

Regulatory Cooperation between Japan and the EU (draft)

Building on the existing cooperation on regulations and standards, the Ministry of Economy, Trade and Industry and the Directorate General for internal market, industry, entrepreneurship and SMEs consider that cooperation at earlier stage in their respective legislative process is more effective and preferable to avoid potentially damaging discrepancies and help solving existing difficulties. They are of the view that, as two of the world's largest and most sophisticated economies, cooperation to eliminate, reduce and prevent *behind-the-border issues*, while bearing in mind that legitimate policy objectives of regulations and standards such as safety are fully respected, will permit to enjoy the following benefits:

Firstly, addressing the *behind-the-border issues* would be a large source of economic growth for both.

Secondly, cooperation on regulations and standards between Japan and the EU enhances the competitiveness of their own industries, by reducing cost of compliance especially for SMEs, by providing market readiness for new technologies on a global scale, and by together encouraging third countries to adopt international regulations and standards so that they enjoy better living standards with best products of the highest quality.

Thirdly, METI and DG GROW, through this enhanced cooperation, covering all issues under their competence or beyond, could play a role in giving new momentum to the development and implementation of international regulations and standards.

Based on the view above, regulatory cooperation has been started in following areas:

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Robotics

Robotics is considered to be a strategic area to grow both in Japan and the EU. SPARC, the world's largest research and innovation program for robotics, has been launched in the EU, aiming at creating over 240,000 jobs and gaining more than 40% share of the global robotics market. In Japan, robotics is one of the key areas of the Japan Revitalization Strategy, in which it targets to increase the size of the robotics market to \$24 billion USD in 2020, three times larger than at current.

Experts from METI and DG GROW have ~~agreed to start exploratory talks~~ on regulatory issues for robotics. The issue they ~~expect to look into~~ is CE mark certification for personal care robots. Personal care robots are certified either as machinery or medical devices depending on their intended use.

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~~Following this exploratory work~~ METI and DG GROW ~~may~~ consider ~~setting up a WG on the robotics sector and deepening their policy dialogue to explore uniform application of product certification~~. Consideration will be given to the existing relevant technical ~~specifications (safety standard EN ISO 13482 with a clear delimitation to ISO 13485 relevant to medical device robots)~~.

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Chemicals

Risk assessment of chemical substances

As for risk assessment of existing chemical substances, in Japan it is conducted by the Government of Japan under the CSCL (Risk Assessment of Existing Chemicals under the Chemical Substance Control Law). In the EU under REACH, industry ensures safe use of the chemicals registered with the European Chemical Agency (ECHA). For substances registered in quantities above 10 tons/year/company, companies prepare and submit chemical safety report (CSR) to ECHA. Member States evaluate certain substances included into the Community Rolling Action Plan (CoRAP) to clarify whether their use poses risk to human health or the environment.

Although the policy choices underpinning the regulations differ between Japan and the EU, as for regulatory cooperation, authorities of both sides have exchanged information related to the progress of evaluation and risk assessment/management of chemical substances.

As for nanomaterials and endocrine disrupters, both sides consider the possibility of cooperation, while observing international policy trends, in particular the activities of the OECD.

Transferring information of chemical substances

As for a scheme for transferring information of chemical substances, both in Japan and the EU, providing SDS (Safety Data Sheet) to professional users is a mandatory obligation for transferring of hazardous chemical substances themselves and in mixtures, but there is no regulation for transferring information of chemical substances in articles.

However, in the EU, article 33 of REACH sets obligation for providing information on the presence of substances of very high concern on the Candidate List in articles to allow safe use of the articles. As a minimum the name of the substance has to be communicated.

METI is currently engaged in a project with the Japanese industry to develop an information transferring system on textile, daily products, construction materials and raw materials etc., Promotion of such a system at international level would be beneficial, following the existing international standard of the system for the electric and electronics area. METI and DG GROW have agreed that relevant regulatory authorities exchange information and suggested to invite both EU and Japanese industry representatives to EU-Japan working group discussions on the topic at the appropriate time.

Revision of Flammability Classification in GHS

It appears that, in practice, with the current criteria under the UN GHS (Globally Harmonized System of Classification and Labelling of Chemicals) almost all flammable gases are classified as “extremely flammable”, making no distinction between for instance hydrogen and refrigerant gases in hazard identification and communication, whereas industrial standards have acknowledged differences in flammability. This might hamper the use of non-ozone depleting and low global warming potential (GWP) gases. A review of the flammability criteria will therefore be carried out by a joint working group of the sub-committees of experts for UN GHS and TDG (Transport of Dangerous Goods) during the biennium 2015/16 under the lead of Belgium and Japan. The group shall explore the possibility to develop new subdivisions in Category 1.

