

GENERAL AGREEMENT ON

RESTRICTED

TARIFFS AND TRADE

TBT/W/138

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Special Distribution

Committee on Technical Barriers to Trade

CONFORMITY ASSESSMENT PROCEDURES

Proposal by the European Economic Community

The European Economic Community proposes to amend the following provisions of the Agreement on Technical Barriers to Trade.

AMENDMENT TO ANNEX I (DEFINITIONS)

Insert a new definition 11:

Conformity assessment procedure

Any technical procedure used, directly or indirectly, to give positive assurance that a product conforms with the applicable technical regulations or standards.

Explanatory note:

For the purposes of this Agreement, possible conformity assessment procedures or elements thereof are, inter alia, a manufacturer's declaration of conformity regarding the product or the quality assurance system used; the submission or availability of information regarding the product or the quality assurance system used; testing or inspection of the product or the quality system used; certification of the product or registration of the quality assurance system used; application of a mark of conformity; accreditation of testing laboratories, inspection bodies, or certification bodies; type approval, lot approval or unit approval of the product or approval of the quality assurance system used; good manufacturing practices; good laboratory practices; good clinical practices.

AMENDMENT TO ARTICLE 1.5

Replace Article 1.5 with the following:

1.5 All references in this Agreement to technical regulations, standards and conformity assessment procedures shall be construed to include any amendments thereto and any additions to the rules or the product coverage thereof, except amendments and additions of an insignificant nature.

AMENDMENTS TO ARTICLES 5 TO 9 (SECTIONS "CONFORMITY WITH TECHNICAL REGULATIONS AND STANDARDS" AND "CERTIFICATION SYSTEMS")

Replace Articles 5 to 9 with the following:

CONFORMITY ASSESSMENT PROCEDURES

Article 5

Preparation, adoption and application of conformity assessment procedures by central government bodies

5.1 Parties shall ensure that, in cases where a positive assurance is required that products conform with technical regulations or standards, their central government bodies apply the following provisions to products originating in the territories of other Parties:

5.1.1 conformity assessment procedures shall be formulated, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Parties under conditions no less favourable than those accorded to suppliers of like products of national origin or originating in any other country; access entails suppliers' right to an assessment of conformity under the rules of the procedure, including the right to have conformity assessment activities undertaken at the site of facilities and to receive the mark of the system, when these are foreseen by the procedure;

5.1.2 conformity assessment procedures shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade; this means, inter alia, that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create; where other conformity assessment procedures offer equivalent or better confidence, Parties shall, whenever possible and without prejudice to Article 6, accept the results of those procedures as well;

5.1.3 decisions on applications for conformity assessment shall be made as expeditiously as possible; at their request, applicants shall be informed of the progress of their application, with any delays being explained; applicants shall be informed as soon as possible and in a precise manner of any deficiencies in their application; while deficiencies are being corrected, the conformity assessment procedure shall, whenever possible, continue, with any additional deficiencies being reported to the applicant in a similar manner;

- 5.1.4 any fees imposed for conformity assessment procedures shall be equitable in relation to any fees chargeable for assessing the conformity of like products of national origin or originating in any other country;
- 5.1.5 the siting of facilities used in conformity assessment procedures and the selection of samples shall not be such as to cause unnecessary inconvenience to applicants;
- 5.1.6 information requirements shall be limited to what is necessary to assess conformity and determine fees; at the request of the applicant, the confidentiality of information he submits shall be respected, within the limits set by guidelines or recommendations issued by international standardizing bodies;
- 5.1.7 whenever specifications of a product are changed subsequent to its determination of conformity to the applicable technical regulations or standards, the conformity assessment procedure for the modified product shall be limited to what is necessary to determine whether adequate confidence exists that the product still meets the technical regulations or standards concerned;
- 5.1.8 a procedure shall exist to review complaints concerning the operation of a conformity assessment procedure and to take corrective action when a complaint is justified.
- 5.2 Nothing in Article 5, paragraph 1 shall prevent Parties from carrying out reasonable spot checks.
- 5.3 In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent, Parties shall ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures except where, as duly explained upon request, such guides or recommendations 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.
- 5.4 With a view to harmonizing conformity assessment procedures on as wide a basis as possible, Parties shall play a full part within the limits of their resources in the preparation by appropriate international standardizing bodies of guides or recommendations for conformity assessment procedures.

