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DRAFT PROPOSAL^{*/} FOR

**“AN INTERNATIONAL MODEL FOR TECHNICAL HARMONISATION BASED ON
GOOD REGULATORY PRACTICE FOR THE PREPARATION, ADOPTION AND
APPLICATION OF TECHNICAL REGULATIONS VIA THE USE OF INTERNATIONAL
STANDARDS”**

This draft paper contains a proposal for an "International Model", which was edited by the ad hoc Team of Specialists on Standardization And Regulatory Techniques ("START" Team) at its meeting in May 2001.

It is recalled that the first draft of the "International Model" as it was presented to the tenth session of the Working Party in November 2000 can be found in UNECE document TRADE/WP.6/2000/8.

The present document is reproduced in the form and language in which it was received by the secretariat.

^{*/} This paper is being submitted without formal editing.

DRAFT PROPOSAL FOR

“AN INTERNATIONAL MODEL FOR TECHNICAL HARMONISATION BASED ON GOOD REGULATORY PRACTICE FOR THE PREPARATION, ADOPTION AND APPLICATION OF TECHNICAL REGULATIONS VIA THE USE OF INTERNATIONAL STANDARDS”

FOREWORD

- The proposal reproduced below has been suggested and prepared by the UNECE *ad hoc* team of specialists on Standardization And Regulatory Techniques (“START”).
- The START Team was established in September 1999. It works under the auspices of the UNECE Working Party on Technical Harmonization and Standardization Policies (WP.6) which, at its ninth session in May 1999, decided to establish this team to examine the relationship between international standardization and technical regulations. The formation of the team has been confirmed by the UNECE Committee for Trade, Industry and Enterprise Development.
- 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.
- The proposal constitutes a model with 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 “Model”. The detailed procedures for any such implementation will have to be elaborated by the interested countries.
- This proposal was edited by the “START” Team in May 2001. It takes into account the comments expressed during presentations of the “Model” that were made to the WTO Committee on Technical Barriers to Trade (25 February and 19 May 2000 and 29 June 2001, Geneva), the ASEM meeting (1 March 2000, Bangkok), the OECD special meeting on technical barriers to trade (16-17 March 2000, Paris) and the CIS meeting of standardization agencies (23-25 May 2001, Dushanbe, Tajikistan). The UNECE has also convened an informal expert meeting (7 June 2000, Geneva) to explore the benefits of the “Model” when applied in different sectors/product areas.
- The first draft of the “International Model” was presented to the WP.6 session in November 2000 which supported activities of the “START” Team, the draft model and asked for new nominations to the Team.
- The annex for administrative and institutional provisions (annex C) is currently under preparation.
- This proposal has not undergone formal editing.

INTRODUCTION

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. Where harmonization is deemed useful by interested countries, the draft “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

7. 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 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.

8. 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.

9. 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.

10. 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

11. 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;

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

12. 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.

13. 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.

14. 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.

15. 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.

16. 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

17. The CRO 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).

Recognized Conformity Assessment Bodies (RCABs)

18. 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

19. 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

20. 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.

21. 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).

22. 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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LIST OF ANNEXES

ANNEX A

List of abbreviations used in the International Model

ANNEX B

Principal elements to be included in a CRO

ANNEX C

(under preparation)

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
