►**B**

AGREEMENT

on mutual recognition in relation to conformity assessment between the European Community and New Zealand

(OJ L 229, 17.8.1998, p. 62)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand	L 356	2	22.12.2012

▼B

AGREEMENT

on mutual recognition in relation to conformity assessment between the European Community and New Zealand

THE EUROPEAN COMMUNITY and the GOVERNMENT OF NEW ZEALAND, hereinafter referred to as 'the Parties',

CONSIDERING the traditional links of friendship that exist between them,

CONSIDERING their shared commitment to promoting the enhancement of product quality, with a view to ensuring the health, safety and environment of their citizens,

DESIRING to conclude an agreement providing for the mutual recognition of the respective conformity assessment procedures required for market access to the territory of the Parties,

TAKING INTO ACCOUNT the improved conditions of trade between the Parties which the mutual recognition of test reports and certificates of conformity will bring about,

AWARE of the positive contribution that mutual recognition can have in encouraging greater international harmonisation of standards and regulations,

NOTING the close relationship between New Zealand and Australia as confirmed in the Australian and New Zealand Closer Economic Relations Trade Agreement and the Trans-Tasman Mutual Recognition Arrangement as well as the growing level of integration of the New Zealand and Australian conformity assessment infrastructures through the Agreement concerning the establishment of the Council of the Joint Accreditation System of Australia and New Zealand (JAS-ANZ),

NOTING the close relationship between the European Community and Iceland, Liechtenstein and Norway through the Agreement on the European Economic Area, which makes it appropriate to consider the conclusion of a parallel mutual recognition agreement between New Zealand and these countries equivalent to this Agreement,

BEARING IN MIND their status as Contracting 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

1. General terms used in this Agreement and its Annexes shall have the meaning given in the definitions contained in ISO/IEC Guide 2 (1991) 'General terms and their definitions concerning standardisation and related activities' and in EN 45020 (1993 edition) unless the context requires otherwise. In addition, the following terms and definitions shall apply for the purpose of this Agreement:

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

▼B

'Conformity assessment body' means a body whose activities and expertise include performance of all or any stage of the conformity assessment process;

'Designation' means the authorisation by a designating authority of a conformity assessment body to perform conformity assessment activities; 'designated' has a corresponding meaning;

'Designating authority' means a body with the legal power to designate, suspend or withdraw designation of conformity assessment bodies under its jurisdiction.

2. The terms 'conformity assessment body' and 'designating authority' apply mutatis mutandis to other bodies and authorities with corresponding functions referred to in some Sectoral Annexes.

Article 2

General obligations

1. The Government of New Zealand shall accept attestations of conformity including test reports, certificates, authorisations and marks of conformity as required by legislation and regulations identified in the Sectoral Annexes issued by designated conformity assessment bodies in the European Community in accordance with this Agreement.

2. The European Community shall accept attestations of conformity including test reports, certificates, authorisations and marks of conformity as required by legislation and regulations identified in the Sectoral Annexes, issued by designated conformity assessment bodies in New Zealand in accordance with this Agreement.

3. This Agreement shall not entail mutual acceptance of the standards or technical regulations of the Parties or mutual recognition of the equivalence of such standards or technical regulations.

Article 3

Sectoral coverage

1. This Agreement concerns the conformity assessment procedures to satisfy mandatory requirements covered by the Sectoral Annexes.

▼M1

2. Each Sectoral Annex shall, in general, contain the following information:

(a) a statement of its scope and coverage;

(b) the legislative, regulatory and administrative requirements pertaining to the conformity assessment procedures;

(c) the designating authorities;

(d) a set of procedures for the designation of conformity assessment bodies, and

(e) additional provisions as required.

▼M1

Article 4

Scope and coverage

This Agreement shall apply to products specified in the statement of scope and coverage in each Sectoral Annex.

▼B

Article 5

Conformity assessment bodies

In accordance with the terms of the Annex and the Sectoral Annexes, each Party recognises that the conformity assessment bodies designated by the other Party fulfil the conditions of eligibility to assess conformity in relation to their requirements as specified in the Sectoral Annexes. In designating such bodies, the Parties shall specify the scope of the conformity assessment activities for which they have been designated.

▼M1

Article 6

Designating authorities

1. The Parties shall ensure that the designating authorities responsible for designating conformity assessment bodies have the necessary power and competence to designate, suspend, remove suspension and withdraw the designation of such bodies.

