

L. INTERNATIONAL MODEL FOR TECHNICAL HARMONIZATION BASED ON GOOD REGULATORY PRACTICE FOR THE PREPARATION, ADOPTION AND APPLICATION OF TECHNICAL REGULATIONS VIA THE USE OF INTERNATIONAL STANDARDS

Note from the secretariat

1. This paper contains a recommendation based on the proposal for an "International Model", as submitted to the UNECE Working Party on Technical Harmonization and Standardization Policies at its eleventh session in October 2001 (documents TRADE/WP.6/2001/8, TRADE/WP.6/2001/8/Corr.1 and TRADE/WP.6/2001/8/Add.1). The proposal for an "International Model" was prepared by the ad hoc Team of Specialists on STandardization And Regulatory Techniques ("START" Team).

2. At this session the Working Party decided:

- that there is a clear market need and interest from Governments in further reducing trade barriers and facilitating market access;
- that the elaborated "International Model" provides a voluntary framework which could contribute to facilitating market access through the establishment of sectoral agreements between interested member countries;
- to request secretariat to include the text of the "International Model" in the set of UNECE Recommendations on Standardization Policies
- to call on the "START" Team to:
 - as a follow-up to request from the UNECE Committee for Trade, Industry and Enterprise Development (see ECE/TRADE/280, paragraph 64), to explore with UNECE Subsidiary Bodies the possibilities of using the principles and concept of the "International Model" in their areas of competence so as to identify potential pilot projects;
 - to assist with sectoral initiatives based on the "International Model" as forthcoming from interested parties and as requested.

Background

3. Regulators can deploy a number of means to prevent technical regulations from constituting unnecessary barriers to trade. The WTO Agreement on Technical Barriers to Trade (TBT) explicitly refers to using international standards as a basis for technical regulations (cf. Art. 2.4 and cf. Art. 2.6), and to accepting as equivalent the technical regulations of other Members (cf. Art. 2.7). It also encourages the use of relevant international guides or recommendations as a basis for conformity assessment procedures (cf. Art. 5.4), and the conclusion of agreements for the mutual recognition of the results from each other's conformity assessment procedures (cf. Art. 6.3).

4. At the First Triennial Review, the WTO/TBT Committee reiterated that good regulatory practice for the preparation, adoption and application of technical regulations was a priority for Members to facilitate trade, and it was agreed at the Second Triennial Review to continue an information exchange in this regard while noting that minimizing the use of mandatory technical regulations and using voluntary international standards, where appropriate, could reduce the regulatory burden and open up market access opportunities. WTO members also agreed on this occasion that regular information

exchange between the Committee and other relevant bodies would be useful.

5. The UNECE Working Party on Technical Harmonization and Standardization Policies (WP.6) has provided for more than 30 years an interface between the regulatory and the standardization community, for instance, by keeping a standardization list by which regulators can flag areas where they would deem it useful for voluntary standards to be developed, possibly for subsequent use in relation with technical regulations. The United Nations Economic Commission for Europe, under which Working Party 6 operates, also has a longstanding record of offering member countries a platform for the harmonization of national technical regulations such as is done in the area of motor vehicles (UNECE Working Party 29-World Forum for Harmonization of Vehicle Regulations).

6. However, international technical harmonization could be even further advanced by reducing the regulatory burden and using international standards where appropriate. For this purpose, in 1999, Working Party 6 established an ad hoc team of specialists on Standardization and Regulatory Techniques (the "START" Team).

7. The "International Model" recognizes that a framework for ensuring that technical regulations and standards do not create barriers to trade exists in the WTO Agreement on TBT. The Model adds to this framework by suggesting solutions for the practical implementation of technical harmonization and draws from existing schemes for good regulatory practice to be used in the process of international technical harmonization.

8. The "International Model" provides a set of voluntary principles and procedures for sectoral application. Countries that would like to harmonize their technical regulations may wish to implement the principles and procedures as suggested by the "International Model". To this end the details of procedures for such application will have to be drawn up by the interested countries.

