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DRAFT PROJECT*

**FOR "AN INTERNATIONAL MODEL FOR IMPLEMENTING GOOD REGULATORY
PRACTICE FOR THE PREPARATION, ADOPTION AND APPLICATION OF
TECHNICAL REGULATIONS VIA THE USE OF INTERNATIONAL STANDARDS"**

This draft paper contains the description of the project prepared by the ad hoc Team of Specialists on Standardization And Regulatory Techniques ("START" Team)

It is recalled that this Team was established at the decision of the Working Party at its session in May 1999 with the view to examine how technical regulations can make wider use of international standardization (for details see report of the ninth session, TRADE/WP.6/1999/18 of 13 July 1999)

This is a working document, presented for discussion and comments to delegates on issues to be discussed under agenda items 4 and 7(b)

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* This paper is being submitted without formal editing.

DRAFT

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

FOREWORD

1. The Project reproduced below has been suggested and prepared by the UN/ECE *ad hoc* team of specialists on Standardization And Regulatory Techniques (“START”).
2. The START Team was established in September 1999. It works under the auspices of the UN/ECE 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 UN/ECE Committee for Trade, Industry and Enterprise Development.
3. The proposed “International Model” draws from existing schemes for good regulatory practice to be used in the process of international technical harmonization.
4. When completed, the “International Model” will be a conceptual document 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”. To this end the details of these procedures will have to be elaborated at a later stage.
5. This revised draft was prepared by the START Team in June 2000. It takes into account the comments expressed during presentations of the “Model” that were made to the session of the WTO Committee on Technical Barriers to Trade (25 February and 19 May 2000, Geneva), ASEM meeting (1 March 2000, Bangkok) and the OECD special meeting on technical barriers to trade (16-17 March 2000, Paris). The UN/ECE convened also an informal expert meeting (7 June 2000, Geneva) to explore the benefits of the “Model” when applied in different sectors/product areas.
6. The START Team will continue to work on the current draft which foresees, for example, preparation of a number of annexes covering administrative and technical procedures for implementation of the “International Model” and other issues.
7. This draft paper has not undergone formal editing.

INTRODUCTION

1. Discussions within different international organizations and fora show a clear desire to harmonize 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 that comprises 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 had 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 UN/ECE 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 UN/ECE 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 activities in the area of technical harmonisation, particularly under the WTO/TBT Agreement, and it is appropriate to develop further practical dimensions of procedures complementary and coherent to the TBT Agreement. This could be done by way of a general mechanism for the co-existence of harmonized technical regulations and international standards. Information for the development of the following proposed provisional "International Model" is also derived from useful work in other international fora. These include the WTO's work in trade policy review, the OECD's work in regulatory reform and international standards, and the Asia-Pacific Economic Cooperation's (APEC) and the Asia-Europe Meetings's (ASEM) work in 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 set up in the WTO/TBT Agreement. In particular, 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 should be non-discriminatory.

6. The draft "International Model" provides practical steps aimed at facilitating and accelerating the harmonization of technical regulations.

PROPOSAL FOR A MECHANISM AND PROCESS 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 countries. The nature of such harmonization might be limited to the definition of "Common Regulatory Objectives" (CROs). Such objectives will address legitimate concerns of governments relating to public health, safety or the protection of the environment (elements to be included in a CRO to be set out in Annex B). The CROs would be transposed into technical regulations at national level by those countries who agreed on them. For demonstration of compliance with CROs a possible means could be recourse to international standards. It is proposed that the CROs could either be linked to existing international standards or that a call could be made for the development of new ones.

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 “International Model” covers both these issues.

9. If the system of CROs is to be effective in opening 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. Thus, each CRO would need to contain provisions that compliance would have to be determined, assured and demonstrated (through Supplier’s Declaration of Conformity, certification by recognised Conformity Assessment Bodies etc.).

10. Countries that have agreed on a CRO would assure that products, which comply with the CRO and the associated IRSs, 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 (UN/ECE Commission) of these measures. The other countries would under such circumstances be free to take appropriate measures and ultimately restrict the free circulation of relevant products from this country on their markets.

Identification of the need for harmonization

11. The need for harmonization of TRs might be identified by one of the following “trigger” mechanisms:

- (a) By specialists from a particular sector/industry and raised in national, regional or international fora;
- (b) In studies specially commissioned by governments, international organizations, business groups, non-governmental organizations (NGOs);
- (c) Through initiatives by one or more particular countries to harmonize their TRs at an international level;
- (d) Through “complaint-based” initiatives when a country is responding to complaints from foreign or national business operators concerning its TR regime;
- (e) When it concerns new or revised TRs, the existing notification procedures under the WTO/TBT Agreement requires proposed technical regulations/conformity assessment procedures to be systematically notified. This might be regarded as a “trigger” mechanism to examine the need for a TR. If this need is recognized by other countries they might be willing to state their interest in having that TR internationally harmonized.

12. A country interested in initiating the mechanism for harmonizing technical regulations could address the United Nations Economic Commission for Europe (UN/ECE) to launch a “Call for Participation” by other member countries of the United Nations. The purpose of such a Call would be to explore the interest for international harmonization in a particular sector or group of products. 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.

Process of harmonizing technical regulations

13. The administrative procedure proposed for the preparation or revision of CROs is to be 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 country could join this group or participate as an observer at this work.

