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SYSTEMS FOR THE ACCREDITATION OR APPROVAL OF TESTING LABORATORIES,  
INSPECTION OR QUALITY SYSTEMS REGISTRATION BODIES

Proposal by the United States

INTRODUCTION

The lack of acceptance of laboratory test data between countries is a persistent and costly non-tariff barrier to trade. Currently, the Agreement on Technical Barriers to Trade (Standards Code), which was designed expressly to prevent such barriers to trade, does not address the accreditation of testing laboratories, or the approval of bodies performing inspections and registration of quality systems.

Frequently, central government bodies do not undertake testing, inspection or the registration of quality systems themselves. Rather, they approve or accredit non-governmental bodies and, in some cases, manufacturers, to perform such functions. Essentially, laboratory accreditation schemes specify criteria for assessing the technical competence and quality systems of laboratories designed to ensure the reliability and validity of test results. Such schemes provide a basis for determining which laboratories are suitable for performing such services as testing and inspection. Such schemes can be used to relieve the central government body of the burden of providing such services, and by making more facilities available, can improve economic efficiency.

The purpose of this proposal is to ensure that national treatment is not denied by the criteria used for accreditation or approval purposes. National treatment as applied to governmental laboratory accreditation schemes would mean that applications from laboratories, whether foreign or domestic, would be treated on the same basis. National treatment is denied when a government requires testing by accredited laboratories and, pursuant to the laws of such country, laboratories must be located in the territory of that country. This denies equally qualified laboratories located in the territories of other Parties national treatment. This type of situation is arguably covered by section 5.1.5 of the Standards Code:

"The siting of test facilities and the selection of samples for testing shall not be such as to cause unnecessary inconvenience for importers, exporters, or their agents".

The wording of the Agreement, however, is not precise, and has thus far not been operational in this regard.

The provisions set out in this proposal do not require any Party to set up accreditation or approval systems. The proposed amendments to the Standards Code would require that such systems, if operated by a Party, be handled fairly, and that Parties treat all applications for accreditation or approval in the same manner, whether they are filed by domestic or foreign applicants.

Summary of Proposal

The attached proposal suggests the following changes be made to the Standards Code:

1. Inserting several additional articles (articles 7 and 8) to the Code that relate directly to accreditation of testing laboratories and the approval of bodies performing inspection and registration of quality systems. The proposed articles parallel the current Articles governing certification systems.
2. Modifying, where appropriate, other articles of the Code to ensure consistence (i.e., certain "Global Changes" and revised Article 5.2).

PROPOSAL TO AMEND THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE

The following changes are suggested in order to provide for non-discriminatory treatment in systems for the accreditation or approval of testing laboratories, inspection or quality systems registration bodies.

A. New Articles Are Added As Follows:

New Article 7

Systems for the Accreditation or Approval of Testing Laboratories, Inspection or Quality Systems Registration Bodies Operated by Central Government Bodies

With respect to their central government bodies:

7.1 Parties shall ensure that systems for the accreditation or approval of testing laboratories, inspection or quality system registration bodies, are not formulated or applied with a view to creating obstacles to international trade. They shall likewise ensure that neither such systems themselves nor their application have the effect of creating unnecessary obstacles to international trade.

7.2 For procedures for the accreditation or approval of testing laboratories, inspection or quality system registration bodies, Parties shall use relevant international recommendations and guides, or the relevant parts of them, as a basis of their procedures except where, as duly explained upon request, such international recommendations and guides or relevant parts are inappropriate for the Parties concerned for, inter alia, such reasons as national security requirements: the prevention of deceptive practices: protection for human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological problems.

7.3 Parties shall ensure that such systems are formulated and applied so as to grant access for testing laboratories, inspection or quality system registration bodies sited in territories of other Parties under conditions no less favourable than those accorded to national or any other Party's testing laboratories, inspection and quality system registration bodies, including the determination that testing laboratories, inspection or quality system registration bodies are able and willing to fulfil the requirements of the system. Access for testing laboratories, inspection or quality system registration bodies is obtaining accreditation or approval from an importing Party under the rules of the system. Access for testing laboratories, inspection or quality system registration bodies also includes the right to issue test reports, to issue registrations for quality systems and to conduct surveillance under conditions no less favourable than those accorded to national or any other Part's testing laboratories, inspection or quality system registration bodies. Such test report, registration of the quality system or conduct of surveillance shall be accepted by the Party under terms no less favourable than those accorded to national or any other Party's testing laboratories, inspection or quality system registration bodies.

