

Joint Statement for EU-Japan Regulatory Cooperation

13 December 2016

I . EU-Japan EPA/FTA and Regulatory Cooperation

BusinessEurope and KEIDANREN have 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 EU-Japan EPA/FTA. While efforts to reduce and eliminate NTMs that constitute barriers in both markets should continue, the EU and Japan need to shift their cooperation into a higher gear to strive for a seamless business environment through regulatory cooperation using means such as harmonization and mutual recognition of standards and regulations, but without lowering safety standards.

Proactively creating common ground is a priority. Especially when the sentiments on anti-globalization and protectionism are on the rise, defining and implementing an outward-looking trade strategy is definitely needed. Although a number of issues are still pending in the negotiations, through this paper we would like to highlight areas of common ground for European and Japanese businesses in the area of regulatory cooperation.

Without an EPA/FTA, it would be difficult to reinforce regulatory cooperation requiring long-term undertakings. The measures cited in this recommendation should be incorporated into the EPA/FTA, including its Annexes, if any, as far as possible. A mechanism should be included in the EPA/FTA to promote regulatory cooperation between the EU and the government of Japan with the involvement of the relevant ministries and agencies on both sides. The EU-Japan EPA/FTA should be concluded as quickly as possible and with the maximum level of ambition 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, 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.

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.

II. Horizontal Cooperation

1. Regulatory Coherence and Transparency

a) In designing and developing regulations, the EU and Japan should each take into account the other party's regulatory approach, relevant international standards and their impacts on bilateral trade and investment.

b) When introducing or revising domestic regulations or standards, the EU and Japan should 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) The EU and Japan should promote harmonization and mutual recognition of standards and regulations in the following ways:

i. Development of standards and regulations at the international level where regulatory objectives are identical.

ii. Harmonization of standards and regulations. If relevant international standards exist, they should be applied by both sides and adopted in national technical rules.

Where technical requirements are identical, or where harmonized standards exist, the results of testing should be accepted by the regulatory authorities concerned or accredited conformity assessment bodies of either party, thereby avoiding unnecessary duplicate testing on both sides. For relevant sectors if it is difficult to unify or harmonize standards and regulations, mutual recognition should be promoted based on the

presumption that a product which is lawfully marketed by one party and which offers the same level of regulatory requirements (e.g. safety) can be imported and distributed by the other. Competent authorities shall define and monitor the implementation of this mutual recognition. One of the reasons why the existing Agreement on Mutual Recognition (MRA) between the European Community and Japan 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, where appropriate, mutual recognition of the standards and regulations applied by each party which have the same level of requirements (e.g. safety) should be promoted.

3. Mechanism for Ongoing Regulatory Cooperation

- a) The EU-Japan EPA/FTA should provide for a mechanism to reinforce regulatory cooperation comprising representatives of relevant ministries and agencies such as the regulatory and industrial authorities.
- b) The functions of the mechanism should include monitoring the implementation of agreements for regulatory cooperation and proposing their revision to reflect technical progress and changing societal needs.
- c) A commissioner and a cabinet member should be involved in the mechanism in order to be fully effective to its purpose.
- d) The voice of businesses should be reflected to the full extent as possible to ensure that effective regulations which correspond to society's needs can be implemented at the lowest social cost and the mechanism can fulfill its functions as described above.

III. Sectoral and Specific Cooperation:

1. Sectoral Cooperation

The following are some recommendations for future regulatory cooperation on the basis of the achievements to date of the EU-Japan sectoral dialogue encouraged by BusinessEurope and KEIDANREN.

(1) Automobiles

Since 1990, the Japan Automobile Manufacturers Association, Inc. (JAMA) and the

European Automobile Manufacturers Association (ACEA) have held regular bilateral consultation meetings to discuss issues such as environmental measures and safety. JAMA and ACEA participated in the past five sector-to-sector meetings jointly hosted by BusinessEurope and KEIDANREN¹.

ACEA and JAMA will encourage more countries, particularly in Asia, to accede to the Agreement of 20 March 1958 (the 1958 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 Recognition of Approvals Granted on the Basis of these Prescriptions. In addition to the 1958 Agreement, both Japan and the EU have signed the 1998 Agreement, which aims to facilitate the development and establishment of Global Technical Regulations (GTR) and to promote harmonization of existing technical regulations. The EU, Japan and the US are jointly working on the improvement in the implementation of this Agreement. This is supported by ACEA and JAMA as well.

In the case of technical requirements in areas where a GTR has not yet been transferred into national law, or fully developed (e.g. gas tanks for fuel cell vehicles), Japan and the EU will cooperate at the technical level with the common objective to address this issue in a pragmatic manner, for instance through an ad-hoc bilateral arrangement to recognize each other's requirements and approval procedures as a prelude to full harmonization within the framework of WP 29. ACEA and JAMA support this approach.

