

**AGREEMENT ON MUTUAL RECOGNITION
IN RELATION TO
CONFORMITY ASSESSMENT
BETWEEN
CANADA AND SWITZERLAND**

(December 3, 1998)

Note:

This document is intended to be a working tool for those who wish to refer to the *Agreement on Mutual Recognition in Relation to Conformity Assessment between Canada and Switzerland*. It does not constitute an official document.

AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT BETWEEN CANADA AND SWITZERLAND

THE SWISS FEDERAL COUNCIL AND THE GOVERNMENT OF CANADA ("the Parties"),

CONSIDERING the traditional links of friendship that exist between Switzerland and Canada,

CONSIDERING that on the basis of the 1997 Arrangement on commercial and economic cooperation between Switzerland and Canada, both Parties have expressed a desire to establish a more formal framework for the conduct of collaboration in the field of mutual recognition in relation to conformity assessment,

CONSIDERING the Parties' interest in strengthening the rules governing free and unhindered international trade,

CONSIDERING the improved conditions for trade between the Parties which the mutual recognition of tests, certificates and marks of conformity will bring about,

RECOGNISING the importance of maintaining their respective high standards of health and safety,

BEARING in mind the close relationship of both Parties with the EC and the EFTA/EEA Member States,

BEARING in mind their status as Parties to the Agreement Establishing the World Trade Organisation and conscious in particular of their obligations under the World Trade Organisation Agreement on Technical Barriers to Trade,

HAVE AGREED as follows:

ARTICLE I: Definitions

General terms concerning conformity assessment used in this Agreement and its annexes shall have the meaning given in the definitions contained in Guide 2 (1996 edition) of the International Organisation for Standardisation and the International Electrotechnical Commission, unless specifically defined otherwise in this Agreement and its Sectoral Annexes. In addition, the following terms and definitions shall apply to this Agreement:

Agreement means the Framework Agreement and all the Sectoral Annexes;

Conformity Assessment means systematic examination to determine the extent to which a product, process or service fulfils specified requirements;

Conformity Assessment Body means a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled.

Designating Authority means a body with power to designate, monitor, suspend designation or withdraw designation of Conformity Assessment Bodies under its jurisdiction.

Designation means the authorization by a Designating Authority of a Conformity Assessment Body to perform conformity assessment activities.

Regulatory Authority means a government agency or other entity, that exercises a legal right to control the use or sale of products within a Party's jurisdiction, and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

In the event of an inconsistency between ISO/IEC Guide 2 and definitions in this Agreement or its Annexes, the definition in this Agreement shall prevail.

ARTICLE II: General Obligations

1. The Sectoral Annexes to this Framework Agreement constitute integral parts of this Agreement.
2. The Government of Canada shall accept the results of conformity assessment procedures, including certifications of compliance, as required by the Canadian legislation and regulations identified in the Sectoral Annexes, produced by designated Conformity Assessment Bodies or Authorities in Switzerland in accordance with this Agreement.
3. Switzerland shall accept the results of conformity assessment procedures, including certifications of compliance, as required by the Swiss legislation and regulations identified in the Sectoral Annexes, produced by designated Conformity Assessment Bodies or Authorities in Canada in accordance with this Agreement.
4. Where transitional rules have been specified in Sectoral Annexes, the above rules will apply following the successful completion of the transitional phase.
5. This Agreement shall not be construed to entail mutual acceptance of standards or technical regulations of the Parties and, unless otherwise specified in a Sectoral Annex, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

ARTICLE III: General Coverage of the Agreement

1. This Agreement applies to conformity assessment procedures for products covered by its Sectoral Annexes.
2. Each Sectoral Annex shall contain the following items, as appropriate:
 - a statement on the product scope and coverage;
 - a description of the relevant legislative, regulatory and administrative provisions pertaining to the conformity assessment procedures and technical regulations;
 - a list of designated Conformity Assessment Bodies or Authorities, or a source from which to obtain such a list;
 - a list of authorities responsible for designating the conformity Assessment Bodies and the source of the procedures and criteria;
 - a description of the mutual recognition obligations;
 - a Sectoral Transition Plan;
 - a description of the Joint Sectoral Group;
 - a sectoral contact point in each Party's territory;

guidelines for corrective actions.

3. For a given product or sector, the specific rules contained in the relevant Sectoral Annex shall prevail over the more general provisions of the Framework Agreement.

