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 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 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.

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 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

1. 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.

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:

(a) amending Sectoral Annexes;

(b) giving effect to the decision to designate or withdraw the designation of a particular conformity assessment body;

(c) 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;

(d) determining the status of conformity assessment bodies whose technical competence has been contested;

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

(f) 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) a Party designating or withdrawing designation of a conformity assessment body shall forward its proposal in writing to the other Party;

(b) 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

(c) 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:

(a) 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;

(b) 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;

(c) review various aspects of the implementation and operation of each Sectoral Annex, including health and safety aspects; and

(d) 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 within 15 days of 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:

(a) 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

(b) 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 recognised 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 assessment services provided by the other Party.

Article XVII

Agreements with other countries

Except where there is written agreement between the Parties, obligations contained in mutual recognition agreements concluded by either Party with a country not party to this Agreement shall have no force and effect with regard to the other Party.

Article XVIII

Territorial application

This Agreement and its Annexes shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied, and under the conditions laid down in that Treaty 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 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 Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish languages, each text being equally authentic.

Hecho en Londres, el catorce de mayo de mil novecientos noventa y ocho.

Udfærdiget i London den fjortende maj nitten hundrede og otteoghalvfems.

Geschehen zu London am vierzehnten Mai neunzehnhundertachtundneunzig.

Έγινε στο Λονδίνο, στις δεκατέσσερις Μαΐου χίλια εννιακόσια ενενήντα οκτώ.

Done at London on the fourteenth day of May in the year one thousand nine hundred and ninety-eight.

Fait à Londres, le quatorze mai mil neuf cent quatre-vingt-dix-huit.

Fatto a Londra, addì quattordici maggio millenovecentonovantotto.

Gedaan te London, de veertiende mei negentienhonderd achtennegentig.

Feito em Londres, em catorze de Maio de mil novecentos e noventa e oito.

Tehty Lontoossa neljäntenätoista päivänä toukokuuta vuonna tuhatyhdeksänsataayhdeksänkymmentäkahdeksan.

Som skedde i London den fjortonde maj nittonhundranittioåtta.

Por la Comunidad Europea

For Det Europæiske Fællesskab

Für die Europäische Gemeinschaft

Για την Ευρωπαϊκή Κοινότητα

For the European Community

Pour la Communauté européenne

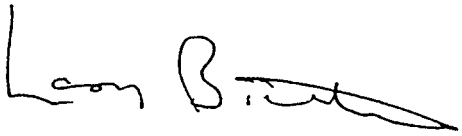
Per la Comunità europea

Voor de Europese Gemeenschap

Pela Comunidade Europeia

Euroopan yhteisön puolesta

På Europeiska gemenskapens vägnar



Por el Gobierno de Canadá

For Canadas regering

Für die Regierung Kanadas

Για την κυβέρνηση του Καναδά

For the Government of Canada

Pour le gouvernement du Canada

Per il governo del Canada

Voor de regering van Canada

Pelo Governo do Canadá

Kanadan hallituksen puolesta

På Kanadas regerings vägnar

SECTORAL ANNEX ON TELECOMMUNICATIONS TERMINAL EQUIPMENT, INFORMATION TECHNOLOGY EQUIPMENT AND RADIO TRANSMITTERS

1. PURPOSE

The purpose of this Annex is to establish a framework for the acceptance of test reports and, at the end of a transitional period, certificates of conformity issued in the territory of one Party in accordance with the regulatory requirements of the other Party, as referenced in Attachment 1.

This Annex constitutes a Sectoral Annex to the Framework Agreement on mutual recognition between Canada and the European Community.

2. SCOPE AND COVERAGE

2.1. The provisions of this Annex shall apply to the following types of telecommunications terminal equipment, radio transmitters and information technology equipment:

(a) equipment intended for connection to the public telecommunications network in order to send, process or receive information, whether the equipment is to be connected directly to the 'termination' of the network or to interwork with such a network, being connected directly or indirectly to the termination point. The system of connection may be wire, radio, optical or other electromagnetic means;

(b) equipment capable of being connected to a public telecommunications network even if it is not its intended purpose, including information technology equipment having a communication port;

(c) those categories of radio transmitters defined and specified in Attachment 2.

2.2. A list of the interfaces and services covered by each Party is referenced at Attachment 2.

2.3. Both Parties agree that the following is an illustrative but not exhaustive list of covered categories of radio transmitters:

— short range devices, including low power devices such as cordless telephones/microphones,

— land mobile, including:

  — private mobile radio (PMR/PAMR),

  — mobile telecom,

  — paging systems,

— terrestrial fixed,

— satellite mobile,

— satellite fixed,

— broadcast,

— radio determination.

3. THE APPROVAL REQUIREMENTS

3.1. This Annex shall apply to all mandatory approval requirements, adopted within the territories of the Parties, by government organisations and/or bodies which have the legal powers to enforce a technical requirement, for the equipment referenced in Attachment 2. The relevant technical requirements are specified under the legislation referenced in Attachment 1.

3.2. Any requirements and conformity assessment procedures applied to domestic products shall be applied with no additional requirements or variations to products or conformity assessment results originating from the other Party.

4. CONFORMITY ASSESSMENT ACTIVITIES

4.1. Both Parties affirm that their conformity assessment bodies, recognised under this Annex, are authorised to perform the following activities with regard to each other's technical requirements for telecommunications terminal equipment, radio transmitters and information technology equipment:

— for terminal attachment and radio transmission requirements — testing, issuing and acceptance of test reports, performance of required technical evaluation and certification of compliance with the requirements of the laws and regulations applicable in the territories of the Parties for products covered under this Annex,

— for electromagnetic compatibility (EMC) — the recognition of each other's certificates of compliance, suppliers' declaration and technical construction file, as required. The detailed provisions are described in the Sectoral Annex on ENC,

— for electrical safety/low voltage — the acceptance of testing and certification of the covered products to the electrical safety requirements of the other Party. The detailed provisions are described in the Sectoral Annex on electrical safety,

— for quality management — the recognition of one Party's quality management certificates in accordance with the regulatory requirements of the other Party.

4.2. Certificates of conformity delivered by the designated conformity assessment bodies of each Party under the provisions of this Annex will be recognised by the authorities of the other Party without any further assessment of the products.

5. INSTITUTIONS

5.1. **Designating authorities**

(a) Designating authorities are those authorities and organisations responsible for designating and assuring the competence of conformity assessment bodies to test and certify equipment covered by this Annex to the requirements of the other Party. The designating authorities for the purpose of this Annex are listed in Attachment 3. The designating authorities may seek the services of their accreditation system in carrying out these responsibilities.

(b) Each Party shall notify the other within ten (10) working days of changes in the identity of their designating authorities and their authority to carry out the obligations under this Annex.

5.2. **Designated conformity assessment bodies**

(a) For the purpose of this Annex, each Party will designate competent conformity assessment bodies to carry out conformity assessment to the requirements of the other Party. Each Party shall ensure that the designated bodies comply with the criteria and standards set out in the regulatory requirements of the other Party. In making designations, the Parties shall indicate the products and procedures for which they have been designated. A list of designated bodies, together with an indication of the products and procedures for which they have been designated, is included in Attachment 4.

(b) Conformity assessment bodies designated under this Annex shall be recognised as competent to perform the conformity assessment activities for which they have been designated.

(c) Designation, suspension or withdrawal of conformity assessment bodies under this Annex shall be in conformance with procedures determined by the Joint Committee established under the Framework Mutual Recognition Agreement.

(d) Where a complaint or any other circumstance arises concerning a conformity assessment body's ability to perform under this Annex, the appropriate designating authority must take action to the mutual satisfaction of the Parties. Where necessary, such problems may be considered by the Joint Committee established under the Framework Mutual Recognition Agreement in order to reach a solution.

6. TRANSITIONAL ARRANGEMENT

6.1. There will be a transitional period of 18 months before the provisions of this Annex, notably section 4, become fully operational.

6.2. This transitional period will be used by the Parties:

(a) to exchange information on and develop better understanding of their respective regulatory requirements;

(b) to develop mutually agreed mechanisms for exchanging information on changes in technical requirements or methods of designating conformity assessment bodies;

(c) to monitor and evaluate the work carried out by designated conformity assessment bodies operating during the transitional period.

6.3. During the transitional period the Parties will also reciprocally recognise test reports and related documents issued by designated conformity assessment bodies of the other party in accordance with the provisions of this Annex. To this end, the approving authorities listed in Attachment 5 shall accept test reports and related documents, and evaluations from the designated bodies in the territory of the other Party, for the purposes of approval, without imposing additional requirements, and shall ensure that:

— on receipt of test reports, related documents and a first evaluation of conformity, the dossiers are promptly examined for completeness,

— the applicant is informed in a precise and complete manner of any deficiency,

— an request for additional information is limited to omissions, inconsistencies or variances from the technical regulations or standards,

— procedures for equipment modified subsequent to a determination of compliance, are limited to procedures necessary to determine continued conformance,

— requirements and conformity assessment procedures applied to domestic products shall be applied with no additional requirements or variations to products or test results originating from the other Party.

6.4. Each approving authority commits itself to issuing approvals or advising the applicant no later than six (6) weeks from receipt of the test report and evaluation from a designated body in the territory of the other Party.

6.5. At the end of the transitional period the Parties will proceed to full mutual recognition of certificates of compliance issued by designated bodies in the other Party. Any proposal made during or at the end of the transitional period to limit the scope of recognition of any designated conformity assessment body or to exclude it from the list of bodies designated under this Annex shall be based on objective criteria and documented. Any such body may apply for reconsideration once the necessary corrective action has been taken. To the extent possible, the Parties will implement such action prior to the expiry of the transitional period.

7. ADDITIONAL PROVISIONS

Subcontracting

7.1. Any subcontracting shall be in accordance with the subcontracting requirements of the other Party.

7.2. The conformity assessment bodies shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting. These details will be available to the other Party on request.

Post-market surveillance

7.3. For the purpose of post-market surveillance, the Parties may maintain any existing labelling and numbering requirements. The assignment of the numbers may take place in the territory of the exporting Party. The numbers will be allocated by the importing Party.

7.4. When a report of misuse of a mark of conformity or of a hazard involving an approved product covered under this Annex has occurred, both Parties will jointly determine the scope of the misuse and the nature and degree of corrective action to be taken.

Joint Telecommunications Group

7.5. The Joint Committee established under the Framework Mutual Recognition Agreement may appoint a Joint Telecommunications Group which shall meet as required to discuss technical, conformity assessment and technology issues relating to this Annex.

Exchange of information and mutual assistance

7.6. Each Party shall establish a contact point to provide answers to all reasonable inquiries from the other Party regarding procedures, regulations and complaints.

7.7. As provided in the transitional arrangements set out in section 6.2 the Parties may jointly sponsor two seminars, one in Canada and one in the European Community, concerning the relevant technical and product approval requirements during the first year after the Annex enters into force.

7.8. The Parties shall also inform each other of changes to relevant regulations, specifications, test methods, standards and administrative procedures within thirty (30) working days of their domestic notification.

Regulatory changes and updating the Annex

7.9. In the event that there are changes to the regulations referenced in Attachment 1 or the introduction of new regulations affecting conformity assessment procedures taking place in either Party, the Parties will update this Annex.

Cross-referencing

7.10. Where products covered by this Annex are subject also to electrical safety or EMC requirements the relevant provisions of the Sectoral Annexes on electrical safety and EMC will also apply.

