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Ad Hoc Team of Specialists on Standardization and Regulatory Techniques

Revision of Recommendation L on an International Model for Product/Service Conformity Based on Transnational Regulatory Cooperation

Submitted by the WP.6 Chair*

Summary

This recommendation provides guidance on how to establish a common regulatory arrangement (CRA) which is a voluntary mechanism that countries can adopt in order to help harmonize product regulations and reduce redundant conformity verifications. This directly supports the World Trade Organization (WTO) Technical Barriers to Trade (TBT), articles 2.4 and 2.6 on the use of international standards as a basis for technical regulations and article 5.4 on the use of relevant international guides as a basis for conformity assessment procedures. This recommendation was first approved in 2001 and revised in 2015.

Mandate:

The Working Party on Regulatory Cooperation and Standardization Policies (WP.6) Programme of work for 2024 foresees the "Review for possible updates the *Recommendation L on International Model for Transnational Regulatory Cooperation Based on Good Regulatory Practice* notably to provide guidance on services and processes harmonization" (ECE/CTCS/2023/14, paragraph 10a).

Proposed decision

"Member States adopted the *Revision of Recommendation L: International Model for Product/Service Conformity Based on Transnational Regulatory Cooperation* (ECE/CTCS/WP.6/2023/13)."

* This document is submitted under the responsibility of the WP.6 Chair. This document has not been edited by a professional editor.

I. Introduction

1. The Working Party on Regulatory Cooperation and Standardization Policies (WP.6), noting that:

- There is a clear market need from trade and industry and a positive interest from Governments in further reducing trade barriers and facilitating market access.
- The international model for a common regulatory arrangement (CRA) (see annex) developed by the United Nations Economic Commission for Europe (UNECE) provides a voluntary framework for regulatory cooperation that facilitates market access through the use of good regulatory practice and options for the establishment of sectoral agreements between interested United Nations Member States.
- The international model provides good regulatory practices that facilitate global harmonization of national or regional regulations.
- The international model is a flexible mechanism for market access of products and services following relevant international standards and related practices.

II. Recommended practice

2. Recommends that:

L.1 Regulators use the process outlined in the annex to develop voluntary cooperation based on good regulatory practice in regulatory fields and accompanying trade and industry sectors.

L.2 Countries foresee a mechanism to communicate their adoption of the international model.

Annex

Principal elements for regulatory harmonization based on good regulatory practice in regulatory fields and accompanying trade and industry sectors

1. The principal issues to be addressed by interested regulators in a common regulatory arrangement (CRA) document, would include:

- Legitimate regulatory objectives for the public interest, such as public health, safety or environmental protection.
- Applicable international standards that contain requirements for products and services.
- Ways of assuring and demonstrating compliance with the regulatory objectives.
- Provisions on third-party assessment bodies, when recourse to third-party assessment is needed.
- Provisions for post-market surveillance.

2. The CRA would specify the following principal elements.

A. Scope statement

3. A scope statement is a statement of the products and/or services areas that are covered by the CRA.

4. Regulators should agree on the products and/or services for which legitimate regulatory objectives are required. For this purpose, regulators may use international classification schemes such as the harmonized commodity description and coding system to identify products and/or services.

B. Requirements on products and/or services

5. Legitimate regulatory objectives reflect the requirements to protect public interest in areas such as human health or safety, animal or plant life or health or the environment. The requirements needed for protection of legitimate objectives should lay down the principal issues of concern and be specified in terms of performance requirements rather than design or descriptive characteristics. Requirements should be limited to relevant aspects and be proportionate to the hazard inherent in a given product and/or services area.

6. The detailed provisions on how to meet the requirements of the regulatory objectives should preferably be specified in applicable international standards. Applicable international standards which can assist in meeting these regulatory objectives partially or in whole should be listed.

C. Compliance clause

7. The CRA should contain a provision on how compliance is demonstrated. The CRA may contain a provision that products and/or services complying with the referenced international standards are presumed to comply with the requirements.

8. Regulators should agree on the range and contents of possible conformity assessment procedures that are considered to give the necessary level of protection under the CRA. The CRA should also specify the conditions under which suppliers can make a choice if more than one option is provided for. Such options are, for instance, self-declaration of conformity, third party certification or inspection or service agreement. When applicable, such as for

high-risk products and/or services, this could be registered within a national (or regional) registry/ies and could be accessed by other Government agencies which accept the CRA.

9. In considering such options regulators should aim to avoid duplicative conformity assessment testing and certification for products (and replacement parts that are included in the product certification) or for services that add unnecessary costs and time delays.

10. When applicable, the CRA should also contain provisions on the conformity assessment bodies that are recognized to assess and attest compliance as well as the competence criteria to be fulfilled by such bodies.

D. Market surveillance clause

11. Regulators having agreed on a CRA are responsible for market surveillance on their territory and in line with national or regional regulations, have the right to withdraw products and/or services from their markets if these are not in compliance with the CRA.

12. The CRA should contain a provision (protection clause) for cases when products and/or services claim conformity with the CRA but do not conform to its requirements. Under such circumstances, the regulator may, with the intention to preserve legitimate objectives, withdraw such a product and/or service from its market. Furthermore, the CRA should contain a provision that the regulator using the protection clause should state specifically what products and/or services have been removed from the market and what requirements of the CRA have been claimed to be met but have not been met.

13. In a case where products and/or services are in conformity with the CRA or the applicable international standard but are still found to endanger legitimate objectives, the regulator having agreed on a CRA could withdraw such products and/or services from the market or restrict free circulation. In this case, the use of the protection clause should also be subject to the condition that the regulator using it should indicate the reasons for this decision.

14. Any penalties or sanctions to non-compliance are not expected to be integrated into a CRA, but rather covered under national or regional regulations.