2. In making such designations, suspensions, removals of suspension and withdrawals, designating authorities shall, unless specified otherwise in the Sectoral Annexes, observe the procedures for designation set out in Article 12 and the Annex.

▼B

Article 7

Verification of designation procedures

▼M1

1. The Parties shall exchange information concerning the procedures used to ensure that the designated conformity assessment bodies under their responsibility comply with the legislative, regulatory and administrative requirements outlined in the Sectoral Annexes and the competence requirements specified in the Annex.

▼B

2. The Parties shall compare methods used to verify that the designated conformity assessment bodies comply with the legislative, regulatory and administrative requirements outlined in the Sectoral Annexes and the competence requirements specified in the Annex. Existing systems for the accreditation of conformity assessment bodies in the two Parties may be used for such comparison procedures.

▼B

3. Such comparison shall be carried out in accordance with the procedures to be determined by the Joint Committee established under Article 12.

Article 8

Verification of compliance of conformity assessment bodies

1. Each Party shall ensure that conformity assessment bodies designated by a designating authority will be available for verification of their technical competence and compliance with other relevant requirements.

2. Each Party has the right to contest 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.

▼M1

3. Such contestation has to be justified in an objective and argued manner and in writing to the other Party and to the Joint Committee.

▼B

4. Where the Joint Committee decides that verification of technical competence or compliance is required, it will be carried out in a timely manner jointly by the Parties with the participation of the relevant designating authorities.

5. The result of this verification will be discussed in the Joint Committee with a view to resolving the issue as soon as possible.

▼M1

6. Except when decided otherwise by the Joint Committee, the contested conformity assessment body shall be suspended by the competent designating authority from the time its technical competence and compliance is contested in accordance with this Article until either agreement is reached in the Joint Committee on the status of that body or the challenging Party notifies the other Party and the Joint Committee that it is satisfied as to the technical competence and compliance of that body.

Article 9

Exchange of information

1. The Parties shall exchange information concerning the implementation of the legislative, regulatory and administrative provisions identified in the Sectoral Annexes and shall maintain an accurate list of conformity assessment bodies designated in accordance with this Agreement.

2. Consistent with their obligations under the World Trade Organization Agreement on Technical Barriers to Trade, each Party shall inform the other Party of the changes it intends to make to the legislative, regulatory and administrative provisions relating to the subject matter of this Agreement and shall, except as provided for in paragraph 3 of this Article, notify the other Party of the new provisions at least 60 calendar days before their entry into force.

▼M1

3. Where a Party takes urgent measures that it considers warranted by considerations of safety, health or protection of the environment in order to manage a risk posed by a product covered by a Sectoral Annex, it shall notify immediately the other Party of the measures, with a brief indication of their objective and rationale, or as otherwise specified in the Sectoral Annex.

▼B

Article 10

Uniformity of conformity assessment procedures

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 coordination and comparison exercises conducted by each of the Parties in the relevant areas covered by the Sectoral Annexes.

Article 11

Agreements with other countries

The Parties agree that mutual recognition agreements concluded by either Party with a country which is not a party to this Agreement shall in no way entail an obligation upon the other Party to accept test reports, certificates, authorisations and marks of conformity issued by conformity assessment bodies in that third country, save where there is an express agreement between the Parties.

Article 12

Joint Committee

1. A Joint Committee made up of representatives of the two Parties shall be established. It is responsible for the effective functioning of the Agreement.

2. The Joint Committee shall determine its own rules of procedure. It shall take its decisions and adopt its recommendations by consensus. It can decide to delegate specific tasks to subcommittees.

▼M1

3. The Joint Committee shall meet at least once a year unless the Joint Committee or the Parties decide otherwise. If required for the effective functioning of this Agreement, or at the request of either Party, an additional meeting or meetings shall be held.

4. The Joint Committee may consider any matter related to the functioning of this Agreement. In particular, it shall be responsible for:

(a) amending the Sectoral Annexes in accordance with this Agreement;

(b) exchanging information concerning the procedures used by either Party to ensure that the conformity assessment bodies maintain the necessary level of competence;

▼M1

(c) in accordance with Article 8, appointing a joint team or teams of experts to verify the technical competence of a conformity assessment body and its compliance with other relevant requirements;

(d) exchanging information and notifying the Parties of modifications of legislative, regulatory and administrative provisions referred to in the Sectoral Annexes including those which require modification of the Sectoral Annexes;

(e) resolving any questions relating to the application of this Agreement and its Sectoral Annexes, and

(f) adopting new Sectoral Annexes in accordance with this Agreement.