- 5.5 Whenever a relevant guide or recommendation issued by an international standardizing body does not exist or the technical content of a proposed conformity assessment procedure is not substantially the same as the technical content of relevant guides or recommendations issued by international standardizing bodies, and if the conformity assessment procedure may have a significant effect on trade of other Parties, Parties shall:
- 5.5.1 publish a notice of the proposal in a publication at an early appropriate stage, in such a manner as to enable interested parties to become acquainted with it;
 - 5.5.2 notify the GATT secretariat of the products to be covered by the proposed procedures together with a brief description of the nature and objective of those procedures;
 - 5.5.3 upon request provide, without discrimination, to other Parties, particulars or copies of the proposed procedures and, whenever possible, identify the parts which in substance deviate from relevant guides or recommendations issued by international standardizing bodies;
 - 5.5.4 allow, without discrimination, reasonable time for other Parties to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.
- 5.6 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 5, paragraph 5, as it finds necessary, provided it shall, upon adoption of the procedure:
- 5.6.1 notify immediately the GATT secretariat of the products covered by the procedure together with a brief description of the nature and objective of that procedure;
 - 5.6.2 upon request provide, without discrimination, to other Parties, particulars or copies of the rules of the procedure and, whenever possible, identify the parts which in substance deviate from relevant guides or recommendations issued by international standardizing bodies;
 - 5.6.3 allow, without discrimination, other Parties to make comments in writing, discuss these comments upon request and take these written comments and the results of these discussions into account.
- 5.7 Parties shall ensure that all conformity assessment procedures which have been adopted by central government bodies are published promptly in such a manner as to enable interested parties to become acquainted with them.

Article 6

Mutual recognition agreements concerning conformity assessment procedures

- 6.1 Where a Party's conformity assessment procedures require a positive assurance from one or more designated testing, inspection, registration, certification, accreditation or approval bodies, that Party shall, on the request of another Party, be willing to enter into negotiations for the conclusion of one or more agreements for the mutual recognition of the practices, methods, and work results of such bodies in both Parties.
- 6.2 It is recognized that Parties may request in such negotiations that the following criteria are satisfactorily met before concluding an agreement:
- (a) adequate and enduring technical competence of the bodies concerned, so that confidence in the continued reliability of their practices, methods and work results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;
 - (b) limitation of the recognition to work results produced by those bodies that have been designated in the agreement under the conditions laid down therein;
 - (c) a balanced situation with regard to the advantages derived by the Parties to the agreement in all matters relating to conformity assessment for the products concerned.

Article 7

Conformity assessment procedures operated by local government bodies and non-governmental bodies

- 7.1 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 which operate conformity assessment procedures, as well as non-governmental regional bodies which operate conformity assessment procedures and of which one or more of their non-governmental bodies are member, comply with the provisions of Article 5, with the exception of Article 5, paragraph 5, sub-paragraph 2, and Article 5, paragraph 6, sub-paragraph 1. In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging local government bodies or non-governmental bodies operating conformity assessment procedures to act in a manner inconsistent with any of the provisions of Article 5.

- 7.2 Parties shall ensure that their central government bodies rely on conformity assessment procedures operated by non-governmental bodies or local government bodies only if these latter bodies comply with the provisions of Article 5, with the exception of Article 5, paragraph 5, sub-paragraph 2, and Article 5, paragraph 6, sub-paragraph 1.

AMENDMENTS TO ARTICLE 10 (ENQUIRY POINTS)

Replace Article 10.1.3 with the following:

- 10.1.3 any conformity assessment procedures, or proposed conformity assessment procedures, which are operated within its territory by central or local government bodies, or by national or local non-governmental bodies which have legal power to enforce a technical regulation, or by regional non-governmental bodies of which such bodies are members or participants;

Replace Article 10.2.2 with the following:

- 10.2.2 any conformity assessment procedures, or proposed conformity assessment procedures, which are operated within its territory by national or local non-governmental bodies, or by regional non-governmental bodies of which such bodies are members or participants.