Attachment 1

Legislative, regulatory and administrative provisions

European Community	Canada
Directive 98/13/EC of the European Parliament and of the Council	Telecommunications Act
Council Directive 73/23/EEC as amended by Directive 93/68/EEC	Radiocommunication Act
Council Directive 89/336/EEC, as amended by Directives 92/31/EEC and 93/68/EEC	CRTC Telecom Decision No 82-14
European Commission Decisions established under Directive 98/13/EC	Certification Standard CS-03
EC Member States' legislations and regulations in respect of:	Certification Procedure CP-01
(a) non-harmonised analogue connection to the public switched telecommunications network	Radiocommunication Regulations
(b) non-harmonised radio transmitters (civilian application)	Radio Standards Procedure (RSP) No 100: radio equipment certification procedure
Handbook of the implementation of Directive 98/13/EC (ADLNB and ACTE approved)	Canadian Electrical Code
	Terminal equipment list (TEL)
	Radio equipment list (REL)
	Licence exempt radio apparatus standards list
	Broadcasting certificate exempt radio apparatus standards list
	Category I equipment standards list
	Category II equipment standards list

Attachment 2

Coverage

European Community	Canada
In specific terms, the following interfaces and services are included:	In specific terms, the following interfaces and services are included:
ISDN basic rate access	ISDN basic access
ISDN primary rate access	ISDN primary rate access
ISDN telephony	X.21 access
X21/V.24/V.35 access	X.25 access
X25 access	Digital service access:
PSTN non-voice	— 1,2 kbps
ONP leased line terminal types:	— 2,4 kbps
— 64 kbit/sec	— 9,6 kbps
— 2 048 kbit/s unstruktured	— 4,8 kbps
— 2 048 kbit/s structured	— 19,2 kbps
— 34 Mbit/s access	— 56,0 kbps
— 140 Mbit/s access	— 64,0 kbps
— 2 wire analogue	— 1 544,0 kbps
— 4 wire analogue	— 45 Mbps
	2 wire analogue tie trunks/ops
	4 wire analogue tie trunks/ops
Analogue connections to the public switched telecommunications networks	Analogue connections to the public switched telecommunications networks
All harmonised and non-harmonised radio transmitters, with the exception of:	All radio transmitters subject to radiocommunication regulations (see Appendix 1) with the exception of:
— a medical device within the meaning of Article 1 of Council Directive 93/42/EEC of 14 June 1993	— medical devices and active implantable medical devices including all radio transmitters in connection with the medical service including instruments, telemetry radio links and other radio equipment primarily used in hospitals and health care facilities
— an active implantable medical device within the meaning of Article 1 of Council Directive 90/385/EEC of 20 June 1990	— spark ignition systems of vehicles including all radio transmitters in connection with the spark ignition systems of vehicles
— a component or separate technical unit of a vehicle within the meaning of Council Directive 72/245/EEC of 20 June 1972 or Council Directive 92/61/EEC of 30 June 1992	— radio equipment used by radio amateurs within Article 1, definition 53, of the ITU Radio Regulations unless the equipment is available commercially
— radio equipment used by radio amateurs within Article 1, definition 53, of the ITU Radio Regulations unless the equipment is available commercially	— maritime equipment including all radio transmitters in connection with the maritime service, either ship-borne or shore installations
— equipment within the scope of Directive 96/98/EC (the Marine Directive)	— cable and wiring
— cable and wiring	— receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting services
— receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting services	

European Community	Canada
— products, appliances and components within the meaning of Article 2 of Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation — air-traffic-management equipment and systems within the meaning of Article 1 of Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic management equipment and systems — apparatus exclusively used for activities concerning public security, defence, State security (including the economic well-being of the State when the activities relate to State security matters) and the activities of the State in areas of criminal law	— aeronautical equipment including all radio transmitters in connection with the aeronautical (civil) service either air-borne or terrestrial installations, for the purpose of aircraft navigation, air-traffic control, air safety and radio communication for the air-traffic service (i.e. this does not include commercial telephone service to and from aircraft) — apparatus exclusively used for activities concerning public security, defence, State security (including the economic well-being of the State when the activities relate to State security matters) and the activities of the State in areas of criminal law
A radio transmitter is defined as being any radio frequency device or combination of devices intended for, or capable of being used for any transmission or emission of signs, signals, writing, images, sounds or intelligence of any nature by means of electromagnetic waves of frequencies lower than 3 000 GHz propagated in space without artificial guide. For the purpose of this Annex no radiotransmitters using frequencies lower than 9 Khz are covered	A radio transmitter is defined as being any radio frequency device or combination of devices intended for, or capable of being used for any transmission or emission of signs, signals, writing, images, sounds or intelligence of any nature by means of electromagnetic waves of frequencies lower than 3 000 GHz propagated in space without artificial guide. For the purpose of this Annex no radiotransmitters using frequencies lower than 9 Khz are covered

Attachment 3

Designating authorities

European Community and Member States	Canada
— *Belgium* Institut belge des services postaux et des télécommunications Belgisch instituut voor postdiensten en telecommunicatie — *Denmark* Telestyrelsen — *Germany* Bundesministerium für Wirtschaft — *Greece* Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications — *Spain* Ministerio de Fomento — *France* Ministère de l'économie, des finances et de l'industrie — *Ireland* Department of Transport, Energy and Communications — *Italy* Ispettorato Generale TLC — *Luxembourg* Administration des Postes et Télécommunications — *Netherlands* De Minister van Verkeer en Waterstaat — *Austria* Bundesministerium für Wissenschaft und Verkehr — *Portugal* Instituto das Communicações de Portugal — *Finland* Liikenneministeriö/Trafikministeriet Telehallintokeskus/Teleförvaltringscentralen — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Department of Trade and Industry	Industry Canada for terminal attachment, radio transmitters and EMC Standards Council of Canada for electrical safety Standards Council of Canada for quality management systems registrars

Attachment 4

Designated conformity assessment bodies

(This should give name, address, telephone and fax number, contact point, products, standards and conformity assessment procedures for which designation has been made, by reference to the legislative requirements of the other Party.)

———

Attachment 5

Approval authorities

European Community and Member States	Canada
(To be determined)	Industry Canada

Appendix 1

RADIO TRANSMITTERS STANDARDS LIST UNDER RADIOCOMMUNICATION REGULATIONS

Interference-causing equipment standards

Specification	Title	Issue	Date
ICES 001	Industrial, scientific and medical radio frequency generators	2	13.8.1994
ICES 003	Digital apparatus	3	22.11.1997
ICES 004	Alternating current high voltage power systems	1	6.1991

Radio standards specifications

Specification	Title	Issue	Date
RSS 118	Land and subscriber stations: voice, data and tone modulated, angle modulation radiotelephone transmitters and receivers operating in the cellular mobile bands 824 to 849 MHz and 869 to 894 MHz	2 Note 1	19.8.1990
Addendum to 118		1	1.9.1990
Annex A to 118	Cellular system mobile station — land station compatibility standard		22.10.1983
Supplement 1993-1	Supplement 1993-1 to radio standards specifications (RSS) 118		12.6.1993
RSS 118 mod.	Amendment 2 to RSS 118		24.8.1996
RSS 119	Land mobile and fixed radio transmitters and receivers, 27,41 to 960 MHz	5	24.8.1996
RSS 123	Low power licensed radiocommunication devices	1 Provisional	24.2.1996
RSS 125	Land mobile and fixed radio transmitters and receivers, 1,705 to 50,0 MHz, primarily amplitude modulated	2	24.8.1996
RSS 128	800 MHz dual-mode cellular telephones	1 Provisional	12.6.1993
RSS 128 mod.	Amendments to RSS 128		24.8.1996
RSS 129	800 MHz dual-mode CDMA cellular telephones	1 Provisional	24.2.1996

Specification	Title	Issue	Date
RSS 129 mod.	Amendments to RSS 129		24.8.1996
RSS 130	Digital cordless telephones in the band 944 to 948,5 MHz	2	23.1.1993
Annex 1 to RSS 130	CT2Plus class 2: specification for the Canadian common air interface for digital cordless telephony, including public access services	2	23.1.1993
Attachment 1 to RSS 130	European Telecommunications Standards Institute interim standard /I-ETS 300 131		4.1992
RSS 131	Radio signal enhancers for the mobile telephone service	1 Provisional	24.2.1996
RSS 133	2 Ghz personal communications services	1 Provisional	29.11.1997
RSS 134	900 MHz narrowband personal communications service	1 Provisional	24.8.1996
RSS 135	Digital scanner receivers	1 Provisional	26.10.1996
RSS 136	Land and mobile stations radiotelephone transmitters and receivers operating in the 26,960 to 27,410 MHz general radio service	5	1.1.1977
RSS 137	Location and monitoring services (902 to 928 MHz)	1 Provisional	29.11.1997
RSS 210	Low power licence-exempt radiocommunication devices	2	24.2.1996

Note 1: Supplement 1993-1 issued 12 June 1993 applies to RSS 118.

Additional radio standards specifications may be found in the broadcasting regulatory section of the index.

Broadcast equipment technical standards

Specification	Title	Issue	Date
BETS-1	Technical standards and requirements for low power announce transmitters in the frequency bands 525 to 1,705 kHz and 88 to 107,5 MHz	1	1.11.1996
BETS-3	Technical standards and requirements for radio apparatus that form part of a master antenna television (MATV) broadcasting	1	1.11.1996
BETS-4	Technical standards and requirements for television broadcasting transmitters	1	1.11.1996
BETS-5	Technical standards and requirements for AM broadcasting transmitters	1	1.11.1996
BETS-6	Technical standards and requirements for FM broadcasting transmitters	1	1.11.1996
BETS-8	Technical standards and requirements for FM transmitters operating in small remote communities	1	1.11.1996
BETS-9	Technical standards and requirements for television transmitters operating in small remote communities	1	1.11.1996
BETS-10	Technical standards and requirements for television transmitters in the 2,596 to 2,686 MHz band	1	1.11.1996
BETS-11	Technical requirements respecting the identifications of broadcasting stations	1	1.11.1996

Broadcast specifications and standards

Specification	Title	Issue	Date
BTS 1-1	Broadcast transmission standard AM broadcasting stereophonic operation	1 Provisional	6.2.1988
BTS 1-2	Broadcast transmission standard: AM broadcasting RF emission limits	1 Provisional	11.1989
BTS 3	Broadcasting transmission standard: television broadcasting	2	5.1990
BS 14	Broadcast specification: television broadcast videotext	1 Provisional	19.6.1981

SECTORAL ANNEX ON ELECTROMAGNETIC COMPATIBILITY (EMC)

1. SCOPE AND COVERAGE

1.1. The provisions of this Annex shall apply to the following:

— electromagnetic compatibility of equipment as defined in Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto,

— electromagnetic compatibility of equipment regulated under sections of the Canadian Radiocommunications Act.

2. THE REQUIREMENTS

2.1. The relevant technical requirements are specified under the legislation and regulations referenced in Attachment 1.

2.2. Any requirements and conformity assessment procedures applied by one Party to its domestic products shall be applied with no additional requirements or variations to products or conformity assessment results originating from the other Party.

3. CONFORMITY ASSESSMENT ACTIVITIES

3.1. Each Party agrees to recognise all of the other Party's reports, certificates, and technical construction files, as required, under their respective legislation without any further assessment of the products.

3.2. Both Parties agree to recognise each other's suppliers declarations of compliance, as required under their respective legislation.

4. INSTITUTIONS

4.1. **Designating authorities**

(a) The designating authorities for the purpose of this Annex are listed in Attachment 2.

(b) Each Party shall notify the other within ten (10) working days of changes in the identity of their designating authorities and their authority to carry out the obligations under this Annex.

4.2. **Designated conformity assessment bodies**

(a) Conformity assessment bodies designated under this Annex shall be recognised as competent to perform the conformity assessment activities for EMC. Each Party shall ensure that the designated bodies comply with the criteria and standards set out in the regulatory requirements of the other Party. A list of designated bodies is included in Attachment 3.

(b) Designation, suspension or withdrawal of conformity assessment bodies under this Annex shall be in conformance with procedures determined by the Joint Committee established under the Framework Mutual Recognition Agreement.