5. Any amendments to the Sectoral Annexes made in accordance with this Agreement and any new Sectoral Annexes adopted in accordance with this Agreement shall be notified promptly in writing by the Joint Committee to each Party, and shall come into effect as determined by the Joint Committee.

6. The following procedure shall apply in relation to the designation of a conformity assessment body:

(a) a Party wishing to designate a conformity assessment body shall forward its proposal to that effect to the other Party in writing, adding supporting documentation, as may be defined by the Joint Committee;

(b) in the event that the other Party consents to the proposal or upon the expiry of 60 calendar days without an objection having been lodged, in accordance with any applicable procedures established by the Joint Committee, the conformity assessment body shall be considered to be a designated conformity assessment body under the terms of Article 5;

(c) in the event that, under Article 8, the other Party contests the technical competence or compliance of the proposed conformity assessment body within the aforementioned 60-day period, the Joint Committee may decide to carry out a verification of the body concerned, in accordance with Article 8;

(d) in the case of the designation of a new conformity assessment body, conformity assessment carried out by such a body shall be valid from the date on which it becomes a designated conformity assessment body in accordance with this Agreement;

(e) either Party may suspend, remove the suspension of, or withdraw the designation of a conformity assessment body under its jurisdiction. The Party concerned shall immediately notify the other Party and the Joint Committee of its decision in writing, together with the date of such decision. The suspension, removal of suspension or withdrawal of the designation shall take effect from the date of the Party's decision;

(f) in accordance with Article 8, either Party may, in exceptional circumstances, contest the technical competence of a designated conformity assessment body under the jurisdiction of the other Party. In this case the Joint Committee may decide to carry out a verification of the body concerned, in accordance with Article 8.

▼M1

7. In the event that the designation of a conformity assessment body is suspended or withdrawn, conformity assessment carried out by that body before the date of effect of the suspension or withdrawal shall remain valid unless either the responsible Party has limited or cancelled that validity, or the Joint Committee determines otherwise. The Party under whose jurisdiction the suspended or withdrawn conformity assessment body was operating shall notify the other Party in writing of any such changes relating to a limitation or cancellation of validity.

▼B

8. 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 mutual recognition implementing arrangements established by this Agreement.

Article 13

Territorial application

This Agreement shall apply, as regards the European Community, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, as regards New Zealand, this Agreement shall not apply to Tokelau unless the Parties have exchanged Notes agreeing the terms on which this Agreement shall apply.

Article 14

Entry into force and duration

1. This Agreement shall enter into force on the first day of the second month following the date on which the Parties have exchanged Notes confirming the completion of their respective procedures for the entry into force of this Agreement.

2. Either Party may terminate this Agreement by giving the other Party six months' notice in writing.

Article 15

Final provisions

1. The Annex to this Agreement forms an integral part thereof.

2. Any amendment to this Agreement shall be done by mutual agreement.

▼M1

3. The Joint Committee may adopt Sectoral Annexes to which Article 2 applies and which will provide the implementing arrangements for this Agreement.

4. Amendments to the Sectoral Annexes, and the adoption of new Sectoral Annexes, shall be determined by the Joint Committee.

▼B

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

Hecho en Wellington, el veinticinco de junio de mil novecientos noventa y ocho.

Udfærdiget i Wellington den femogtyvende juni nitten hundrede og otteoghalvfems.

Geschehen zu Wellington am fünfundzwanzigsten Juni neunzehnhundertachtundneunzig.

Έγινε στο Ουέλλιγκτον, στις είκοσι πέντε Ιουνίου χίλια εννιακόσια ενενήντα οκτώ.

Done at Wellington on the twenty-fifth day of June in the year one thousand nine hundred and ninety-eight.

Fait à Wellington, le vingt-cinq juin mil neuf cent quatre-vingt-dix-huit.

Fatto a Wellington, addì venticinque giugno millenovecentonovantotto.

Gedaan te Wellington, de vijfentwintigste juni negentienhonderd achtennegentig.

Feito em Wellington, em vinte e cinco de Junho de mil novecentos e noventa e oito.

Tehty Wellingtonissa kahdentenakymmenentenäviidentenä päivänä kesäkuuta vuonna tuhatyhdeksänsataayhdeksänkymmentäkahdeksan.

Som skedde i Wellington den tjugofemte juni nittonhundranittioåtta.

