



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.05.1998
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98/0167 (ACC)

**Proposal for a Council Decision
on the conclusion of an Agreement between the European Community and Canada
on Mutual Recognition in relation to Conformity Assessment**

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. The Agreement

On the basis of the negotiating directives issued by the Council on 21.9.92. the European Commission has negotiated and initialled an agreement on the mutual recognition of conformity assessment (Mutual Recognition Agreement, or MRA) with Canada. A Text of the Agreement initialled in June 1997 is annexed.

This memorandum provides an assessment of the Agreement in the light of the negotiating directives approved by the Council, and recommends that the Council decide to approve the Agreement by means of a Council decision to that effect.

I.1 Assessment of the Agreement

The Commission considers that the initialled Agreement is in conformity with the Council's negotiating directives, takes account of the views expressed by the 113 MRA Committee, which gave detailed advice to the Commission during the negotiations, and provides benefits to the European Community. The Agreement does not contain a rule of origin. As for the United States this proved to be non-negotiable with Canada.

Member States are in the process of designating a considerable number of conformity assessment bodies (CABs). Once these bodies have been provisionally accepted by Canada subject to formal acceptance by decision of the Joint Committee, the Secretariat of the Council will receive this list of CABs by way of a Commission Staff paper.

Sufficient confidence exists between the Parties to the Agreement to allow them to proceed.

I.1.1 Framework Agreement

The Agreement consists of a framework agreement and a series of sectoral annexes. An article-by-article assessment of the framework follows:

Pre-ambule : this sets out the basic objectives of the mutual recognition agreement in terms of trade facilitation

Article I: Definitions: these are self-explanatory.

Article II: General Obligations: this sets out the obligation of each Party to accept the conformity assessment results carried out to its requirements by the other Party, according to the terms of the sectoral annexes. Notably, the provision establishes acceptance of product certifications and authorisations of each Party. This Article also establishes the link between the basic obligations of the Agreement and its sectoral annexes.

Article III: Sectoral Coverage: this Article provides that the conformity assessment procedures to which the Agreement applies are specified in the individual sectoral annexes, and describes the content of the annexes.

Article IV: Transitional Arrangements: this Article refers to the transitional arrangements set out in the annex, to the necessity of a time period for completion and the possibility of amending it, and the need to move to full implementation by the end of the period unless there is documentary evidence of a failure of competence.

Article V: Civil Liability: this Article confirms the existing civil liability laws and responsibilities in the territories of the parties and provides for adequate arrangements to be made for such liabilities. It also provides for notification and mutual assistance in the event of a suit.

Article VI: Conformity Assessment Bodies (CABs): this Article recognises that CABs operate to the requirements of the importing Party and that a designation constitutes a formal recognition by the designating Party that a CAB has the technical competence and has undertaken to comply with the importing Party's requirements.

Article VII: Designating Authorities: this is a key provision requiring designating authorities to have the necessary formal powers over the bodies they designate. This article thus provides a treaty guarantee that Canada has the necessary authority to designate, suspend or withdraw bodies.

Article VIII: Verification of Compliance By Conformity Assessment Bodies: this Article establishes the right for one Party to challenge the compliance of bodies in the other Party. Verification will be carried out by the Party in whose territory the CAB is located. The CAB will be suspended where disagreement over its status has been confirmed by the Joint Committee, unless otherwise decided by that Committee. As advised by Member States in the 113 Committee MRA Group, the right of verification has been closely circumscribed to prevent it from being carried out routinely or unilaterally.

Article IX: Exchange of Information: a basic transparency provision.

Article X: Monitoring of the Agreement: this Article ensures that bodies of each Party remain coordinated so as to be able, continuously, to correctly interpret the regulatory requirements of the other Party.

Article XI: Joint Committee: this Article requires the establishment of a Joint Committee to administer the Agreement on behalf of the Parties. Duties of the Joint Committee include formally adopting changes to the Sectoral annexes to add or remove conformity assessment bodies, and discussing divergence of view.

Article XI.4 sets out detailed procedures for designation of bodies and the right of the other Party to contest such designations according to certain rules. The Article does not give the Joint Committee the right to extend the scope and coverage of the agreement to include new sectors. This has to be mandated by the Parties.

Article XII: Joint Sectoral Groups: this Article provides for the establishment of joint sectoral groups for individual sectoral annexes comprising the appropriate authorities and experts to assist the Joint Committee.

Article XIII: Sectoral Contact Point, Management of Information, Assistance and Emergency Action: this provides for contact points to handle exchange of information, management of the agreement and emergency action.

Article XIV: Safeguards: this Article provides that an importing Party retains all powers under its domestic law, and within its territory, to take measures against products certified by another Party. These powers must be exercised in accordance with the principle of non-discrimination.

Article XV: Market Access: this Article provides that recognition by one Party is dependent on continued access being granted by the other Party for duly certified products, and on the continued existence of authorities capable of implementing the Agreement by that other. New conformity assessment procedures applying to covered products will be brought within the scope of the Agreement, unless jointly decided otherwise, so as to preserve negotiated market access benefits.

Article XVI: Fees: this provides that a Party shall not charge fees for conformity assessments carried out by other Parties in accordance with the Agreement.

Article XVII: Agreements with other countries: this Article provides that Mutual Recognition Agreements between Parties to this Agreement and other countries shall have no force in regard to the other Party to this Agreement.

Articles XVIII, XIX, XX: these are standard institutional and legal provisions. It should be noted that the Agreement is of unlimited duration, and that there is no scope for a Party unilaterally to terminate an individual sectoral annex.

I.1.2 The Sectoral Annexes

There follows an assessment of the content of each sectoral annex in terms of its coverage, the type of mutual recognition arrangements envisaged for the sector, and the trade and other implications. In making this assessment, the Commission has kept in mind the following elements:

- a) whether the sectoral annex provides for genuine mutual recognition, i.e. whether all relevant conformity assessment procedures for a particular sector have been captured;
- b) whether the sectoral arrangements include evaluation of conformity not only to Federal law in Canada, but also to sub-Federal regulations where they exist;

- c) the level of trade between the Community and Canada for the sectors and products covered;
- d) the views expressed by Member States and European industry groups on the benefits of mutual recognition;
- e) the precedential nature (if any) of arriving at a mutual recognition agreement with Canada in the sectors covered;
- f) overall consistency with Community policy objectives in the field of standardisation, certification, designation of conformity assessment bodies and the removal of technical barriers to trade.

The sectoral assessment is followed by an overall appreciation of the benefits of the Agreement.

The Commission draws Member States' attention to the trade figures for each covered sector in the Annex to this note. These figures show that for every sector concerned, the Community has a rough trade balance with Canada. Third party certification (the subject of the MRA) applies most commonly to industrial products at the higher end of technology, in respect of which both the Community and Canada are major exporters.

A priori, this may indicate that the trade facilitation benefits of the Mutual Recognition should accrue to both the Community and Canada. We note however, that trade flows only give a partial picture of the likely benefits. The balance of benefits depends on additional factors, in particular the following:

- a) the range of products within a sector subject to third party certification. Obviously, if in a given sector one Party has more comprehensive certification requirements, the trade facilitation benefits to the other i.e. exporting Party may be proportionately greater;
- b) the complexity and accessibility of the conformity assessment requirements of each Party, including the extent to which each Party applies internationally recognised standards or technical requirements for the sector in question. Generally, this is not a major issue in the case of Canada which has adopted international standards, regulations and conformity systems fairly systematically.

The Commission notes that industrial groups consulted throughout the negotiations, such as Eurobit and Orgalime, while supporting the agreement, have not always been able to quantify the costs or time taken to obtain conformity assessment of their products in third countries, including Canada. It is therefore not feasible in every case to determine the extent of savings in time, cost or market opportunity of the arrangements set out in this agreement. This may only be possible once the agreement has been in operation for some time. What can be ascertained however is whether we have addressed industry's concern that any agreement provide reciprocal levels of market access, in terms of conformity assessment procedures.

The Agreement also presents important advantages from the point of transparency, market access, avoidance of duplication especially of cost, and general facilitation of trade. This is of particular importance for small and medium sized companies.

On the basis of a rough calculation it is estimated that this Agreement will create cost savings for the exporting industry of at least 20 MECU and an equivalent amount in terms of cost savings to exporters to the EU, some part of which will be passed on to European importers or consumers.

Where relevant, the above factors are taken into account in the assessment of each sectoral annex.

Pharmaceuticals Good Manufacturing Practice (GMP)

This annex establishes mutual recognition of each Party's inspections of pharmaceutical sites according to the GMP standards of each, which are effectively equivalent.