5. TRANSITIONAL ARRANGEMENT

5.1. The mutual recognition provisions of this Annex, notably section 3, will take effect 18 months following the entry into force of this Annex.

5.2. During the period between the signing of the Agreement and its coming into effect, the Parties will work together to:

1. enhance their respective familiarity with each other's regulatory requirements;

2. exchange information and review the work carried out by designated conformity assessment bodies; and

3. demonstrate to each other's satisfaction their capability to carry out conformity assessment to the requirements of the other Party.

6. ADDITIONAL PROVISIONS

Subcontracting

6.1. Any subcontracting of conformity assessment shall be in accordance with the subcontracting requirements of the other Party.

6.2. The conformity assessment bodies shall record and retain details of its investigation into the competence and compliance of its subcontractors and maintain a register of all subcontracting. These details will be available promptly to the other Party on request.

Post-market surveillance

6.3. For the purpose of post-market surveillance, the Parties may establish labelling, numbering or marking requirements. The assignment of numbers or affixing of labels or marks may take place in the territory of the exporting party.

Exchange of information and mutual assistance

6.4. Each Party shall establish a contact point to provide answers to all reasonable inquiries from the other Party regarding procedures, regulations and complaints.

6.5. The Parties shall also inform each other of changes to relevant regulations, specifications, test methods, standards and administrative procedures within thirty (30) working days of their domestic notification.

Regulatory changes and updating the Annex

6.6. In the event that there are changes to the technical regulations and conformity assessment procedures referenced in Attachment 1 or in the event of the introduction of new regulations in the jurisdiction of either Party, the Parties will update this Annex.

Cross-referencing

6.7. Where products covered by this Annex are subject also to electrical safety or radio or telecommunication attachment requirements the relevant provisions of the Sectoral Annexes on electrical safety, telecommunication terminal equipment, information technology equipment and radio transmitters will also apply.

Attachment 1

Legislative, regulatory and administrative provisions

European Community	Canada
Council Directive 89/336/EEC, as amended by Council Directive 92/31/EEC and Directive 98/13/EC of the European Parliament and of the Council	Radiocommunication Act Radiocommunication Regulations (Appendix I)
EC Member States' legislation and regulations in respect of EMC for non-harmonised radio transmitters (civilian application)	Category II equipment standards list

Attachment 2

Designating authorities

The designating authority for Canada is Industry Canada.

The designating authorities for the European Community are as follows:

— *Belgium*

Ministère des Affaires Économiques

Ministerie van Economische Zaken

— *Denmark*

— for telecommunication equipment:

Telestyrelsen

— for other equipment:

Danmarks Elektriske Materielkontrol (DEMKO)

— *Germany*

Bundesministerium für Wirtschaft

— *Greece*

Υπουργείο Μεταφορών και Επικοινωνιών

Ministry of Transport and Communications

— *Spain*

— for telecommunication equipment:

Ministerio de Fomento

— for other equipment:

Minsterio de Industria y Energía

— *France*

Ministère de l'économie, des finances et de l'industrie

— *Ireland*

Department of Transport, Energy and Communications

— *Italy*

Ministero dell'Industria, del Commercio e dell'Artigianato

— *Luxembourg*

Ministère des Transports

— *Netherlands*

De Minister van Verkeer en Waterstaat

— *Austria*

— for telecommunication equipment:

Bundesministerium für Wissenschaft und Verkehr

— for other equipment:

Bundesministerium für wirtschaftliche Angelegenheiten

— *Portugal*

Instituto das Comunicações de Portugal

— *Finland*

— for telecommunication equipment:

Liikenneministeriö/Trafikministeriet

— for other equipment:

Kauppa- ja teollisuusministeriö/Handels- och industriministeriet

— *Sweden*

Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontroll (SWEDAC)

— *United Kingdom*

Department of Trade and Industry

Attachment 3

Designated conformity assessment bodies

(This should give name, address, telephone and fax number, contact point, products, standards and conformity assessment procedures for which designation has been made, by reference to the legislative requirements of the other Party.)

Appendix 1

Interference-causing equipment standards

Specification	Title	Issue	Date
ICES 001	Industrial, scientific and medical radio frequency generators	2	13.8.1994
ICES 003	Digital apparatus	3	22.11.1997
ICES 004	Alternating current high voltage power systems	1	6.1991

SECTORAL ANNEX ON ELECTRICAL SAFETY

1. PURPOSE

1.1. The purpose of this Annex is to establish a framework for the acceptance of electrical products through the recognition of conformity assessment carried out by bodies which comply with the requirements of the other Party, while maintaining the integrity of the safety system in each of the Parties.

1.2. This Annex also sets out procedures for the recognition of:

(a) conformity assessment bodies (CABs) in Canada by the European Community (EC); and

(b) CABs in the EC by Canada.

2. SCOPE AND COVERAGE

2.1. For access to the EC: the safety of electrical equipment falling within the scope of the Low Voltage Directive (Council Directive 73/23/EEC of 19 February 1973 as amended by Directive 93/68/EEC) [1].

2.2. For access to Canada: low voltage electrical equipment, including medical devices, covered by the Canadian Electrical Code, except for those products specifically excluded under the Low Voltage Directive (other than medical devices).

2.3. The legislative, regulatory and administrative requirements applicable in each Party and the regulatory authorities responsible for electrical safety are listed in Attachment 1.

3. RESPONSIBLE/DESIGNATING AUTHORITIES

3.1. Authorities set out in Attachment 2 are those organisations/public authorities responsible for assuring the competence and the control of CABs to certify electrical equipment in their territories to the requirements of the other Party.

4. TRANSITION PHASE

4.1. The transitional arrangements shall operate for a term of eighteen (18) months from the time this MRA enters into force.

4.2. The purpose of the transition phase is to provide the responsible/designating authorities with an opportunity to build confidence and understanding of each other's procedures for recognising CABs and in the ability of those bodies to carry out their mandates. Successful completion of the transition phase should result in the determination by the responsible authorities that nominated CABs comply with the applicable criteria and are competent to conduct conformity assessment activities acceptable to the other Party.

4.3. During the transition phase, the authorities may jointly sponsor two seminars, one in Canada and one in the EC, concerning the relevant technical and product approval requirements.

5. OPERATION OF THE TRANSITION PHASE

5.1. During the transition phase, Canadian CABs shall accept test reports and related documents issued by nominated CABs in the other territory. For Community CABs, they must satisfy the following requirements:

[1] The categories of equipment and phenomena outside the scope of the Directive are: electrical equipment for use in an explosive atmosphere; electrical equipment for radiology and medical purposes; electrical parts for goods and passenger lifts; electricity meters; plugs and socket outlets for domestic use; electric fence controllers; radio-electrical interference; specialised electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which Member States participate.

(a) be a participant in the International Electrotechnical Commission (IEC) scheme of the IECEE for recognition of results of testing to standards for safety of electrical equipment (certification bodies (CB) scheme) under the IEC system for conformity testing to standards for safety of electrical equipment (IECEE) as defined in IECEE Document 02/1992-05; or

(b) have a contractual arrangement for acceptance of test data with a certification organisation accredited by the Standards Council of Canada.

5.2. During the transition phase, Community CABs will:

(a) test products to Canadian requirements;

(b) issue a comprehensive testing and evaluation file (i.e. assessment data, reports) for submission by the manufacturer of the tested products to a certification organisation in Canada.

5.3. Canadian certification organisations shall ensure that:

(a) they inform the applicant and the Community CAB in a precise and complete manner of any deficiency;

(b) they limit any request for additional information or samples to omissions, inconsistencies or variances from the technical regulations or standards; and

(c) certification is done on the basis of existing procedures, including the application of their mark.

6. MARKING OF CONFORMITY

6.1. During the transition phase, the Joint Committee shall develop mutually acceptable mechanisms and procedures for marking of products to be exported to Canada in order to indicate their conformity with Canadian requirements. Such markings shall be under the control of CABs recognised by the responsible/designating authorities, provide for traceability, give sufficient information to consumers, and not give rise to confusion with other markings of conformity. For access to the EC market, the CE marking shall apply.

7. OPERATIONAL PHASE

7.1. During the operational phase, the Parties will proceed to full mutual recognition of results of conformity assessment activities, as required under their respective legislation. CABs recognised by the responsible designating authorities shall operate as follows:

(a) for access to the EC market:

if a product is challenged under the Low Voltage Directive, a report drawn up by a Canadian CAB recognised under this agreement shall be considered by the EC as if it were a report drawn up by a European notified body;

(b) for access to the Canadian market:

CABs from the EC will be accredited in accordance with Standards Council of Canada (SCC) criteria for accreditation of certification bodies recognised in Canada and will be issued a certificate of accreditation. The following conditions are deemed to be equivalent to those prescribed criteria:

(i) evidence of satisfactory performance in the transition phase; and

(ii) accreditation by a European accreditation organisation according to applicable and relevant ISO/IEC guides adapted to Canadian and European conditions for accreditation of certification organisations; and

(iii) evidence of procedures for follow-up of certification activities including the identification of a contact point responsible for initiating action with manufacturers of the products when necessary.

7.2. The Parties will encourage the establishment of mutual recognition agreements between the European accreditation organisations and the SCC.

7.3. Following the entry into force of the operational phase, the inclusion of additional CABs will be done in accordance with the rules set out in the Framework Agreement and in this Annex.

8. LIMITED SCOPE OR DENIAL OF RECOGNITION FOR THE PURPOSES OF CERTIFICATION

8.1. Upon request, a CAB may be required to provide additional documentary evidence to facilitate its passage from the transitional to the operational phase.

8.2. In the event that a proposal is made during, or at the end of the transition phase, requesting a responsible/designating authority to limit the scope of recognition of any designated CAB or to exclude it from the list of bodies accredited/designated, in accordance with the procedures outlined in the Framework Agreement, such a proposal shall be based on objective reasons and shall be properly documented in writing to the Joint Committee.

8.3. A CAB which has been granted limited recognition or has been denied recognition, may apply for re-evaluation after corrective action has been taken.

9. FOLLOW UP OF CERTIFICATION ACTIVITIES

9.1. The authorities in each Party (see Attachments 1 and 2) retain the right to question the performance of CABs operating in the context of this Annex. (Upon reasoned request, the authorities in one Party may request a copy of the certification report prepared to its requirements in the territory of the exporting Party. This report shall be provided promptly and without charge.)

9.2. CABs shall have in place a plan of action with their certification clients, for enabling the withdrawal of non-conforming or hazardous products from the market place. That plan shall identify a contact point responsible for initiating action with manufacturers of the products in question.

10. JOINT ELECTRICAL SAFETY GROUP

10.1. The Joint Committee established under the Mutual Recognition Agreement shall appoint a Joint Electrical Safety Group (JESG).

10.2. The Group (JESG) shall consist of an equal number of representatives from Canada and the EC.

10.3. The Group may review issues of concern to either Party and no one shall refuse a request by the other to address such issues.

10.4. The Group may issue recommendations to the Joint Committee regarding concerns raised by the representatives of either Canada or the EC.

10.5. The Group shall establish its own rules of procedures, and take its decisions and adopt its recommendations by consensus of the Parties.

