflammable,” rather than “highly inflammable” (Figure II-1-5-2-4).

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{figure.png}
\caption{Figure III-1-5-2-4 Labels for highly flammable gases (left: GHS, right: TDG)}
\end{figure}

Source: Reprinted from the document on the Globally Harmonized System of Classification and Labelling of Chemicals (United Nations)

In fields not limited to the ones previously mentioned, incorporating the perspective of “rule making” into business management will continue to be one of the important keys for Japanese companies for the future. More specifically, it is necessary for Japanese companies to be sensitive to trends in policies and rules around the world, to establish optimal internal systems based on awareness of the importance of regarding the development of institutional programs as part of business strategy, and to take effective approaches suited to the circumstances and policy frameworks of individual countries. Nevertheless, activities that can be conducted by companies are limited, so approaches taken by the government are essential. The government will promote awareness about the importance of “rule making” and will at the same time use its influence on various actors.

\begin{itemize}
\item GWP is a relative measure of a gas’s heat-trapping effect per unit of concentration in the atmosphere over 100 years compared with CO2.
\item GHS stands for the Globally Harmonised System of Classification and Labelling of Chemicals. GHS is a U.N. framework for classifying all chemicals by risk (explosiveness, inflammability, acute toxicity, carcinogenicity, ozone layer hazard, etc.) and specifying labeling concerning chemicals’ risks and toxicity and the procedures for handling them. It is an international standard for regulations enforced by individual countries with regard to transport, storage, construction, labor safety, etc.
\item TDG stands for UN Recommendations on the Transport of Dangerous Goods. The recommendations are issued every two years by a U.N. expert committee in order to ensure the safety of international transport of dangerous goods. It is intended to ensure the consistency of regulations enforced by individual countries with regard to labor safety, consumer protection, storage, environmental protection, etc.
\end{itemize}