

Recommendations for Japan-EU Regulatory Cooperation
- Looking Beyond Concluding the EPA/FTA -

I. Why Is Now the Time for Regulatory Cooperation?

1. Economic Globalization

As corporate value chains expand globally, differences in domestic regulations and other non-tariff measures are having increasing impact on business costs. In a world where people, goods, capital, information and knowledge flow easily across global borders, any given country's domestic regulations, adopted to protect people from environmental risks, safeguard their health and safety, protect personal data, etc., can only be effective if due consideration is given to coherence with other countries' regulations. In order to minimize negative effects of domestic regulations on trade and investment, without compromising their legitimate purposes such as those noted above, there is a need to ensure regulatory coherence and transparency and promote regulatory cooperation through means such as harmonization and mutual recognition of standards and regulations.

The World Trade Organization (WTO), which was established to formulate trade rules, monitor their implementation, and settle disputes, would be the most appropriate platform for such cooperation. The Doha Round that started in 2001, however, has been limited in the scope of its negotiations and has failed to bridge the gap between developed and emerging countries, and now seems to be bogged down. At least for the moment, therefore, it is not realistic for the WTO to assume the role of promoting regulatory cooperation.

2. Progress of Mega-EPA/FTA Negotiations

As part of efforts to reduce the negative effects of domestic regulations on trade and investment, Japan and the EU have conducted a series of government dialogues on regulatory and institutional reform. What has been achieved so far, however, is not satisfactory. Against this background, both sides' business communities called for the

launch of negotiations for an EPA/FTA on the basis of a binding commitment instead of dialogue¹. Thus, reduction and elimination of non-tariff measures constitutes an important element in the negotiations which started in April 2013.

The EU and the US discussed regulatory cooperation for almost twenty years before the Transatlantic Trade and Investment Partnership (TTIP) negotiations were launched in July 2013. Reflecting this historical background, regulatory cooperation is one of the three pillars of TTIP negotiations, along with market access and trade rules.

Bearing in mind that rules, standards and regulations are not givens, but should be developed by Japan on its own initiative in cooperation with other countries, Japan should take the lead in regulatory cooperation without lagging behind the EU and the US, thereby promoting growth in the future. In doing so, it is essential for Japan to cooperate with the EU, which is negotiating an EPA/FTA with Japan on the basis of common values and shared principles.

II. Why Cooperate with the EU?

1. Common Values and Shared Principles

The EU is a partner which shares the values of freedom, democracy, the rule of law and human rights as well as principles such as the market economy. Thus the EU is one of the most appropriate partners for Japan to cooperate with in designing, developing, and enforcing various categories of regulations and highlighting their universal value to third countries and regions. Such cooperation with the EU is of great significance from the perspectives outlined below.

2. Strong Regulatory Influence

¹ For instance, see the following Keidanren policy papers.

"Toward Japan-EU Economic Integration -Second Proposal for Japan-EU Economic Partnership Agreement-" (April 2009)

<http://www.keidanren.or.jp/english/policy/2009/037.html>

"Call for the Start of Negotiations on Japan-EU Economic Integration Agreement -Third Proposal for Japan-EU Economic Partnership Agreement-" (November 2009)

<http://www.keidanren.or.jp/english/policy/2009/099.html>

"Japan-EU Summit: Time for an EIA" (April 2010)

<http://www.keidanren.or.jp/english/policy/2010/036.pdf>

The EU is skilled at formulating regulations and influencing other countries to adopt the same regulations. The EU boasts the largest single market in the world. It has 28 member states which constitute a block vote in formulating and changing regulations at international fora applying "the one country, one vote" principle. The unification of the EU market can itself be regarded as the result of regulatory cooperation among member states. The proven ability of the EU to coordinate various interests and views of member states and its experience in formulating, enforcing and monitoring regulations beyond national borders furnish it with external cohesive power. Furthermore, the EU has been successful in elevating its local agenda to the international level by emphasizing universal values to which other countries and regions are receptive.