METI and DG GROW will exchange views on the technical review of the classification of flammable gases under the UN GHS, taking account of the work that will be carried out by joint working group of the sub-committees of experts for UN GHS and TDG (Transport of Dangerous Goods) during the biennium 2015/16.

Automobile

METI and DG GROW engage in the Industrial Cooperation Dialogue covering the regulatory aspects of the automotive industry that are under their respective responsibility. They also cooperate to prepare joint proposals at the TBT committee in this sector.

In 2014, Japan and the EU have actively participated in the activities to establish, develop common approaches to Regulations in WP29 of the UNECE and have been working together on international standardization under the ISO/IEC.

METI and DG GROW held Working Group under the Industrial Policy Dialogue in October 2014, with attendance of experts from private sector, where UN-R110 and GTR Phase 2 on hydrogen and fuel cell vehicles were discussed.

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METI and DG GROW will seek for other new areas in the context of automobile regulations and standards under the Industrial Policy Dialogue.

Conflict Minerals

As for “a draft regulation of responsible sourcing of minerals originating in conflict-affected and high-risk area”, DG TRADE and GROW agree to exchange views with METI on developments when appropriate and with the aim to encourage broader use of due diligence

| amongst upstream but also downstream operators.

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METI and DG GROW also continue to deepen the cooperation in the following areas;

Eco-Design Policies

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METI and DG GROW will cooperate for environmental standards and related assessment methods for respective categories of industrial and consumer products, based on sufficient consultation with stakeholders and the discussions in the Climate change and Environment working group in February 2015. The objective will be to have common assessment methods where possible, and a clear mapping of regulatory product requirements.

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Construction

Regarding sustainability criteria for the environmental performance of construction products,

METI and DG GROW will cooperate on regulations and standards which are essential for the construction sector in both the EU and Japan. Focus will be made on the following subjects:

- Existing market potential in Japan and EU for trade in the construction sector, including construction products as well as foreign direct investment.
- Opportunities for regulatory and standards alignment inter alia for sustainability criteria and resource efficiency.
- Business and technological cooperation potential for European companies and Japanese companies, including SMEs.

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Resource efficiency

In the EU, "Resource efficiency" is a key element for the promotion of circular economy. EU withdrew an earlier proposal for the promotion of the circular economy and is working on the preparation of a revision to take place in the course of 2015.

METI considers that 3R (Reuse, Reduce and Recycle) can contribute to overcoming resource constraints and promotion of the circular economy.

METI and DG GROW will continue to exchange views on policies and regulations to realize the circular economy.

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Medical devices

METI and DG GROW will cooperate to consider enhancing market readiness for medical devices in emerging market.

IT and manufacturing industry

The European Commission released the report “advanced manufacturing for clean production” to improve productivity as well as waste and pollution management. The ICT-enabled intelligent manufacturing used in “smart factories” can be taken as example of “advanced manufacturing”. The pervasive influence of IT on manufacturing process can bring new aspects of manufacturing to policy attention pertaining, e.g. in robotics or sustainability. Some member states also adopt national initiatives on “advanced manufacturing”.

In METI, revision of the Growth Strategy is being discussed, where reshaping of industrial structure by digitalization of manufacturing and spread of “Internet of Things”, etc. is one of key topics.

METI and DG GROW will deepen dialogue on policies for advanced manufacturing for concrete measures to reap the afore –mentioned benefits.

Forced Localization Measures on ICT industry

Numbers of emerging economies are implementing Forced Localization Measures (FLMs) on ICT industry, including data localization requirement.

Impact of the FLMs will not be limited in the ICT industry but to other areas.

METI, DG GROW and DG Trade exchange views for FLMs, and will promote further cooperation.

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Personal Data Protection

In the EU, “a draft Regulation of the Personal data protection: processing and free movement of data (General Data Protection Regulation)” is under discussion. In Japan, Policy Outline of the Institutional Revision for Utilization of Personal Data has been adopted in June 2014, and the amendment bill of Act on the Protection of Personal Information will be submitted early 2015.

For the further strengthening of the economic relationship between Japan and the EU, METI, DG JUST and DG GROW will cooperate with a view to promoting cross-border data flows whilst respecting parties' legislative frameworks on flows of personal data.