With the introduction of advanced technologies to emerging economies, national mandatory requirements for technologies related to environment and safety are proliferating, and the social cost of regulatory compliance is mounting. In order to reduce the cost of the development, production, import and export of finished vehicles and parts, UNECE WP 29 is finalizing plans for the introduction of a system of International Whole Vehicle Type Approval (IWVTA), designed to change the basis of reciprocal recognition of approvals from equipment and parts to the whole vehicle. ACEA and JAMA will encourage the governments of the EU and Japan as well as other present and potential signatories of the 1958 Agreement to implement the IWVTA, in order that consumers can more easily purchase new products with state-of-the-art technology. The governments of emerging economies will also benefit from the early

¹ Keidanren-BusinessEurope Sector-to-sector meetings were held in Brussels in March 2012, April 2013, March 2014, April 2015 and in Tokyo in June 2016.

introduction of advanced safety and environmental technologies. To facilitate regulatory harmonization at WP 29, ACEA and JAMA will continue to cooperate bilaterally as well as within the framework of the International Organization of Motor Vehicle Manufacturers (OICA).

(2) Chemicals

The Japan Chemical Industry Association (JCIA) and the European Chemical Industry Council (Cefic) have built a close relationship through the International Council of Chemical Associations (ICCA). JCIA participated in the past five sector-to-sector meetings organized by BusinessEurope and KEIDANREN. Cefic joined the first four meetings.

JCIA and Cefic agree on the necessity of regulatory cooperation. 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 within ICCA and has recently developed a set of basic principles for regulatory cooperation, which every country can follow without decreasing its standards. ICCA identified three core areas of regulatory cooperation, i.e. (1) increased transparency in regulatory processes, (2) cooperation on prioritization of substances for review and collaboration on chemical assessment and (3) enhanced scientific cooperation, particularly on emerging regulatory issues. In addition, the task force is currently finalizing supporting material on regulatory cooperation with more detailed information on the three core areas and the illustration of examples to be followed. Shared approaches to chemicals assessment will prevent trade-related divergences and support mutually beneficial economic integration. Additionally, this will specifically support improved understanding and engagement of various stakeholders, including SMEs and the public, and build confidence in regulatory systems. 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 EU-Japan FTA should be utilized effectively.

There is a potential to improve the cooperation between regulators to avoid as far as possible unnecessary costs caused by different regulations. Appropriate mechanisms could be the exchange of information on new and emerging scientific issues between the regulators and the use of relevant international standards, e.g. Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and OECD Guidelines for the Testing of Chemicals. Being mindful of discussions on chemicals management in international organizations such as the OECD, JCIA and Cefic will 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 chemicals hazard and risk assessment including harmonization of the regulatory approach concerning polymers are to be considered for international regulatory cooperation.

(3) ICT

JEITA and DIGITALEUROPE have been working on various issues facing ICT industries in Japan and the EU. They participated in the past five sector-to-sector meetings organized by BusinessEurope and KEIDANREN.²

JEITA and DIGITALEUROPE are committed to cooperate with each other to reinforce regulatory cooperation, notably towards the harmonization of Japanese and European systems and standards at the international level to align technical requirements where possible, while maintaining high levels of safety, and the simplification in the distribution of digital technology products. In order to accelerate regulatory cooperation, avoid unnecessary differences in rules and guarantee a high level of consumer protection, DIGITALEUROPE and JEITA will continue industry-to-industry dialogue towards this common goal. They also urge negotiators to promote the development of international rules that will enable the EU and Japan to fight against rising protectionist policies. This is particularly directed towards the growing trend in mandating localization, such as required technology transfers and local sourcing. Increasingly, forced localization requirements are also being considered with regard to data—namely, requirements that

² As for the fifth meeting, DIGITALEUROPE participated in writing.

data be stored in country. 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. JEITA, DIGITALEUROPE and their US partner 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 the European and Japanese business communities will strive for coherence among the institutions of countries and regions by utilizing other fora such as the Japan-EU EPA/FTA, the WTO, the TiSA negotiations, the International Telecommunication Union (ITU), and the OECD with a view to securing the free flow of data and the global value chains which rely on it.

Request for the EU

On the basis of EU directives, 21 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 abolished or at least reviewed and replaced by alternative models of compensation when justified by a duly conducted harm assessment.

(4) Medical devices

The Japan Medical Imaging and Radiological Systems Industries Association (JIRA) and the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) work together through DITTA (the global association for diagnostic imaging, radiation therapy, healthcare IT, and electromedical and

radiopharmaceutical manufacturers). JIRA and COCIR participated in the past five sector-to-sector meetings between BusinessEurope and KEIDANREN³.

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 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 the 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 the IMDRF.