One proof of the EU's regulatory influence is that regulations similar to REACH, which has been effective since June 2007, are being introduced in China, Russia, South Korea, Turkey and other countries. The EU regulations on personal data protection and conflict minerals now under discussion have the potential to influence regulations in other countries. The EU assumes responsibility for 488 technical committee secretariats at ISO/IEC, far exceeding the US and Japan at 144 and 98, respectively.

By promoting cooperation with the EU as described above, Japan could reduce its business costs and exercise leadership in regulatory cooperation at a global level, including in third countries and regions. Being mindful that the regulatory influence of the EU depends on area or sector, it would be useful if Japan could cooperate with the EU from the regulatory design stage. Needless to say, regulatory cooperation with the EU does not mean that Japan should accept EU regulations as they stand.

3. EU Expectations of Regulatory Cooperation with Japan

The EU also recognizes the necessity of regulatory cooperation with Japan. In the joint press statement of the 22nd EU-Japan Summit on 7 May 2014², for example, the EU and Japan emphasized their willingness to enhance cooperation in areas such as regulations, standards and conformity assessment procedures, aiming at compatibility and convergence through the appropriate application of international standards, notably in the automotive sector. EU sources have indicated that regulatory cooperation with Japan should be regarded as a stepping stone toward rolling out the

² <http://www.mofa.go.jp/mofaj/files/000037966.pdf>

same regulatory system to other Asian markets.

Similarly, in business circles, in its recommendations on 8-9 April 2014, the EU-Japan Business Round Table maintained³ that as two of the world's largest and most advanced economies, the EU and Japan should play a leadership role in promoting global regulatory cooperation with the aim of developing an open, seamless global business environment that will help create new growth opportunities, not just for the EU and Japanese economies, but also for the rest of the world.

In a joint statement with KEIDANREN on 15 November 2013⁴, BUSINESSEUROPE, which consists of business federations in European countries, called upon governments of both the EU and Japan to "be attentive to preempt any unnecessary regulatory divergence among the advanced economies and work out a common set of rules that is globally relevant." At the third sector-to-sector meeting jointly hosted by BUSINESSEUROPE and KEIDANREN, both sides reaffirmed the above joint statement and recognized that "without cooperation between the EU and Japan, which share fundamental values and principles, global rules would not take shape. Regulatory coherence and cooperation among the advanced economies would be conducive to promoting structural reforms necessary to generate growth and jobs."⁵

4. Challenges to be Addressed by Japan

In parallel with promoting regulatory cooperation with the EU, Japan needs to strengthen its ability to design and develop regulations and to enhance its regulatory influence over other countries. To this end, it is necessary for Japan to maintain its attractiveness as a market by sustaining its economic growth and to further integrate itself with other countries and regions as a single market by extending EPA/FTA networks, thereby increasing like-minded countries. Japan also needs to maintain its technological strength and propose regulations for utilizing its own technologies and knowhow, together with the universal values and principles behind them. The KEIDANREN vision entitled "Toward the Creation of a More Affluent and Vibrant Japan" (January 2015) noted that "harmonization of standards and regulations among Japan, the US and Europe should be promoted and such a harmonized system should be extended to other countries including emerging economies so that Japan's excellent

³ <http://www.eu-japan-brt.eu/ja/joint-recommendations-authorities>

⁴ <http://www.keidanren.or.jp/en/policy/2013/098.html>

⁵ <http://www.keidanren.or.jp/en/policy/2014/017.html>

technology and knowhow can be utilized to solve global challenges."