▼B

Por la Comunidad Europea

For Det Europæiske Fællesskab

Für die Europäische Gemeinschaft

Για την Ευρωπαϊκή Κοινότητα

For the European Community

Pour la Communauté européenne

Per la Comunità europea

Voor de Europese Gemeenschap

Pela Comunidade Europeia

Euroopan yhteisön puolesta

På Europeiska gemenskapens vägnar

Por Nueva Zelanda

For New Zealand

Für Neuseeland

Για τη Νέα Ζηλανδία

For New Zealand

Pour la Nouvelle-Zélande

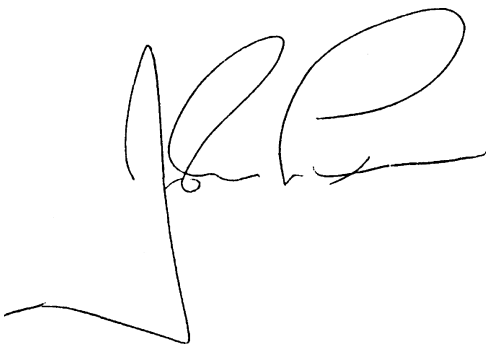
Per la Nuova Zelanda

Voor Nieuw-Zeeland

Pela Nova Zelândia

Uuden-Seelannin puolesta

För Nya Zeeland



▼B

ANNEX

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 competence 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,

— 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 competence 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' COMPETENCE

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

▼B

(a) **Accreditation**

Accreditation shall constitute a presumption of technical competence 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 competence of accreditation bodies and conformity assessment bodies accredited by them; or

(iii) the accreditation bodies, operating under the authority of the designating authority, take 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 competence 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 competence 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.

▼B

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 consultations 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.

▼M1

9. Designating authorities shall inform their Party's representatives on the Joint Committee, established under Article 12 of this Agreement, of the conformity assessment bodies to be designated, suspended or withdrawn. The designation, suspension or withdrawal of designation of conformity assessment bodies shall take place in accordance with this Agreement and the rules of procedure of the Joint Committee.

10. When advising their Party's representative on the Joint Committee established under this Agreement, of the conformity assessment bodies to be designated, 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 and e-mail address;

(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 competence.

▼B

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 Committee.

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.

▼B

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.

▼M1

SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION TO THE EUROPEAN COMMUNITY – NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

SCOPE AND COVERAGE

1. The provisions of this Sectoral Annex cover all medicinal products which are industrially manufactured in New Zealand and in the European Union, and to which Good Manufacturing Practice (GMP) requirements apply.

   For medicinal products covered by this Sectoral Annex, each Party will recognise the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other Party and the relevant manufacturing authorisations granted by the competent authorities of the other Party.

   In addition, the manufacturer's certification of the conformity of each batch to its specifications will be recognised by the other Party without re-control at import.

   'Medicinal products' means all products regulated by the pharmaceutical legislation in the European Union and New Zealand referred to in Section I. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radiopharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feedingstuffs, and, where appropriate, vitamins, minerals, herbal remedies and homoeopathic medicinal products.

   'GMP' is that part of quality assurance which ensures that products are consistently produced and controlled during manufacture to the quality standards appropriate to their intended use and as required by the marketing authorisation granted by the importing Party. For the purpose of this Sectoral Annex it includes the system whereby the manufacturer receives the specification of the product and/or process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification (equivalent to Qualified Person certification in the European Union).

2. With respect to medicinal products covered by the legislation of one Party ('regulating Party') but not the other, the manufacturing company may request the authority nominated by the relevant contact point of the regulating Party listed in point 12 of Section III, for the purpose of this Agreement, that an inspection be made by the locally competent inspection service. This provision will apply, inter alia, to the manufacture of active pharmaceutical ingredients and intermediate products and products intended for use in clinical trials, as well as jointly determined pre-marketing inspections. Operational arrangements are detailed under point 3(b) of Section III.

Certification of manufacturers

3. At the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture of medicinal products will certify that the manufacturer:

▼M1

— is appropriately authorised to manufacture the relevant medicinal product or to carry out the relevant specified manufacturing operation;

— is regularly inspected by the authorities, and

— complies with the national GMP requirements recognised as equivalent by the two Parties, referred to in Section I. Where different GMP requirements are used as a reference (in line with the provisions in point 3(b) of Section III), this is to be mentioned in the certificate.

The certificates will also identify the site(s) of manufacture (and contract testing laboratories, if any). The format of the certificate will be decided by the Joint Sectoral Group.