Attachment 1

Legislative, regulatory and administrative requirements and regulatory authorities

(*re* Articles 2(3) and 9(1))

European Comunity	Canada
Council Directive 73/23/EEC as amended by Directive 98/13/EC of the European Parliament and of the Council EC regulatory authorities: list is the same as per Attachment 2, except for Sweden which has the following regulatory authority: Elsäkerhetsverket (National electrical safety board)	The Canadian Electrical Code as referenced in the provincial/territorial legislation is under the responsibility of the following provincial/territorial regulatory authorities: — *Alberta* The Safety Codes Act, Statutes of Alberta, 1991, Chapter S-0.5; Alberta Department of Labour, Technical and Safety Services — *British Columbia* Electrical Safety Act, Chapter 109 Electrical Safety Regulation, B.C. Reg 253/96 Ministry of Municipal Affairs & Housing — *Manitoba* The Manitoba Hydro Act, 1976 Provincial Regulations 126-94 amended in September 1995 Manitoba Hydro — *New Brunswick* The Electrical Installation and Inspection Act 84-165 The General Regulation 82-215 The Lighting Protection Regulation Department of Advanced Education and Labour — *Newfoundland* Public Safety Act Electrical Regulations, 1996 Department of Government Services and Lands — *Northwest Territories* Electrical Protection Act, R.S.N.W.T 1988, C.E-3 Department of Public Works and Services — *Nova Scotia* The Electrical Installation and Inspection Act Nova Scotia Department of Labour — *Ontario* The Power Corporation Act, Revised Statutes of Ontario, 1990, Chapter P18, Section III Ontario Regulation 612-94 Ontario Hydro — *Prince Edward Island* The Electrical Inspection Act The Electrical Inspection Act Regulations Department of Community Affairs and Attorney General

European Comunity	Canada
	— *Quebec* Loi sur les installations électriques, L.R.Q., Chapter I-13.01 Règlement sur les installations électriques, I-13.01, R.3 Code de l'électricité du Québec Régie du bâtiment du Québec — *Saskatchewan* The Electrical Inspection Act, 1993 Electrical Inspection Regulations SaskPower — *Yukon* The Electrical Protection Act OIC 1992-017 Electrical Protection Act Yukon Regulations Yukon Department of Community and Transportation Services

Attachment 2

Designating authorities

The authorities responsible for the designation of conformity assessment bodies under this Agreement are:

(a) for the European Community:

— *Belgium*

Ministère des Affaires Économiques

Ministerie van Economische Zaken

— *Denmark*

Boligministeriet

— *Germany*

Bundesministerium für Arbeit und Sozialordnung

— *Greece*

Υπουργείο Ανάπτυξης

Ministry of Development

— *Spain*

Ministerio de Industria y Energía

— *France*

Ministère de l'économie, des finances et de l'industrie

— *Ireland*

Department of Enterprise and Employment

— *Italy*

Ministero dell'Industria, del Commercio e dell'Artigianato

— *Luxembourg*

Ministère des Transports

— *Netherlands*

Staat der Nederlanden

— *Austria*

Bundesministerium für wirtschaftliche Angelegenheiten

— *Portugal*

Under the authority of the Government of Portugal: Instituto Português da Qualidade

— *Finland*

Kauppa- ja teollisuusministeriö/Handels- och industriministeriet

— *Sweden*

Under the authority of the Government of Sweden:

Styrelsen för ackreditering och teknisk kontroll (SWEDAC)

— *United Kingdom*

Department of Trade and Industry

(b) for Canada:

— The Standards Council of Canada, a Federal Crown corporation established by an Act of Parliament in 1970, amended in 1996.

SECTORAL ANNEX ON RECREATIONAL CRAFT

SECTION I

Scope and coverage

1.1. This Annex applies to all recreational craft, including personal watercraft, which in the European Community or in Canada are subject to a conformity assessment or approval procedure by an independent conformity assessment or approval body.

1.2. The product coverage shall be as determined by the relevant legislation of each party, which is:

(a) for the European Community:

recreational craft as defined in Article 1 of Directive 94/25/EC;

(b) for Canada:

pleasure craft as defined by the Canada Shipping Act, Chapter 1487, Small Vessel Regulations as referenced in Transport Canada's Publication No TP1332.

1.3. Parties agree that mutual recognition will operate under this Annex according to the following arrangements:

(a) for evaluation against European Community requirements, conformity assessment bodies designated by Canada will establish certificates of compliance according to the provisions of Directive 94/25/EC. These certificates will be recognised in the European Community without any further assessment of the products to which they relate;

(b) for approval according to Canadian requirements, conformity assessment bodies designated by the European Community will certify the product according to the requirements set out in Chapter 1487 of the Canada Shipping Act Small Vessel Regulations, and issue the appropriate compliance plates and other required documentation. Products so certified may be placed on the Canadian market without undergoing any further approval procedures.

SECTION II

Legislative, regulatory and administrative requirements

2.1. For the European Community:

Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft.

2.2. For Canada:

Regulatory requirements — The Canada Shipping Act, Chapter 1487, Small Vessel Regulations referenced in Transport Canada's Publication No TP1332

Construction standards for small vessels which includes personal watercraft as defined by and certified to ISO/DIS 13590.

SECTION III

Authorities responsible for designating the conformity assessment bodies as specified by conformity assessment modules

3.1. For the European Community:

Member States administrations or entities as indicated in Attachment 1.

3.2. For Canada:

Canadian coastguard.

SECTION IV

Procedures for designating conformity bodies

4.1. For the purpose of the Annex, each Party will designate competent conformity assessment bodies to carry out conformity assessment and approvals to the requirements of the other Party. Such designation will be carried out according to the procedures set out in the Mutual Recognition Framework Agreement. A list of designated conformity assessment bodies, together with the products and procedures for which they have been designated, is in Attachment 2.

4.2. Each Party will accept that the designated conformity assessment bodies comply with the requirements for such bodies established by the other Party.

These are:

(a) for the European Community, bodies which are notified bodies in accordance with Directive 94/25/EC are deemed to be in compliance with Canadian requirements.

A 'notified body' for the EC is a third party authorised to perform the conformity assessment tasks specified in Directive 94/25/EC, which has been appointed by a Member State from the bodies falling within its jurisdiction. The notified body has the necessary qualifications to meet the requirements laid down in Directive 94/25/EC and has been notified to the Commission and to the other Member States;

(b) for Canada, the procedures and criteria for designation of conformity assessment bodies shall comply with the relevant provisions of Directive 94/25/EC.

SECTION V

Transitional arrangement

There will be a transitional arrangement of 18 months prior to the operation of this Annex. During this transitional period, the Parties will:

(a) exchange information on, and develop greater familiarity with, their respective regulatory requirements; and

(b) carry out the policy, legislative and regulatory changes necessary for the provisions of this Annex.

SECTION VI

Additional provisions

6.1. In accordance with the relevant provisions of the Mutual Recognition Framework Agreement, the Parties shall ensure the continued availability of the names of their respective notified bodies or conformity assessment bodies, and will regularly supply details of certifications issued in order to facilitate post-market surveillance.

6.2. The Parties note that, to the extent that requirements for electrical safety or electromagnetic compatibility apply to products covered by this Sectoral Annex, the provisions of the Sectoral Annexes on electrical equipment and electromagnetic compatibility shall apply.

Attachment 1

Designating authorities

For the European Community	For Canada
— *Belgium* Ministère des communications et de l'infrastructure Ministerie van Verkeer en Infrastructuur — *Germany* Bundesministerium für Wirtschaft — *Spain* Ministerio de Fomento — *France* Ministère de l'équipment, des transports et du logement Ministère de l'économie, des finances et de l'industrie — *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato — *Netherlands* De Minister van Verkeer en Waterstaat — *Finland* Liikenneministeriö/Trafikministeriet — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Department of Trade and Industry	The Canadian coastguard

Attachment 2

Designated conformity assessment bodies

— European Community:

notified bodies which have been notified by the Member States of the European Community, and whose names and reference numbers have been published in the *Official Journal of the European Communities*.

— Canada:

to be determined.

SECTORAL ANNEX ON GOOD MANUFACTURING PRACTICES (GMP)

1. PURPOSE

1.1. This Mutual Recognition Agreement (MRA) Sectoral Annex on good manufacturing practices (GMP) compliance certification pertaining to medicinal products/drugs has been developed by the European Community (EC) and Canada to:

(a) enhance bilateral regulatory cooperation;

(b) establish mutual recognition for GMP compliance certification and acceptance of manufacturing authorisations/licences directly issued by the authorities designated equivalent after the successful completion of a confidence building exercise;

(c) develop an infrastructure for on-going communications/consultations between Canada, the European Commission, and the regulatory authorities of the EC Member States to enable regulators to determine and maintain the equivalency of their GMP compliance programmes.

2. GENERAL CONSIDERATIONS

2.1. The underlying premise behind a MRA for GMP compliance certification is that it can be demonstrated that Canada and the EC Member States have equivalent GMP compliance programmes, and therefore the issuance of a certificate of manufacturing authorisation/licence by an authority of one Party certifying that a facility is in compliance with GMPs, would be all the evidence required by the other Party to accept that facility as being in compliance for the manufacturing/control of medicinal/drug products or to issue a similar certificate of manufacturing authorisation/licence. It should be understood that equivalent does not mean identical but it does mean leading to the same result.

2.2. The acceptance by an authority of a certificate of manufacturing authorisation/licence issued by the other authority will depend on the successful completion of a confidence building exercise and on an evaluation of its results. Only certification by authorities with GMP compliance programmes (including the supporting infrastructure of regulatory requirements, standards, processes, and quality systems, etc.) mutually recognised as equivalent will be accepted.

2.3. The MRA on medicinal products/drug GMP is built on three pillars:

(a) the concept of a GMP compliance programme (Appendix 4);

(b) a 'two-way' alert system (Appendix 5);

(c) a transition period including a confidence building exercise (Appendix 6).

3. SCOPE AND COVERAGE

3.1. The provisions of this Annex will cover all medicinal products/drugs which have undergone one or a series of manufacturing process(es) (e.g. fabrication, repackaging, labelling, testing, wholesaling activities) in Canada and in the European Community, and to which good manufacturing practice (GMP) requirements apply in both jurisdictions. Recognition will be limited to the manufacturing process(es) carried out and subject to inspections in the respective territories of the Parties.

3.2. This Annex may also apply, on a voluntary basis, to products covered by the legislation of one Party but not the other if agreed to by the authorities concerned.

3.3. The product coverage shall be as determined by the relevant legislation of each Party. Appendix 1 names the legislations and contains an indicative list of products concerned.

3.4. For the purpose of this Annex, GMP includes the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorisation (MA)/drug identification number (DIN) or licence holder or applicant and ensures the product is made in compliance with the specifications (equivalent to qualified person certification in the EC).

Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards:

— appropriate to their intended use, and

— required by the marketing authorisation or product specifications and by assignment procedure of the drug identification number or the licence.

3.5. Product or process oriented inspections will be carried out by one Party at the request of the other Party. For pre-approval inspections, the Parties agree to exchange pre-approval inspection reports to the extent required under the importing Party's laws and regulations, for the purpose of their respective product approval procedures. Lot-to-lot release for biologicals is excluded from this Agreement.

4. CONFIDENTIALITY

4.1. Each Party will protect from public disclosure any non-public confidential technical, commercial and scientific information, including trade secrets and proprietary information that is provided by the other Party.

4.2. Each Party reserves the right to make public the results of any conformity assessment, including the conclusions of inspection reports, provided by the other Party, in situations in which public health safety may be affected.

5. MANAGEMENT MECHANISMS

5.1. A joint sectoral group will be established for the purposes of the management of this Sectoral Agreement. The joint sectoral group will establish its composition and determine its own rules and procedures. Its role is described in Appendix 3. The group will include representatives of the therapeutic products programme in Health Canada, of the European Commission, and of the relevant EC authorities. It will be co-chaired by a member of each of the two Parties.

6. RESOLUTION OF DIVERGENT VIEWS

6.1. Divergent views which have not been resolved between the authorities will be referred to the joint sectoral group for resolution. In the case of inability of the joint sectoral group to resolve these divergent views, either Party may bring the matter to the attention of the Joint Committee.

7. TRANSITION PERIOD

7.1. **Time frame**

The confidence building period will commence upon the signing of the MRA and is expected to be completed within 18 months.

7.2. **Confidence building programme**

At the beginning of the transitional period, the joint sectoral group will elaborate a joint confidence building programme. The implementation of this programme will permit the determination of the capability of each Party's authority to perform GMP compliance certification (guidance provided in Appendix 6).