14. Upon completion of the text of the CROs, the countries having agreed on them would, with a view to having an open and transparent process, announce to the United Nations (UN/ECE Commission) their intention to nationally implement them in national technical regulations. Other member countries of the United Nations would be invited to implement them either immediately or in due time. The UN would register the CROs and their implementation in national technical regulations.

The International Standardization Request

15. Once the CROs are completed, the countries having agreed on them would request the United Nations (UN/ECE Commission) to issue an "International Standardization Request", ISR (according to the format to be set out in Annex D) which would request the named international standardization bodies (ISBs) to provide standards that meet the technical requirements of the CROs. Upon proposal from the international standardization bodies the countries having agreed on the CROs would recognise the standards provided as a means of demonstration of compliance with the CROs. If they do, such standards should be given the name "Internationally Recognized Standards" (IRs) within the "International Model".

16. It would appear that some kind of international group or panel of technical experts ("Technical Advisory Panel", TAP) may be required in order to assist interested countries in the preparation of the CROs and the ISRs. Such technical advice would be offered to achieve the necessary coherence between the CROs, and between different ISRs to be made to different ISBs. In addition, the TAP should help identify the relevant ISBs to be approached with the ISRs, and upon request provide advice to the UN member countries on other associated technical matters. The preparation and adoption of standards in response to ISRs would remain the sole responsibility of the ISBs.

Co-operation in the standardization process

17. It is assumed that countries having agreed on the CROs would support the technical work in the ISBs for the execution of the ISR (for example, in the form of hosting a technical committee). Moreover, they are expected to take a constructive approach and contribute resources for the execution of the standardization work. It is also expected that they would refrain from activities that would conflict with or jeopardise the standardization work in preparation.

Use of the Internationally Recognised Standards

18. When the standard has been completed in response to the ISR it should be registered within the United Nations (UN/ECE Commission) as an IRS. Countries having agreed on the CROs would commit themselves to use the IRs when they have transposed the CROs into their national technical regulations. Thereby products complying with IRs would be given a presumption of conformity with related national technical regulations.

Determining and assuring conformity with a CRO

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

Recognised Conformity Assessment Bodies (RCABs)

20. The technical competence of the Conformity Assessment Bodies (CABs) in the field defined by the scope of the CRO could be attested through accreditation (by an accreditation body recognized as such by the government of a member country of the United Nations) or by equivalent means. The countries, which have agreed on a CRO, could designate CABs as “recognized” to perform assessment and attestation under the national technical regulations which transpose the CROs. In addition, countries that have agreed on the CROs should notify RCABs to the United Nations (UN/ECE Commission). A list of such bodies would be annexed to the CROs kept in the register of the United Nations (UN/ECE Commission).

Claim of conformity with a CRO by the supplier

21. Products within the scope of a CRO would carry some means (e.g. a SDoC or a certificate of conformity) demonstrating either that the supplier claims the conformity with the CRO or that conformity has been assessed and attested by a RCAB. In either case documented evidence should be provided with the product. The nature of such evidence should be specified in the CRO. All claims of compliance must include the registration number allocated by the United Nations (UN/ECE Commission) for the applicable CRO.

Market surveillance and protection clause

22. Countries having agreed on CROs remain responsible for market surveillance on their territory. If a country finds products claiming conformity with a CRO that do not actually conform with its requirements, they may, with the intention to preserve public health and safety or other legitimate objectives, take action to withdraw such a product from their market. However, use of such a “Protection Clause” (PC) should be subject to a condition that the country using it should state, to the United Nations (UN/ECE Commission), 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.

23. If the supplier is from the same country as the country making use of the PC, notification to the United Nations (UN/ECE Commission) is still requested, so that other countries could take similar actions. If the supplier is from a country different from the one declaring the PC, the countries concerned should try to solve the issue between them. Other countries may associate themselves with such a process. In any case such action should be declared to the United Nations (UN/ECE Commission).

Resolving disputes

24. Use of the PC between countries having agreed on CROs may trigger a process in WTO when regarded as “a technical regulation which may have a significant effect on trade of other (WTO) Members” (Article 2.5 of the WTO/TBT Agreement). If the matter is dealt with by the WTO the United Nations (UN/ECE Commission) would take no further action.

25. If on the other hand no action has been triggered in the WTO as a result that this matter has not been considered to fall under the provisions of Article 2.5 of the WTO/TBT Agreement or for other reasons (e.g., that the country declaring the use of the protection provisions is not a WTO Member), then the United Nations (UN/ECE Commission) should convene a “Dispute Resolution Panel” (DRP). The countries having agreed on the CRO should agree to abide by the decision of such panel (if appropriate an appeal mechanism should be foreseen).

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LIST OF ANNEXES

ANNEX A

List of abbreviations used in the International Model

ANNEX B

Elements to be included in a Common Regulatory Objective (CRO)

ANNEX C

Administrative procedure for the call for participation in formulating Common Regulatory Objectives (CROs) and the preparation of CROs

ANNEX D

Format for an International Standardization Request (ISR)

ANNEX D

List of abbreviations used in the “International Model”

CAB	Conformity Assessment Body
CRO	Common Regulatory Objective
DRP	Dispute Resolution Panel
IRS	Internationally Recognized Standard/Specification
ISB	International Standardizing Body
ISR	International Standardization Request
PC	Protection Clause
RCAB	Recognised Conformity Assessment Body
SDoC	Supplier’s Declaration of Conformity
TAP	Technical Advisory Panel
TR	Technical Regulation