Recognition of inspection results and the ensuing certificate of GMP compliance removes the need for companies in each Party to be inspected by the authorities of the other Party. Each party accepts the GMP certificate issued by the exporting Party's authority and the products traded do not need further batch testing and control upon import.

European industry and Member States' inspection authorities (Working Group on Inspection and control of medicinal products and the Pharmaceutical Committee) have been consulted at every step of the negotiation and support the arrangements negotiated. The Community is an important exporter to Canada, (see Annex).

The scope of the Agreement is as broad as possible and covers all medicinal products, which have undergone one or a series of manufacturing processes, e.g. fabrication, repackaging, labelling, testing, wholesaling to which GMP applies. An indicative list of such products is also included (appendix 1 of sectoral annex). Veterinary immunologicals are not covered.

The sectoral annex applies to all pharmaceutical products subject to GMP in either Party. This permits inspections to be carried out against each Party's domestic GMP requirements in most cases. In (marginal) cases where a product is classed as a pharmaceutical in one Party but not the other, the agreement enables the exporting party's inspection authority to certify GMP to the importing Party's requirements on a voluntary basis.

The Agreement also lists the applicable legislation and relevant certifying authorities. It also sets out in a series of appendices (3 to 6) to the sectoral annex, guidelines for the setting up and functioning of a Joint Sectoral Group which will play an important role in the management of the Agreement, components of a GMP compliance programme, components of a two-way alert programme and the phases of a confidence-building period.

The MRA on medicinal products / Drug GMP is built on three pillars:

- 1) a GMP Compliance Program. Only certification by authorities with GMP Compliance Programs (including the supporting infrastructure of regulatory requirements, standards, processes, and quality systems, etc.) mutually recognised as equivalent will be accepted.

The elements of such a system are described in Appendix 4 of the sectoral annex to the Agreement. The European Community and Canada both operate such systems at present;

- 2) a two-way alert system. The Joint Sectoral Group to be set up to manage this sector 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 of the sectoral annex;
- 3) a transition period of 18 months including a confidence building exercise. At the beginning of the transition period, the Joint Sectoral Group will elaborate a Joint Confidence Building Program. The implementation of this program will permit the determination of the capacity of each Party's authority to perform GMP compliance certification (guidance provided in Appendix 6 of the sectoral annex). This will comprise three phases, review and evaluation of laws and other documentation, evaluation of processes and procedures, and decision making on the success of the exercise and conclusions.

While providing mutual benefits to pharmaceutical companies, and some savings to inspection authorities, we consider that the MRA in this sector establishes a good precedent for other negotiations. The present agreement also establishes mechanisms for longer-term cooperation between respective inspection authorities which will not only ensure the agreement continues to be properly applied, but will stimulate further harmonisation initiatives in other fields of medicines controls, such as Good Clinical and Laboratory Practices. The systems in place are largely similar and with equivalent coverage, and the Agreement is a very balanced one for these reasons.

Medical Devices

The sectoral annex provides for mutual recognition of certificates for medical devices subject to third party certification procedures in either Party, with a few specific exceptions. Coverage is therefore determined according to the two existing Community Directives for medical devices, and for Canada their domestic legislation in this field. The annex thus covers all conformity assessment procedures in the Parties, including final certification and approval.

The Agreement provides for the full recognition of certificates issued by either side (with an additional brief supporting report to be issued with European certificates). Attachments I and II contain lists of designation authorities and Conformity Assessment Bodies (to be filled out after the confidence building exercise).

The Agreement also provides that each Party shall respect the criteria laid down in the other Party's regulations or guidelines in designation of CABs (non-binding guidance is provided in Attachment V of the sectoral annex).

The Parties will also ensure that a two-way alert system is in place at all times.

The Agreement also provides for a transition period (18 months) which will evaluate the capabilities of the Regulatory / Designating Authorities, the designated Conformity Assessment Bodies and the functioning of a two-way alert system in accordance with a set of steps and criteria set out in Attachments III to IV of the sectoral annex.

The system to determine Conformity Assessment bodies capabilities will include both accreditation and other means. The Parties will also, during the transition, work to harmonise their assessment dossier.

The requirements of third party premarket assessment are extensive on both sides and cover up to 90% of the field. In this respect therefore we consider that the agreement presents a balance of advantages to both parties.

In the light of the above, we believe European industry is content with the proposed MRA in this sector.

The Commission considers that the MRA in this sector sets the right precedents in terms of our long term objectives. All certification procedures are covered and a link between mutual recognition and harmonised procedures has been made. The prospect of an MRA with the Community was a major factor in Canada's recent overhauling of its legislation, which now closely resembles the EC system.

Electrical Safety

This Annex covers the testing and certification requirements set out in the EC's Low Voltage Directive and corresponding Canadian legislation and regulations at provincial level, including medical devices which are not covered by the EC Low Voltage Directive.

European industry groups have been consulted on the proposed MRA and have expressed support provided that we ensure that any agreement provide for reciprocity of market access and not lead to the introduction of new and more onerous requirements. Given the existing openness of the EC regime, and the fact that the necessary Canadian legislation is covered under the sectoral annex, these requirements have clearly been met. While manufacturers self certification exists in the EC third party certification is required for certain categories of products in Canada. It is also the case that in the past certification was required under each Provincial regulation. This is no longer the case as a result of the Agreement and one certificate issued by a designated European CAB will now suffice. There are therefore clear advantages in the Agreement from an EC perspective.

The Agreement provides for a transitional arrangement of 18 months 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. During the transition period EC and Canadian CABs shall accept test reports issued by designated CABs in each others' territory provided they fulfil certain conditions.

Electromagnetic Compatibility (EMC)

In view of the "horizontal" application of EMC requirements to a wide range of electrical, machinery and telecommunications products, coverage of the EMC phenomenon in the MRA is necessary to achieve the objective of covering all relevant conformity assessment procedures.

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. Both Parties also agree to recognise each other's suppliers declaration of compliance as required under their respective legislation.

The Agreement also provides for a transitional arrangement of 18 months. During this period the Parties will work together to ensure familiarity with each other's regulatory requirements, exchange information and review the work carried out by designated Conformity Assessment Bodies and demonstrate to each other's satisfaction their capability to carry out conformity assessment to the requirements of the other Party.

Telecommunications Terminal Equipment

There is a special annex on Telecommunications equipment but both sectoral annexes on electrical safety and electromagnetic compatibility also apply. These annexes apply to all telecommunications terminal equipment (TTE) regulated under the relevant Community Directives, non-harmonised national legislation for analogue, and radio transmitters, and the corresponding Canadian legislation.

The Agreement provides for recognition of the conformity assessment certificates (set out in detail in Art. 4 of the sectoral annex) of Conformity Assessment Bodies designated by the Parties. The Conformity Assessment Bodies will be required to comply with the criteria and standards set out in the regulatory requirements of the other Party (a list of Designating and Approval Bodies and Designated Bodies with an indication of the products and procedures for which the latter have been designated, have or will be set out in Attachments 3, 4 and 5 of the sectoral annex). The Agreement also lists the relevant Canadian standards (appendix 1).

The Agreement provides for a transitional period of 18 months, during which time the Parties will recognise test reports issued by designated CABs. Also during this period the Parties will exchange information and develop a better understanding of the Parties' respective regulatory requirements, to develop mechanisms for exchanging information on changes to technical requirements to maintain and evaluate the work carried out by the designated Conformity Assessment Bodies during the transitional period. At the end of the transitional period the Parties will grant full mutual recognition of certificates of compliance.

European industry organisations have been consulted extensively on the MRA negotiations and have supported the objectives provided that access by means of recognition to all Canadian conformity assessment systems, including product approvals, is achieved. In this connection, the agreement provides for reciprocal recognition of all conformity assessment procedures including final certification without further product assessment by the importing party.

Recreational Craft

The sectoral annex for recreational craft applies to all recreational craft, including personal watercraft, which are subject to third party certification in the European Community or Canada. The Agreement covers all relevant legislation (Directive 94/25) and the Federal regulations in Canada (none exist at the Provincial level). While the Canadian system is largely based on manufacturer's self declaration, a limited third party intervention is still required and there is therefore a mutual advantage in concluding an agreement.

The Parties will recognise certificates issues by each other's designated Conformity Assessment Bodies without any further assessment of the products to which they relate.

The Agreement provides for a transitional arrangement of 18 months in which the Parties will exchange information on and develop greater familiarity with their respective regulatory requirements, and carry out the policy legislative and regulatory changes necessary for the provisions of their annex.

I.1.3 Relations with EFTA States, members of the European Economic Area

In accordance with the general information and consultation procedures set out in the EEA Agreement and Protocol 12 of the said Agreement, the Commission has kept EFTA / EEA States regularly informed about developments in the negotiations and has informed them on the final result of the negotiations.