Going forward, those Japanese companies which are active in the EU market need to maintain close communications between headquarters and local subsidiaries in order to be attentive to regulatory affairs in the EU and to be actively engaged in the development of regulations from the initial stage. Major industry associations are also expected to cooperate with their European and American counterparts on a daily basis. More specifically, sufficient financial and human resources must be given to local offices with a clear mandate. Headquarters must be always ready to give appropriate instructions expeditiously when decisions are required for anything beyond the mandate given to local offices. In cases where stances taken by Japanese companies are identical to those of their European and American counterparts, it will sometimes be more effective to lobby regulatory authorities or the persons concerned through them. There are also ample opportunities to make the voice of Japanese companies heard to the EU through governmental dialogue, and day-to-day communication with the Government of Japan plays an important role. There are examples of Japanese industries which have sent personnel to the Japan Business Council in Europe (JBCE) to work on European policy matters for many years, beginning with the design stage of environmental regulations such as REACH and RoHS.

5. Japan-EU EPA/FTA and Regulatory Cooperation

KEIDANREN has been encouraging industrial sector-to-sector dialogue to identify mutually beneficial solutions to non-tariff measure (NTM) issues, which are a major subject for negotiation in the Japan-EU EPA/FTA. While efforts to reduce and eliminate NTM barriers in both markets should continue, Japan and the EU need to shift their cooperation into a higher gear to strive for a seamless business environment through harmonization and mutual recognition of standards and regulations. Proactively creating common ground is the priority, rather than highlighting differences between Japan and the EU.

Without an EPA/FTA, it would be difficult to reinforce regulatory cooperation requiring long-term undertakings. Some of the measures cited in Chapters III and IV of this recommendation that can be agreed upon should be incorporated into the EPA/FTA. To address other measures which need to be further discussed after conclusion of the EPA/FTA, a mechanism for ongoing discussion should be included

in the EPA/FTA with a view to solving such issues via cooperation between the governments of Japan and the EU with the involvement of regulatory authorities. The Japan-EU EPA/FTA should be concluded as quickly as possible in order to serve as the institutional foundation for regulatory cooperation.

Along with the EPA/FTA, regulatory cooperation should be promoted through international fora such as the OECD, APEC and the UN Economic Commission for Europe (ECE); bilateral and regional mutual recognition agreements (MRAs); international frameworks organized by regulatory authorities in specific areas such as the International Medical Devices Regulators Forum (IMDRF) and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); adoption of international standards including ISO standards; and OECD guidelines and principles.

III. Regulatory Cooperation with the EU: Horizontal Cooperation

Regulatory cooperation described below should be conducted across all industrial sectors and areas by relevant government ministries and agencies in a unified manner under political leadership. Adequate human resources and sufficient time need to be invested. On the EU side, due attention should be paid to ensuring that there will be no difference in the situations of member states.

1. Regulatory Coherence and Transparency

a) In designing and developing regulations, Japan and the EU each take into account the other party's regulatory approaches, relevant international standards and their external impacts.

b) When introducing or revising domestic regulations, Japan and the EU notify and consult with the other party, supply available scientific and technical data, and solicit comments at an early stage.

2. Harmonization and Mutual Recognition of Standards and Regulations

a) Japan and the EU promote harmonization and mutual recognition of standards and regulations in the following ways:

i. Unification of standards and regulations.

ii. Harmonization of standards and regulations. If relevant international standards exist, they should be applied to both sides or used as the basis for harmonization. Even if no unified or harmonized standard or regulation exists, mutual recognition should be promoted based on the assumption that a certain product which is lawfully produced and traded by one party should be imported and distributed by the other. One of the reasons why the existing Agreement on Mutual Recognition (MRA) between Japan and the European Community has not been fully utilized is that it is limited to mutual acceptance of the results of assessments undertaken by conformity assessment bodies in the other party. Taking this into consideration, mutual recognition should be based on functional equivalence of standards and regulations.

b) As a minimum, Japan and the EU should exchange information and secure transparency through means such as notification at a sufficiently early stage before the introduction, revision and publication of standards and regulations.