Certificates will be issued expeditiously, and the time taken should not exceed 30 calendar days. In exceptional cases, such as when a new inspection has to be carried out, this period may be extended to 60 calendar days.

Batch certification

4. Each batch exported will be accompanied by a batch certificate prepared by the manufacturer (self-certification) after a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate will attest that the batch meets its specifications and will be kept by the importer of the batch. It will be made available upon request of the competent authority.

When issuing a certificate, the manufacturer will take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate will detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It will contain a statement that the batch processing and packaging records were reviewed and found to be in conformity with GMP. The batch certificate will be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Union the ‘qualified person’ as referred to in relevant European Union legislation. In New Zealand, the responsible person is named on the licence to manufacture issued under the relevant New Zealand legislation.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

Subject to Section III, general GMP inspections will be carried out against the GMP requirements of the exporting Party. The applicable legislative, regulatory and administrative provisions related to this Sectoral Annex are set out in the Table.

However, the reference quality requirements of products to be exported, including their manufacturing method and product specifications, will be those of the relevant product marketing authorisation granted by the importing Party.

▼**M1**

Applicable legislative, regulatory and administrative provisions for the European Union	Applicable legislative, regulatory and administrative provisions for New Zealand
— Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products, as amended	— Medicines Act, 1981 — Medicines Regulations, 1984
— Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended	— New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Parts 1, 2, 4 and 5 — Agricultural Compounds and Veterinary Medicines Act, 1997
— Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended	— Agricultural Compounds and Veterinary Medicines Regulations, 2001
— Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, as amended	— Agricultural Compounds and Veterinary Medicines (ACVM) Standard for Good Manufacturing Practice — Agricultural Compounds and Veterinary Medicines (ACVM) Guideline for Good Manufacturing Practice
— Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended	— and any legislation adopted on the basis of, or that amends, the above legislation
— Guide to Good Distribution Practice (94/C 63/03)	
— Volume 4 — Guidelines for good manufacturing practices for medicinal products for human and veterinary use	

SECTION II

OFFICIAL INSPECTION SERVICES

The lists of official inspection services related to this Sectoral Annex have been jointly determined by the Parties and will be maintained by them. If a Party requests from the other Party a copy of its latest lists of official inspection services, the requested Party will provide the requesting Party with a copy of those lists within 30 calendar days of the date of receipt of the request.

▼M1

SECTION III

OPERATIONAL PROVISIONS

1. **Transmission of inspection reports**

Upon reasoned request, the relevant inspection services will forward a copy of the last inspection report of the manufacturing or control site, in the case where analytical operations are contracted out. The request may concern a 'full inspection report' or a 'detailed report' (see point (2). Each Party will deal with these inspection reports with the degree of confidentiality requested by the Party of origin.

If the manufacturing operations of the medicinal product in question have not been inspected recently, i.e. when the last inspection dates back to more than two years or a particular need to inspect has been identified, a specific and detailed inspection may be requested. Parties will ensure that 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.

2. **Inspection reports**

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.

3. **Reference GMP**

(a) Manufacturers will be inspected against the applicable GMP of the exporting Party (see Section I).

(b) With respect to medicinal products 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 will inspect against its own GMP or, in the absence of specific GMP requirements, against the applicable GMP of the importing Party. This will also be the case when the locally applicable GMP are not considered equivalent, in terms of quality assurance of the finished product, to the GMP of the importing Party.

Equivalence of GMP requirements for specific products or classes of products (e.g. investigational medicinal products, starting materials) will be determined according to a procedure established by the Joint Sectoral Group.

4. **Nature of inspections**

(a) Inspections will routinely assess the compliance of the manufacturer with GMP. These are called general GMP inspections (also regular, periodic, or routine inspections).

(b) 'Product- or process-oriented' inspections (which may be 'pre-marketing' inspections as relevant) focus on the manufacture of one or one series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) will be provided in confidence to the inspectorate.

▼M1

5. **Inspection/establishment fees**

The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees will not be charged to manufacturers located on the territory of the other Party for products covered by this Sectoral Annex.

6. **Safeguard clause for inspections**

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. Should such an inspection take place, inspection costs may be recovered.

7. **Exchange of information between authorities and approximation of quality requirements**

In accordance with the general provisions of this Agreement, the Parties will exchange any relevant information necessary for the ongoing mutual recognition of inspections. For the purposes of demonstration of capability in cases of significant changes to regulatory systems in either of the Parties, additional specific information may be requested by either Party in relation to an official inspection service. Such specific requests may cover information on training, inspection procedures, general information and document exchange, and transparency of agency audits of official inspection services relevant to the operation of this Sectoral Annex. Such requests should be made through and managed by the Joint Sectoral Group as part of an ongoing maintenance programme.