The EFTA / EEA States have had preliminary talks with Canada for negotiating a mutual recognition agreement equivalent to the one to be concluded between the Community and Canada.

I.1.4 Overall Appreciation

The Commission considers that the proposed MRAs create an acceptable balance of benefits for all parties overall, when all sectors are taken together. The overall trade balance with Canada would also suggest that the Agreement will work in favour of EC exporters. In all sectors the Community has secured effective market access - in terms of access to all mandatory procedures of the other party. Canada has accepted the Community's approach of reciprocally recognising not only testing, but also certificates and approvals of conformity to the other's requirements, including where applied through sub-Federal legislation. This is a significant development, and establishes a good precedent for other MRA negotiations. The agreement will allow Community exporters, if they so choose, to test and certify their products to Canadian requirements prior to export, and then access those markets without any further conformity assessment requirements. This will facilitate Community exports. European industry federations have been consulted on the agreement and have supported them.

Since Canada generally bases its product standards and regulations, and criteria for accepting Community bodies on established international or European norms, this will enable European conformity assessment bodies to participate in the agreement and offer their services to European exporters. The Commission has received indications that a large number of EC conformity assessment bodies would be interested to work in the framework of this Agreement, and this indicates both their technical capacity and economic interest in the Agreement.

In several sectors the agreement caters for the further development of the parties' regulatory regimes, with the aim of ensuring that future rules do not undermine the benefits of the agreement. And in several sectors, the agreement will help to promote wider acceptance of the Community's regulatory approach and technical requirements.

II. The Draft Council Decision

A proposal for a Council decision on the conclusion of the Agreement is attached. The decision has two objectives:

a) to approve, on the basis of Articles 113 and 228 of the Treaty, the draft Agreement; and

b) to establish the appropriate Community procedure to enable the Commission, assisted by the 113 Committee (Mutual Recognition), to represent the Community in the Joint Committee and in the Joint Sectoral Groups established by the Sectoral Annexes, and that the Community position in that Joint Committee and in the Joint Sectoral Groups in case of changes to the annexes and other sectoral questions be determined, in conformity with Article 228, paragraph 4 of the Treaty, by the Commission in consultation with the 113 Committee.

On this second aspect, it is noted that in Article XI of the Agreement, a Joint Committee of the Parties operates. This Joint Committee is responsible for the management of the Agreement and has the delegated power to amend existing sectoral annexes. Such right of amendment is restricted only to procedural issues concerned with implementation, essentially: amending the references to the regulations applicable to covered sectors; amending the annexes further to decisions to recognise, suspend, remove, or alter the scope of activity of conformity assessment bodies or designating authorities in the Agreement. The power to amend the framework agreement, to delete sectoral annexes or to add new sectoral annexes rests with the Parties.

It is accordingly proposed that:

a) the Commission, assisted by the 113 Committee (Mutual Recognition) should represent the Community in the Joint Committee and in the Joint Sectoral Groups established by the Sectoral Annexes, and that the Community position in that Joint Committee and in the Joint Sectoral Groups in case of changes to the annexes and other sectoral questions be determined, in conformity with Article 228, paragraph 4 of the Treaty, by the Commission following consultation of the above mentioned Committee.

b) for all other issues, the Community position shall be determined by the Council, acting by qualified majority on a proposal from the Commission.

The Commission therefore proposes that the Council adopts the appended decisions, and indicates the person who, on behalf of the Community, signs the Agreement.

Proposal for a Council Decision
on the conclusion of an Agreement
between the European Community and Canada
on Mutual Recognition in relation to Conformity Assessment
(.../.../EC)

The Council of the European Union,

Having regard to the Treaty establishing the European Community, and in particular Article 113 in conjunction with Article 228, paragraph (2), (3), first subparagraph, and (4) thereof,

Having regard to the proposal of the Commission,

Whereas the Agreement on Mutual Recognition in relation to Conformity Assessment between the European Community and Canada, initialled on 30 May / 10 June 1997, has been negotiated and should be approved,

Whereas certain tasks for implementation have been attributed to the Joint Committee established by the Agreement, and in particular the power to amend the Sectoral Annexes thereto;

Whereas the appropriate internal procedures should be established to ensure the good functioning of the Agreement, and whereas it is therefore necessary to delegate to the Commission the power to proceed to certain technical amendments of the Agreement and to take certain decisions for its implementation.

Decides:

Article 1

The Agreement on Mutual Recognition in relation to Conformity Assessment between the European Community and Canada, including its Annexes are hereby approved on behalf of the European Community.

The text of the Agreement and the Annexes are attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Community, transmit the note provided for in Article XIX of the Agreement¹.

¹ The date of entry into force of the Agreement will be published in the Official Journal of the European Communities.

Article 3

1. The Commission shall represent the Community in the Joint Committee and in the Joint Sectoral Groups established by the Sectoral Annexes, provided for in Articles XI and XII of the Agreement, assisted by the special committee established under Article 113 of the EC Treaty (Mutual Recognition). The Commission shall proceed, after consultation with this committee, to the appointments, exchange of information and requests for verifications referred to in Articles IX, X, XI, paragraph 3, letters (c) and (e), XII (b) and XIII of the Agreement and the equivalent provisions of its Sectoral Annexes.
2. The position to be taken by the Community in the Joint Committee or if appropriate by the Joint Sectoral Groups shall be determined, with regard to amendments of the Sectoral Annexes (Article XI, paragraph 3, letter (a) and paragraph 4 of the Agreement) and verification of compliance in accordance with Articles VIII and XI para 4 letter (c) of the Agreement by the Commission following consultation of the above mentioned special committee.
3. In all other cases the position of the Community for a decision in the Joint Committee or Joint Sectoral Groups shall be determined by the Council, acting by qualified majority on a proposal from the Commission. The same procedure shall apply to decisions taken by the EC in the framework of Articles XV.3 and XIX.4.

Done at Brussels,

For the Council
The President

85, 19, 20

EU TRADE WITH CANADA 1995 (MECU)

IMPORT			EXPORT		
Products	Canada	%	Products	Canada	%
Pharmaceuticals	95	0.8	Pharmaceuticals	351	3.4
Medical Devices	79	0.7	Medical Devices	97	0.9
Telephonic & Telegraphic Equipment	266	2.3	Telephonic & Telegraphic Equipment	38	0.4
Electrical Equipment	834	7.1	Electrical Equipment	838	8.1
Recreational Craft	27	0.2	Recreational Craft	18	0.2
Total	1 300	11.1	Total	1 342	13.0
TOTAL	11 707	100.0	TOTAL	10 337	100.0

EU TRADE WITH CANADA 1996 (MECU)

IMPORT			EXPORT		
Products	Canada	%	Products	Canada	%
Pharmaceuticals	88	0.8	Pharmaceuticals	411	3.8
Medical Device	104	0.9	Medical Devices	116	1.1
Telephonic & Telegraphic Equipment	213	1.9	Telephonic & Telegraphic Equipment	53	0.5
Electrical Equipment	988	8.6	Electrical Equipment	881	8.2
Recreational Craft	24	0.2	Recreational Craft	4	0.3
Total	1 416	12.3	Total	1 465	13.9
TOTAL	11 478	100.0	TOTAL	10 689	100.0

SOURCE:

Pharmaceuticals: (ch 30)
 Medical Devices: (ch 9018, 9019, 9020, 9021, 9022)
 Telephonic & telegraphic Equipment: (ch 8517)
 Electrical Equipment: (ch 85)
 Recreational Craft: (ch 8903)

Source: EUROSTAT (COMEXT)

Brussels, 29 October 1997

**AGREEMENT ON MUTUAL RECOGNITION
BETWEEN CANADA AND THE EUROPEAN COMMUNITY**

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AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT BETWEEN CANADA AND THE EUROPEAN COMMUNITY

The Government of Canada and the European Community ("the Parties")

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

Considering that on the basis of past experience under the 1976 Framework Agreement on commercial and economic cooperation between the European Communities and Canada, and in order to further develop their dialogue in the area of standards as specified in the 1990 Declaration on EC-Canada Relations, both Parties have expressed a desire to establish a more formal framework for the conduct of collaboration in the field of mutual recognition in relation to conformity assessment,

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

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

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

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

Have agreed as follows:

ARTICLE 1: DEFINITIONS

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

- **Agreement** means the Framework Agreement and all the Sectoral Annexes.
- **Conformity Assessment** means systematic examination to determine the extent to which a product, process or service fulfils specified requirements.
- **Conformity Assessment Body** means a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled.