3. Mechanism for Ongoing Regulatory Cooperation

a) In addition to the business environment committee functions stipulated in the EPA/FTAs Japan has concluded to date, the Japan-EU EPA/FTA should provide for a mechanism to reinforce regulatory cooperation comprising representatives of government agencies, including regulatory authorities, and the private sector. The involvement of both governmental and private sector representatives is a prerequisite for the mechanism to be effective. Governments prevent deviation from standards and regulations, while private businesses have current expertise on technological trends which serve as the basis for standards and regulations.

b) The functions of the mechanism should include monitoring the implementation of agreements for regulatory cooperation and proposing amendments to agreements.

IV. Regulatory Cooperation with the EU: Sectoral and Specific Cooperation

1. Sectoral Cooperation

The following is a summary of achievements in Japan-EU sectoral dialogues encouraged by KEIDANREN and the future course of action for regulatory

cooperation.

(1) Automobiles

Since 1990, the Japan Automobile Manufacturers Association, Inc. (JAMA) has held regular bilateral consultation meetings with the European Automobile Manufacturers Association (ACEA) to discuss issues such as environmental measures and safety. JAMA and ACEA participated in the past three sector-to-sector meetings jointly hosted by KEIDANREN and BUSINESSEUROPE⁶.

① Activities related to Japan-EU EPA/FTA

As part of its dialogue with ACEA, JAMA has addressed non-tariff measures (NTMs) in Japan pointed out by the EU during the scoping exercise and called upon the Government of Japan to provide solutions to them. With regard to technical regulations, for example, in order to align its domestic regulations with the EU, Japan has made efforts to reduce the cost of development and production by adopting UNECE regulations agreed at the UNECE World Forum for Harmonization of Vehicle Regulations (WP.29). Japan has so far adopted 37 out of 47 passenger vehicle UNECE regulations. The remaining ten regulations are scheduled for adoption by 2016. The number of approvals for establishing automobile repair and service workshops has increased every fiscal year since the Government of Japan issued technical guidelines to local governments in March 2012. The adoption of UNECE regulations is also being targeted in standards and certification procedures for high-pressure gas tanks, and the Industrial Policy Dialogue between the governments of Japan and the EU is proceeding toward that end. In cooperation with ACEA, JAMA is poised to pursue solutions to NTMs related to regulatory harmonization raised by ACEA at the end of 2014.

② Course of action for regulatory cooperation

Going forward, in cooperation with EU governments and car manufacturers, JAMA will encourage Asian countries to accede to the Agreement concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles and the Conditions for Reciprocal

⁶ Keidanren-BUSINESSEUROPE Sector-to-sector meetings were held in Brussels in March 2012, April 2013 and March 2014.

Recognition of Approvals Granted on the Basis of these Prescriptions, of 20 March 1958 (1958 Agreement).

With the introduction of advanced technologies to emerging economies, legal requirements for technologies related to environment and safety are increasing in those countries, and the time and money associated with assessment of conformity with such requirements and certification are mounting. In order to make conformity assessment and certification more efficient, International Whole Vehicle Type Approval (IWVTA), which is designed to change the basis of reciprocal recognition of approvals from equipment and parts to whole vehicle, is thus being deliberated in UNECE WP.29. Japan and the EU will join forces to promote such regulatory harmonization which will enable consumers to easily purchase new products with state-of-the-art technology and will benefit the governments of emerging economies in a manner that enables them to introduce advanced safety and environmental technologies without any difficulty and to develop sound domestic industries. To facilitate regulatory harmonization at WP.29, JAMA will continue to cooperate with ACEA through such means as synchronizing positions at the International Organization of Motor Vehicle Manufacturers (OICA), which is composed of 35 national trade associations.

(2) Chemicals

The Japan Chemical Industry Association (JCIA) has built a close relationship with the European Chemical Industry Council (Cefic) through the International Council of Chemical Associations (ICCA). JCIA and Cefic participated in the past three sector-to-sector meetings between Japan and the EU.

① Activities related to Japan-EU EPA/FTA

JCIA has cooperated with Cefic to call for the early conclusion of the Japan-EU EPA/FTA, including issuance of two joint statements (June 2012 and November 2013).

