# No. 48325

# European Community and Canada

Agreement on mutual recognition between the European Community and Canada (with annexes). London, 14 May 1998

**Entry into force:** 1 November 1998 by notification, in accordance with article XIX

**Authentic texts:** Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish

**Registration with the Secretariat of the United Nations:** Council of the European Union, 8 February 2011

Only the authentic English and French texts of the Agreement are published herein. The other authentic texts of the Agreement are not published in this volume, in accordance with article 12 (2) of the General Assembly Regulations to give effect to Article 102 of the Charter of the United Nations, as amended, and the publication practice of the Secretariat.

# Communauté européenne et Canada

Accord de reconnaissance mutuelle entre la Communauté européenne et le Canada (avec annexes). Londres, 14 mai 1998

Entrée en vigueur: 1<sup>er</sup> novembre 1998 par notification, conformément à l'article XIX

**Textes authentiques :** danois, néerlandais, anglais, finnois, français, allemand, grec, italien, portugais, espagnol et suédois

**Enregistrement auprès du Secrétariat des Nations Unies :** Conseil de l'Union européenne, 8 février 2011

Seuls les textes authentiques anglais et français de l'Accord sont publiés ici. Les autres textes authentiques de l'Accord ne sont pas publiés dans ce volume, conformément au paragraphe 2 de l'article 12 du règlement de l'Assemblée générale destiné à mettre en application de l'Article 102 de la Charte des Nations Unies, tel qu'amendé, et de la pratique du Secrétariat dans le domaine des publications.

# [ ENGLISH TEXT – TEXTE ANGLAIS ]

# AGREEMENT

# on mutual recognition between the European Community and Canada

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The EUROPEAN COMMUNITY and the GOVERNMENT OF CANADA ('the Parties'),

CONSIDERING the traditional links of friendship that exist between Canada and the European Community:

CONSIDERING that on the basis of past experience under the 1976 Framework Agreement on commercial and economic cooperation between the European Communities and Canada, and in order to further develop their dialogue in the area of standards as specified in the 1990 Declaration on EC-Canada relations, 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 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 1

#### 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 authorisation 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 definitions 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 the European Community in accordance with this Agreement.
- 3. The European Community shall accept the results of conformity assessment procedures, including certifications of compliance, as required by the European Community and Member States 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) a statement on the product scope and coverage;
- (b) a description of the relevant legislative, regulatory and administrative provisions pertaining to the conformity assessment procedures and technical regulations;
- (c) a list of designated conformity assessment bodies or authorities, or a source from which to obtain such a list.
- (d) a list of authorities responsible for designating the conformity assessment bodies and the source of the procedures and criteria;
- (e) a description of the mutual recognition obligations;
- (f) a sectoral transition plan;
- (g) a description of the joint sectoral group;
- (h) a sectoral contact point in each Party's territory;
- (i) 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.
- 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.
- In the ease 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 judgment 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 one of the Parties 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

- The Parties shall exchange information concerning the implementation 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 sixty (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.