- **Designating Authority** means a body with power to designate, monitor, suspend designation or withdraw designation of Conformity Assessment Bodies under its jurisdiction
- **Designation** means the authorisation by a Designating Authority of a Conformity Assessment Body to perform conformity assessment activities.
- **Regulatory Authority** means a government agency or other entity, that exercises a legal right to control the use or sale of products within a Party's jurisdiction, and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

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

ARTICLE II: GENERAL OBLIGATIONS

1. The Sectoral Annexes to this Framework Agreement constitute integral parts of this Agreement.
2. The Government of Canada shall accept the results of conformity assessment procedures, including certifications of compliance, as required by the Canadian legislation and regulations identified in the Sectoral Annexes, produced by designated Conformity Assessment Bodies or Authorities in 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 State 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 judgement by the Party that the Conformity Assessment Body has demonstrated an acceptable level of technical competence in providing services identified in the designation and further has agreed to comply with the requirements of the other Party, as set out in a Sectoral Annex.

4. In accordance with the terms of the Sectoral Annexes, each Designating Authority will make available, if requested, a statement of technical competence of their designated Conformity Assessment Bodies.

ARTICLE VIII: VERIFICATION AND SUSPENSION OF CONFORMITY ASSESSMENT BODIES

1. Each Party has the right to challenge the technical competence and compliance of Conformity Assessment Bodies under the jurisdiction of the other Party. This right will be exercised under exceptional circumstances only and justified, in an objective and reasoned manner in writing, to the Joint Committee. The Joint Committee will discuss such requests.

2. Where the Joint Committee, either on its own initiative or on a recommendation from the relevant sectoral group, comes to the conclusion that verification of technical competence or compliance of a Conformity Assessment Body operating in the territory of the other Party is required, it will be carried out in a timely manner by the Party in whose territory the Body in question is located, or by the Parties jointly if they agree. The Party may seek the assistance of its Designating Authority in carrying out the verification.

3. Unless decided otherwise by the Joint Committee, the contested Conformity Assessment Body will be suspended by the competent Designating Authority from the time that a disagreement over the status of that body has been confirmed in the Joint Committee. The body in question shall remain suspended until agreement has been reached in the Joint Committee on the future status of that Body.

4. A certificate of conformity or other documentation for a product issued by a Conformity Assessment Body, that is subsequently removed by the Joint Committee or Designating Authority, shall remain valid unless there is a specific decision by the appropriate Regulatory Authority based on health and safety considerations for the removal of the product from the market.

ARTICLE IX: EXCHANGE OF INFORMATION

1. The Parties shall exchange information concerning the implementation of the legislative, regulatory and administrative provisions identified in the Sectoral Annexes.

2. Each Party shall inform the other Party of changes related to the subject matter of this Agreement, and shall, except where considerations of safety, health and environmental protection require more urgent action, notify the other Party of the new provisions at least 60 days before their entry into force.

3. Each Party shall promptly notify the other Party of any changes of its Designating Authorities and Conformity Assessment Bodies.

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 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 fifteen 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 to the territory of Canada and to the territories in which the Treaty establishing the European Community is applied, and under the conditions laid down in that Treaty.

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

1. This Agreement and the Sectoral Annexes are drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portugese, Spanish and Swedish languages, each text being equally authentic.

EU-CANADA MRA

**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 of Conformity Assessment 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 electro-magnetic 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 organizations 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, recognized under this Annex, are authorized 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 to the requirements of the laws and regulations applicable in the territories of the Parties for products covered under this Annex;
 - for electro-magnetic 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 EMC;
 - 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 recognized 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 organizations 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 recognized 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 recognize 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;
 - any 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

SUB-CONTRACTING

- 7.1 Any sub-contracting shall be in accordance with the sub-contracting 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 sub-contracting. 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 labeling 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 above 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 would (also) apply.

ATTACHMENT 1**LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS**

EUROPEAN COMMUNITY	CANADA.
<p>Council Directive 91/263/EEC, as supplemented by Council Directive 93/97/EEC and amended by Council Directive 93/68/EEC</p> <p>Council Directive 73/23/EEC as amended by Council Directive 93/68/EEC</p> <p>Council Directive 89/336/EEC, as amended by Council Directives 92/31/EEC and 93/68/EEC</p> <p>European Commission Decisions established under Council Directives 91/263/EEC and 93/97/EEC.</p> <p>The EC Member States' legislations and regulations in respect of:</p> <p>(a) non-harmonized analogue connection to the public switched telecommunications network;</p> <p>(b) non-harmonized radio transmitters (civilian application).</p> <p>Handbook of the implementation of 91/263/EEC (ADLNB and ACTE approved).</p>	<p>Telecommunications Act</p> <p>Radiocommunication Act</p> <p>CRTC Telecom Decision No 82-14</p> <p>Certification Standard CS-03</p> <p>Certification Procedure CP-01</p> <p>Radiocommunication Regulations</p> <p>Radio Standards Procedure (RSP) #100: Radio Equipment Certification Procedure</p> <p>Canadian Electrical Code</p> <p>Terminal Equipment List (TEL)</p> <p>Radio Equipment List (REL)</p> <p>Licence Exempt Radio Apparatus Standards List</p> <p>Broadcasting Certificate Exempt Radio Apparatus Standards List</p> <p>The Category I Equipment Standards List</p> <p>The Category II Equipment Standards List</p>

ATTACHMENT 2
COVERAGE

EUROPEAN COMMUNITY	CANADA
<p>In specific terms, the following interfaces and services are included:</p> <p>ISDN Basic Rate Access ISDN Primary Rate Access ISDN Telephony X21/V.24/V.35 Access X25 Access PSTN Non-Voice ONP Leased Line Terminal types: -64 kbits/sec -2048 kbit/s unstructured -2048 kbit/s structured -34 Mbit/s access -140 Mbit/s access -2 wire analogue -4 wire analogue</p> <p>Analogue connections to the public switched telecommunications networks</p>	<p>In specific terms, the following interfaces and services are included:</p> <p>ISDN Basic Access ISDN Primary Rate Access X.21 Access X.25 Access Digital Service Access -1.2 kbps -2.4 kbps -9.6 kbps -4.8 kbps -19.2 kbps -56.0 kbps -64.0 kbps -1,544 kbps -45 Mbps 2 wire analogue tie-trunks/ops 4 wire analogue tie-trunks/ops</p> <p>Analogue connections to the public switched telecommunications networks</p> <p>All radio transmitters to Radiocommunication Regulations (See Appendix 1) with the exception of:</p>

EUROPEAN COMMUNITY

All harmonised and non-harmonised radio transmitters, with the exception of:

- a medical device within the meaning of Article 1 of Council Directive 93/42/EEC of 14 June 1993;
- an active implantable medical device within the meaning of Article 1 of Council Directive 90/385/EEC of 20 June 1990;
- a component or separate technical unit of a vehicle within the meaning of Council Directive 72/245/EEC of 20 June 1972 of 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;
- equipment within the scope of Directive 96/98/EC (The Marine Directive);
- cable and wiring;
- receive only radio equipment intended to be used solely for the reception of sound and TV Broadcasting Services;
- products, appliances and components within the meaning of Article 2 of Council Regulation (EEC) 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;

CANADA

* 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.

* spark ignition systems of vehicles including all radio transmitters in connection with the spark ignition systems of vehicles.

* 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;

* Cable and wiring

* receive only radio equipment intended to be used solely for the reception of sound and TV Broadcasting Services;

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, defense, 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.

EUROPEAN COMMUNITY

- 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 electro-magnetic 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.

CANADA

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 electro-magnetic 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 & MEMBER STATES	CANADA
Austria Bundesministerium für wirtschaftliche Angelegenheiten, Sektion IX/2 Belgium BIPT Denmark Telestyrelsen Finland Ministry of Telecommunications Germany Bundesministerium für Wirtschaft Greece Ministry of Transport & Communications France Ministère de l'Economie , des finances et de l'industrie Ireland Dept. Of Transport, Energy & Communications Italy Ministero della Comunicazione DGRQS and ISETI (radio transmitters) Luxembourg Administration des Postes et Telecommunications Netherlands Min Verkeer en Waterstaat, Telecom, en Post Dept Portugal Instituto das Comunicacoes Spain Ministerio de Obras Publicas y Transportes Sweden Styrelsen för ackreditering och teknisk kontroll (SWEDAC) U.K. Dept of Trade & Industry (DTI)	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 no., 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 (To be determined)	Canada Industry Canada
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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	August 13, 1994
ICES 003	Digital Apparatus	3	November 22, 1997
ICES 0040	Alternating Current High Voltage Power Systems	1	June 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 - 849 MHz and 869 - 894 MHz	2	Aug. 19, 1990
Addendum to 118		1	Sept. 1, 1990
Annex A to 118	Cellular System Mobile Station - Land Station Compatibility Standard		Oct. 22, 1983
Supplement 1993-1	Supplement 1993-1 to Radio Standards Specifications (RSSs) Nos. 118		June 12, 1993
RSS 118. mod	Amendment N° 2 to RSS 118		Aug. 24, 1996
RSS 119	Land Mobile And Fixed Radio Transmitters and Receivers, 27.41 - 960 MHz	5	Aug. 24, 1996
RSS 123	Low Power Licensed Radiocommunication Devices	1 Provisional	Feb. 24, 1996
RSS 125	Land Mobile And Fixed Radio Transmitters and Receivers, 1.705 to 50.0 MHz, Primarily Amplitude Modulated	2	Aug. 24, 1996
RSS 128	800 MHz Dual-Mode Cellular Telephones	1 Provisional	June 12, 1993