② Course of action for regulatory cooperation

JCIA and Cefic agree on the necessity of regulatory cooperation, which is listed in the above joint statements as one of the issues to be considered. Both associations are studying specific steps they should take, bearing in mind negotiations on measures related to regulatory cooperation between the EU and the US in the framework of the

Transatlantic Trade and Investment Partnership (TTIP). Regulatory cooperation has also been addressed in the chemical dialogue at the Asia-Pacific Economic Cooperation (APEC) forum, where a working group involving governments has been established to exchange information among member economies. A task force has also been established in ICCA to identify basic principles for regulatory cooperation. The task force will prepare some recommendations on how to secure transparency in the process of developing laws and where to place priority in chemicals management. In promoting regulatory cooperation, due attention should be paid to TTIP negotiations, so that Japan-EU arrangements do not lag behind the EU and the US with regard to standardization, and negotiations on the Japan-EU EPA/FTA should be utilized effectively. Being mindful of discussions on chemicals management in international organizations such as the OECD, JCIA will cooperate closely with Cefic to ensure industry views are reflected in a timely and appropriate manner.

Given the fact that regulations similar to the EU REACH rules prevail as a global standard, Japan needs to make its Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (The Chemical Substances Control Law) commensurate with international trends in chemicals management. More specifically, cooperation on hazard assessment for chemical substance risk management and harmonization of notification systems concerning polymers are to be considered for international regulatory cooperation.

(3) ICT

JEITA has been working on various issues facing ICT industries in cooperation with DIGITALEUROPE, which represents the digital technology industry in Europe.

JEITA and DIGITALEUROPE participated in the past three sector-to-sector meetings between Japan and the EU.

① Activities related to Japan-EU EPA/FTA

JEITA has cooperated with DIGITALEUROPE to call for the elimination of tariffs and NTMs between Japan and the EU, including issuance of two joint statements (November 2012 and April 2013). To promote the Japan-EU EPA/FTA, JEITA also issued similar joint statements with Intellect, which represents the UK technology industry (July 2012) and ANITEC, which represents the Italian information,

telecommunication and electronics industries (June 2012).

② Course of action for regulatory cooperation

JEITA and DIGITALEUROPE are poised to cooperate with each other to reinforce regulatory cooperation, as expressed in the above joint statement (April 2013), which notes that "the harmonization of Japanese and European systems and standards, the simplification in the distribution of digital technology products as well as the development of international rules will enable the EU and Japan to fight against rising protectionist policies. This is particularly directed towards some newly-emerging economies and the growing trend in creating systems and standards that give preferential treatment to their own industries. In order to accelerate regulatory cooperation, DIGITALEUROPE and JEITA will continue industry-to-industry dialogue towards this common goal." The following is an example of such efforts based on the recognition that coherent systems among advanced countries, including the US, will help prevent protectionist measures from prevailing in third countries.

Rolling back forced localization measures

More and more forced localization measures (FLMs) are being introduced, especially in emerging economies, aimed at strengthening local capabilities related to technology, research, development and production. Without any measures to roll back FLMs, their rise would inhibit the globalization of information services, thereby having negative impacts on all industries. In cooperation with DIGITALEUROPE and the Information Technology Industry Council (ITI) in the US, JEITA has accelerated its efforts to stem the further proliferation of FLMs. JEITA, DIGITALEUROPE and ITI, inter alia, are sounding the alarm about the possible detrimental effects of data localization requirements on the growth of the world economy.

Moreover, in addition to existing policy dialogues with the EU and the US respectively, the Japanese business community will strive for coherence among the institutions of countries and regions by utilizing other fora such as the Japan-EU EPA/FTA, the International Telecommunication Union (ITU), OECD and APEC with a view to securing the free flow of data.