7.3. **Budget**

Each of the Parties to the MRA will be responsible for the costs of its participation in the confidence building activities.

7.4. **Administrative provision**

Medicinal products/drugs from manufacturing sites with a good track record of compliance in the importing Party, and that have been placed on a list of qualified sites, will be exempted from retesting requirements. The list will be developed by the joint sectoral group.

7.5. **End of transitional period**

7.5.1. At the end of the transitional period, the joint sectoral group will proceed to a joint evaluation of the equivalency and capabilities of the compliance programmes of the participating authorities (Appendix 2).

7.5.2. Those determined as not being equivalent to the other Party's GMP compliance programme will not be listed in Appendix 2 at the end of the transitional period. Proposals to limit the recognition of the equivalence of an authority or exclude it from the Appendix should be based on objective criteria and documented evidence.

7.5.3. Authorities may be placed in Appendix 2 for specific categories of manufacturing processes (e.g. biologicals, radiopharmaceuticals). Excluded authorities (or not included for a given manufacturing process) may apply for re-consideration of their status once the necessary corrective measures have been taken.

8. OPERATIONAL PHASE

8.1. **General provisions**

8.1.1. The European Community and Canada agree that, for medicinal products/drugs covered by this Annex, each Party will recognise the conclusions of the GMP compliance programme carried out by the other Party in its territory, and the relevant certificates of manufacturing authorisations/licences granted by the deemed equivalent authorities of the other Party listed in Appendix 2. In addition, the certification by the manufacturer on the conformity of each batch will be recognised by the other Party without re-control at import.

8.1.2. Manufacturers located in Canada or a Member State of the European Community whose relevant authority is not listed in Appendix 2 or is not included for the relevant category manufacturing processes may ask that an inspection be carried out by any of the authorities listed in Appendix 2. The batch and the compliance certificates issued according to this procedure will be recognised by the other Party provided that equivalent enforcement procedures against that facility can be subsequently ensured in case of non-compliance.

8.1.3. With respect to medicinal products/drugs covered by the pharmaceutical legislation of the importing Party but not the exporting one, the locally competent inspection service willing to carry out an inspection of the relevant manufacturing operations shall inspect against its own GMPs if relevant, or, in the absence of specific GMP requirements, against the applicable GMPs of the importing Party. This will also be the case when the locally applicable GMPs are not considered equivalent, in terms of quality assurance of the finished products, to the GMPs of the importing Party.

This provision may also apply to the manufacturer of active pharmaceutical ingredients, intermediate products, and products intended for use in clinical trials.

8.1.4. It will be the responsibility of the authorities covered by the Annex to ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, which could affect the protection of public health, is communicated to the other Party with the appropriate degree of urgency as defined in the 'two-way' alert programme.

Contact points will be agreed between both Parties to permit authorities and manufacturers to inform the authorities of the other Party with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

8.1.5. *Certification of manufacturers*

At the request of an exporter, an importer or of an authority of the other Party, the authorities responsible for granting certificates of manufacturing authorisations/licences and for the supervision of the manufacture of medicinal products/drugs will certify that the sites used for manufacture and/or control:

(a) are appropriately authorised to manufacture and/or control the relevant medicinal product/drug or to carry out the relevant specified operations,

(b) are regularly inspected by the authorities, and

(c) comply with the GMP requirements recognised as equivalent by the two Parties.

The certificates of manufacturing authorisation/licence will also identify the site(s) of manufacture. A Canadian and a European Community example of such certificates are attached at Appendix 7 for illustrative purposes.

Certificates of manufacturing authorisations/licences will be issued expeditiously, and the time taken should not exceed 30 days. In cases when a new inspection has to be carried out, this period may be extended to 60 days.

8.1.6. *Batch certification*

Each batch exported will be accompanied by a batch certificate issued by the manufacturer ('self certification') after a full qualitative and quantitative analysis of all active constituents to ensure that the quality of the products complies with the requirements of the marketing authorisation/product approval.

When issuing this certificate, the manufacturer will take into account the provisions of the current WHO certification scheme on the quality of medicinal products/drugs moving in international commerce. This certificate will attest that the batch meets the specifications and has been manufactured in accordance with the relevant marketing authorisation/product approval, detailing the specifications of the product, the analytical methods referenced, the analytical results obtained, and containing a statement that the batch processing and packaging records were reviewed and found in conformity with GMPs.

The batch certificate will be signed by the person responsible for releasing the batch for sale or supply. In the European Community the 'qualified person' is referred to in Article 21 of Directive 75/319/EEC, and in Canada, the nominated person responsible for manufacturing quality control is as specified in the Food and Drug Regulations, Division 2, Section C.02.014 (1).

8.1.7. *Fees*

The regime of inspection/establishment licence fees is determined by the location of the manufacturer. The cost recovery programmes and the fees pertaining to the issuance of manufacturing authorisations/licences in each jurisdiction will remain the responsibility of that jurisdiction.

The Parties shall endeavour to ensure that any fees imposed for services will be cost-oriented and take into account relevant cost factors. If no services are rendered by one Party, fees should not be charged.

8.1.8. Each Party reserves the right to conduct its own inspection for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party, which has the option of joining the inspection. Recourse to this safeguard clause should be an exception.

8.1.9. The decision to suspend or revoke a licence will rest with the issuing Party.

8.2. **Information sharing**

8.2.1. In accordance with the general provisions of the Annex, the Parties will exchange all information necessary to determine and maintain the equivalence of GMP compliance programmes. In addition, the relevant authorities in Canada and in the EC will keep each other informed of all new technical guidance, inspection procedures, or changes in regulation (these include: guidance documents, publications of references to standards, forms, documents relating to the application of legal requirements). Each Party will consult the other before adopting these changes to ensure the continued equivalency of the GMP compliance programmes. Concerns will be raised to the joint sectoral group.

8.2.2. Upon reasoned request, the relevant inspection service shall forward a copy of the last inspection report of the manufacturing or control site, in case analytical operations are contracted out. The request may concern a 'full inspection report' or a 'detailed report'. A 'full inspection report' comprises a site master file (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A 'detailed report' responds to specific queries about a firm by the other Party. Parties will ensure that such inspection reports are forwarded in no more than 30 days, this period being extended to 60 days should a new inspection be carried out.

8.3. **Two-way alert system**

8.3.1. The joint sectoral group will ensure that an efficient and effective 'two-way' alert system is in place at all times. Elements of such a system are described in Appendix 5.

8.3.2. It shall be the responsibility of the authorities covered by the Annex to ensure that any suspension or cancellation (total or partial) of certification of compliance is communicated to the other relevant authorities with the appropriate degree of urgency.

8.3.3. Each Party shall notify the other Party of any confirmed problem reports, corrective actions, or recalls related to products covered under the scope of this Annex. Each Party will respond to special requests for information and will ensure that authorities make available relevant information, as requested.

Contact points are identified in Appendix 5.

9. MONITORING OF THE AGREEMENT

9.1. The continuous monitoring of the GMP compliance programmes determined to be equivalent at the conclusion of the confidence building period and any subsequent decisions concerning that equivalence must be made according to a mutually developed and managed equivalence maintenance programme. This programme will be managed by the joint sectoral group.

9.2. The Parties undertake to hold regular consultations, under the auspices of the joint sectoral group set up under this Annex, to ensure the continued relevancy and accuracy of this Annex. Canada and Member State authorities may organise meetings to discuss specific questions and issues.

9.3. Authorities must participate in maintenance activities, as established under the joint sectoral group, in order to maintain their status as listed in Appendix 2.

10. APPENDICES

10.1. Appendices 1 and 2 constitute integral parts of this Annex.

10.2. Appendices 3, 4, 5, 6 and 7 are general guidelines.

Appendix 1

1. **List of applicable legislation**

1.1. For the European Community:

Directive 65/65/EEC as modified;

Directive 75/319/EEC as modified;

Directive 81/851/EEC as modified;

Directive 91/356/EEC as modified;

Directive 91/412/EEC as modified;

Regulation (EC) No 2309/93;

Directive 92/25/EEC;

Guide to good distribution practice (94/C 63/03);

Current version of the 'Guide to good manufacturing practice', Volume IV of Rules governing medicinal products in the European Community.

1.2. For Canada:

Food and Drugs Act and Regulations, Health of Animals Act and Regulations for the issuance of permits for materials of animal origin.

2. **Indicative list of products**

Recognising that precise definitions of medicinal products and drugs are to be found in the legislation referred to above, an indicative list of products covered by the Agreement is given below:

— human pharmaceuticals including prescription and non-prescription drugs, and medicinal gases,

— human biologicals including vaccines, stable medicinal products derived from human blood or human plasma, biotherapeutics, and immunologicals,

— human radiopharmaceuticals,

— veterinary pharmaceuticals, including prescription and non-prescription drugs, and pre-mixes for the preparation of veterinary medicated feeds,

— where appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products, and

— active pharmaceutical ingredients or bulk pharmaceuticals (NB: APIs are not GMP regulated).

Appendix 2

Authorities

For the European Community:

Belgium	Inspection générale de la pharmacie Algemene Farmaceutische Inspectie
Denmark	Laegemiddelstyrelsen
Germany	Bundesministerium für Gesundheit
Greece	Εθνικός Οργανισμός Φαρμάκου Ministry of Health and Welfare National Drug Organisation (EOF)
Spain	— for medicinal products for human use: Ministerio de Sanidad y Consumo Subdirección General de Control Farmacéutico — for medicinal products for veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA) Dirección General de la Producción Agraria
France	— for medicinal products for human use: Agence du Médicament — for veterinary medicinal products: Agence Nationale du Médicament Vétérinaire
Ireland	Irish Medicines Board
Italy	— for medicinal products for human use: Ministero della Sanità Dipartimento Farmaci e Farmacovigilanza — for medicinal products for veterinary use: Ministero della Sanità Dipartimento alimenti e nutrizione e sanità pubblica veterinaria — Div. IX
Luxembourg	Division de la Pharmacie et des Médicaments
Netherlands	De Minister van Volksgezondheid, Welzijn, en Sport Inspectie voor de Gezondheidszorg
Austria	Bundesministerium für Arbeit, Gesundheit und Soziales
Portugal	— for human and veterinary (non-immunologicals): Instituto da Farmácia e do Medicamento — INFARMED — for veterinary immunologicals: Direcção-Geral de Veterinaria
Finland	Lääkelaitos/Läkemedelsverket (national agency for medicines)
Sweden	Läkemedelsverket — medical products agency

United Kingdom	— for human and veterinary (non-immunological): Medicines Control Agency — for veterinary immunologicals: Veterinary Medicines Directorate
European Community	Commission of the European Communities European Agency for the Evaluation of Medicinal Products (EMEA)

For Canada:

Therapeutic products programme, Health Canada, Ottawa

Bureau of Veterinary Drugs, Food Directorate, Health Canada, Ottawa

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Appendix 3

Joint sectoral group

A joint sectoral group (JSG) will be established to manage the confidence building process and to monitor the operations of the MRA thereafter.

The JSG will be co-chaired by a member from each Party and will determine its own composition, ensuring, to as great a degree as possible, consistent membership. The role of the JSG will be to ensure communications with the Joint Committee and to manage the transition period and to monitor the continued implementation of this Annex including, but not limited to:

— making decisions on activities required to define and establish the equivalence of compliance programmes and the 'two-way' alert system,

— assessing the results of the confidence building exercise, and determining which regulatory authorities are deemed equivalent. The JSG will prepare a list of the equivalent regulatory agencies and provide its recommendations to the Joint Committee,

— providing directions to experts that will conduct the evaluation of the respective GMP compliances programmes, and undertake joint activities (e.g. inspections, workshops) and

— making decisions on the necessary arrangements of the MRA maintenance programme.