RSS 128. mod	Amendments to RSS 128		Aug. 24, 1996
RSS 129	800 MHz Dual-Mode CDMA Cellular Telephones	1 Provisional	Feb. 24, 1996
RSS 129. mod	Amendments to RSS-129		Aug. 24, 1996
RSS 130	Digital Cordless Telephones in the Band 944 to 948.5 MHz	2	Jan. 23, 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	Jan. 23, 1993
Attachment 1 to RSS 130	European Telecommunications Standards Institute Interim Standard /I-ETS 300 131		April 1992
RSS 131	Radio Signal Enhancers for the Mobile Telephone Service	1 Provisional	Feb. 24, 1996
RSS 133	2 Ghz Personal Communications Services	1 Provisional	Nov. 29, 1997
RSS 134	900 MHz Narrowband Personal Communications Service	1 Provisional	Aug. 24, 1996
RSS 135	Digital Scanner Receivers	1 Provisional	Oct. 26, 1996
RSS 136	Land and Mobile Station Radiotelephone Transmitters and Receivers Operating in the 26.960 - 27.410 MHz General Radio Service	5	Jan. 1, 1977

RSS 137	ation and Monitoring Services (902-928 MHz)	1 rovisional	ov. 29, 1997
RSS 210	Low Power Licence-Exempt Radiocommunication Devices	2	Feb.24, 1996

Note 1: Supplement 1993-1 issued June 12, 1993 applies to RSS-118 and 182.

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 525-1,705 kHz and 88-107.5 MHz	1	Nov. 1, 1996
BETS-3	Technical Standards and Requirements for Radio Apparatus that Form Part of a Master Antenna Television (MATV) Broadcasting Undertaking	1	Nov. 1, 1996
BETS-4	Technical Standards and Requirements for Television Broadcasting Transmitters	1	Nov. 1, 1996
BETS-5	Technical Standards and Requirements for AM Broadcasting Transmitters	1	Nov. 1, 1996
BETS-6	Technical Standards and Requirements for FM Broadcasting Transmitters	1	Nov. 1, 1996
BETS-8	Technical Standards and Requirements for FM Transmitters Operating in Small Remote Communities	1	Nov. 1, 1996
BETS-9	Technical Standards and Requirements for Television Transmitters Operating in small Remote Communities	1	Nov. 1, 1996
BETS-10	Technical Standards and Requirements for Television Transmitters in the 2,596-2,686 Mhz Band	1	Nov. 1, 1996
BETS-11	Technical Requirements Respecting the Identifications of Broadcasting Stations	1	Nov. 1, 1996

BROADCAST SPECIFICATIONS AND STANDARDS

Specification	Title	Issue	Date
BTS 1-1	Broadcast Transmission Standard AM Broadcasting Stereophonic Operation	1 Provisional	Feb. 6, 1988
BTS 1-2	Broadcast Transmission Standard: AM Broadcasting RF Emission Limits	1 Provisional	Nov. 1989
BTS 3	Broadcasting Transmission Standard: Television Broadcasting	2	May 1990
BS 14	Broadcast Specification: Television Broadcast Videotext	1 Provisional	June 19, 1981

EU-CANADA MRA

**SECTORAL ANNEX ON
ELECTRO-MAGNETIC COMPATIBILITY
(EMC)**

1. SCOPE AND COVERAGE

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

- Electro-magnetic compatibility of equipment as defined in EC Council Directive 89/336/EEC of May 3, 1989, on the approximation of the laws of the Member States relating to electro-magnetic 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 recognize 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 recognize 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 recognized 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

SUB-CONTRACTING

- 6.1 Any sub-contracting of conformity assessment shall be in accordance with the sub-contracting 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 sub-contracting. 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 would also apply.

ATTACHMENT 1**LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS**

EUROPEAN COMMUNITY	CANADA
<p data-bbox="188 577 798 678">Council Directive 89/336/EEC, as amended by Council Directives 91/263/EEC, 92/31/EEC, 93/68/EEC and 93/97/EEC</p> <p data-bbox="188 712 798 851">The EC Member States' legislation and regulations in respect of EMC for non-harmonized radio transmitters (civilian application).</p>	<p data-bbox="833 577 1165 611">Radiocommunication Act</p> <p data-bbox="833 645 1276 712">Radiocommunication Regulations (Appendix I)</p> <p data-bbox="833 745 1396 779">The Category II Equipment Standards List</p>

ATTACHMENT 2**DESIGNATING AUTHORITIES**

The Designating Authority for Canada is Industry Canada.

The Designating Authorities for the European Community are as in the following table:

Member State	Competent Authorities	Sectors of Activity
Austria	Bundesministerium für wirtschaftliche Angelegenheiten Abteilung IX/4 Landstrasser Hauptstrasse 55-57 1031 WIEN	All equipment except telecommunication equipment
Austria	Bundesministerium für öffentliche Wirtschaft und Verkehr Radetzkystrasse 2 1030 WIEN	Telecommunication equipment
Austria	Zulassungsbüro Nordbergstrasse 15 1091 WIEN	Telecommunication equipment
Austria	Fernmeldebüro für Wien, Niederösterreich und Burgenland Nordbergstrass 15 1091 WIEN	Telecommunication equipment
Austria	Fernmeldebüro für Steiermark und Kärnten Neutorgasse 46 8011 GRAZ	Telecommunication equipment
Austria	Fernmeldebüro für Oberösterreich und Salzburg Domgasse 1 4010 LINZ	Telecommunication equipment

Austria	Fernmeldebüro für Tirol und Voralberg Maximilianstrasse 2 6010 INNSBRUCK	Telecommunication equipment
Belgium	Ministère des Affaires Economiques Administration de l'Energie Service Equipements et Produits Energétiques 154, Bd Emile Jacqmain 1210 BRUXELLES	Autorité fédérale pour la coordination de la mise en application de la législation CEM Haute surveillance et surveillance du marché pour tout produit
Belgium	Ministère de l'Emploi et du Travail Administration de la Sécurité du Travail Rue Belliard, 51 1040 BRUXELLES	Surveillance du marché dans le domaine des produits relevant de la protection des travailleurs
Belgium	Institut Belge des Services Postaux et des Télécommunications (auprès du Ministère des Communications et de l'Infrastructure) Tour Astro Av. de l'Astronomie, 14, BP21 1030 BRUXELLES	Surveillance du marché dans le domaine des produits relevant des perturbations radio émetteurs et récepteurs radio. Réseau de télécommunication.
Denmark	Telestyrelsen Holsteinsgade 63 2100 COPENHAGEN	
Finland	Ministry of Trade and Industry P.O. Box 230 00171 Helsinki	Industrial manufacturing equipment Medical and scientific apparatus Information technology equipment Domestic appliances and household electronic equipment Educational electronic equipment Lights and fluorescent lamps
Finland	Telecommunications Administration Centre P.O. Box 53 00211 HELSINKI	Telecommunications terminal equipment Radio equipment Telecommunications networks

Finland	Turvatekniikan keskus (TUKES) Safety Technology Authority P.O. Box 123 Lönnrotinkatu 37 00181 HELSINKI	
France	Ministère de l'Industrie, des Postes et des Télécommunications et du Commerce Extérieur Direction Générale des Stratégies Industrielles Sous-Direction de la Qualité pour l'Industrie et la Normalisation 22, rue Monge 75005 PARIS	
Germany	Bundesamt für Post und Telekommunikation (BAPT) Referat 124 Postfach 8001 55003 MAINZ	All equipment
Germany	Bundesministerium für Post und Telekommunikation (BMPT) Referat 314 Postfach 8001 53105 BONN	All equipment
Greece	Ministry of Transport & Communications 49, Syngrou Avenue 11780 ATHENS	
Ireland	Department of Transport, Energy and Communications 44 Kildare Street Dublin 2	
Italy	Ministero delle Comunicazioni (DGRQS) Viale America 201 00144 ROMA	
Italy	Ministero dell'Industria, del Commercio e dell'Artigianato (DGSPC) Via Molise 2 00187 ROMA	

