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A POLICY FRAMEWORK FOR MUTUAL RECOGNITION ACTIVITY

Contribution from Canada

During the Second Triennial Review, delegations discussed a range of approaches to conformity assessment, including mutual recognition agreements. Further to the Committee's request during the Second Triennial Review for Members to supply information on different mechanisms used in their jurisdictions for the acceptance of conformity assessment results, Canada is pleased to submit this paper on its experience and policy framework related to mutual recognition activities.

I. EXECUTIVE SUMMARY

1. In an effort to decrease non-tariff barriers to trade which may be associated with standards, technical regulations and their conformity assessment procedures, Canada has entered into Mutual Recognition Agreements/Arrangements (MRAs) covering various industrial sectors. Given that MRA negotiation and implementation can be a labour intensive process, the Canadian experience has been that neither the federal government nor other key players in the MRA process (e.g. regulatory departments, sub-national jurisdictions) can respond positively to all MRA-related requests. Therefore, it has been determined that clear domestic criteria for MRA activity are important to ensure that this activity reflects both Canada's economic interests as well as those of Canadian stakeholders.

2. The following key considerations have been identified in establishing priorities for future MRA-related activity: tangible economic benefits; determination of most appropriate regulatory tool; support from key players, underlying compatibility in the regulatory systems of the potential MRA parties; and sufficient resources for MRA negotiation and implementation. The framework also outlines Canadian priorities for future MRA activity, which at this time focus primarily on successful implementation of existing MRAs.

II. PURPOSE

3. To develop a policy framework for mutual recognition activity in non-sanitary-phytosanitary (SPS) product sectors, which supports and reflects Canada's regulatory objectives as well as our bilateral and multilateral trade interests and obligations.[1]

[1] This framework is intended to cover products or sectors which fall under the auspices of the Technical Barriers to Trade (TBT) Agreement of the World Trade Organization (WTO). It is not intended to cover mutual recognition activity which falls under the scope of the WTO Sanitary-Phytosanitary (SPS) Agreement.

III. BACKGROUND

4. It is clear that standards and technical regulations can represent significant non-tariff barriers to trade. Manufacturers often face requirements to test and certify product to different national standards and regulatory requirements before it can be sold on local markets. The need to undertake various product testing and certification processes in order to comply with differing rules raises various potential barriers to trade. These include, *inter alia*: increased costs and delays associated with the repetition of tests for different markets; increased transportation costs if the product is considered not to comply with the importing country's regulatory requirements and must be returned to the exporting country; and delays and costs associated with inspection visits which may be undertaken by authorities in the importing country.[2]

5. The Agreement on Technical Barriers to Trade (TBT), which resulted from the Uruguay Round, explicitly recognizes the potential value of MRAs through the following reference in Article 6.3:

> Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of each other's conformity assessment procedures.

6. The Mutual Recognition Agreements or Arrangements (MRAs)[3] to which Canada has become a Party involve conformity assessment (e.g. the testing and certification procedures undertaken to assess whether a product meets the requirements set out in a given standard or regulation). These MRAs cover specific sectors, in which they provide for recognition of inspection results, test reports and/or conformity certificates issued by bodies located in the territory of the exporting party (or parties), but deemed capable of testing to the importing party's regulatory requirements. These MRAs are intended to facilitate trade and reduce the burden on both industry and regulatory agencies, but in a manner that respects jurisdictional responsibilities and health and safety objectives.

7. Canada has been involved in the negotiation of a number of bilateral and multilateral MRAs on conformity assessment during the past five years. These include three multi-sectoral MRAs with the European Union, Switzerland, and Norway, Iceland and Liechtenstein (the EFTA-EEA countries), covering telecommunications equipment; electro-magnetic compatibility; electrical safety; medical devices; pharmaceutical good manufacturing practices (GMPs); and recreational craft. (Recreational craft is not yet included in the Canada-Switzerland MRA). With respect to single sector MRAs, a bilateral Mutual Recognition Arrangement on Telecommunications, Radio and Information Technology Equipment was concluded with Korea in 1997. Multilateral arrangements in the telecommunications sector include the APEC MRA for Conformity Assessment of Telecommunications Equipment, and the MRA for Conformity Assessment of Telecommunications Equipment for the Americas, negotiated under the auspices of the Inter-American Telecommunications Commission (and known as CITEL). Finally, ongoing discussions among the New World Wine Producers (NWWP) have led to initialling of a Mutual Acceptance Agreement (MAA) on wine-making practices among some NWWP countries, (which include Argentina, Australia, Canada, Chile, New Zealand, South Africa and the United States of America).