③ Request for the EU

On the basis of EU directives, 20 member states have introduced different private copying levy schemes. These schemes cover a wide range of products and the compensation fees for reproducing copyrighted works for private use are generally high. In an environment of severe competition, not only would it be difficult to pass on these costs to consumers, but they could also inhibit production and sale of products covered by and subject to the schemes. Such schemes should be reviewed and abolished if necessary, and a different method adopted to compensate the creators whose works are reproduced.

(4) Medical devices

The Japan Medical Imaging and Radiological Systems Industries Association (JIRA) has built a close relationship with the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) through DITTA (the global association for diagnostic imaging, radiation therapy, healthcare IT, and electromedical and radiopharmaceutical manufacturers). JIRA and COCIR participated in the past three sector-to-sector meetings between Japan and the EU⁷.

① Activities related to Japan-EU EPA/FTA

JIRA and COCIR have worked together to eliminate NTMs in the Japanese market pointed out by the EU during the scoping exercise. As a result of these joint efforts, Japan's Pharmaceutical Affairs Law was revised in November 2013 and the Pharmaceutical and Medical Devices Act (PMD Act) came into effect in November 2014. Under the new law, the third party accreditation system has been expanded, QMS audits have been streamlined, stand-alone medical software has been regulated as a form of independent medical device, and package inserts (Tempu-Bunsho) can be omitted under certain conditions.

② Course of action for regulatory cooperation

In 2011 the International Medical Device Regulators Forum (IMDRF) was established with a view to securing international regulatory coherence on the basis of the achievements of the Global Harmonization Task Force (GHTF), which included

⁷ As for the second meeting, COCIR participated in writing.

participation by regulatory authorities and industry representatives from Japan, Europe, the US, Canada and Australia. GHTF issued documents concerning matters such as classification of medical devices and basic safety requirements, on the basis of which national regulations are designed. DITTA has been organized mainly by the industries of Japan, the US and Europe to effectively reflect industry views in discussion at IMDRF. Through DITTA, Japanese industry will cooperate with Europe and the US to secure regulatory coherence with Brazil, China and other emerging economies which are members of IMDRF.

③ Request for the EU

The EU plans to change its medical device directives into regulations. Under the new regulations, it will be necessary to avoid: a) increasing the number of devices which are subject to monitoring reports after sale; b) setting unique safety standards; and c) disclosing post-sale monitoring data and clinical data to healthcare providers and the general public.

(5) Pharmaceuticals

The Japan Pharmaceutical Manufacturers Association (JPMA) has built a close relationship with the European Federation of Pharmaceutical Industries Associations (EFPIA) through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and international gatherings of pharmaceutical industrial associations like the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). JPMA and EFPIA participated in the last two sector-to-sector meetings between Japan and the EU.

① Activities related to Japan-EU EPA/FTA

JPMA and EFPIA have worked together to eliminate NTMs in the Japanese market pointed out by the EU during the scoping exercise. These efforts have achieved some progress including alignment with international standards. Specifically, the Good Clinical Practice (GCP) Ordinance was amended in December 2012 and the Minimum Requirements for Biological Products were revised in June 2013 with a view to ensuring consistency with international standards in terms of specifications and testing methods for vaccines.

② Course of action for regulatory cooperation

Since 1990 Japan, the EU and the US have worked on harmonization of regulations, including testing methods necessary for new drug approvals and format of documents to be submitted, thereby preventing unnecessary repetition of various tests to reduce inefficiency in drug development and application for approvals and deliver better medicines to patients more speedily. ICH is scheduled to become a global framework, consisting of regulators and industry representatives from Japan, the US, Europe and various other countries. Within this framework Japan and the EU will cooperate with the US to call upon emerging economies to harmonize their regulations with advanced countries. Japan, the EU and the US will also take various other opportunities to join forces to urge emerging economies to harmonize regulations which are not dealt with in ICH.

③ Request for the EU

In the EU, where generic drugs are approved regardless of existing patents, it is necessary to introduce an "early resolution mechanism" in order to ensure the legal stability of pharmaceutical business, thereby reducing the burden of litigation concerning generic drug applications and approvals during the patent period of brand-name drugs.