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) and the European Federation of Pharmaceutical Industries Associations (EFPIA) have built a close relationship 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 four sector-to-sector meetings organized by BusinessEurope and KEIDANREN

Since 1990 Japan, the EU and the US have worked on harmonization of regulations,

³ As for the second meeting, COCIR participated in writing.

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. The 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 the ICH.

The EU and Japan should reduce differences in regulatory requirements leading to expensive duplication of studies, and resource and time consuming redundancies. Additional requirements which are not scientifically justified and increase development costs for manufacturers and that unnecessarily delay access to medicines for patients, should be removed with a view to facilitate global drug development. Although the MRA between the EU and Japan has been in place since 2002, its scope is limited. The MRA should be reviewed to include other products, such as active pharmaceutical ingredients, sterile products and biopharmaceuticals (including vaccines). Expanding the MRA to cover vaccines will contribute to accelerating the availability of vaccines in Japan and further reduce the so-called “Vaccines Gap”.

(6) Textiles

The Japan Textile Federation (JTF) and the European Apparel & Textile Confederation (EURATEX) have an annual top level dialogue. JTF and EURATEX participated in the first sector-to-sector meeting organized by BusinessEurope and KEIDANREN⁴.

JTF and EURATEX will continue to explore the possibility of agreeing on:

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

⁴ JTF participated in writing.

standards in this area.

ii) Harmonizing technical regulations and approaches 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) minimizing technical requirements and harmonizing 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) Considering the short life cycle of textile and apparel designs, setting out rules for securing expedited protection for them on the basis of Article XXV§2 of the WTO TRIPS Agreement.

(7) Others

Railway sector

In addition to the above mentioned sectors, a Japanese railway operator participated in the last four sector-to-sector meetings organized by BusinessEurope and KEIDANREN. The Association of the European Rail Industry (UNIFE) joined the second, third and fourth meetings. In contrast to other sectors, dialogue did not focus on regulatory cooperation, but on procurement by Japanese railway operators.

Following the ‘one-year package’ on railways, 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 an overview of contractual procedures and elements to be considered in screening. One JR operator out of six has been reaching out to suppliers from overseas, for example by opening up a new international tender process for the procurement of railcars and holding seminars to promote mutual understanding with EU suppliers by exchanging information on procurements, procurement procedures and products/technologies. BusinessEurope and Keidanren would welcome further positive developments.

In parallel, the governments of Japan and the EU hosted the Railways Industrial

Dialogue five times. The Industrial Dialogue has already contributed to enhance mutual understanding in the sector. It should be held on a regular basis to accompany the FTA negotiations and lead to more tangible results in terms of market opening. BusinessEurope and Keidanren also call on the European and Japanese authorities to solve the remaining issues by the end of the negotiations.

Agri-Food sector

It is also noted that the EU food and drink industry is supportive of EU-Japan regulatory cooperation to solve, reduce and prevent any unnecessary regulatory divergences in the area of food and drink. While no sector-to-sector dialogue exists to date, the European food and drink industry is keen to explore possibilities of cooperation with like-minded Japanese counterparts. Some of the issues which the EU side would like to address are related to the harmonization of standards; developing recommendations on how to resolve non-tariff measures; the promotion and adoption of internationally recognized standards; and strengthening government-to-government cooperation in this area.

2. Cooperation on Specific Issues

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

(1) Cross-border data flows

The Internet and ICT services have become a strong enabler for trade, economy, and society. The free movement of data across borders is now essential to all companies engaged in international business. The EU and Japan should set digital trade principles, including horizontal provisions safeguarding cross-border flows of data, and resisting calls for the mandatory and unjustifiable localization of data.

The EU and Japanese Industries are committed to complying with national data protection laws. Compliance can be achieved, while cross-border data flows can be allowed at the same time.

In Japan, amendments to the Act on the Protection of Personal Information were passed through the Diet last year. They significantly strengthen discipline on the protection of personal information by establishing a data protection agency which will function as the center of administration for protecting personal information and introducing new

provisions to deal with issues beyond national borders. Moreover, the Trans-Pacific Partnership (TPP) Agreement which was concluded last year has a provision that the cross-border transfer of information including personal information shall be allowed. Considering these recent developments, the EU and Japan should strive to reach an agreement to mutually ensure the free cross-border transfer of personal information between themselves, while protecting personal information, under the EU General Data Protection Regulation adopted in April 2016 as part of the Digital Single Market initiative and the amended Japan's Act on the Protection of Personal Information.

Furthermore, the EU and Japan 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 Flow 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 Croatia do not participate in the unitary patent system and Spain, Poland and Croatia have not joined the Agreement on the Unified Patent Court. The EU and Japan need to work together to bring all EU member states on board.

(3) Measures to combat counterfeit goods

As part of efforts to combat the proliferation of counterfeit and pirated goods through enhanced international cooperation and more effective international enforcement, the EU and Japan should 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.

(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 the EU and Japan need to join forces to enable a truly effective set of rules.

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