

**CANADA'S APPROACH TO VOLUNTARY
CONFORMITY ASSESSMENT**

Submission by Canada

I INTRODUCTION

1. The Second Triennial Review of the Technical Barriers to Trade (TBT) Agreement made significant progress on the longstanding issue of international standards in the Decision on Principles for the Development of International Standards, Guides and Recommendations (Annex 4). However, apart from agreement on an indicative list of the different approaches to conformity assessment (Annex 5), the review did not substantially address the issue of conformity assessment. In particular, the TBT Committee was unable to agree on the adoption of best practices or principles governing conformity assessment and provided little guidance on how this matter could be addressed in the future. It is expected that this issue will be more properly addressed during the 2003 Third Triennial Review.

2. As a follow-up to the Second Triennial Review, this paper highlights key elements of Canada's experience in the area of voluntary conformity assessment. The sharing of information on national approaches to conformity assessment helps promote the development of best practices and procedures and a broader understanding on how to implement the TBT Agreement in ways that minimize trade barriers.

II ACCREDITATION

3. In Canada the voluntary conformity assessment system is based on accreditation.¹ Achievement of consistent results through accreditation is dependent on the application of internationally harmonized standards, guides and recommendations that have been developed on the basis of consensus. Such documents encapsulate criteria and procedures related both to accreditation bodies and accredited programs (e.g. inspection, testing, calibration, quality and environmental system registration/certification, product certification and certification of personnel). This foundation provides the necessary confidence among users of conformity assessment services, including business and government, and accounts for the growth of accreditation-based conformity assessment services throughout the world.

4. Annex Four of the Report of the Second Triennial Review of the TBT Agreement extends the seven (7) principles for the development of international standards to include the development of those international standards, guides and recommendations related to conformity assessment. Aligning such documents with core TBT principles promotes their wider acceptance among members of the global conformity assessment community. Canada, through the Standards Council of Canada

¹ The First Triennial Review of the TBT Agreement noted that among the different approaches to conformity assessment, accreditation represents an independent test of the technical competence of conformity assessment bodies (CABs).

(SCC), is an active participant in the development of the international standards, guides and recommendations. The SCC participates in a number of Working Groups (WGs) of the International Organization for Standardization's (ISO) Committee on Conformity Assessment (CASCO) and holds the convenorship of Working Group 22, which is undertaking revision of ISO/IEC Guide 60 - *Code of good practice for conformity assessment*.

5. Accreditation activities based on the use of international standards, guides and recommendations provides additional benefits for conformity assessment organizations. Increasing global acceptance and application of these documents is helping to foster greater international harmonization of conformity assessment practices and procedures. This trend is apparent in the evolution of international and regional conformity assessment systems.² Such systems have expanded rapidly in recent years, encompass members from both developed and developing countries and link accreditation bodies that apply internationally-harmonized standards and guides. These systems provide for recognition of the equivalency of voluntary accreditation programs and policies through the development of multi-lateral arrangements (MRAs/MLAs).

6. International and regional conformity systems provide the framework for an emerging global accreditation regime based on the principle "one accreditation, accepted everywhere". These systems have the potential to reduce or eliminate duplicative costs of conformity assessment and reduce delays in the delivery of products to market. The signing of the ILAC MRA in November 2000 and the decision to extend the PAC and IAF MLAs to include environmental management systems and product certification are key milestones in this process. The TBT Agreement endorses international and regional accreditation systems and encourages TBT Members both to participate in the arrangements and adopt their corresponding documents. However, there remain a number of challenges including wider consumer and regulatory acceptance and the need for greater participation by developing countries and small and medium sized enterprises (SMEs). The reciprocal acceptance of accreditation-based conformity assessment results will require a certain level of confidence and mutual trust that will take time to cultivate and promote. TBT Members are encouraged to involve all domestic stakeholders so that the full benefits of national participation in these systems are realized. The SCC has signed agreements in ILAC, IAF, APLAC, IAAC and PAC and participates in the policy direction of these organizations.

7. The SCC operates Canada's national voluntary accreditation program. Currently, there are accreditation programs for organizations involved in testing, calibration, product certification, registration/certification of ISO 9000 quality and ISO 14000 environmental management systems, auditor training, and auditor certification. Users of conformity assessment services value the recognition that accreditation brings, as indicated by growing demands for the service. Between 2001 and 2002, the total number of organizations accredited by the Standards Council of Canada reached 377, a sixteen (16) percent increase over 2000-2001. New programs are expected in the growing list of sectors in the ISO 9000 and ISO 14000 areas. In addition, new programs for the accreditation of bodies that certify personnel and for the accreditation of inspection bodies, utilizing ISO/IEC 17024 *Conformity assessment – General requirements for bodies operating certification of persons* and ISO/IEC 17020:1998 *General criteria for the operation of various types of bodies performing inspection* respectively, will soon be launched.

