



**PRACTICAL GUIDELINES FOR REGULATORS ON  
CONFORMITY ASSESSMENT PROCEDURES: PROPOSAL**

*Submission from Japan*

The following communication, dated 13 November 2019, is being circulated at the request of the delegation of Japan.

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**1 INTRODUCTION**

1.1. Japan considers that the ongoing exchange of information among WTO members at the Eighth Triennial Review has been very fruitful and welcomes the diverse experiences of WTO Members in the process of developing the conformity assessment guidelines. It is well understood that the quality of infrastructure for conformity assessment varies between WTO Members, and that it is at the discretion of regulators to choose the most suitable conformity assessment procedure according to their own situations.

1.2. Meanwhile, in accordance with the TBT Agreement, each WTO Member is required to not create unnecessary obstacles to international trade when taking measures necessary for regulatory purposes, such as protection of human health and safety. In addition, it is understood that WTO Members comply with the principle of using relevant international standards as a basis for their technical regulations. Furthermore, WTO Members are supposed to comply with their international commitments such as the principle of most-favoured-nation treatment, national treatment, and fulfilment of TBT notification obligations. Japan believes that WTO Members set their regulatory frameworks with the most appropriate conformity assessment procedures considering their own circumstances such as historical backgrounds, cultural and economic situations.

1.3. Accordingly, Japan would like to underline the importance that this guideline will be practical to use and provide a wide range of options that regulators can refer to, when designing their regulatory schemes with conformity assessment procedures, so that the regulatory schemes will not create unnecessary obstacles to international trade, while the guideline should not be prescriptive nor restrictive as already agreed.

**2 JAPAN'S EXPERIENCE**

2.1. The following are several common practices related to standards and conformity assessment procedures being implemented in Japan, which might be helpful for other Members.

**2.1 International Standards/Guides**

2.2. Japan recognizes that there are already ISO/IEC international standards and guides for conformity assessment, which have been mostly adopted as national standards (JIS) and published for users.

**2.2 Conformity Assessment Schemes**

2.3. In designing conformity assessment schemes, regulators should be aware of their obligation to avoid unnecessary duplication of conformity assessments, and available mechanisms to do so. It is

also necessary to coordinate domestically among relevant regulations. International standards should play a very important role in avoiding duplicative conformity assessments.

2.4. WTO Members are required to use international standards, where they exist, as the bases of the technical regulations. In such cases, Japanese regulations often stipulate "JISXXXX or equivalent" as a measure to demonstrate conformity with technical regulations to the extent appropriate for the purpose of the law.

2.5. Acceptance of conformity assessment results to avoid unnecessary duplication has been encouraged by the TBT Committee, and the "Indicative List of Approaches to Facilitate Acceptance of the Results of Conformity Assessment" has been created as the G/TBT/1/Rev.14 Annex Part1. Regulators are expected to consider whether the methods listed on the indicative list can be implemented when designing their conformity assessment procedures.

2.6. In the 7th Triennial Review, Japan presented the status of acceptance of test reports using international schemes. Since then, the IECEE CB scheme on electrical safety testing and GLP scheme in OECD on testing of chemicals have been further utilized. The number of CB scheme testing reports issued in 2018 has increased by 6.8% from the previous year to 101,460, increasing year by year. As the number of issued test reports increases, the scheme owner has been making efforts to enhance the reliability of the system.

2.7. Contracts between domestic conformity assessment body (CAB) and foreign CAB form a core part in the acceptance of IECEE CB scheme test reports in Japan, in which regulators can accept test reports based on the contracts between CABs or CB testing laboratories (CBTLs). In this case, the regulator should know details of the content of such contracts.

2.8. Furthermore, Japan would like to explain again about cross-border designation of CABs that Japan has been implementing for several years, which has been found the most practical and effective scheme. In Japan, equal treatment of CABs located either in Japan or outside Japan has been secured under several regulations, in which foreign CABs are able to be designated directly by regulatory authorities of Japan. In particular, in the regulation on electrical safety, MRAs (Mutual Recognition Agreements) concluded in the past have not been used at all for a certain period of time due to the progress of the use of IECEE CB scheme and the cross-border designation scheme of foreign CABs.

2.9. Regarding the bilateral MRA between nations, it takes time to understand each other's legal and regulatory scheme and technical regulation including testing/certification and accreditation mechanisms. In addition, as reported at the past thematic sessions by some countries, both parties of an MRA must always keep track of details of each other's regulations. Considering these large administrative costs, regulators should first consider the acceptance of test reports or test data based on international schemes such as the IECEE CB Scheme or GLP in OECD, as well as the cross-border designation of foreign CABs by relevant regulatory authorities, which could be most likely more effective and efficient.

### **2.3 Risk Assessment**

2.10. It is important to design conformity assessment procedures based on scientific approaches. The system to collect relevant data has found to be playing an important role.

2.11. Regulators should be therefore aware of existence of risk assessment documents, including ISO/IEC standards and guides. Japan would like to emphasize that specific conformity assessment methods should not be automatically adopted depending on the degree of risk.

2.12. For example, it may not be always determined by a degree of risk itself whether the regulatory objectives can be achieved by self-declaration of conformity that is supplemented by post-market measures such as market surveillance, or in combination with quality management systems, or third-party certification. It could be according to the circumstances of each country with possible allocation of public resources. It is also essential to constantly review the conformity assessment system by collecting and analysing information on product accidents.

## **2.4 Legal or Administrative Framework other than the Conformity Assessment System to Achieve Legal Objectives**

### **2.4.1 Product Recall System**

2.13. After experiencing past severe product accidents, Japan's product recall system has been revised and improved in various ways.

2.14. When there is a high probability that accidents or safety problems may occur with a product, the government can issue a recall order based on law.

2.15. In addition, when there is a possibility found to be causing a safety problem with a product, the relevant business operator may voluntarily recall the products for repair, etc. as a preventive measure. For this type of occasion, what is important is to increase the recall collection rate by disseminating the potential risk information to consumers, vendors and others.

### **2.4.2 Product Accident Report Disclosure System**

2.16. As reported at the previous thematic session, Japan has developed and implemented the product accident report disclosure system to respond to a series of fatal accidents caused by specific defective products. Following the analysis of product accident reports being collected through the system, regulators may develop or amend technical regulations of specific products, and/or introduce conformity assessment procedures.

## **3 CONCLUSION**

3.1. Japan provides this submission for the discussion of development of non-prescriptive and practical guidelines on potential approaches of conformity assessment for regulators to refer to. To ensure that conformity assessment procedures will not create unnecessary obstacles to international trade, Japan hopes that members would actively participate in this discussion to fill the guidelines with reference examples of good practice.

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