The JSG will meet as needed to adopt the confidence building working plan, resolve issues, and monitor the progress of the confidence building exercise. The Joint Committee will be kept informed of the agendas and conclusions of meetings as well as on the progress made during the transition period.

Appendix 4

Components of a GMP compliance programme

1. *Legislative and regulatory requirements and scope*

   — empowering legislation and regulations including authority to enforce laws and regulations, powers given to inspectors to conduct inspections, authority to remove violative products from the market, etc.,

   — suitable controls on conflict of interest.

2. *Regulatory directives and policies*

   — procedures for designating inspectors,

   — enforcement policies/guidelines/procedures (inspection, re-inspection, corrective action),

   — codes of conduct/ethics,

   — training/certification policies/guidelines,

   — alert/crisis management policies/procedures/guidelines,

   — organisational structure, including roles, responsibilities and reporting relationships.

3. *Good manufacturing practices (GMP) standards*

   — scope/detials of GMPs necessary for the control of the manufacturing of drug products,

   — process validation requirements.

4. *Inspection resources*

   — staffing — initial qualifications, certification of inspectors,

   — number of inspectors in relation to size of industry (in-house, contract, third party),

   — training/certification programmes/processes (e.g. frequency of training),

   — quality assurance mechanisms to ensure effectiveness of training programmes.

5. *Inspection procedures (pre-inspection, inspection, and post-inspection activities)*

   — inspection strategy (type, scope, scheduling, focus of inspection, notification of inspections, risk-based inspections),

   — pre-inspection preparation/requirements,

   — format and content of inspection reports (including support tools, e.g. hardware),

   — inspection methodology (access to and review of firm's files and databases, collection of evidence, data review, sample collection, interviews),

   — standard operating procedures (SOPs) for inspection,

   — post-inspection activities (procedures for report issuance, follow-up, decision making),

   — storage of inspection data.

6. *Inspection performance standards*

   — frequency/number of inspections, quality and timeliness of inspection reports, norms/frequency/ procedures for re-inspection and corrective action.

7. *Enforcement powers and procedures*

   — provision of written notices of violation to firms,

   — non-compliance management procedures/mechanisms (recall, suspension, quarantine of products, licence revocation, seizure, prosecution),

   — appeal mechanisms,

   — other measures to promote voluntary compliance by firms.

8. *Alert and crisis systems*

   — alert mechanisms,

   — crisis management mechanisms,

   — alert performance standards (appropriateness and timeliness of alert).

9. *Analytical capability*

   — access to laboratories with capacity to handle necessary analysis,

   — standard operating procedures (SOPs) for analytical support,

   — processes for validation of analytical methods.

10. *Surveillance programme/measures (used by firms and by regulatory authority)*

    — sampling and audit procedures,

    — recall monitoring (including effectiveness controls and verification of procedures),

    — consumer complaint system/procedures,

    — adverse reaction reporting system/procedures,

    — drug product defect reporting system/procedures.

11. *Quality management systems*

    — quality management/assurance system/procedures to ensure the ongoing suitability and effectiveness of policies, procedures, guidelines and systems used to achieve the objectives of the GMP compliance programme, including establishment of standards and annual audit and review.

Appendix 5

Components of a 'two-way' alert programme

1. *Documentation*
   - — definition of a crisis/emergency and under what circumstances an alert is required,
   - — standard operating procedures (SOPs),
   - — mechanism of health hazards evaluation and classification,
   - — language of communication and transmission of information.
2. *Crisis management system*
   - — crisis analysis and communication mechanisms,
   - — establishment of contact points,
   - — reporting mechanisms.
3. *Enforcement procedures*
   - — follow-up mechanisms,
   - — corrective action procedures.
4. *Quality assurance system*
   - — pharmacovigilance programme,
   - — surveillance/monitoring of implementation of corrective action.

Contact points

For the purpose of this agreement, the contact points for any technical question, such as exchange of inspection reports, inspectors training sessions, technical requirements, will be:

— for Canada,

the Director-General, Therapeutic Products Programme, Health Canada, 2nd Floor, Health Protection Building, AL: 0702A, Tunney's Pasture, Ottawa, Ontario, K1A OL2, Canada. Tel. (1-613) 947 03 69, fax (1-613) 952 77 56; and

— for the European Community,

the Director of the European Agency for the Evaluation of Medicinal Products, 7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom. Tel. (44-171) 418 84 00, fax 418 84 16.

Appendix 6

Phases of a confidence building period

The determination of the equivalency of the GMP compliance programmes by the joint sectoral group will be designed around the following three phases:

1. *Review and evaluation of documentation (exchange of documentation)*
   - legal instruments (regulations/legislation/directives)/guidelines on GMPs,
   - inspection programmes (scope, policies, directives, procedures),
   - crisis management systems (scope, criteria, policies, directives, procedures),
   - requirements for inspection reports,
   - analytical laboratory systems,
   - alert reports.
2. *Evaluation of processes and procedures*
   - audit of systems and procedures,
   - exchange/evaluation of reports,
   - monitoring of alert systems including handling of recalls,
   - joint inspections of manufacturers to determine equivalency of inspection methods,
   - exchange of inspectors or organisation of joint workshops (optional).
3. *Decision making on the success of the exercise and conclusions*
   - evaluation of results of the confidence building exercise,
   - action to take, development of options and solutions to address issues,
   - determination of competent agencies that meet evaluation criteria,
   - establishment of the conditions and mechanisms for on-going maintenance of the certification programme (develop quality management system, audit mechanism and a consultation/on-going dialogue process).

Appendix 7

Certificate of pharmaceutical manufacturer in the framework of the Agreement on mutual recognition between Canada and the European Community, Sectoral Annex on medicinal products GMP inspection and batch certification

As requested by the ..... (*)

on . . ./. . ./. . . (date) (reference: .....), the competent authority of ..... (**) confirms the following:

The company .....

whose legally registered address is: .....

has been authorised, under Directive 75/319/EEC (Article 16) and Directive 81/851/EEC (Article 24) transposed in the national legislation of ..... (**), under the authorisation reference number

covering the following site(s) of manufacture (and contract testing laboratories, if any):

1. .....

.....

2. .....

.....

3. .....

.....

to carry out the following manufacturing operations:

+ complete manufacture (***)

+ partial manufacture (***), i.e. (detail of manufacturing operations authorised): .....

.....

for the following medicinal product: .....

for human use/use in animals (***).

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on . . ./. . ./. . . (date), it is considered that the company complies with the good manufacturing practice requirements referred to in the Agreement on Mutual Recognition between Canada and the European Community.

. . ./. . ./. . . (date)

For the competent authority

.....
(Name and signature of the officer responsible)

(*) Insert exporting or importing firm or Health Canada.
(**) Insert European Community Member State or European Community as required.
(***) Delete that which does not apply.

Health Canada Santé Canada

Establishment Licence

Licence Number
100001-A
Numéro de la licence

PROGRAMME DES PRODUITS THÉRAPEUTIQUES
THERAPEUTIC PRODUCTS PROGRAMME

Licence d'établissement

This licence is issued in accordance with the Food and Drugs Act & Regulations (Division 1A & 2) for the following activities and categories of drugs:

Cette licence est délivrée conformément à la Loi et aux Règlements sur les aliments et drogues (titres 1A et 2) pour les activités et les catégories de drogues suivantes:

STERILE / *STÉRILE* NO / NON	Pharmaceutical *Prod. pharmaceutique*	Vaccines *Vaccins*	Blood [3] *Sang*	Schedule D [4] *L'annexe D*	Schedule C [5] *L'annexe C*	[6]
Fabricate ***Manufacturer***						
Package / label ***Emballer-étiqueter***						
Test [1] ***Test***						
Distribute [2] ***Distribuer***						
Import ***Importer***						
Wholesale ***Vendre en gros***						

[1] Perform the tests, including any examinations required under Division 2 / *Analyser conformément au titre 2.*
[2] Distribute as set out in paragraph C.01.A.003 (a) and/or (b) / *Distribuer au sens de l'alinéa C.01.A.003 (a) et/ou (b).*
[3] Whole blood and its components / *Sang entier et ses composants.*
[4] Drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components / *Drogue visée à l'annexe D de la Loi, autre qu'un vaccin ou que le sang entier et ses composants.*
[5] Drugs listed in Schedule C to the Act / *Drogue visée à l'annexe C de la Loi.*
[6] Drugs listed in the Schedule to Part G of the Food and Drug Regulations, drugs listed in Schedule F to the Food and Drug Regulations, narcotics as defined in section 2 of the Narcotic Control Regulations / *Drogue visée à l'annexe de la Partie G des Règlements sur les aliments et drogues, drogue visée à l'annexe F des Règlements sur les aliments et drogues, stupéfiants au sens de l'article 2 des Règlements sur les stupéfiants.*

Issued On / Émise le: 1998-01-01

MINISTER OF HEALTH MINISTRE DE LA SANTÉ	Countersigned: Director General, Therapeutic Products Directorate *Contresigné par: Directeur général, Direction des produits thérapeutiques*

This licence is the property of the Therapeutic Products Directorate and must be returned upon demand.
Cette licence appartient à la direction des produits thérapeutiques et doit être retournée sur demande.

Health Canada Santé Canada

Establishment Licence

Licence Number
100125-A
Numéro de la licence

PROGRAMME DES PRODUITS THÉRAPEUTIQUES
THERAPEUTIC PRODUCTS PROGRAMME

Licence d'établissement

This licence is issued in accordance with the Food and Drugs Act & Regulations (Division 1A & 2) for the following activities and categories of drugs:

Cette licence est délivrée conformément à la Loi et aux Règlements sur les aliments et drogues (titres 1A et 2) pour les activités et les catégories de drogues suivantes:

STERILE / *STÉRILE* NO / NON	Pharmaceutical *Prod. pharmaceutique*	Vaccines *Vaccins*	Blood [3] *Sang*	Schedule D [4] *L'annexe D*	Schedule C [5] *L'annexe C*	[6]
Fabricate ***Manufacturer***						
Package / label ***Emballer-étiqueter***						
Test [1] ***Test***						
Distribute [2] ***Distribuer***						
Import ***Importer***						
Wholesale ***Vendre en gros***						

[1] Perform the tests, including any examinations required under Division 2 / *Analyser conformément au titre 2.*
[2] Distribute as set out in paragraph C.01.A.003 (a) and/or (b) / *Distribuer au sens de l'alinéa C.01.A.003 (a) et/ou (b).*
[3] Whole blood and its components / *Sang entier et ses composants.*
[4] Drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components / *Drogue visée à l'annexe D de la Loi, autre qu'un vaccin ou que le sang entier et ses composants.*
[5] Drugs listed in Schedule C to the Act / *Drogue visée à l'annexe C de la Loi.*
[6] Drugs listed in the Schedule to Part G of the Food and Drug Regulations, drugs listed in Schedule F to the Food and Drug Regulations, narcotics as defined in section 2 of the Narcotic Control Regulations / *Drogue visée à l'annexe de la Partie G des Règlements sur les aliments et drogues, drogue visée à l'annexe F des Règlements sur les aliments et drogues, stupéfiants au sens de l'article 2 des Règlements sur les stupéfiants.*

This licence is subject to the additional conditions as indicated in the attached:

Cette licence est assujettie aux conditions supplémentaires indiquées dans le feuillet ci-joint:

Foreign Site Annex / Annexe concernant les sites étrangers

Issued On / Émise le: 1998-01-01

MINISTER OF HEALTH MINISTRE DE LA SANTÉ	Countersigned: Director General, Therapeutic Products Directorate *Contresigné par: Directeur général, Direction des produits thérapeutiques*

This licence is the property of the Therapeutic Products Directorate and must be returned upon demand.
Cette licence appartient à la direction des produits thérapeutiques et doit être retournée sur demande.