ARTICLE IV: Transitional Arrangements

1. The Parties agree to implement the transition commitments on confidence building where included in the Sectoral Annexes.
2. The Parties agree that each Sectoral Transition Plan shall specify a time period for completion.
3. The Parties may amend any transition period by mutual agreement through the Joint Committee established under this Agreement, taking account of recommendations made by the relevant Joint Sectoral Groups.
4. Passage from the transitional phase to conditions of full mutual recognition shall proceed unless there is documented evidence demonstrating a lack of technical competence in a Party's conformity assessment.

ARTICLE V: Civil Liability

1. Nothing in this Agreement is intended to change or modify the law in the territory of either Party applicable to civil liability of manufacturers, distributors, suppliers, Conformity Assessment Bodies, Designating Bodies, Regulatory Authorities or governments, to consumers or among each other, in respect of the design, manufacture, testing, inspection, distribution or sale of products that have undergone conformity assessment pursuant to this Agreement.
2. The Parties agree that their respective Conformity Assessment Bodies are required to make adequate arrangements for liabilities arising from their operations and activities under this Agreement. The Parties, through the Joint Committee, shall from time to time consider whether their respective Conformity Assessment Bodies continue to meet that requirement and whether the interests of the Parties are adequately protected.
3. Each Party shall promptly notify the other Party of any suit or other proceedings threatened or commenced in the territory of such Party arising from or in connection with conformity assessment performed by a Conformity Assessment Body of the other Party.
4. Each Party shall cooperate with the other Party in the investigation and defence of any suit or proceeding where the interests of either Party are at risk. In particular, the Parties shall render reasonable assistance in obtaining relevant documents and access to material witnesses required in the investigation and defence of such suits or proceedings.

ARTICLE VI: Designating Authorities

1. The Parties shall ensure that the Designating Authorities responsible for designating the Conformity Assessment Bodies specified in the Sectoral Annexes shall have the necessary authority to designate, monitor, suspend and withdraw the designations of such Bodies.
2. In the case of suspension of a designation or removal of such a suspension, the Designating Authority of the Party concerned shall immediately inform the other Party and the Joint Committee.

3. The Parties shall exchange information concerning the procedures used to ensure that their designated Conformity Assessment Bodies continue to comply with the legislative, regulatory and administrative provisions of this Agreement.

ARTICLE VII: Conformity Assessment Bodies

1. The Conformity Assessment Bodies designated in the territory of the exporting Party shall operate to the requirements of the importing Party and fulfil the conditions of eligibility for conformity in relation to those requirements.
2. In designating such bodies, the Designating Authorities shall specify, in each Annex, the scope of conformity assessment activities for which such Bodies have been designated.
3. The designation constitutes a formal judgement by the Party that the Conformity Assessment Body has demonstrated an acceptable level of technical competence in providing services identified in the designation and further has agreed to comply with the requirements of the other Party, as set out in a Sectoral Annex.
4. In accordance with the terms of the Sectoral Annexes, each Designating Authority will make available, if requested, a statement of technical competence of its designated Conformity Assessment Bodies.

ARTICLE VIII: Verification and Suspension of Conformity Assessment Bodies

1. Each Party has the right to challenge the technical competence and compliance of Conformity Assessment Bodies under the jurisdiction of the other Party. This right will be exercised under exceptional circumstances only and justified, in an objective and reasoned manner in writing, to the Joint Committee. The Joint Committee will discuss such requests.
2. Where the Joint Committee, either on its own initiative or on a recommendation from the relevant Sectoral Group, comes to the conclusion that verification of technical competence or compliance of a Conformity Assessment Body operating in the territory of the other Party is required, it will be carried out in a timely manner by the Party in whose territory the Body in question is located, or by the Parties jointly if they agree. The Party may seek the assistance of its Designating Authority in carrying out the verification.
3. Unless decided otherwise by the Joint Committee, the contested Conformity Assessment Body will be suspended by the competent Designating Authority from the time that a disagreement over the status of that Body has been confirmed in the Joint Committee. The Body in question shall remain suspended until agreement has been reached in the Joint Committee on the future status of that Body.
4. A certificate of conformity or other documentation for a product issued by a Conformity Assessment Body, that is subsequently removed by the Joint Committee or Designating Authority, shall remain valid unless there is a specific decision by the appropriate Regulatory Authority based on health and safety considerations for the removal of the product from the market.

ARTICLE IX: Exchange of Information

1. The Parties shall exchange information concerning the implementation and application of the legislative, regulatory and administrative provisions identified in the Sectoral Annexes.
2. Each Party shall inform the other Party of changes related to the subject matter of this Agreement, and shall, except where considerations of safety, health and environmental

protection require more urgent action, notify the other Party of the new provisions at least 60 days before their entry into force.