8. Mutual Recognition Agreement/Arrangement activity by Canada is taking place in the broader context of government activities related to international regulatory cooperation, including

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[2] A 1996 OECD study found that testing and certifying compliance to these requirements represent from 2 - 10 per cent of overall production costs.

[3] In the Canadian context, an Agreement is a legally binding instrument under international law. It has the force of a treaty and is ratified by the executive power. An Arrangement is a non-legally binding international instrument, done under the authority of the Minister of Foreign Affairs.

accreditation and certification; MRAs; equivalence (uni-directional acceptance or recognition of foreign regulatory approaches or decisions); and full harmonization (identical regulations or use of international standards). In addition, organizations such as the Standards Council of Canada are active in various international and regional voluntary accreditation-based arrangements, while Canadian conformity assessment organizations also participate in sector-based private sector MRAs, such as the IECEE CB Scheme for the Safety of Electrical Products. In short, while government-to-government MRAs can certainly be useful, it is important to note that they are only one of a number of tools which can be used in efforts to reduce or simplify regulatory requirements. Moreover, MRAs may only be one step in longer-term regulatory efforts, for example a move toward full harmonization.

IV. ISSUE

9. As awareness of the general concept of MRAs has increased, Canada has had requests from countries interested in negotiating such agreements. However, resource constraints limit Canada's ability to respond to MRA-related demands given that negotiation of MRAs, particularly those covering multiple sectors, is a labour intensive exercise. (The Canada-EU MRA took three years to negotiate). Moreover, implementation of existing MRAs has significant short and medium-term implications with respect to personnel and financial resources.

10. These constraints and resource implications affect key Canadian players in the MRA process, including the Department of Foreign Affairs and International Trade, regulatory departments, as well as sub-national jurisdictions (e.g. Canadian provinces and territories). In addition, although evaluation of Canada's existing MRAs is still ongoing, these MRAs do raise questions as to the most effective and efficient means of achieving various regulatory cooperation objectives.

11. In short, clear criteria for undertaking new MRA negotiations, enhancing existing MRAs, or engaging in other regulatory cooperation activity, are needed to ensure that this activity continues to reflect Canada's trade interests, as well as the views of interested domestic partners and stakeholders. The resource constraints of the various involved parties must also be considered, particularly given the importance of effectively implementing existing MRA obligations. Therefore, the following is intended to outline a transparent set of criteria for determining possible Canadian involvement in mutual recognition activity.

V. MRA PRIORITY SETTING CRITERIA

12. From a Canadian perspective key considerations for establishing priorities for MRA activity include: clear demonstration of tangible trade and regulatory benefits from conclusion of an MRA; assessment of alternative regulatory tools; support from jurisdictional partners and stakeholders; the need for a basic underlying compatibility in the regulatory systems of the potential contracting parties; and sufficient resources to ensure effective MRA negotiation and implementation.

A. DEMONSTRATED BENEFIT/ASSESSMENT OF ALTERNATIVES

13. MRA activity should serve to meet a clearly demonstrated need. In other words, there should not be an *a priori* assumption that all regulatory areas would benefit from inclusion in an MRA and assessment of possible alternative tools for regulatory cooperation will be important. There must also be consideration of whether any MRA should cover multiple sectors, or focus on a single sector. Advantages of multi-sector MRAs include the opportunity for trade-offs during the negotiation phase, as well as the ability to generate greater public awareness upon conclusion of the MRA. On the other hand, single-sector MRAs are almost always easier to negotiate and implement.

14. Regardless of whether single or multiple sectors are being considered, there should be a significant volume of existing export trade (or documented trade potential) in the sector(s) being examined, along with a strong indication that an MRA would significantly reduce barriers or transaction costs. The sector(s) or product(s) being considered for MRA activity should be significantly affected by differing standards and/or conformity assessment procedures; in some cases regulatory requirements are not sufficiently burdensome to warrant the resources which would be required to develop and implement an MRA. In addition, the complexity of some regulatory requirements means that MRAs may again not be a suitable tool for use in efforts to reduce or simplify these requirements. In cases where the regulatory culture is markedly different, the most effective approach may involve consideration of other options, including the use of alternative tools for regulatory cooperation.

15. Other issues which need to be considered with respect to the cost/benefit of a possible MRA include: impacts on existing regulatory systems; costs and benefits for consumers; potential implementation costs at both the national and sub-national level; and the potential impact on domestic suppliers of those products which may enter under an MRA.

B. KEY PLAYERS

16. In the Canadian context, key players in the MRA process include: trade policy officials at all levels of government; regulatory policy officials, who depending on jurisdictional responsibilities may be federal, provincial/territorial, or even municipal authorities; inspectors; industry, in particular exporters; conformity assessment and accreditation bodies; and consumers. The general interests of each of the listed parties are outlined below. Other parties may also be interested depending on the nature of the MRA being considered.