Health Canada Santé Canada

Establishment Licence

Licence Number
100125-A
Numéro de la licence

PROGRAMME DES PRODUITS THÉRAPEUTIQUES
THERAPEUTIC PRODUCTS PROGRAMME

Licence d'établissement

Foreign Site Annex / Annexe concernant les sites étrangers

The following sites are considered to be in GMP Compliance: *Les sites suivants sont considérés comme étant conformes aux BPF:*

Company Name / Nom de l'entreprise		
Street/Rue:	***City/Ville:***	***Country/Pays:***
Activity/Activite: **FABRICATE / FABRICATION** **PACKAGE / CONDITIONNEMENT**		
Category/Catégorie: **PHARMACEUTICAL / MÉDICAMENT**		***Sterile/Stérile*** **NO / NON**

SECTORAL ANNEX ON MEDICAL DEVICES

1. PURPOSE

1.1. This Mutual Recognition Agreement (MRA) Annex on conformity assessment and compliance certification pertaining to medical devices has been developed by the European Community and Canada to enhance bilateral medical device regulatory cooperation while facilitating global trade and maintaining the same high standards of health and safety in both jurisdictions.

1.2. Furthermore this Annex calls for the development of an infrastructure for on-going communications/consultations between regulatory and/or designating authorities and conformity assessment bodies of each Party to enable regulators to determine and maintain the equivalence of their medical device conformity assessment capabilities and to develop a cooperative approach to post-market vigilance.

2. SCOPE AND COVERAGE

2.1. This Annex applies to all medical devices which in Canada or the European Community are subject to conformity assessment procedures, including scientific technical evaluations of high risk medical devices and quality systems assessments, by a conformity assessment body.

2.2. The product coverage shall be as determined by the relevant legislation of each Party, which is:

(a) for the European Community:

— Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended,

— Council Directive 93/42/EEC of 14 June 1993 concerning medical devices;

(b) for Canada:

— the Food and Drugs Act and Medical Devices Regulations (proposed for promulgation 1998) as amended from time to time,

— the Canadian Electrical Code (as it relates to medical devices),

— the Radiation Emitting Devices Act and Regulations as amended from time to time (as they relate to medical devices).

It shall not, however, apply to the following products:

— *in vitro* diagnostic medical devices,

— devices incorporating, as an integral part, a substance which, if used separately, may be considered to be a medicinal product,

— breast implants,

— medical devices incorporating tissues of human or animal origin. However, medical devices incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, will be included within the scope of this Sectoral Annex.

Both Parties may, however, decide by common agreement, to extend the application of this Annex to the aforementioned or any other medical devices.

3. CONFIDENTIALITY

3.1. Each Party will protect from public disclosure any non-public confidential technical, commercial and scientific information, including trade secrets and proprietary information provided by the other Party.

3.2. Each Party reserves the right to make public the results of any conformity assessment reports in situations where public health may be affected.

4. RESOLUTION OF DIVERGENT VIEWS

4.1. Divergent views which have not been resolved between the regulatory authorities will be referred to the joint sectoral group for resolution. In the event that the joint sectoral group is unable to resolve these divergent views, either Party may bring the matter to the attention of the Joint Committee.

5. MANAGEMENT MECHANISM

5.1. A joint sectoral group will be established for the purposes of management of this Sectoral Annex. Its role will be to make decisions concerning the definition, establishment, and evaluation of conformity assessment procedures and programmes, the establishment of the 'two-way' alert programme, the management of the confidence building period and the definition of a maintenance programme supporting the continued operation of the MRA. The group will include representatives of Health Canada and of the European Community's competent authorities and co-chaired by a member of each of the two Parties.

6. TRANSITION PERIOD

6.1. **Time frame**

The confidence building period will commence upon the signing of the MRA and is expected to be completed within 18 months.

6.2. **Confidence building programme**

At the beginning of the transitional period, the joint sectoral group will elaborate a joint confidence building programme (guidance provided in Attachment III). The implementation of this programme shall establish each Party's capability to perform conformity assessments in compliance with the requirements and procedures of the other Party. The evidence shall provide practical relevance to the decisions regarding the operational phase.

The confidence building programme should include the following actions and activities:

(a) the organisation of seminars aiming to inform regulatory/designating authorities and conformity assessment bodies on each Party's regulatory system, procedures and requirements;

(b) the conduct of workshops aiming to provide, for regulatory/designating authorities, a common understanding and exchange of information regarding requirements and procedures for the designation and surveillance of conformity assessment bodies (CABs);

(c) for scientific technical evaluations, an inter-comparison exercise which would consist of parallel evaluations (double blind evaluations), made by the conformity assessment body in each territory, of a manufacturer's technical submission against the requirements of the intended market for that device, will be undertaken. Full reports and recommendations shall be exchanged for comparison. A certificate of compliance can be issued by the body responsible for the relevant market during this inter-comparison study. The inter-comparison study should take place on a sampling basis comprising a sufficient number of cases spread over the range of different medium to high-risk technologies with the involvement of each Party's regulatory/designating authorities and CABs. Additional evidence with respect to the competency of regulatory/designating authorities and CABs can be requested by either Party;

(d) for quality systems assessments, an inter-comparison exercise which would consist of the participation of regulatory/designating authorities in audits carried out by CABs of the other Party on the basis of requirements of the other Party. Audit management, methods and reports will be compared. The inter-comparison study should take place on a sampling basis comprising a sufficient number of cases spread over the range of different technologies with the involvement of each Party's regulatory/designating authorities and CABs. Additional evidence with respect to the competency of regulatory/designating authorities or CABs can be requested by either Party;

(e) the design, development and testing of a two-way alert system (see guidance in Attachment IV);

(f) the establishment of contact points between regulatory/designating authorities and CABs of both Parties;

(g) the participation in information exchange meetings with particular focus on conformity assessment and vigilance, including participation in staff training sessions. The exchange of staff will also be encouraged; and

(h) during the confidence building programme, where one Party has developed sufficient confidence in the evaluation methods and results of the other, it may at its own discretion, establish the relevant document of compliance permitting market access for its own jurisdiction based on the evaluation reports of the other Party without the full submission.

Participation in activities referenced under (c) and (d) should be understood as means to provide, on an exemplary basis, supplementary evidence in relation to the process of designation and surveillance of CABs.

6.3. **Budget**

Each of the Parties to the MRA will be responsible for the costs of its participation in the confidence building activities.

6.4. **End of transition period**

No later than 18 months after the entry into force of this Agreement, the joint sectoral group shall proceed to a joint evaluation of the experience gained. This evaluation will cover the adequacy of the confidence building programme, the capabilities of regulatory/designating authorities and the capabilities of the designated conformity assessment bodies.

Recommendations to list CABs in Attachment II of this Annex shall be made by participating regulatory/designating authorities, listed in Attachment I, to the joint sectoral group on the basis of the results of the confidence building programme. Conformity assessment bodies that have been accepted by the joint sectoral group will be listed in Attachment II with an indication of their specific conformity assessment expertise and the fields of medical device technologies for which they are recognised. The corresponding regulatory/designating authority responsible for a CAB will also be listed in Attachment II. Proposals to limit the recognition of capabilities of CABs should be based on objective evidence and documented. The joint sectoral group may recommend that a CAB not be listed in Attachment II, provided there is documented evidence demonstrating its lack of capabilities. Excluded CABs may apply for reconsideration of their status once the necessary corrective measures have been taken and confirmed.

Where no agreement on any of the above matters has been reached in the joint sectoral group, the matter will be referred to the Joint Committee under the Framework Agreement.

The Parties shall enter into the operational phase provided that there is representation of each Party's CABs in Attachment II.

The Agreement will also be re-examined at the end of the transitional period to take account of the regulatory evolution of each Party. Consideration shall be given to a single submission/evaluation/quality systems assessment which simultaneously satisfies the requirements of each jurisdiction.

7. OPERATIONAL PHASE

7.1. **General obligations**

The provisions of this section will apply only to conformity assessment carried out in the Parties' respective territories by conformity assessment bodies recognised under this Sectoral Annex.

The European Community and Canada agree that, for medical devices covered by this Annex, each Party will recognise the conclusions of the conformity assessment carried out by the other Party and the certificate of compliance granted by the conformity assessment body of the other Party, without further reassessment.

For evaluation against European requirements, Health Canada or other conformity assessment bodies designated by Canada shall establish the conclusions of completed conformity assessment as referred to in the active implantable medical device and the medical device Directives, and issue the appropriate certificate of compliance. The responsible authorities in the European Community will, without any further reassessment, accept the certification as evidence of compliance with the premarket requirements of the relevant European Directives.

For evaluating against Canadian requirements, the European CABs shall establish the conclusions of the examination and submit to Health Canada an abbreviated supporting report and certificate of compliance which includes such conclusions. Based on these documents, and without any further reassessment, Health Canada will accept the certification as evidence of compliance with the premarket requirements of the Canadian medical devices Regulations.

Each Party shall make available to the other Party, upon reasoned request, any information which has been reviewed as part of the assessment of a medical device for the purpose of issuing certificates of compliance.

Each Party reserves the right, at any time, to question information with respect to the designation process or the performance of conformity assessments against the requirements of its regulatory regime. Furthermore, each Party reserves the right to conduct its own conformity assessments for reasons identified to the other Party. Justification for such action shall be based on documented evidence and notification is to be provided in advance to the other Party. Recourse to this action should be an exception.

7.2. **Procedures for designation of CABs**

The procedures to be followed by the designating authorities of each Party in designating CABs shall respect the criteria laid down in the other Party's regulations or guidelines (non-binding guidance is provided in Attachment V).

7.3. **Information sharing**

In accordance with the general provisions of the Annex, the Parties will exchange all information necessary to determine and maintain equivalence of conformity assessment procedures. In addition, each Party shall share with the other Party information generated within the framework of its regulatory system which is relevant for the operation of conformity assessment procedures (i.e. guidance documents, publications of references to standards, forms, documents relating to the application of legal requirements). Each Party shall associate regulatory/designating authorities and conformity assessment bodies of the other Party in activities of exchange of information and experience.

In special cases, particularly emergency situations, all those involved in the implementation of this Annex will endeavour to provide all documentation requested by one of the Parties in an expeditious manner.

7.4. **Two-way alert system**

The joint sectoral group will ensure that an efficient and effective 'two-way' alert system is in place at all times. Elements of such a system are described in Attachment IV.

Each Party shall notify the other Party of any confirmed problem reports, corrective actions, or recalls related to products that it has evaluated under the terms of this Agreement. Each Party will respond to special requests for information on particular devices and will ensure that its designated authorities and conformity assessment bodies make available relevant information on these devices, as requested.

It shall be the responsibility of the regulatory authorities covered by this Annex to ensure that any suspension or cancellation (total or partial) of a certificate of compliance is communicated to each other with the appropriate degree of urgency.

7.5. **Fees**

The regime of registration or conformity assessment fees is determined by the location of the manufacturer. The cost recovery programmes and the fees pertaining to the issuance of a certificate of compliance in each jurisdiction will remain the responsibility of that jurisdiction. Conformity assessment fees will not be charged by one Party to manufacturers located on the territory of the other Party, where the conformity assessment was conducted by a conformity assessment body located in the other Party's territory.

7.6. **Monitoring of the Agreement**

The continuous monitoring of the equivalency of designation processes and conformity assessments for each Party's requirements that have been determined to be equivalent at the conclusion of the confidence building programme, and any subsequent decisions concerning that equivalence, must be made according to mutually developed and managed equivalence maintenance and implementation activities. This will be managed by the joint sectoral group.

The Parties will undertake to hold regular consultations, within the joint sectoral group set up under this Annex to ensure the continued relevancy and accuracy of this Annex. The regulatory/designating authorities and conformity assessment bodies will organise meetings to discuss specific questions and issues.

