WTO Symposium on Conformity Assessment Procedures

(Geneva, 8-9 June 1999)

Following the First Triennial Review of the Agreement on Technical Barriers to Trade (TBT) the WTO TBT Committee decided at its meeting on 31 March 1999 to organize a Symposium on Conformity Assessment Procedures to deepen its understanding of a number of different issues including:

- relevant international guides and recommendations for conformity assessment;
- the types of conformity assessment procedures (CAPs) and the conditions for their application;
- the various approaches for the recognition of the results of CAPs; and
- the role of international and regional systems for conformity assessment.

Each of these themes was taken up in a separate session with Main Speakers and Panelists followed by Panel Discussions.

The Symposium was held in the new conference hall of the WTO headquarters with over 150 participants, including 36 speakers (with 41 lectures) who represented 8 international organizations (BIPM, IAF, IEC, ILAC, ISO, OECD, OIML and WTO), 6 regional organizations (APLAC, EA, EC, IAAC, PAC and SADCA) and over 20 national institutions and private companies.

Introductory Session

The Symposium began with a brief presentation of the main provisions of the Agreement on CAPs followed by presentations by a number of speakers on the CAPs that are used for business transactions in the market place. It was recognized that CAPs should not create unnecessary obstacles to trade; at the same time it was noted that effective harmonized CAPs are a necessary mechanism to establish confidence between different players in the market place.

Session I

Relevant International Guides and Recommendations for Conformity Assessment

This session focused on ISO/IEC Guides, on Committee Members' experience in the use of relevant international guides, and the extent to which those guides and recommendations have served as a basis for the implementation of CAPs by bodies in their territories, and have helped to ensure a harmonized approach to conformity assessment. These guides are widely used both by developed and developing countries. It was noted that it is important to develop guides reasonably quickly so as to meet the needs of the market place. It was also noted that while different conformity assessment players could in theory use the same international standards, variations in interpretation (based on language and geographical differences for example) could lead to different applications. It was suggested that international trade could stand to benefit from CAPs, which are transparent, impartial and based on international standards.

Among the main speakers the Chairman of the ISO Committee on Conformity Assessment introduced the activity of ISO/CASCO and mentioned that among other elements CASCO would focus on:

- revising and reissuing publications/Guides as standards;
- developing a comprehensive system of documented guidance; and
- taking users' experience into consideration in priority setting and content revision.

The BIML representative introduced those OIML activities that are of relevance to the issues dealt with in the four Symposium Sessions:

• the development of OIML Recommendations - as international standards - that specify harmonized metrological performance requirements of the measuring instruments concerned and detailed conformity assessment procedures to harmonize the tests to which measuring instruments are submitted;

- the operation of the OIML Certificate System, which facilitates trade of measuring instruments;
- the recent establishment of a new OIML technical body to develop a Mutual Acceptance Agreement on OIML pattern evaluations and two interpretation documents on applying ISO DIS 17025 and ISO/IEC Guide 65 for assessment of pattern evaluation test laboratories and legal metrology certification bodies respectively;
- the development of an OIML International Document on *Initial verification of measuring instruments utilizing the manufacturer's quality system*; and
- projects envisaged which take into account the needs of developing countries.

Panelists - among others the Chairpersons of ILAC and IAF - reported on the experience of their respective organizations on the use of the relevant International Guides/Recommendations as practitioners.

Session II

Various Types of Conformity Assessment Procedures and their Conditions of Application

It was noted that third party evaluation of conformity is widely used, supported in many cases by national accreditation systems as a tool for demonstrating the technical competence of conformity assessment bodies. It is used for the assessment of conformity to both voluntary standards (for products and quality systems) and to mandatory regulations. A number of issues were raised, e.g. the need for harmonized and consistent accreditation procedures, and a code of good practice for conformity assessment bodies.