(6) Textiles

The Japan Textile Federation (JTF) has an annual top-level dialogue with the European Apparel & Textile Confederation (EURATEX). JTF and EURATEX participated in the first sector-to-sector meeting between Japan and the EU⁸.

① Activities related to Japan-EU EPA/FTA

On the basis of the top-level dialogues, JTF emphasized in its joint statement with EURATEX that the Japan-EU EPA/FTA should envision "harmonization and compliance with international standards in the regulatory area" as well as ensuring "duty-free access from day one for all textile and clothing products with full reciprocity and no exceptions." As a result of a series of dialogues preceding the statement and efforts to lobby the Government of Japan, Japan Industrial Standards on

⁸ JTF participated in writing.

care labels are scheduled to be aligned with the relevant ISO standards, thereby adapting them to overseas markets including Europe.

② Course of action for regulatory cooperation

JTF will continue to engage in dialogue with EURATEX to explore the possibility of agreeing on:

i) Minimizing requirements for compulsory labelling affixed to products while maintaining the current level of consumer protection, more specifically, a) minimizing the number of compulsory labelling requirements, b) approximating or aligning names used to designate textile fibers on the basis of ISO standards, and c) harmonizing or mutually recognizing care instruction symbols based on ISO standards in this area.

ii) Harmonizing technical regulations and approaches to guaranteeing product safety and consumer protection in order to avoid unnecessary costs incurred due to divergence in regulations and approaches, more specifically, a) establishing a common list of chemicals that are prohibited or restricted, b) harmonizing technical requirements and relevant testing and presentation methods, and c) standardizing methods for measuring the quality of certain specialized textiles, such as high-function and high-performance fibers.

These two approaches are identical to those that the European and American industries have taken toward their governments in the context of TTIP and therefore contribute to reinforcement of regulatory cooperation among Japan, the EU and the US.

iii) Studying ways of protecting textile and apparel designs from copying activities through intellectual property rights systems that are mutually beneficial and suited to the short life cycle of such designs, and working together to lobby both governments on this issue.

(7) Other

In addition to the above-mentioned sectors, a Japanese railway operator and the Association of the European Rail Industry (UNIFE) participated in the last two sector-to-sector meetings between Japan and the EU. In contrast to other sectors, dialogue focused not on non-tariff measures and regulatory cooperation, but on procurement by Japanese railway operators. Taking into account points made by

UNIFE and other European associations and companies, some Japanese railway operators have redesigned their websites to include codes of conduct regarding material procurement, lists of main procurements expected in the fiscal year, and standard flows of contractual procedures and elements to be considered in screening. One operator has been proactively procuring from overseas, for example by opening up a new international tender process for the procurement of railcars and holding seminars to promote mutual understandings with EU suppliers by exchanging information on procurements, procurement procedures and products they can offer. The governments of Japan and the EU hosted the Railways Industrial Dialogue twice. The second dialogue in December last year discussed improvement of market access, technical regulations and safety standards, together with the present status of the Japan-EU EPA/FTA.

2. Cooperation on Specific Issues

Courses of action for cooperation on specific issues are set out below.

(1) Personal data protection

Smoother trans-border data flow would require, among other things, international harmonization of national and regional regulations and institutions related to appropriate treatment of personal data.

In Japan, draft amendments to the Act on the Protection of Personal Information will be deliberated in the present Diet session. Disciplines for the treatment of personal data will be significantly strengthened when the draft is passed and enacted. A third-party organization will be established and new provisions will be introduced to deal with issues beyond national borders. On the premise that the draft will be enacted, as a minimum, businesses that meet requirements set by international mechanisms and standards, such as certification of conformity with the APEC Cross Border Privacy Rules System, should qualify to transfer data without any difficulties between Japan and the EU. While proposed regulations on data protection have been under discussion in the EU as well, Japan's draft amendments are expected to precede the EU legislation. In order to secure institutional coherence between Japan and the EU, the Japan-EU EPA/FTA should have a provision enabling consultation on rules for trans-border data transfer to continue.