Introduction

9. Discussions within different international organizations and fora show a clear desire for the convergence of technical regulations with a view to limiting obstacles to international trade and to facilitating market access. Some international technical regulations exist, but they tend to be cumbersome and burdened with details. They have also proven to be difficult to prepare. As a consequence such regulations, once in place, can be difficult to amend. Detailed agreements between a large number of regulatory authorities are frequently difficult to obtain, and such regulations tend not to achieve full consensus.

10. A regulatory framework comprising broad common regulatory objectives might be easier to compile and might more easily find consensus. For the detailed requirements that implement common regulatory objectives recourse could be made to established mechanisms of International Standardizing Bodies, which provide a forum for all interested parties (including regulatory authorities), and have established a degree of trust at the international level.

11. These problems have been recognized by the UNECE Working Party on Technical Harmonization and Standardization Policies (WP.6), which at its ninth session in May 1999 commissioned a team of specialists to investigate the question. This team was established under the acronym "START"

(Standardization And Regulatory Techniques), and the UNECE Committee for Trade, Industry and Enterprise Development has confirmed its formation. The work of the Team is intended to provide guidance for good regulatory practice and a mechanism for co-operation between regulatory authorities, standardizers and industry, so that legislation can make appropriate use of standards.

12. There are major efforts regarding the elimination of technical barriers to trade, particularly under the WTO/TBT Agreement, and it is appropriate to develop further the practical dimensions of procedures that are complementary to and coherent with the TBT Agreement. This could be done by way of a general mechanism for linking harmonized technical regulations and international standards. Information used in the development of the following proposed, provisional “International Model” was also derived from useful work undertaken in other international fora. These include the WTO’s work on trade policy review, the OECD’s work on regulatory reform and international standards, and Asia-Pacific Economic Cooperation's (APEC) and the Asia-Europe Meeting's (ASEM) work on creating guidelines on good regulatory practice.

13. It is, for example, assumed that whenever a new or revised technical regulation (TR; for abbreviations used, see [Annex A](#)) is being prepared, regulators should follow the principles found in the WTO/TBT Agreement. In particular, it is assumed that TRs should be based on relevant international standards, when they exist or their completion is imminent, except when such standards would be ineffective or inappropriate for the technical regulation in question; that TRs should not be more trade-restrictive than necessary and that they should be non-discriminatory.

14. Where harmonization is deemed useful by interested countries, the “International Model” provides practical steps aimed at facilitating and accelerating the harmonization of technical regulations by agreeing on Common Regulatory Objectives (CROs) for applicable products or product areas (sectors).

Proposal for a Model for the Harmonization of Technical Regulations and Free Circulation of Compliant Products

Basic elements for harmonization and free circulation

15. The “International Model” addresses the steps to be followed when harmonization of technical regulations is favoured by a number of UN member countries. The nature of such harmonization should preferably be limited to agreeing on Common Regulatory Objectives (CROs). Such objectives will address legitimate concerns of governments, for instance, those related to public health, safety or the protection of the environment. The principal elements to be included in a CRO are set out in [Annex B](#). The CRO shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. The CROs would be transposed into technical regulations at national level by those countries who agreed on them. The mechanism for national transposition of CROs is to be defined by individual UN member countries according to their national legal practice. For demonstration of compliance with CROs a possible means could be recourse to relevant international standards.

16. A distinction should be made between the specifications applicable to products, as such, and the conformity assessment requirements to be used to ensure that the products placed on the market conform to the characteristics required. The CROs shall cover these issues.

17. If the system of CROs is to be effective in facilitating trade, there would need to be mechanisms to ensure that products falling within the scope of the CRO, that complied with its terms, and were properly attested as doing so, could be placed on the market in the countries that have agreed on the CRO.

18. Countries that have agreed on a CRO would assure that products, which comply with the CRO, could be placed on their market for free circulation without being subject to any additional product or conformity assessment requirements (e.g. testing or certification). If a country imposes additional requirements, despite having agreed on a CRO, it shall inform the other countries (through the United Nations Economic Commission for Europe (UNECE)) of these measures. The other countries would, under such circumstances, be free to take appropriate measures and ultimately restrict the free circulation on their markets of relevant products from the country that has approved additional requirements.