It was indicated that some regulators accept supplier declarations of conformity in certain sectors. In some instances these declarations have to be underpinned by test results obtained from an accredited conformity assessment body. It was recognized that while supplier declaration is appropriate some cases, it is not appropriate in areas of great risk, and that it has to be accompanied by appropriate legislation, for example on liability, and effective post-market surveillance. In this respect, concerns were raised regarding the responsibility for products originating from abroad.

The European Commission representative, speaking of third party evaluation of conformity and accreditation, stressed that the main goal of the EC's regulatory system is to achieve confidence among all actors in the market place.

A speaker from the USA presented a national experience on supplier declaration of conformity mentioning that a number of US regulatory agencies also relied on this method, which saved costs, associated with assuring conformance.

Session III

Approaches with Respect to the Recognition of Conformity Assessment Procedure Results

It was noted that numerous mutual recognition agreements (MRAs) had been concluded, and that several different types of MRAs existed, e.g. between regulatory bodies (i.e. government to government) and nonregulatory bodies (i.e. private sector). It was recognized that the cost-effectiveness of MRAs was an issue that needed to be assessed carefully. Costs tend to be extremely high when conformity assessment systems are different in participating countries. While the numerous benefits from MRAs were stressed, it was explained by several speakers that MRAs are not the only option to address recognition issues, and may not be the appropriate option in a number of cases. It was also noted that they could not remedy serious market access problems.

Some concerns were expressed with respect to the discriminatory effects on trade of some governmental MRAs.

MRAs in the non-regulatory sector were also discussed and it was stated that the principle of national treatment for third party conformity assessment bodies from other countries/regions could enable those parties to participate in conformity assessment activities under conditions not less favorable than domestic bodies. MRAs in the non-regulatory sector could create a global network of organizations which are authorized to conduct conformity assessment for different requirements imposed by a variety of markets and facilitate quick market access.

In addition to MRAs, attention was drawn to the autonomous recognition of conformity as a tool for the recognition of conformity assessment results and which is in accordance with the TBT Agreement. Although reciprocity should not be set as a precondition for autonomous recognition, the establishment of confidence is essential. While participation by relevant conformity assessment bodies in international and regional systems could facilitate this process, other means such as peer evaluation could also be employed.

The European Commission representative spoke of different kinds or levels of mutual recognition agreements and their cost effectiveness comparing costs and benefits, and the Swiss representative presented positive national experience in the recognition of the results of foreign conformity assessment (autonomous recognition).

Session IV

The Role of International and Regional Systems for Conformity Assessment

A number of international organizations (such as BIPM, ILAC, IAF and IEC) and regional bodies (such as APLAC, EA, IAAC and SADC) introduced their systems and activity in the field of conformity assessment.

It was recognized that:

- international guides are commonly used by these systems;
- these systems play a useful role in coordinating the conformity assessment bodies;
- through these systems technical assistance could be provided and technical know-how could be transferred to developing countries;
- regional systems could be formed/tailored to address the particular situation of different regions; and
- there is a need to avoid the duplication of work among different systems at all levels.

The BIPM representative gave an overview on the existing international and regional systems for conformity assessment in metrology (including the OIML Certificate System), introduced the activities of the BIPM and noted that after several years' preparatory work a Mutual Recognition Agreement on measurement standards and calibrations was expected to be signed on the occasion of the 21st Conférence Générale des Poids et Mesures (CGPM) to be held in Paris in October 1999.

The ILAC representative gave a presentation on MRAs in the international laboratory community and ILAC's role in these arrangements. She explained ILAC's objectives to foster confidence between member bodies and to assist countries in developing laboratory accreditation systems, which is fundamental in supporting trade. She observed the trend that bilateral MRAs were moving to regional ones, which were easier to operate and explained that ILAC could play a useful role to enable new regions and unaffiliated laboratories to integrate into the system, coordinate regional accreditation programs and provide a global network in the long term. ILAC has already established liaisons with ISO, IEC, IAF, BIPM, OIML and WTO and regional laboratory accreditation systems in the Asia-Pacific, Europe, South and North America.

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