

Recommendations for Japan-EU Regulatory Cooperation [Outline]
-Looking beyond concluding the EPA/FTA -

I. Why Is Now the Time for Regulatory Cooperation?

1. Economic Globalization

- As corporate value chains expand globally, difference in domestic regulations and other NTMs 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 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,

⇒ **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.**

2. Progress of Mega-EPA/FTA Negotiations

- In the negotiations on the Japan-EU EPA/FTA, reduction and elimination of NTMs constitutes an important element.
- In the TTIP negotiations, regulatory cooperation is one of the three pillars, along with market access and trade rules.

⇒ **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.**



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, human rights as well as principles such as the market economy.

2. Strong Regulatory Influence

The EU is skilled at formulating regulations and influencing other countries to adopt the same regulations. It boasts the largest single market in the world, and has 28 member states which constitute a block vote in formulating and changing regulations at international fora. The proven ability of the EU and its experience in the process of the market unification has furnished it with external cohesive power. Furthermore, the EU has been successful in elevating its local agenda to the international level.

3. EU Expectations of Regulatory Cooperation with Japan

The EU also recognizes the necessity of regulatory cooperation with Japan.

e.g. "Joint Press Statement of the 22nd EU-Japan Summit," "EU-Japan Business Round Table Recommendations," "KEIDANREN-BUSINESSEUROPE Joint Statement," "News Release on EU- Japan EPA/FTA: Third sector-to-sector meeting held in Brussels"

4. Challenges to be Addressed by Japan

Japan needs to strengthen its ability to design and develop regulations and to enhance its regulatory influence over other countries by:

- a) maintaining its attractiveness as a market by sustaining its economic growth;
- b) further integrating itself with other countries and regions as a single market by extending EPA/FTA networks, thereby increasing like-minded countries;
- c) maintaining its technological strength and propose regulations for utilizing its own technologies and knowhow, together with the universal values and principles behind them.

5. Japan-EU EPA/FTA and Regulatory Cooperation

- Without an EPA/FTA, it would be difficult to reinforce regulatory cooperation.
- Some of the measures cited in Chapter III and IV 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.
- The Japan-EU EPA/FTA should be concluded as quickly as possible in order to serve as the institutional foundation for regulatory cooperation.



III. Regulatory Cooperation with the EU: Horizontal Cooperation

1. Regulatory Coherence and Transparency

- 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.
- 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

- Japan and the EU unify and harmonize their standards and regulations or mutually recognize them on the basis of functional equivalence.
- 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

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

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

1. Sectoral Cooperation

- (1) Automobiles
- (2) Chemicals
- (3) ICT
- (4) Medical devices
- (5) Pharmaceuticals
- (6) Textiles
- (7) Other

- ① Activities related to Japan-EU EPA/FTA
- ② Course of action for regulatory cooperation

(See next page.)

2. Cooperation on Specific Issues

- (1) Personal data protection
- (2) Unification of European patent system
- (3) Measures to combat counterfeit goods
- (4) EU regulations on conflict minerals



V. Starting Point for a New Economic Order

- 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.
- Regulatory cooperation with the EU is an important challenge to constitute the starting point for a new economic order envisaged by KEIDANREN.
- 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.

Sector	① Activities related to Japan-EU EPA/FTA	② Course of action for regulatory cooperation
Automobiles	<p>JAMA has called upon the GOJ to provide solutions to NTMs in Japan pointed out by the EU. As a result of it, for instance, Japan has so far adopted 37 out of 47 passenger vehicle UNECE regulations. 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.</p>	<ul style="list-style-type: none"> • In cooperation with EU governments and car manufacturers, JAMA will encourage Asian countries to accede to 1958 Agreement. • With the introduction of advanced technologies to emerging economies, Japan and the EU will join forces to promote the introduction of IWVTA which is designed to change the basis of reciprocal recognition of approvals from equipment and parts to whole vehicle.
Chemicals	<p>JCIA has cooperated with Cefic to call for the early conclusion of the EPA/FTA, including issuance of two joint statements.</p>	<ul style="list-style-type: none"> • JCIA and Cefic 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 TTIP. • Regulatory cooperation has also been addressed in the chemical dialogue at the APEC and ICCA. 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. • Japan needs to make the Chemical Substances Control Law commensurate with international trends in chemicals management.
ICT	<p>JEITA has cooperated with DIGITALEUROPE to call for the elimination of tariffs and NTMs, including issuance of two joint statements. To promote the Japan-EU EPA/FTA, JEITA also issued similar joint statements with Intellect (UK) and ANITEC (Italy).</p>	<ul style="list-style-type: none"> • JEITA and DIGITALEUROPE are poised to cooperate with each other to reinforce regulatory cooperation based on the recognition that coherent systems among advanced countries, including the US, will help prevent protectionist measures from prevailing in third countries. • In cooperation with DIGITALEUROPE and ITI in the US, JEITA has accelerated its efforts to stem the further proliferation of forced localization measures, aimed at strengthening local capabilities related to technology, research, development and production (They are sounding the alarm about the possible detrimental effects of data localization requirements on the growth of the world economy).
Medical devices	<p>JIRA and COCIR have worked together to eliminate NTMs in the Japanese market pointed out by the EU. As a result of these joint efforts, Japan's Pharmaceutical Affairs Law was revised and the Pharmaceutical and Medical Devices Act came into effect. 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.</p>	<ul style="list-style-type: none"> • Through DITTA which has been organized mainly by the industries of Japan, the US and Europe, Japanese industry will cooperate with Europe and the US to secure regulatory coherence with emerging economies which are members of IMDRF.
Pharmaceuticals	<p>JPMA and EFPIA have worked together to eliminate NTMs in the Japanese market pointed out by the EU. These efforts have achieved some progress including alignment with international standards. Specifically, GCP ordinance was amended, and the Minimum Requirements for Biological Products were revised with a view to ensuring consistency with international standards in terms of specifications and testing methods for vaccines.</p>	<ul style="list-style-type: none"> • 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.
Textiles	<ul style="list-style-type: none"> • 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." • Japan Industrial Standards on care labels are scheduled to be aligned with the relevant ISO standards, thereby adapting them to overseas markets including Europe. 	<ul style="list-style-type: none"> • 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; 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; 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.
Other	<ul style="list-style-type: none"> • In contrast to other sectors, dialogue in railway sector focused not on non-tariff measures and regulatory cooperation, but on procurement by Japanese railway operators. 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. 	