Japan and the EU should join forces to promote rule-making at the international level, including third countries, on the basis of the measures incorporated in the OECD Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data (adopted in 1980 and updated in 2013).

(2) Unification of European patent system

Descriptions and drawings required in the validation procedure for patent applications need to be translated into each official national language. In countries which are members of the London Agreement, submission of translated documents has not been necessary since May 2008, but in other countries which are not members of the agreement translated documents are still required. This incurs significant costs, including translation costs, which contribute to the low number of Japanese patent applications in Europe. Major expenditure is required in cases where companies file actions in courts in multiple countries. Against this background, the entry into force of the European unitary patent and unified patent litigation system has long been awaited. The present situation is that Spain and Italy do not participate in the unitary patent system and Spain and Poland have not joined the Agreement on the Unified Patent Court. Japan and the EU need to work together to bring all EU member states on board.

(3) Measures to combat counterfeit goods

It is important that more countries should sign the Anti-Counterfeiting Trade Agreement (ACTA) so that crackdowns on counterfeited and pirated products can be more effective. It would also be useful for Japan and the EU to reinforce cooperation between their customs authorities and among their respective customs, police and patent agencies to detect and prevent fraud, ascertain damages caused by infringement and take countermeasures as part of efforts to strengthen measures to combat counterfeited and pirated products in third countries.

(4) EU regulations on conflict minerals

A proposed regulation on conflict minerals is currently under discussion in the EU. Bearing in mind the situation in the US, where conflict mineral regulations have been put in place, the scope of conflict-affected and high-risk areas and requirements to be "responsible importers" should not be excessively burdensome to businesses and other

entities, but proportionate to the purpose of cutting off funding sources for armed forces in conflict-affected and high-risk areas. The industries of both Japan and the EU need to join forces to enable a truly effective set of rules.

V. Starting Point for a New Economic Order

Considering that emerging economies will further increase their economic weight in the world, building on what will be achieved through cooperation with the EU, Japan will have to promote regulatory cooperation among advanced countries including the US and extend cooperation to third markets including emerging economies. To this end, strategic and multilayered undertakings are required. In addition to the EPA/FTAs Japan is negotiating with countries and regions other than the EU, the agenda should include review of existing EPA/FTAs, reinforcement of other bilateral consultative mechanisms, and utilization of international fora such as APEC and OECD. Taking into account the possibility that regulatory cooperation among advanced countries may not lead to optimum global solutions, multilateral consultation including developing countries will be also necessary in some cases.

As well as leading to expanding markets for businesses and increasing opportunities for industrial cooperation, including in third markets, a seamless business environment on a global scale and a level playing field through regulatory cooperation would also contribute to the interests of consumers and users. In this sense regulatory cooperation is conducive to "the creation of a more affluent and vibrant Japan" as envisaged by KEIDANREN.

In its vision, KEIDANREN contemplates that mega-EPA/FTAs and plurilateral agreements should be used as stepping stones toward WTO rules, thereby establishing a multilateral free trade and investment system as a new economic order by 2030. More specifically, under the strategy "networking mega-EPA/FTAs and more," the promotion of regulatory cooperation among advanced countries and the extension of cooperation to emerging economies are listed as one of the mid-term goals for 2020. Regulatory cooperation with the EU is an important challenge to constitute the starting point for meeting this target.

By promoting regulatory cooperation based on the recommendations above, it is

necessary to make the Japan-EU EPA/FTA different from Japan's other EPA/FTAs, so that it can appropriately be regarded as one of the world's mega-EPA/FTAs. It is also necessary to ensure that the Japan-EU EPA/FTA is agreed in principle within this year. Now is the time for both the governments and private sectors of Japan and the EU to shift into high gear and accelerate efforts to promote regulatory cooperation.