17. Interested partners at the sub-national level (e.g. provinces and territories) clearly include trade policy officials, and in areas of sub-national regulatory jurisdiction, the regulatory community including inspectors, all of whom have an interest and responsibility for protecting human health and safety and the environment, and ensuring accountability. Over the longer term, regulators (at both the national, or sub-national level) can also benefit from the increased efficiencies associated with a MRA, which can free up limited public resources for use on other regulatory tasks. The contact and information exchange between regulators, which is implicit in negotiation and implementation of MRAs, is also beneficial. Specifically, interaction by regulators with their counterparts increases familiarity and comfort with the systems in place in other countries, facilitates effective response in situations where problems do arise, and helps keep regulators up to date with respect to best practices in other jurisdictions.

18. Exporters are generally important beneficiaries of Mutual Recognition Agreements or Arrangements on Conformity Assessment. For exporters, these agreements signal increased trade opportunities for regulated products, eliminating the need for duplicative testing by providing the option of meeting the regulatory requirements of other countries in a simplified and cost-effective manner. However, producers for the domestic market may also be affected by the implications of an MRA. Other interested parties in the MRA process include conformity assessment bodies, accreditation bodies, and consumers. The interest of conformity assessment bodies lies largely in the impact MRAs may have on their business, including enhanced opportunities for testing domestic product for conformity to foreign requirements, as well as potential reductions in opportunities to test foreign product destined for the domestic market. Accreditation bodies (e.g. the Standards Council of Canada) are generally involved through their role in ensuring the technical competence of conformity assessment bodies participating in the MRA, thereby helping to build the needed confidence among regulators. Consumer interests, which are often represented by consumer associations, generally involve ensuring that MRAs have no negative impact with respect to health, safety and environmental

considerations (not unlike regulators and inspectors). In addition, MRA activity can have clear consumer benefits with respect to facilitating access to reasonably-priced, quality products.

19. Given the importance of support from jurisdictional partners and stakeholders, it is critical that they be consulted both prior to the initiation of MRA negotiations, and provided with ongoing and comprehensive briefings during negotiations. (In some areas, of course, these partners would also be closely involved in MRA implementation). It is clear that partners and stakeholders' role in this process must not be underestimated; for example, support from sub-national units for activities in their areas of jurisdictional responsibility would certainly be a key factor in assessing whether to pursuing MRA activity in a particular sector.

C. SYSTEMIC COMPATIBILITY

20. Successful conclusion and implementation of a binding MRA will also be contingent on assessment of a basic compatibility between the existing regulatory systems of the parties to the agreement. Parties must adhere to the disciplines of the WTO Agreement on Technical Barriers to Trade. They should also have a generally comparable level of technical skills/infrastructure in the sector(s) being considered with respect to standards, conformity assessment (e.g. testing and certification activities) and/or regulation. It is also important that the potential MRA partner have a credible system for tracking product and for pursuing legal actions, if this should prove necessary, on the part of domestic consumers. Even where these criteria are met, the signatories' differing conformity assessment requirements for some sectors can nonetheless result in implementation challenges.

D. RESOURCES

21. As previously noted, all players face resource constraints in dealing with MRA activities. Moreover, as demonstrated by Canada's existing MRAs, the resources of those involved in these issues must be sufficient to cover consultation, negotiation and implementation of potential MRAs. New MRA-related activity -- with its upfront costs and longer term benefits -- must be recognized as a priority relative to other issues. As a general rule, however, involved parties would be responsible for the personnel and financial requirements related to their participation in MRA activity. In this regard, the extent of their willingness to commit resources will provide some indication of their interest in and commitment to the activity.

VI. PRIORITIES FOR FUTURE MRA ACTIVITY

22. Canada's current priority is the successful implementation of existing MRAs, in particular the Agreements which cover the European countries. The confidence building phase for most annexes under these agreements is ongoing, and there continue to be various issues for resolution. Successful implementation of the Mutual Acceptance Agreement on wine-making practices among the New World Wine Producers group is another key objective. On the telecommunications side, Industry Canada negotiated and is implementing the APEC and CITEL MRAs. With respect to pharmaceuticals, Health Canada is considering a possible MRA on Good Manufacturing Practices with Australia. This MRA would be very similar to the pharmaceutical annexes found in the MRAs between Canada and the European countries.

23. With respect to "new" activity, it is important to continue the ongoing regulatory dialogue with various key partners. At this time, there are no countries which emerge as obvious candidates for a full-fledged, multi-sectoral MRA.

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