Conformity assessment bodies and regulatory/designating authorities must continue participation in maintenance activities, as established by the joint sectoral group, within the framework of this Annex in order to maintain their status under this Annex as indicated in Attachment II.

Parties may request the addition of regulatory/designating authorities or conformity assessment bodies to Attachment II. The procedure for the acceptance of new regulatory/designating authorities will be as described in the confidence building programme. Conformity assessment bodies will be added to Attachment II upon recommendation from a regulatory/designating authority and joint decision by the joint sectoral group.

7.7. **Contact points**

Contact points are identified in order to permit regulatory authorities and manufacturers to inform the regulatory authorities of the other Party with the appropriate speed in case of quality defects, recalls, and adverse incidents, which could necessitate additional controls or, suspension of the distribution of the product or, suspension or cancellation of a certificate of compliance.

For the purpose of this Agreement, the contact points will be:

for Canada: ....., and

for the European Community (the 15 Member States and the Commission).

8. ATTACHMENTS

Attachments I and II constitute integral parts of this Annex. Attachments III, IV and V are general guidelines.

Attachment I

Regulatory/designating authorities eligible to participate in this Agreement

For the conformity assessment bodies designated by Canada	For the conformity assessment bodies designated by the European Community
Canada Therapeutic products programme, Health Canada	— *Belgium* Ministère de la santé publique, de l'environnement et de l'intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie — *Denmark* Sundhedsministeriet — *Germany* Bundesministerium für Gesundheit — *Greece* Υπουργείο Υγείας Ministry of Health — *Spain* Ministerio de Sanidad y Consumo — *France* Ministère de l'emploi et de la solidarité Ministère de l'économie, des finances et de l'industrie — *Ireland* Department of Health — *Italy* Ministero della Sanità — *Luxembourg* Ministère de la Santé — *Netherlands* Staat der Nederlanden — *Austria* Bundesministerium für Arbeit, Gesundheit und Soziales — *Portugal* Ministerio da Saude — *Finland* Sosiaali- ja terveysministeriö/Social- och hälsovårdsministeriet — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC), designating authority Socialstyrelsen, regulatory authority — *United Kingdom* Department of Health

Attachment II

Designated conformity assessment bodies and their respective designating authorities

For Canada	For the European Community
To be completed after the confidence building programme	To be completed after the confidence building programme

Attachment III

Phases and elements of a confidence building programme

A. REVIEW AND EVALUATION OF ELEMENTS OF CONFORMITY ASSESSMENT (EXCHANGE OF DOCUMENTATION)

1. *Legislative and regulatory requirements and scope*

   — empowering legislation and regulations including authority to enforce laws and regulations, powers given to evaluators and auditors, authority to remove violative products from the market, etc.,

   — suitable controls on conflict of interest.

2. *Regulatory directives and policies*

   — procedures for determining competency of evaluators/auditors,

   — enforcement policies/guidelines/procedures,

   — codes of conduct/ethics,

   — training/certification policies/guidelines,

   — alert/crisis management policies/procedures/guidelines,

   — organisational structure, including roles, responsibilities and reporting relationships.

3. *Quality audit management, methodology and practices*

   — scope/details of operating standards, etc.,

   — auditor qualifications, numbers, training, quality assurance, contracting, etc.

4. *Scientific technical evaluation methodology and practices*

   — scope/details of operating standards, etc.,

   — evaluator qualifications, numbers, training, quality assurance, contracting, etc.

5. *Evaluation and auditing reports*

   — scope and format of reports,

   — content requirements,

   — storage, retrieval and access to reports,

   — scope and format of abbreviated reports, conclusions of conformity assessment and certificates.

6. *Auditing and evaluation procedures*

— audit and evaluation strategy (type, scope, scheduling, focus, notification, risk),

— pre-audit or evaluation preparation/requirements,

— methodology (access to and review of firm's files and databases, collection of evidence, data review, sample collection, interviews),

— post audit and evaluation activities (procedures for report issuance, follow-up, decision making),

— collection/storage of and access to data.

7. *Auditing and evaluation performance standards*

— frequency/number, quality and timeliness of reports, norms/frequency/procedures for re-audit or re-evaluation and corrective action.

8. *Enforcement powers and procedures*

— provision of written notices of violations to firms,

— non-compliance management procedures/mechanisms (recall, suspension, quarantine of products, certificate revocation, seizure, prosecution),

— appeal mechanisms,

— other measures to promote voluntary compliance by firm.

9. *Alert and crisis systems*

— alert mechanisms,

— crisis management mechanisms,

— alert performance standards (appropriationess and timeliness of alert).

10. *Analytical capability*

— access to laboratories with capacity to handle necessary analysis,

— standard operating procedures for analytical support,

— processes for validation of analytical methods.

11. *Surveillance programme/measures (used by manufacturers and by regulatory authorities)*

— sampling and audit procedures,

— recall monitoring (including effectiveness controls and verification of procedures),

— consumer complaint systems/procedures,

— adverse incident reporting systems/procedures.

12. *Quality management systems*

— quality management/assurance systems/procedures to ensure the on-going suitability and effectiveness of policies, procedures, guidelines and systems used to achieve the objectives of the conformity assessment programme, including establishment of standards and annual audit and review.

B. INTER-COMPARISON EXERCISE

— audit of systems and procedures,

— conduct of parallel evaluations (double blind),

— criteria for clinical trial data,

— exchange/evaluation of reports,

— monitoring of alert systems including handling of recalls,

— joint audits of manufacturers to determine equivalency of audit methods,

— exchange of evaluators/auditors or organisation of joint workshops (optional).

C. DECISION MAKING ON THE SUCCESS OF THE INTER-COMPARISON STUDY

— evaluation of results,

— action to take, development of options and solutions to address issues,

— determination of competent conformity assessment bodies that meet evaluation criteria,

— establishment of the conditions and mechanisms for on-going maintenance of the MRA (develop quality management system, audit mechanism and a consultation/on-going dialogue process).

Attachment IV

Components of a 'two-way' alert programme

1. *Documentation*
   - definition of a crisis/emergency and under what circumstances an alert is required,
   - standard operating procedures (SOPs),
   - mechanism of health hazards evaluation and classification,
   - language of communication and transmission of information.
2. *Crisis management system*
   - crisis analysis and communication mechanisms,
   - access to manufacturer's submissions, adverse incident reports and conformity assessment body reports,
   - establishment of contact points,
   - reporting mechanisms.
3. *Enforcement procedures*
   - follow-up mechanisms,
   - corrective action procedures.
4. *Quality assurance system*
   - vigilance programme,
   - surveillance/monitoring of implementation of corrective action.

Attachment V

Guidelines: procedures for the designation and monitoring of conformity assessment bodies

A. GENERAL REQUIREMENTS AND CONDITIONS

1. Designating authorities shall only designate legally identifiable entities as conformity assessment bodies.

2. Designating authorities shall only designate conformity assessment bodies able to demonstrate that they understand, have experience relevant to, and are competent to apply the conformity assessment requirements and procedures of the legislative, regulatory and administrative provisions of the other Party for which they are designated.

3. Demonstration of technical capabilities shall be based on:

   — technological knowledge of the relevant products, processes or services,

   — understanding of the technical standards and the general risk protection requirements for which designation is sought,

   — the experience relevant to the applicable legislative, regulatory and administrative provisions,

   — the physical capability to perform the relevant conformity assessment activity,

   — an adequate management of the conformity assessment activities concerned, and

   — any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed on a continuous basis.

4. The technical capability criteria shall be based on internationally accepted documents supplemented by specific interpretative documents developed as appropriate from time to time.

5. The Parties shall encourage harmonisation of designation and conformity assessment procedures through cooperation between designating authorities and conformity assessment bodies by means of coordination meetings, participation in mutual recognition arrangements, and working group meetings. Where accreditation bodies participate in the designation process they should be encouraged to participate in mutual recognition arrangements.

B. SYSTEM TO DETERMINE CONFORMITY ASSESSMENT BODIES' CAPABILITIES

6. The designating authorities may apply the following processes to determine the technical capabilities of conformity assessment bodies. If necessary, a Party will indicate to the designating authority the possible ways to demonstrate capabilities.

   (a) **Accreditation**

   Accreditation shall constitute a presumption of technical capability in relation to the requirements of the other Party when:

   (i) the accreditation process is conducted in conformance with the relevant international documentation (EN 45000 series or ISO/IEC guides); and either,

   (ii) the accreditation body participates in mutual recognition arrangements where it is subject to peer evaluation, which involves evaluation by individuals with recognised expertise in the field of the work being evaluated of the capabilities of accreditation bodies and conformity assessment bodies accredited by them, or

   (iii) the accreditation body, operating under the authority of a designating authority, takes part, in accordance with procedures to be agreed, in comparison programmes and exchanges of technical experience in order to ensure the continued confidence in the technical competence of the accreditation bodies and conformity assessment bodies. Such programmes may include joint assessments, special cooperation programmes or peer evaluation.

When a conformity assessment body is only accredited to evaluate a product, process or service for compliance with particular technical specifications, designation shall be limited to those technical specifications.

When a conformity assessment body seeks designation to evaluate a particular product, process or service for compliance with essential requirements, the accreditation process shall incorporate elements which will permit assessment of the capability (technological knowledge and understanding of the generally stated risk protection requirements of the product, process or service or their use) of the conformity assessment body to evaluate compliance with those essential requirements.

(b) **Other means**

When appropriate accreditation is not available or when special circumstances apply, the designating authorities shall require the conformity assessment bodies to demonstrate their capabilities through other means such as:

— participation in regional/international mutual recognition arrangements or certification systems,

— regular peer evaluations,

— proficiency testing, and

— comparisons between conformity assessment bodies.

C. EVALUATION OF THE DESIGNATION SYSTEM

7. Once the designation systems to evaluate the capabilities of conformity assessment bodies have been defined by each Party, the other Party may, in consultation with the designating authorities, check that the systems give sufficient assurance that the designation of the conformity assessment bodies satisfies its requirements.

D. FORMAL DESIGNATION

8. Designating authorities shall consult the conformity assessment bodies within their jurisdiction in order to determine their willingness to be designated under the terms of this Agreement. Such consultation should include those conformity assessment bodies who do not operate under the respective legislative, regulatory, and administrative requirements of their own Party, but which may, nevertheless, be interested and capable of working to the legislative, regulatory, and administrative requirements of the other Party.

9. Designating authorities shall inform their Party's representatives on the joint sectoral group, established under this Agreement, of the conformity assessment bodies to be included in or withdrawn from Section XX of the Sectoral Annexes. Designation, suspension or withdrawal of designation of conformity assessment bodies shall take place in accordance with the provisions of this Agreement and the rules of procedure of the joint sectoral group.

10. When advising their Party's representative on the joint sectoral group established under this Agreement, of the conformity assessment bodies to be included in the Sectoral Annexes, the designating authority shall provide the following details in respect of each conformity assessment body:

(a) the name;

(b) the postal address;

(c) the fax number;

(d) the range of products, processes, standards or services it is authorised to assess;

(e) the conformity assessment procedures it is authorised to carry out; and

(f) the designation procedure used to determine capabilities.

E. MONITORING

11. Designating authorities shall maintain, or cause to maintain, on-going surveillance over designated conformity assessment bodies by means of regular audit or assessment. The frequency and nature of such activities shall be consistent with international best practices or as agreed by the joint sectoral group.

12. Designating authorities shall require designated conformity assessment bodies to participate in proficiency testing or other appropriate comparison exercises where such exercises are technically possible within reasonable cost.

13. Designating authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment processes and procedures. This consultation may include joint participation in audits related to conformity assessment activities or other assessments of designated conformity assessment bodies, where such participation is appropriate and technically possible within reasonable cost.

14. Designating authorities shall consult, as necessary, with the relevant regulatory authorities of the other Party to ensure that all regulatory requirements are identified and are satisfactorily addressed.