Identification of the need for harmonization

19. The responsibility for technical regulations and their harmonization lies with national regulatory authorities. The need for harmonization might be identified by one, amongst others, of the following "trigger" mechanisms:

- Studies by specialists from a particular sector/industry that are specially commissioned by governments, international organizations, business groups, or non-governmental organizations (NGOs) and raised in national, regional or international fora;
- Through initiatives by one or more particular countries to harmonize their TRs at an international level;
- Through "complaint-based" initiatives when a country is responding to complaints from foreign or national business operators concerning its TR regime;

20. When it concerns new or revised TRs, the existing notification procedures under the WTO/TBT Agreement require that proposed technical regulations/conformity assessment procedures to be systematically notified. This might also be regarded as a "trigger" mechanism for examining the need for a TR. If this need is recognized by other countries, they might be willing to state their interest in having the proposed TR internationally harmonized.

Process of establishing a CRO

21. A UN member country interested in using the mechanism of this "International Model" for harmonizing technical regulations through establishing CROs could address the United Nations (UNECE) to launch a Call for Participation by other member countries of the United Nations (procedures to be elaborated in Annex C). The purpose of such a Call would be to explore the interest for international harmonization via agreed upon CROs for the products or product areas in question. If such a Call were positively responded to by other member countries of the United Nations, the countries concerned would co-operate in formulating CROs.

22. The procedure proposed for the preparation or revision of CROs and legal formats for their approval is set out in Annex C. Based on the proposal for CROs, interested countries, (effectively, any country

that had responded positively to a Call for Participation) shall co-operate in formulating CROs. During the preparation of CROs by the group of interested countries any other UN member country could join this group or participate in the work as an observer.

23. Upon completion of the text of the CROs, the UN member countries having agreed on them would, with a view to having an open and transparent process, announce to the United Nations (UNECE) their intention to nationally implement them in national technical regulations. Other member countries of the United Nations would be invited, on a voluntary basis, to implement them either immediately or in due time. The UN would register the CROs and their implementation in national technical regulations. Such information would be made publicly accessible.

24. In parallel to the preparation of CROs, countries should explore the existence of relevant international standards to be considered for reference in formulating CROs. In case no relevant standards exist, countries may consult with relevant international standardizing bodies (ISBs), through their official representatives, regarding the initiation of new standards work to support specific CRO provisions. It is assumed that countries collaborating on a CRO would support related standards development activities, within the limits of their available resources. It is also expected that they would refrain from activities that would conflict with or jeopardize this standardization work in preparation.

25. When the relevant international standards are available from international standardizing bodies they should be referred to in the CRO and the conditions for their use should be specified in the CRO.

Determining and assuring conformity with a CRO

26. The Common Regulatory Objectives should contain requirements related to how conformity with its terms is to be assured and demonstrated. Whenever appropriate, the means of assuming compliance should be a Supplier's Declaration of Conformity (SDoC). However, in other cases, particularly when safety and health concerns are important, the UN member countries agreeing on a CRO may find it necessary to make recourse to more stringent conformity assurance procedures. In either case - where the SDoC is considered sufficient, or where a more stringent procedure is required, the procedures should be specified in the CRO. If third party assessment is deemed necessary, the CRO should state that compliance be assessed and attested by Recognised Conformity Assessment Bodies (RCABs).

27. Recognized Conformity Assessment Bodies (RCABs)

28. The requirements with regard to the technical competence of the Conformity Assessment Bodies (CABs) in the field defined by the CRO should be set out as an integral part of the CRO. The countries, which have agreed on the CRO, could designate CABs as recognized to perform assessment and attestation under the CRO. A list of such recognized bodies (RCABs) should be made publically available, for instance, by annexing it to the CRO and such bodies should be registered by the United Nations (UNECE).

Claim of conformity with a CRO by the supplier

29. Products covered by the scope of a CRO would carry some means (e.g. a SDoC or a certificate of conformity) demonstrating either that the supplier claims conformity with the CRO or that conformity

has been assessed and attested to by a RCAB. In either case, documented evidence should be provided with the product. The type of such evidence should be specified in the CRO. All claims of compliance must include the reference to applicable CRO, for example, the registration number allocated by the United Nations (UNECE) for the applicable CRO.