Luxemburg	Service de l'Énergie de L' Etat B.P. 10 2010 LUXEMBOURG	
Netherlands	Ministerie van Verkeer en Waterstaat Hoofdirectie Telecommunicatie en Post Postbus 450 9700 AL GRONINGEN	
Portugal	Instituto das Comunicações de Portugal (ICP) Av. J. Malhoa, 12 1070 LISBOA	
Spain	Ministerio de Fomento Dirección General de Telecomunicaciones Palacio de Telecomunicaciones Plaza de Cibeles, s/n. Planta 5a 28014 MADRID	Equipos de telecomunicación
Spain	Ministerio de Industria y Energia Dirección General de Calidad y Seguridad Industrial Paseo de la Castellana, 160 Planta 12 28071 MADRID	Todos los equipos afectos a la Directiva excepto los equipos de telecomunicacion.
Sweden	National Electrical Safety Board P.O.B. 1371 11193 Stockholm	National co-ordinating authority for implementing the EMC legislation. Supervision and market surveillance authority concerning EMC for all products with the exception of radio transmitters and equipment intended for connection to the public telecommunications network
Sweden	National Post and Telecom Agency P.O.B. 5398 10249 Stockholm	Supervision and market surveillance authority concerning EMC for radiotransmitters and equipment intended for connection to the public telecommunications network

United Kingdom	Department of Trade and Industry Standards Policy Unit 151 Buckingham Palace Road LONDON SW1W 9SS	
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ATTACHMENT 3**DESIGNATED CONFORMITY ASSESSMENT BODIES**

(This should give name, address, telephone and fax no., 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	August 13, 1994
ICES 003	Digital Apparatus	3	November 22, 1997
ICES 0040	Alternating Current High Voltage Power Systems	1	June 1991

EU-CANADA MRA

**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 93/68/EEC) (Footnote 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 EC LVD (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 recognizing CABs and in the ability of those bodies to carry out their mandates. Successful completion of the transition phase should

¹ The categories of equipment outside the scope of the LVD 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.

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 EC CABs, they must satisfy the following requirements:

- 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 Organization accredited by the Standards Council of Canada.

- 5.2 During the transition phase, EC 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 Organization in Canada.

- 5.3 Canadian Certification Organizations shall ensure that:

- a) they inform the applicant and the EC 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 recognized 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 recognized by the Responsible/Designating Authorities shall operate as follows:

- a) For access to the EC market:

If a product is challenged under the LVD, a report drawn up by a Canadian CAB recognized 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 recognized 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 organization according to applicable and relevant ISO/IEC Guides adapted to Canadian and European conditions for accreditation of certification organizations; and
- iii) Evidence of procedures for follow-up of certification activities including the identification of a contact point who shall be 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 organizations 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 marketplace. That plan shall identify a contact point who shall be 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 Community	Canada
<p>Council Directive 73/23/EEC as amended by Council Directive 93/68/EEC</p> <p>EU Regulatory Authorities: list is the same as per Attachment 2</p>	<p>The Canadian Electrical Code as referenced in the provincial / territorial legislation is under the responsibility of the following provincial / territorial Regulatory Authorities:</p>
	<p>Alberta: The Safety Codes Act, Statutes of Alberta, 1991, Chapter S-0.5; Alberta Department of Labour, Technical and Safety Services;</p>
	<p>British Columbia: Electrical Safety Act, Chapter 109 Electrical Safety Regulation, B.C. Reg 253/96 Ministry of Municipal Affairs & Housing;</p>
	<p>Manitoba: The Manitoba Hydro Act, 1976 Provincial Regulations 126-94 amended in September 1995 Manitoba Hydro;</p>
	<p>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;</p>
	<p>Newfoundland: Public Safety Act Electrical Regulations, 1996 Department of Government Services and Lands;</p>
	<p>Northwest Territories: Electrical Protection Act, R.S.N.W.T. 1988, C.E-3 Department of Public Works and Services;</p>

	<p>Nova Scotia: The Electrical Installation and Inspection Act Nova Scotia Department of Labour;</p>
	<p>Ontario: The Power Corporation Act, Revised Statutes of Ontario, 1990, Chapter P18, Section III Ontario Regulation 612-94 Ontario Hydro;</p>
	<p>Prince Edward Island: The Electrical Inspection Act The Electrical Inspection Act Regulations Department of Community Affairs and Attorney General;</p>
	<p>Québec: 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;</p>
	<p>Saskatchewan: The Electrical Inspection Act, 1993 Electrical Inspection Regulations SaskPower;</p>
	<p>Yukon: The Electrical Protection Act OIC 1992-017 Electrical Protection Act Yukon Regulations Yukon Department of Community and Transportation Services</p>

ATTACHMENT 2**DESIGNATING AUTHORITIES**

1. The Authorities responsible for the designation of conformity assessment bodies under this agreement are:

a) For the European Community:

- **Austria:** Bundesministerium für wirtschaftliche Angelegenheiten
- **Belgium:** Ministère des Affaires Economiques/Ministerie van Economische Zaken
- **Denmark:** Elektricitetsradet
- **Finland:** Ministry of Trade and Industry
- **France:** Ministère de l'Economie, des Finances et de l'Industrie
- **Germany:** Bundesministerium für Arbeit und Sozialordnung
- **Greece:** Ministry of Development
- **Ireland:** Department of Enterprise, Trade and Employment
- **Italy:** Ministero dell'Industria
- **Luxembourg:** Service de l'Energie de l'Etat
- **Netherlands:** Ministerie van Economische Zaken
- **Portugal:** under authority of the Ministry of Industry: Instituto Portugees da Qualidade
- **Spain:** Ministerio de Industria y Energia
- **Sweden:** under authority of the Government of Sweden: Styrelsen for 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.

EU-CANADA MRA

**SECTORAL ANNEX
FOR
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 #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 Directives 94/25 EEC. These certificates will be recognized in the European Community without any further assessment of the products to which they relate.

b) for approval 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

European Parliament and European Council Directive 94/25 EEC on The Approximation of the Laws, Regulations and Administration Provisions of the Member States Relating to Recreational Craft.

2.2. for Canada

Regulatory Requirements - The Canada Shipping Act, Chapter 1487, Small Vessel Regulations which referenced in Transport Canada's Publication #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 Coast Guard

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 authorized 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
Member States Administrations as indicated in the Directive 94/25/EEC, Article 9.1	The Canadian Coast Guard

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.

EU-CANADA MRA

**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 Authorizations / 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 Authorization / 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 Authorization / 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 recognized 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) (eg 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. The 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 MA / 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).

The 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 Authorization (MA) or product specifications and by assignment procedure of the Drug Identification Number (DIN) 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 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 **Appendix6**).

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 this Appendix 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 recognize the conclusions of the GMP compliance programme carried out by the other Party in its territory, and the relevant Certificates of Manufacturing Authorizations / 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 recognized 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 authorization, 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 Authorizations / 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 Authorization / 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 calendar days. In cases when a new inspection has to be carried out, this period may be extended to 60 calendar 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 Authorization / 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 Authorization / 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 Authorizations / 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 calendar days, this period being extended to 60 calendar 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 organize 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 81/352 EEC as modified
Directive 91/356 EEC as modified
Directive 91/412 EEC as modified
Regulation N° (EC) 2309/93
Directive 25/92 & Guide to Good Distribution Practice
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

Recognizing that precise definitions of medicinal products and drugs are to be found in the legislations 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 (Note: APIs are not GMP regulated)

Appendix 2**AUTHORITIES****For the European Community:**

Austria:	Austrian Inspection Service, Federal Ministry of Health and Consumer Protection, Vienna
Belgium:	Pharmaceutical Inspectorate, Ministry of Social Affairs, Public Health and Environment; Brussels
Denmark:	Medicines Inspectorate, Medicines Division, National Board of Health, Bronshøj
Finland:	National Agency for Medicines, Ministry of Social Affairs and Health, Helsinki
France:	Agency of Medicine, Paris National Agency of Veterinary Medicine, Paris
Germany:	Federal Ministry of Health, Bonn Paul-Ehrlich Institute, Langen 16 Landers
Greece:	National Drug Organization (EOF), Ministry of Health, Athens
Ireland:	National Drugs Advisory Board, Department of Health, Dublin
Italy:	Central Inspectorate, Ministry of Health, Rome
Luxembourg:	National Laboratory of Health, Luxembourg
The Netherlands:	Inspectorate for Health Care; Ministry of Health, Welfare, and Sport, Rijswijk
Portugal:	Pharmacies and Pharmaceutical Inspection, National Institute of Pharmacy and of Medicine (INFARMED), Lisbon
Spain:	Sub-directorate General for Pharmaceutical Control, Directorate General for Pharmacies and Sanitary Products, Ministry of Health and Consumers, Madrid
Sweden:	Medical Products Agency, Uppsala
United Kingdom:	Medicines Control Agency, London Veterinary Medicines Directorate, Surrey

For Canada:

Therapeutic Products Programme, Health Canada, Ottawa.
Bureau of Veterinary Drugs, Food Directorate, Health Canada,
Ottawa

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
- Organizational structure, including roles, responsibilities and reporting relationships

3. Good Manufacturing Practices (GMP) Standards

- Scope/details 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 firm

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 firm and by regulatory authority)

- Sampling and audit procedures
- Recall monitoring (including effectiveness controls and verifications 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 0L2, Canada. Telephone 1-613-957-0369, Fax 1-613-952-7756; and

for the European Community,

the Director of the Evaluation of Medicinal Products Agency, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone +44-171-418 8400, Fax 418 8416.

