Recommendations on Regulatory Cooperation and Standardization Policies

Revised Edition

L International Model for Transnational Regulatory Cooperation Based on Good Regulatory Practice[1]

The Working Party, 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 and

- the "International Model" developed by the United Nations Economic Commission for Europe provides a voluntary framework for regulatory cooperation that facilitates market access through the use of good regulatory practice and options for establishment of sectoral arrangements between interested UN member countries
- the "International Model" provides good regulatory practices that facilitates global harmonization of national or regional regulation
- the experience gained so far with the "International Model" and developments in international and regional fora shows the importance of a flexible voluntary mechanism for market access of products following relevant international standards and related practices.

Recommends:

L.1 that regulators use the process outlined in Annex A to develop cooperation based on good regulatory practice in regulatory fields and accompanying trade and industry sectors

L.2 that countries wishing to go further and establish special operational transnational sectoral arrangements use the process outlined in Annex B.

[1] Recommendation adopted in 2001 and reviewed in 2015.

Annex A

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

The principal issues to be addressed by interested regulators in a Common Regulatory Arrangement (CRA) document, would include:

- Legitimate regulatory objectives that usually relate to public health, safety or environmental protection, etc.;
- Applicable international standards that contain requirements for systems, processes, 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.

The CRA would specify the following principal elements:

1. Scope statement

A statement of the products or product areas that are covered by the CRA.

Regulators should agree on the products 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.

2. Product requirements

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 or product area.

The detailed provisions on how to meet the requirements of the regulatory objectives should preferably be specified in applicable international standards. Such standards will be referenced in the CRA.

3. Reference to standards clause

The CRA should contain a list of applicable international standards that correspond as a whole or partially to the requirements.

The CRA may contain a provision that products complying with the referenced international standards are presumed to comply with the requirements.

4. Compliance clause

The CRA should contain a provision on how compliance is demonstrated.

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, supplier's declaration of conformity, third party certification or inspection.

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) that add unnecessary costs and time delays.

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.

5. Market surveillance clause

Regulators having agreed on CRA are responsible for market surveillance on their territory and have the right to withdraw products from their markets if these are not in compliance with the CRA.

The CRA should contain a provision (protection clause) that if products claiming conformity with the CRA that do not conform to its requirements, the regulator may, with the intention to preserve legitimate objectives, withdraw such a product from its market. Furthermore, the CRA should contain a provision that the regulator using the Protection Clause should state specifically what products have been removed from the market and what requirements of the CRA have been claimed to be met but have not been met.

In a case where products 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 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.

Annex B

Administrative Procedures and Institutional Provisions

Article 1

General Institutional Framework

1.1 The process of registering Common Regulatory Arrangements (CRAs) and interpreting the provisions of the "International Model" shall be the task of the UNECE Working Party on Regulatory Cooperation n and Standardization Policies (Working Party 6 - WP.6) which shall ensure coordination of the work on requests for technical harmonization received by the UNECE secretariat. If deemed appropriate, Working Party 6 could set up groups of experts to monitor and implement such work in practice.

Article 2

Call for Participation

2.1 Country/Countries shall make a "Call for Participation" through the UNECE secretariat to all United Nations Member States. The Call should contain the necessary information for formulating a CRA. Countries wishing to join the work under such a Call should respond to the secretariat, stating their interest to participate in the work.

2.2 Based on responses to the Call, an open-ended task force composed of interested countries shall be set up with the purpose to jointly develop a CRA regarding the safety, health, environmental protection and other legitimate concerns of governments regarding the products or group of products in question.

2.3 These open-ended task forces should work in a transparent way and participation in them shall be open at any moment to any other United Nations Member State that expresses the wish to join the work. The task forces will agree on their own working procedures. The task forces should inform the UNECE secretariat about their work which will be made publicly available by appropriate means (for example, via the internet).

Article 3

UNECE Registry of Common Regulatory Arrangements

3.1 A registry shall be created and maintained by the UNECE secretariat for CRAs developed under the "International Model". The registry shall be known as the "UNECE Registry for CRAs".

3.2 The countries that agreed on a CRA shall submit it to Working Party 6 through the UNECE secretariat.

3.3 The agreed CRA specified in the paragraph above shall contain the principal elements as set out in annex B to the "International Model". The CRA shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

3.4 If formal elements in the agreed CRA (as specified in the Model) are met, the CRA shall be considered to be established in the UNECE Registry on the date of its submission to the UNECE secretariat.

3.5 The secretariat shall, when registering the a CRA, append copies of all relevant documentation to that CRA. All documentation received by the UNECE secretariat under the provisions of this Article shall be made publicly available by appropriate means (for example, via the Internet).

3.4 The process of the further revision of the already agreed CRA should follow procedures as specified under Article 2 above.

Article 4

National adoption and notification of

application of Registered Common Regulatory Arrangements

4.1 A country that has agreed on a CRA shall submit the CRA to the process used by it to adopt technical requirements specified in the CRA into its own legislation. Any other country at any time may inform the UNECE secretariat about its intention to implement and use the CRA (and, thus, it will follow the procedures as specified under this Article).

4.2 A country that adopts a CRA into its own legislation shall notify the UNECE secretariat in writing of the date on which it will begin to apply that CRA. The notification shall be provided by the country within 60 days after adoption of the CRA.

4.3 A country that is specified in paragraph 1 of this Article and that has not, by the end of the one-year period after the date of the registration of the CRA in the UNECE Registry, adopted the CRA into its legislation, shall report on the status of the CRA in its domestic process. A status report shall be submitted for each subsequent one-year period if no such action has been taken by the end of that period.

4.4. A country that is specified in paragraph 1 of this Article and that accepts products that comply with the technical requirements of a registered CRA without adopting the CRA into its own legislation shall notify the UNECE secretariat in writing of the date on which it began to or will begin to accept such products.

List of abbreviations used in the "International Model"

CAB	Conformity Assessment Body
CRA	Common Regulatory Arrangement
ISB	International Standardizing Body
PC	Protection Clause
RCAB	Recognized Conformity Assessment Body
SDoC	Supplier's Declaration of Conformity
TR	Technical Regulation
UNECE	United Nations Economic Commission for Europe