Market surveillance and protection clause

30. Countries having agreed on CROs are responsible for market surveillance on their territory and have the right to withdraw products from their national markets if the products are not in compliance with the CRO.

31. In case a product is in conformance with a CRO, but is found to endanger health and safety or other legitimate objectives, a country can take necessary steps to withdraw such a product from the market or restrict its free circulation by evoking the protection clause of a CRO (for details see Annex B).

32. Countries should report such actions both relating to domestic and foreign products to the United Nations (UNECE) and indicate the reasons for this decision.

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ANNEX A

List of abbreviations used in the “International Model”

ANNEX B

Principal elements to be included in a CRO

ANNEX C

Administrative Procedures and Institutional Provisions

ANNEX A

List of abbreviations used in the “International Model”

CAB	Conformity Assessment Body
CRO	Common Regulatory Objective
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

ANNEX B

Principal elements to be included in a CRO

A CRO is a mutually agreed document registered by the United Nations (UNECE) and publicly available. By establishing such a document the interested countries agree on elements such as:

Scope statement

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

Countries should agree on the products for which legitimate regulatory objectives are required. For this purpose countries may use international classification schemes such as the harmonized commodity description and coding system.

Product requirements

Legitimate regulatory objectives reflect the requirements of governments 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 principle 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 to a given product or product areas.

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

Reference to standards clause

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

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

Compliance clause

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

Countries should agree on the range and contents of possible conformity assessment procedures which are considered to give the necessary level of protection under the CRO. The CRO 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.

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

Market surveillance and Protection clause

Countries having agreed on CROs are responsible for market surveillance on their territory and have the right to withdraw products from their national markets if not in compliance with the CRO.

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

In a case where products are in conformance with the CRO or the applicable international standards but are still found to endanger legitimate objectives, a country having agreed on a CRO 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 country using it should declare its use to the United Nations (UNECE) and indicate the reasons for this decision

ANNEX C

Administrative Procedures and Institutional Provisions (including the Call for participation in formulating “Common Regulatory Objectives” and the preparation of these Objectives)

Article 1

General Institutional framework

1.1 The process of registering Common Regulatory Objectives (CROs) and interpreting the provisions of the “International Model” shall be the task of the UNECE Working Party on Technical Harmonization 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 (at least three wishing to harmonize their technical regulations according to the “International Model” and to invite other countries to join such a process) shall make a “Call for Participation” through the UNECE secretariat to all UN member states. The “Call” should contain the necessary information for formulating a CRO (cf. [Annex B](#)). Countries wishing to join the work under such a “Call” should respond to the secretariat within three months (from the date of the transmission of the “Call” by UNECE secretariat) stating their interest to participate in the work. The countries which expressed an interest to join the work can start the technical harmonization process three months after the date of transmission of the “Call”.

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 common regulatory objectives (CROs) 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 UN 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 Objectives (CROs)

- 3.1 A registry shall be created and maintained by the UN ECE secretariat for the CROs developed under the “International Model”. The registry shall be known as the “UNECE Registry for CROs”.
- 3.2 The countries that agreed on a CRO shall submit it to Working Party 6 through the UN ECE secretariat.
- 3.3 The agreed CRO specified in the paragraph above shall contain the principal elements as specified in Annex B to the “International Model”. The CRO 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 CRO (as specified in the Model) are met the CRO 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 CRO, append copies of all relevant documentation to that CRO. 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).
- 3.6 The process of the further revision of the already agreed CROs should follow procedures as specified for a “Call for participation” under Article 2.

Article 4

National adoption and notification of application of Registered Common Regulatory Objectives (CROs)

- 4.1 A Country that has agreed on a CRO shall submit the CRO to the process used by it to adopt technical requirements specified in the CRO into its own legislation. Any other country at any moment may inform the UNECE secretariat about its intention to implement and use the CRO (and, thus, it will follow the procedures as specified under this Article).
- 4.2 A Country that adopts a CRO into its own legislation shall notify the UNECE secretariat in writing of the date on which it will begin to apply that CRO. The notification shall be provided by the country within 60 days after its adoption of the CRO.
- 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 CRO in the UNECE Registry, adopted the CRO into its legislation, shall report on the status of the CRO 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 CRO without adopting the CRO 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.

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