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/Legislations 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 organization 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).

EU-CANADA MRA

**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
 - Directive 90/385/EEC relating to active implantable medical devices (OJL 189 of 20 July 1990), as amended.
 - Directive 93/42/EEC relating to medical devices (OJL 169 of 12 July 1993), as amended.
 - (b) for Canada
 - The Food and Drugs Act and Medical Devices Regulations (proposed for promulgation 1997) 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 program 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 Program

At the beginning of the transitional period, the Joint Sectoral Group will elaborate a joint Confidence Building Program (guidance provided in Attachment III). The implementation of this program 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 organization 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 or 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 Program, 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 eighteen 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 Program, 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 Designating/Regulatory Authorities, listed in Attachment I, to the Joint Sectoral Group on the basis of the results of the Confidence Building Program. 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 recognized. 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 re-consideration 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 recognize 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 re-assessment.

For evaluation against European requirements, Health Canada or other Conformity Assessment Bodies designated by Canada shall establish the conclusions of completed conformity assessments 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 re-assessment, 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 re-assessment, 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 Program, 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 organize 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 Program. 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 [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
<p>Canada Medical Devices Bureau, Therapeutic Products Directorate, Health Canada</p>	<p>Austria Federal Ministry of Health and Consumer Protection</p> <p>Belgium Ministere de la Sante publique, de l'Environnement et de l'Integration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie</p> <p>Denmark Sundhedsministeriet</p> <p>Finland Sosiaali-ja terveysministerio</p> <p>Germany Bundesministerium fur Gesundheit</p> <p>Greece Ministry of Health</p> <p>Spain Ministerio Sanidad y Consumo</p> <p>France Ministere de l'Emploi et de la Solidarité</p> <p>Ireland Department of Health</p> <p>Italy Ministero della Sanita</p> <p>Luxembourg Ministere de la Sante</p> <p>Netherlands Ministerie van Volksgezondheid, Welzijn en Sport</p> <p>Portugal Ministerio da Saude</p> <p>Sweden Under the authority of the Government of Sweden: Styrelsen for akkreditering och teknisk kontroll (SWEDAC)</p> <p>United Kingdom Department of Health</p>

ATTACHMENT II**DESIGNATED CONFORMITY ASSESSMENT BODIES AND THEIR RESPECTIVE DESIGNATING AUTHORITIES**

For Canada	For the European Community
To be completed after the Confidence Building Program	To be completed after the Confidence Building Program

ATTACHMENT III**PHASES AND ELEMENTS OF A CONFIDENCE BUILDING PROGRAM**

- 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
 - Organizational 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 (appropriateness 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 verifications of procedures)
 - Consumer complaint systems/procedures
 - Adverse incident reporting systems/procedures
12. Quality Management Systems
- Quality management/assurance systems/procedures to ensure the ongoing 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 organization 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 they are 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 facsimile (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, ongoing 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.

Financial Statement 1998-2002

External trade relations - Mutual Recognition Agreement

1. TITLE

External Trade Relations-
Mutual Recognition Agreements with United States, Canada, Australia, New Zealand and Israel.

2. BUDGETARY HEADINGS: **B7-8500**
 A-7010

3. LEGAL BASIS

- Article 113 of the Treaty of Rome
- Proposal for Council decisions N° on the implementation by the European Commission of mutual recognition agreements with United States, Canada, Australia, New Zealand and Israel.

4. DESCRIPTION OF OPERATION :

4.1 General objective:

The purpose of these agreements is to establish mutual recognition of certification of conformity of products with technical regulations or standards of partners to the agreement.

The major actions which will be pursued by the Commission under this budget line will be the following:

- Confidence-building activities to facilitate the proper implementation of the Agreement.
- Management of the Agreements and maintenance of the necessary degree of confidence.

The Commission will be assisted by experts, particularly in regard to sectoral activities. It will however remain the final arbiter in the management of these agreements.

4.2 Duration of the action; means foreseen for its renewal:

The general action undertaken will be of an indefinite duration. The initial period of confidence-building required by the Agreements will require a more intensive effort and expenditure, but this should be substantially less after 2 years. However, during the life of the Agreements a continued effort will be needed to ensure management and maintenance of confidence.

5. CLASSIFICATION OF EXPENDITURE/REVENUE

5.1 Non-compulsory expenditure ("DNO")

5.2 Differentiated appropriation ("CD")

5.3 Type of revenue involved:
None

6. TYPE OF EXPENDITURE/REVENUE

- *100% subsidy: No*
- *subsidy for co-financing with other sources in the public or private sector?*

Yes, this may be envisaged as a method of funding. Subsidies not normally exceeding 50% will be provided to professional associations and other responsible organisations for activities related to the implementation of the Agreement.

- *Interest subsidy: No*
- *Others*

Financing of events, acquisition of studies, publications and conferences.

- *Should the action prove an economic success, is there provision for all, or part of, the Community contribution to be reimbursed?*

Not relevant

- *Will the proposed operation cause any changes in the level of revenue?*

No

7. FINANCIAL IMPACT ON APPROPRIATIONS FOR OPERATIONS

7.1 Method of calculating the total cost of the operation:

The estimation of costs is based on the anticipated requirements in terms of expenses related to training, seminars, workshops, travel of experts, verification of conformity assessment bodies, information and studies. The total estimated cost is based on the sum of the individual actions.

A range of different actions are foreseen to meet the objectives of the budget-line and costs will vary depending on the nature of action undertaken. Even for similar types of action (e.g. seminars) costs will vary depending on the scope of the action and the degree of specialisation needed.

The costs of specific actions will be determined either:

- by the Commission when it organises activities itself, e.g. seminars
- following invitations to tender issued by the Commission
- following requests for subsidies. In such cases, projects are selected according to how well they meet the criteria which have been established for selection. Subsidies are based on a percentage of total costs and usually the Community funding is limited to a maximum of 50%.

A. Attendance at Joint Committee

These will be attended by Commission officials and some national experts. Travel and per diem expenses should be foreseen within the normal range of such expenses.

B. Attendance at Joint Sectoral Groups

These will also be attended by Commission officials and given the nature of these meetings a larger contingent of national experts. Travel and per diem expenses should be foreseen within the normal range of such expenses.

C. Workshops and Seminars

These will be held to familiarise economic and other operators with the requirements of the Agreement. The cost of these seminars will vary according to the subject matter and location, and will include organisational costs (when in Europe) and substantial travel costs when in the territory of the partner country. Organisational costs in Europe will cost c. 3000 ECUs each. The number of seminars will vary depending on the individual industrial sectors covered by the Agreement.

D. Verification actions

The competence of the conformity assessment bodies (CABs) will in many cases have to be checked, more so in the initial period of the Agreement, but as a matter of course throughout the life of the Agreement to maintain confidence in the system.

This will involve on-site assessment by teams of experts of conformity assessment bodies in the partner country in the initial stages, and subsequently investigation of complaints. This expenditure will be essential in all sectors of the Agreement (... in number) and may involve numerous CABs in each sector including at subfederal or local level in certain cases.

E. Production and dissemination of information

Certain costs may need to be incurred for the dissemination of information. Guides to regulations and assessment procedures may be needed typically at a cost of 10 000 ECUs.

