# January 2020

**DRAFT JOINT SUBMISSION FROM CEFIC AND JCIA**

**ON REGULATORY COOPERATION IN THE CONTEXT OF THE EU-JAPAN ECONOMIC PARTNERSHIP AGREEMENT**

**INTRODUCTION**

As members of the International Council of Chemical Associations (ICCA), the Japan Chemical Industry Association (JCIA) and the European Chemical Industry Council (Cefic) welcome the EU-Japan Economic Partnership Agreement, which entered into force in February 2019. The Japanese and European chemical industries are very important trading partners with more than € 11 billion worth of chemicals going both ways. The agreement will undoubtedly strengthen our bilateral relations and boost trade. It also represents an opportunity and a framework to further develop regulatory cooperation on chemicals. Industries from both sides will therefore actively contribute to the implementation of the agreement including seeking ways to enhance regulatory cooperation.

Enhanced regulatory cooperation would maintain high levels of protection for human health and the environment while promoting resource and cost savings for both governments and industry from the more efficient interaction of different regulatory regimes. Regulatory cooperation is about supporting more efficient, transparent and cost-effective approaches to chemicals management between trading partner countries.

# PRIORITIES FOR REGULATORY COOPERATION

JCIA and Cefic have identified the following areas as core priorities for enhanced regulatory cooperation by Japan and the EU under the Economic Partnership Agreement (EPA):

* Transparent regulator-regulator interactions and transparency in regulatory processes.
* Cooperation on future prioritization of substances for review and collaboration on chemical assessment.
* Enhanced scientific cooperation, particularly on emerging regulatory issues.

Cefic and JCIA believe that the most effective and efficient approach to sound chemicals management is through a combination of transparent science and risk-based regulations and voluntary industry initiatives such as Responsible Care® and the Global Product Strategy (GPS)1.

Enhanced regulatory cooperation can help promote common understanding and provide advice to legislators in advance to prevent divergences. Increased cooperation will lead to more regulatory certainty, objectivity and transparency. It will also increase efficiency, minimize duplication of effort and costs for governments and industry alike. Reducing non-tariff barriers to trade will facilitate greater economic growth and innovation while still sustaining high standards of safety.

Regulatory cooperation should promote a common science-based evaluation framework for risk-based decision making with clear criteria and processes. The following are global industry principles defined by priority areas for engagement by government administrations, regulatory agencies and stakeholders:

## ***Transparency***

Developing mechanisms to increase transparency will build confidence in each other’s regulatory

process and serve as the basis for cooperation between regulators. Key areas encompass:

* Mechanisms for joint consultation between regulators early in the development of new regulations to identify opportunities to align regulatory decisions, to prevent and eliminate regulatory divergences that create non-tariff barriers and harm economic competitiveness. Involvement from industry as well as between regulators is important.
* Commitment by regulators to early publication of draft regulatory initiatives in public domain with meaningful opportunities for stakeholders to provide comment and input into regulatory proposals at the various stages of the regulatory process.
* Shared reviews of regulatory impact assessments for existing policy areas and for the identification of future regulatory priorities as part of a long-term dialogue.
* Opportunity to explain/question the national interpretation of regulatory definitions, standards and scientific evidence.

## ***Prioritization***

Collaboration towards a common approach of future prioritization for chemicals assessment and management will provide for optimal allocation of scarce resources. Burden sharing between governments will significantly accelerate the completion of risk assessments. Governments should prioritize chemicals of highest concern with a focus on chemicals in commerce with highest potential for exposure.

## ***Chemicals assessment***

Shared approaches to chemicals assessment will support improved understanding and engagement of various stakeholders, including small and medium-sized enterprises (SMEs) and the public, and build confidence in the regulatory systems.

To encourage shared approaches, the following areas need to be considered:

* *Data sharing* – authorities on both sides have already started a dialogue on data sharing. Agreeing on a common format, including templates for studies’ results and exchangeability of datasets, as the basis for exchange on safety studies would significantly facilitate data sharing. Both sides could consider contributing to the development of an *international navigator*, which would include existing databases from both sides. This would contribute to the initiative launched by SAICM (Strategic Approach to International Chemicals Management) in cooperation with the OECD and UN Environment, which aims at knowledge and information sharing on chemicals at international level to enhance capacity building efforts. ICCA also recognizes its necessity and supports the initiative.
* *Classification and labeling* – encourage adoption of common classification and labelling following the UN Purple Book eliminating the need for dual classifications and allowing flexibility between the different revisions.

Authorities from both sides could commit to work towards convergence when implementing the **UN GHS (Globally Harmonized System of Classification and Labelling of Chemicals)**. This could notably be done by seeking alignment on the use of the same building blocks as one option. While respecting each other’s procedures, an enhanced EU-Japan cooperation on classification of chemicals could facilitate trade and provide a level playing field for business on both sides. Companies would also benefit from harmonized safety data sheets and labelling of chemical products.

* *Impact Assessments -* require impact assessments including a review of potential trade related impacts from draft regulation.
* *Design -* transparency and flexibility in the design of chemical assessments will help promote broad understanding of the key issues to be assessed and the specific methods, assumptions, and evaluation procedures to be utilized. Input from the research community and stakeholders should be part of this activity, so that the most up-to-date data can be obtained, and the most relevant methods can be considered and used.
* *Data Generation* – promote common data formats and languages, regulatory definitions and standards allowing transferability and reducing the need for duplicative data generation including shared approaches towards testing. Facilitate use of alternative approaches to minimize animal testing.
* *Data Evaluation* – utilize transparent, consistent and scientifically objective data evaluation protocols including methods, assumptions and evaluation procedures to evaluate studies.
* *Scientific evidence* – base data selection and assessments on a clear and consistent framework that takes into account, and integrates, all relevant data and information and gives the greatest weight to information from the most relevant and highest quality studies.
* *Confidential business information* – establish mutually accepted criteria for defining and protecting CBI.

Finally, one area that could address numerous regulatory inefficiencies and potential problems for both government and industry is the harmonization of chemical inventory nomenclature guidance and policy. There are significant historical nomenclature issues in both Japan and the EU which affect the ability of the responsible authorities to maintain accurate chemical inventories and create challenges for industry to identify chemicals and comply with inventory requirements in both jurisdictions. In fact, this is an issue that extends to other global jurisdictions as well. We suggest that both jurisdictions would benefit from developing a framework that established principles for identifying “equivalent substances” so that scarce government and industry resources are not necessarily expended in consultation, notification, and inventory listing of duplicative substances.

# JCIA and Cefic believe that these priorities can serve as a basis for enhanced regulatory cooperation.

This will in turn **ensure strong protection of health and environment,** while respecting national sovereignty and statutory/regulatory requirements in any jurisdiction. I will also **increase transparency for all stakeholders** and support building consumer confidence while significantly reducing costs for regulators and industry alike.