7.4 Parties shall:

- 7.4.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties to become acquainted with it, that they propose to introduce a laboratory accreditation system or system for the approval of inspection or quality system registration bodies;
- 7.4.2 notify the GATT secretariat of the products, processes or services to be covered by the proposed system together with a brief description of the objective of the proposed system;
- 7.4.3 upon request provide, without discrimination, to other parties particulars or copies of the proposed rules of the system;
- 7.4.4 allow, without discrimination, reasonable time for other parties to make comments in writing on the formulation and operation of the system, discuss the comments upon request and take them into account.

7.5 However, where urgent problems of safety, health, environmental protection, or national security arise, or threaten to arise for a Party, that Party may omit such of the steps enumerated in Article 7, paragraph 4 as it finds necessary provided that the Party, upon adoption of the accreditation system or system for the approval of inspection or quality registration bodies, shall:

- 7.5.1 notify immediately the other Parties through the GATT secretariat of the particular system and the products, processes or services covered, with a brief indication of the objective and rationale of the system including the nature of the urgent problems;
- 7.5.2 upon request provide, without discrimination, other Parties with copies of the rules of the system;
- 7.5.3 allow, without discrimination, other Parties to present their comments in writing, discuss these comments upon request and take the written comments and results of such discussions into account.

7.6 Parties shall ensure that all the adopted rules of the system for the accreditation or approval of testing laboratories, inspection or quality system registration bodies are published.

7.7 Nothing in this Article shall prevent Parties from carrying out reasonable spot checks within their territories. The requirements of this Article shall not apply to accreditation systems used by customs officials for purposes of product classification under tariff systems based on the Harmonized System nomenclature or for purposes of origin determination.

### New Article 8

#### Systems for the Accreditation or Approval of Testing Laboratories, Inspection or Quality System Registration Bodies Operated by Local Government and Non-Governmental Bodies

8.1 Parties shall take such reasonable measures as may be available to them to ensure that local government bodies and non-governmental bodies within their territories when operating systems for the accreditation or approval of testing laboratories, inspection or quality system registration bodies comply with the provisions of Article 7, except paragraph 4, sub-paragraph 2, noting that the provision of information referred to in Article 7, paragraph 4, sub-paragraph 3 and paragraph 4, sub-paragraph 2, the notification referred to in Article 7, paragraph 5, sub-paragraph 1, and the comment and discussion referred to in Article 7, paragraph 5, sub-paragraph 3, shall be through Parties. In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such bodies to act in a manner inconsistent with any of the provisions of Article 7.

8.2 Parties shall ensure that their central government bodies rely on systems for the accreditation or approval of testing laboratories, inspection or quality system registration bodies operated by local government and non-governmental bodies only to the extent that these bodies and systems comply with the relevant provisions of Article 7.

3. The following changes are made to other articles to ensure consistency:

#### Global Changes

Except for existing TBT Articles 7, 8 and 9, any reference to "certification system", shall be changed to "certification or system for the accreditation or approval of testing laboratories, inspection or quality system registration bodies".

#### Article 5.2

This paragraph shall be replaced by:

5.2 Parties shall ensure, whenever possible, that their central government bodies accept testing and inspection results, certificates or marks of conformity issued by relevant bodies in the territories of other Parties; or rely upon declaration of conformity by producers in the territories of other Parties even when the testing and inspection methods differ from their own, provided that the relevant body has been accredited or approved under (New) Articles 7 or 8, or provided they are otherwise satisfied that the methods employed in the territory of the exporting Party provide a sufficient means of evaluating conformity with the relevant requirements. It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding declaration of conformity, testing and inspection methods and results, and certificates or marks of conformity employed in the territory of the exporting Party, in particular in the case of perishable products or of other products which are liable to deteriorate in transit.