7.2 Breakdown by elements of the operation

"Trade Agreements with important Trading Partners"

For 1998, this involves the following calculation:

Budget Heading	Amounts (Ecus)	Method of calculation	
		No. of missions	Standard Unit cost
Joint Committee B7-8500	12 940	Bxl 2 Bxl 2 Aus / NZ 2 Israël 1	US: Travel: 2 000 Ecus; per diem: 185 Ecus
Sectoral Groups B7-8500	57 680	Bxl 16 US 8 CAN 8	CAN: Travel: 1 750 Ecus; per diem: 170 Ecus
Seminars B7-8500	103 540	US 10 CAN 10 Aus / NZ 14 Bxl 28	Aus / NZ: Travel: 3 200 Ecus; per diem: 190 Ecus
Verifications B7-8500	142 150	US 18 CAN 18 Aus / NZ 12 Israël 1	Brussels: Travel: 800 Ecus; per diem: 110 Ecus
Information B7-8500	10 000		
B7-8500 Total	326 310	150	

In Ecus
(current prices)

Breakdown	Year 1998	Year 1999	2000	2001	2002	Total 1998-2002
A. Joint Committee	12.940	13 760	12 940	13 760	12 940	66 340
B. Joint Sectoral Groups	57 680	57 680	57 680	57 680	57 680	288 400
C. Seminars	103 540	96 310				199 850
D. Verifications	142 150	142 150	48 430	48 430	48 430	429 590
E. Information	10 000	10 000	10 000			30 000
Total	326 310	319 900	129 050	119 870	119 050	1 014 180

From the year 2000 on the estimates are for information.

7.3 Indication of the timetable for commitment and payment appropriations

	1000 Ecus						
	Year 1998	1999	2000	2001	2002	2003 and following years	Total
Schedule of Commitment	326	319	129	119	119	119	1131
Payment appropriations							
1998	326						326
1999		319					319
2000			129				129
2001				119			119
2002					119		119
2003						119	119
Total	326	319	129	119	119	119	1131

8. WHAT ANTI-FRAUD MEASURES ARE PLANNED IN THE PROPOSAL FOR THE OPERATION ?

Methods of control (submission of reports, etc.) will be included in all contracts between the Commission and beneficiaries.

A close cooperation with the delegations of the Commission and the participation of a representative of the Commission at events in third countries will check on the spot the work to ensure that it corresponds with the terms of reference, contract provisions and required professionalism.

The checks take place before the final payment. The same rule applies to the financial incentives paid to participating companies. Where appropriate, agreements also require organisations to submit financial accounts certified by their auditors.

In those cases involving cooperation with EU industrial federations the accounts are further checked at the Annual General Meeting of the federations concerned.

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1. Specific objectives of the proposed operation, population targeted

- *The specific objectives of mutual recognition agreements are:*

- to avoid duplication of certification by economic operators.
- to promote exports, employment, competitiveness and investment.
- to reduce costs, in particular for small and medium-sized enterprises and ultimately for the consumer.

- *Target population*

The target population are the exporting companies, business associations, chambers of commerce and public institutions of the European Union and the general consumer which will benefit, or have an interest in, the mutual recognition of certification.

9.2. Reasons for the operation

- *Need for intervention from the Community budget*

Under Article 113 of the Treaty of Rome the Community has exclusive competence for commercial policy and these agreements have been negotiated in accordance with a mandate of the Council of Ministers and in consultation with the 113 Committee. The Commission will be responsible for implementation and management of the agreements.

- *Choice of methods of intervention*
 - * *advantages over alternative measures (comparative advantages)*
 - * *analysis of similar operations at Community or national level*
 - * *results and expected multipliers*

The choice of management method (Joint Committee and Joint Sectoral Groups) have been set out in the Agreements and constitute a minimum necessary for the proper functioning of the Agreement. The Agreements also contain provisions for the use of seminars in the initial phases to ensure familiarity with other systems.

These seminars and verifications are also designed to build mutual confidence; verifications will also be required to ensure this confidence is maintained throughout the life of the agreements. Confidence and its maintenance are keys to the successful operation of the agreements.

The importance of this budget is justified when put in perspective with the trade involved in these agreements and the yearly savings for EU exporters which are expected (estimated on a yearly basis at 190 millions ECUs for EU exporters to the US, 20 mio in the case of exports to Canada and 40 mio in the case of exports to Australia and New Zealand).

- *Main factors of uncertainty which could affect the specific results of the operation.*
 - * None

9.3 Monitoring and evaluation of the operation

- *Performance indicators selected*
 - * *Output indicators*
 - * *indicators of impact, following the objectives chosen*

In the case of these Agreements, success can be quantified by trade facilitation through avoidance of duplication of testing and certification and costs. Yearly estimated savings for the European Community are indicated above (9.2).

Success can also be measured by increased EU exports and this factor will be taken into consideration although export performance is subject to such a wide range of variables (e.g. changes in exchange rates) that this can never be the sole factor for evaluation.

- *Evaluation of results*

Progress in the attainment of the Agreements objectives will be monitored by Commission officials, Committees established under the Agreements and by the economic operators concerned.

Details and frequency of the planned evaluation

The evaluation of the effectiveness and usefulness of the agreements will be regularly monitored by the Commission and by the Committees established under the agreements at their annual meetings. The first major evaluation will be at the end of the confidence-building period.

10. ADMINISTRATIVE EXPENSES

Actual mobilisation of the necessary administrative resources will depend on the Commission's annual decision on the allocation of resources, taking into account the number of staff and additional amounts authorised by the budgetary authority. There is no request for additional staff.

10.1 Effect on the number of posts

Type of post	Staff to be assigned to managing the operation		Source		Duration
	<u>Permanent posts</u> DG I + sectoral DGs	<u>Temporary posts</u>	Existing resources in the DGs or departments concerned	Additional resources	
Officials	A	3.5	None	3.5	permanent
	B				
	C	1		1	
Other resources	None				
Total		4.5		4.5	

10.2 Overall financial impact of human resources: 4.5 staff (107 500 Ecus per staff member per year = 483 750 Ecus).

10.3 Increase in other administrative expenditure as a result of the operation (A-7010: travel expenses)

The expenses set out below relate to travel expenses for officials of the Commission attending meetings of the Joint Committee, joint sectoral groups, seminars and verifications, when these are outside Brussels. These will be taken care of by the relevant budget allocations of various Directorates Generals involved.

For 1998 this involves the following calculation:

Budget heading	Amounts (ECU)	Method of calculation		
		No. of missions	Standard Unit cost	
Joint Committee A-7010	22 120	Aus / NZ Israel	4 4	US: Travel: 2 000 ECUs; per diem: 185 Ecus
Sectoral Groups A-7010	20 680	US CAN	4 4	CAN: Travel: 1 750 Ecus; per diem: 170 Ecus
Seminars A-7010	20 680	US CAN Aus / NZ	4 4	Aus / NZ: Travel: 3 200 Ecus; per diem: 190 Ecus
Verifications A-7010	142 150	US CAN Aus / NZ Israel	18 18 12 1	
A-7010 Total	205 630		73	

In ECU

	Year 1998	Year 1999	2000	2001	2002	Total 1998-2002
A. Joint Committee	22 120	20 680	22 120	20 680	22 120	107 720
B Joint Sectoral Groups	20 680	20 680	20 680	20 680	20 680	103 400
C. Seminars	20 680	18 260				38 940
D. Verifications	142 150	142 150	48 430	48 430	48 430	429 590
TOTAL	205 630	201 770	91 230	89 790	91 230	679 650

IMPACT ASSESSMENT FORM
THE IMPACT OF THE PROPOSAL ON BUSINESS
with special reference to small and medium-sized enterprises

Title of proposal

Proposal for a Council Decision on the conclusion of an Agreement between the European Community and Canada on Mutual Recognition in relation to Conformity Assessment.

Reference number

The proposal

The legislation is necessary to conclude an Agreement between the European Community and Canada on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings. This is an agreement negotiated and initialled by the Commission in accordance with the mandate and negotiating directives provided by the Council on 21/9/92.

The impact on business

The business sectors affected are telecommunications terminal equipment, electrical equipment, recreational craft, medicinal products, and medical devices.

The Agreement permits certification of conformity with technical regulations on product safety, etc, to be conducted in Europe for exports destined for Canada. This avoids the necessity for further certification by Canadian conformity assessment bodies before putting them on the Canadian market.

The Agreement therefore presents important advantages from the point of view of transparency, market access, avoidance of duplication especially of cost and general facilitation of trade. This is of particular importance for small and medium-sized enterprises.

The Agreement covers a wide range of sectors spread throughout the Community and an extensive range of firms in these sectors both large and small. the advantages are not limited to specific geographical areas in the Community.

Businesses will have to comply with Canadian regulations and procedures, but the certification, as stated above, will be conducted by conformity assessment bodies located in the Community and designated by the Member States, and not in Canada.

The Agreement will substantially reduce certification costs and improve prospects for exports, employment, investment and competitiveness by European firms.

The Agreement does not contain measures to take account of the specific situation of small and medium-sized firms, but by its nature and by reducing certification costs which are the same for all firms, the agreement will benefit small and medium sized enterprises to a greater extent proportionately than larger firms.

Consultation

The main trade organisations in each sector eg Eurobit, Orgalime, EFPIA, have been consulted and have universally declared their support for the Agreement.

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