3. Each Party shall promptly notify the other Party of any changes of its Designating Authorities and Conformity Assessment Bodies.
4. Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Agreement which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those foreseen by this Agreement.

ARTICLE X: Monitoring of the Agreement

1. The Parties may hold ad hoc consultations within the Joint Committee to ensure the satisfactory functioning of this Agreement.
2. One Party may request the other to carry out, on its behalf, audits and re-evaluations of Conformity Assessment Bodies working to the requirements of the requesting Party. The requesting Party will bear the costs of the audit.
3. In the interests of promoting a uniform application of the conformity assessment procedures provided for in the laws and regulations of the Parties, the designated Conformity Assessment Bodies shall take part, as appropriate, in interpretation sessions conducted by the Regulatory Authorities in each Party in the relevant areas covered by the Sectoral Annexes to this Agreement.

ARTICLE XI: Joint Committee

1. There shall be established under this Agreement a Joint Committee of the two Parties, which will be responsible for the effective functioning of the Agreement.
2. The Joint Committee shall take its decisions and adopt its recommendations by consensus of the Parties. It will meet at least once a year unless it decides otherwise. It shall determine its own rules of procedure. It may establish a Joint Sectoral Group under a Sectoral Annex, and may delegate specific tasks to those Groups. Each Party may invite its representatives from the Joint Sectoral Groups to attend meetings of the Joint Committee when its sectoral interests are the subject of an agenda item.
3. The Joint Committee may consider any matter related to the operation of this Agreement. In particular it shall be responsible for:

amending Sectoral Annexes;

giving effect to the decision to designate or withdraw the designation of a particular Conformity Assessment Body;

exchanging information concerning the procedures used by each Party to ensure that the Conformity Assessment Bodies specified in the Sectoral Annexes maintain the necessary level of competence;

determining the status of Conformity Assessment Bodies whose technical competence has been contested;

exchanging information and notifying the Parties of modifications of legislative, regulatory and administrative provisions referred to in the Sectoral Annexes; and

addressing any questions relating to the operation of this Agreement and its Sectoral Annexes, including questions related to health and safety, market access and the balance of rights and obligations under the Agreement.

4. The following procedure shall apply to the inclusion in or withdrawal from a Sectoral Annex of a Conformity Assessment Body:

a Party designating or withdrawing designation of a Conformity Assessment Body shall forward its proposal in writing to the other Party;

in the event that the other Party consents to the proposal or upon the expiry of 60 days without an objection having been made, the inclusion in or withdrawal from the Sectoral Annex of the Conformity Assessment Body shall take effect; and

in the event that the other Party challenges the technical competence or compliance of a proposed Conformity Assessment Body within the said 60-day period, the Joint Committee may request the proposing Party to carry out a verification, which may include an audit, of the Body concerned, in accordance with the provisions of this Agreement.

ARTICLE XII: Joint Sectoral Groups

1. The Joint Committee may establish Joint Sectoral Groups for individual Sectoral Annexes comprising the appropriate Designating and Regulatory authorities and experts of the Parties. These groups will address the specific conformity assessment and regulatory issues related to a given sector.

2. The responsibility of the Joint Sectoral Groups may include the following:

at the request of a Party, to examine specific problems arising in the implementation of any transitional plans for mutual recognition and to give advisory opinions to the Joint Committee on issues of mutual concern;

furnish information and advice on any matters relating to implementation, and on the regulations, procedures and conformity assessment system related to a particular Annex, as may be requested by a Party;

review various aspects of the implementation and operation of each Sectoral Annex, including health and, safety aspects.

consider issues of interpretation of requirements in the Sectoral Annexes, and where appropriate to make recommendations to the Joint Committee.

ARTICLE XIII: Sectoral Contact Point, Management of Information, Assistance and Emergency Action

1. Each Party shall appoint and confirm in writing the names and addresses of Contact Points to be responsible for activities under each Sectoral Annex.
2. Communications regarding confidence-building activities, emergency actions and regulatory enforcement for products subject to this Agreement, will normally be handled directly by the Sectoral Contact Points.

ARTICLE XIV: Safeguards

1. The appropriate Regulatory Authorities of each Party retain all authority under the applicable law of that Party, to interpret and, as set out in paragraph 2 below, enforce their respective

legislative and regulatory provisions. A Regulatory Authority of the importing Party is not the legal representative of the exporting Party.