8. As governments have downsized and reorganized, public authorities have looked to the voluntary system to provide conformity assessment services. In Canada, accreditation programs have broad acceptance at both national and sub-national levels. The SCC has entered into partnership

² Examples include the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), the Asia-Pacific Laboratory Accreditation Cooperation (APLAC), the Pacific Accreditation Cooperation (PAC), the European co-operation for Accreditation (EA), the Interamerican Cooperation for Accreditation (IAAC) and the Southern Africa Cooperation for Accreditation (SADCA).

programs with a number of federal and provincial departments and agencies to deliver accreditation services in the areas of testing and calibration laboratories. This partnership approach has proven to be cost effective and to satisfy regulatory needs. Another partnership example involves the use of SCC-accredited quality management system (QMS) registrars by Health Canada. After the introduction of new regulations requiring medical devices sold in Canada to be designed and manufactured under a registered QMS that conforms to international standards ISO 13485 or ISO 13488, Health Canada partnered with the SCC to qualify accredited QMS registration organizations to register manufacturers' quality management systems to the appropriate standards. Product certification by an SCC-accredited body is also accepted for a growing range of federally-regulated products and services. Harmonization between provincial jurisdictions in the acceptance of the results of conformity assessment is a longstanding feature of Canada's regulatory environment. In a number of areas in which provinces have regulatory jurisdiction (e.g. electrical safety), products certified by an SCC-accredited product certification body are accepted throughout Canada. This coordinated approach facilitates inter-provincial trade in electrical products and helps ensure provincial compliance with the substantive provisions of the TBT Agreement.

III. OTHER APPROACHES TO CONFORMITY ASSESSMENT

9. The TBT Second Triennial Review noted that there are different approaches to conformity assessment and emphasized the need to maintain flexibility in their application, depending upon the sectors involved and different requirements of Members, including the perceived level of risk. The application of a variety of approaches to conformity assessment poses both opportunities and challenges, particularly for the regulatory community. Suppliers' declaration of conformity (SDoC), a popular method of demonstrating regulatory compliance in a number of sectors (e.g. automobiles, telecommunications and electronics) has received much attention in the TBT Committee. While SDoC may offer economic benefits by reducing delays in delivery to market, its widespread acceptance will depend on a demonstrated capacity to consistently address health and safety concerns, the existence of stringent legal penalties and enforcement networks and the provision of appropriate consumer redress mechanisms. Currently in Canada, regulators accept SDoC in the fields of electromagnetic compatibility (EMC) and telecommunication terminal attachment equipment (TTE). Continued research and dialogue will help to foster a wider understanding of SDoC and its impact on the Canadian regulatory environment. The goal is to engage all involved domestic parties in discussions on this issue in order to gain a balanced view of the costs and benefits of SDoC and provide an understanding of the most appropriate circumstances and sectors for its application. As stated in its paper for the Second Triennial Review, Canada believes that formal accreditation of private testing and inspection bodies operating in support of SDoC would help facilitate wider acceptance of the concept among regulators and the public. The pending completion of the two-part international standard (*ISO/IEC 17050-1 General requirements for suppliers' declaration of conformity and ISO/IEC 17050-2 Supporting documentation for suppliers' declaration of conformity*) will also provide a basis for greater consistency of this conformity assessment approach.

10. Established international product certification schemes also play an important role in Canada's conformity assessment regime. A number of Canadian accredited certification bodies are members of the multilateral IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE CB Scheme) which promotes acceptance of test certificates based on specific IEC standards without the need for further testing and evaluation. Certificates issued under the Scheme are recognized by SCC -accredited certification bodies whose certifications are accepted in Canada by provincial government electrical safety regulators, eliminating the need for re-assessment. In order to demonstrate its openness and multilateral character, The CB Scheme, once previously restricted to IEC members, is now being expanded to include non-IEC members. Manufacturers in developing countries where there are few IEC members are expected to be the primary beneficiaries of the expansion since they will avoid the need for repeat testing once the product has been certified by an IECEE CB Scheme member. A similar IEC scheme for Products used in Explosive Atmospheres, the

IECEX Scheme, is currently gaining strength and is expected to greatly improve market access for products in this sensitive and highly regulated field. Canada is a founding member of the IECEX and is an active participant. The success of the IEC Schemes may have implications for other sectors.

11. Canada notes that participation in the development of international standards and guides, adoption of these documents in support of regulatory objectives, participation in accreditation-based conformity assessment arrangements and sector schemes and participation in and promotion of innovative conformity assessment processes can provide members with a variety of internationally-accepted approaches to conformity assessment. This multi-faceted approach provides a range of voluntary conformity assessment instruments and enables stakeholders to meet multiple customer demands and regulatory requirements.
