

Regulatory Cooperation between Japan and the EU (draft)

Building on the existing cooperation on regulations and standards, METI and DG GROW 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, Japan and the EU, through this enhanced cooperation, could play a role in giving new momentum to the development and implementation of international regulations and standards.

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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 started cooperation on regulatory issues for robotics. The issue they picked up on is CE mark certification for personal care robots. Personal care robots are certified either as machinery or medical devices depending on their intended use.

METI and DG GROW are considering 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).

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

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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.

Automobile

Japan and the EU have actively participated in the activities to establish regulatory instruments in WP29 of the UNECE and have been working together on international standardization under the ISO/IEC.

METI and DG GROW engage in the Industrial Cooperation Dialogue, while Japan conducting dialogue and cooperation with industrial policy authorities of the Member States, and cooperate to consider toward joint proposals at the TBT committee(s).

To facilitate discussions for WP29, METI and DG GROW held Working Groups under the Industrial Policy Dialogue, attended by private sector in October 2014.

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

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**.

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For further strengthening of the economic relationship between Japan and 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.

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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.

Eco-Design Regulation

Japan and the EU will cooperate for environmental standards and related assessment methods for respective category of product so that the most effective and eco-friendly standards and assessment methods are to be set.

Construction sector

Both the EU and Japan are in the process of developing sustainability criteria for the environmental performance of construction products.

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

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- Existing market potential in Japan and EU for trade in the construction sector, including construction products as well as foreign direct investment.

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- Opportunities for regulatory and standards alignment

- Business and technological cooperation potential for European companies and Japanese companies, including SMEs.

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