2. When a Party or one of its Regulatory Authorities has reasons to believe that a product from the other Party, covered under a Sectoral Annex, may compromise the health or safety of persons in its territory, or otherwise fails to satisfy a requirement of the applicable Sectoral Annex, the Party in the receiving territory retains all powers under its applicable domestic law to take all appropriate and immediate measures to withdraw such products from the market, prohibit their placement on the market, restrict their free movement, or initiate a product recall. The Regulatory Authority in whose territory the action has been taken shall inform its counterparts and the Joint Committee immediately after taking such action, giving its reasons.
3. The Parties agree that border inspections and checks of products certified to the importing Party's requirements shall be completed as expeditiously as possible. With regard to any inspections related to internal movement within their respective territories, the Parties agree that these shall be completed in a manner no less favourable than for like domestic goods.

ARTICLE XV: Market Access

1. Each Party's obligation to accord mutual recognition within the terms of a Sectoral Annex to this Agreement is conditional upon the other Party continuing:
 - to provide access to its market for products that, having been subjected to conformity assessment procedures, can be demonstrated to meet the applicable technical requirements; and
 - to maintain in existence Legal and Regulatory Authorities capable of implementing the provisions of this Agreement.
2. Where a Party introduces new or additional conformity assessment procedures affecting a sector covered by a Sectoral Annex the Joint Committee shall, unless the Parties agree otherwise, bring such procedures within the scope of this Agreement and the relevant Annex.
3. If, upon implementation of such new or additional requirements, Conformity Assessment Bodies designated by the other Party in order to meet such requirements have not been recognized by the Party implementing the requirements, the other Party may suspend its obligations under the Sectoral Annex in question.

ARTICLE XVI: Fees

Each Party shall ensure that, for conformity assessment procedures carried out pursuant to this Agreement and its Sectoral Annexes, no fees are charged in its territory for conformity assessments services provided by the other Party.

ARTICLE XVII: Agreements with other Jurisdictions

1. Except where there is written agreement between the Parties, obligations contained in mutual recognition agreements concluded by either Party with a jurisdiction not party to this Agreement shall have no force and effect with regard to the other Party.
2. Unless specified differently in a Sectoral Annex, conformity assessments under this Agreement can be carried out in third jurisdictions provided that:

Switzerland and Canada have in place a mutual recognition arrangement importing and exporting Party; with a third jurisdiction covering the relevant product or procedure. The

Conformity Assessment Body in the third jurisdiction must be specifically recognized by both the importing and the exporting Party;

The manufacturer of the exporting Party and/or its authorized representative in the importing Party's territory must hold the conformity assessment reports at the disposal of the regulatory enforcement authorities in both the exporting and importing jurisdictions for ten years. This documentation shall be provided to both regulatory authorities without charge upon request;

The regulatory authority of the exporting Party shall exercise regulatory responsibility regarding manufacturers from its territory using recognized Conformity Assessments Bodies in a third jurisdiction. The regulatory authority shall cooperate with the importing Party in ensuring that all relevant regulatory requirements of the importing Party are respected and, if required, that necessary enforcement and corrective actions are taken.

ARTICLE XVIII: Territorial Application

This Agreement and its Annexes shall apply, on the one hand, to the territories of Switzerland and of the Principality of Liechtenstein, and, on the other hand, to the territory of Canada.

ARTICLE XIX: Entry into Force, Modification and Duration

1. This Agreement and its Annexes shall enter into force on the first day of the second month following the date on which the Parties have exchanged diplomatic notes confirming the completion of their respective procedures for the entry into force of this Agreement.
2. This Agreement may be amended by the written agreement of the Parties. Amendments to, or decisions to terminate Sectoral Annexes will be made by the Parties through the Joint Committee.
3. The Parties may add Sectoral Annexes upon exchange of diplomatic notes. Such Annexes shall take effect as part of this Agreement 30 days following the date on which the Parties have exchanged diplomatic notes confirming the addition of such an Annex.
4. Either Party may suspend its obligation under a particular Sectoral Annex, in whole or in part, on the basis of a 90-day notice containing reasons submitted to the Joint Committee.
5. Either Party may terminate this Agreement by giving the other Party six months notice in writing.

ARTICLE XX: Final Provisions

This Agreement and the Sectoral Annexes are drawn up in two originals in the English and French languages, each text being equally authentic.

DONE at Ottawa on the third of December in the year one thousand nine hundred and ninety-eight.