In addition, the relevant authorities in New Zealand and in the European Union will keep each other informed of any new technical guidance or changes to inspection procedures. Each Party will consult the other before their adoption.

8. **Official batch release**

The official batch release procedure is an additional verification of safety and efficacy of immunological medicinal products (vaccines) and blood derivatives, carried out by the competent authorities before the distribution of each batch of product. This Agreement does not encompass this mutual recognition of official batch releases. However, when an official batch release procedure applies, the manufacturer will provide, at the request of the importing Party, the official batch release certificate if the batch in question has been tested by the control authorities of the exporting Party.

For the European Union, the official batch release procedure for medicinal products for human use is published by the European Directorate for the Quality of Medicines & HealthCare. For New Zealand, the official batch release procedure is specified in document 'WHO Technical Report Series, No 822, 1992'.

9. **Inspectors' training**

In accordance with the general provisions of this Agreement, training sessions for inspectors, organised by the authorities, will be accessible to inspectors of the other Party. The Parties will keep each other informed of these sessions.

▼M1

10. **Joint inspections**

In accordance with the general provisions of this Agreement, and by mutual arrangement between the Parties, joint inspections may be authorised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form will be established through procedures approved by the Joint Sectoral Group.

11. **Alert system**

Contact points will be designated by the Parties to permit competent authorities and manufacturers to inform the authorities of the other Party with the appropriate speed in case of quality defects, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure will be jointly established.

The Parties will ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with GMP and which could affect the protection of public health, is communicated to the other Party with the appropriate degree of urgency.

12. **Contact points**

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

FOR NEW ZEALAND:

For medicinal products for human use:

Group Manager
Medicines and Medical Devices Safety Authority (Medsafe)
PO Box 5013
Wellington
New Zealand
Tel. 64-4-819 6874
Fax 64-4-819 6806

For medicinal products for use in animals:

Director, Approvals and ACVM Standards
Ministry of Agriculture and Forestry (MAF) PO Box 2526
Wellington 6140
New Zealand
Tel. 64-4-894 2541
Fax 64-4-894 2501

FOR THE EUROPEAN UNION:

The Director of the European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom
Tel. 44-171-418 8400
Fax 44-171-418 8416

▼M1

13. **Joint Sectoral Group**

A Joint Sectoral Group made up of representatives of the Parties will be established under this Sectoral Annex. It will be responsible for the effective functioning of this Sectoral Annex. It will report to the Joint Committee as the Joint Committee will determine.

The Joint Sectoral Group will determine its own rules of procedure. It will take its decisions and adopt its recommendations by consensus. It may decide to delegate its tasks to subgroups.

14. **Divergence of views**

Both Parties will use their best endeavours to resolve any divergence of views concerning, inter alia, compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Joint Sectoral Group.

SECTION IV

CHANGES TO THE LIST OF OFFICIAL INSPECTION SERVICES

The Parties recognise the need for this Sectoral Annex to accommodate change, particularly with regard to the entry of new official inspection services or changes in the nature or role of established competent authorities. Where significant changes have occurred with regard to official inspection services, the Joint Sectoral Group will consider what, if any, additional information is required to verify programmes and establish or maintain mutual recognition of inspections, in accordance with point 7 of Section III.

▼M1

SECTORAL ANNEX ON MEDICAL DEVICES TO THE EUROPEAN COMMUNITY — NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

SCOPE AND COVERAGE

The provisions of this Sectoral Annex will apply to the following products:

Products for export to the European Union	Products for export to New Zealand
(1) All medical devices:	(1) All medical devices:
(a) manufactured in New Zealand; and	(a) manufactured in the European Union; and
(b) subject to third party conformity assessment procedures, both product and quality systems-related; and	(b) subject to third party conformity assessment procedures, both product and quality systems-related, or subject to other requirements under the legislation listed in Section I, as amended.
(c) provided for in Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended; and	
(d) provided for in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended.	
(2) For the purposes of paragraph 1:	(2) For the purposes of paragraph 1:
(a) medical devices provided for in the Appendix are excluded; and	(a) medical devices provided for in the Appendix are excluded; and
(b) unless otherwise provided for or by mutual arrangement by the Parties, ‘manufacture’ of a medical device does not include:	(b) unless otherwise provided for or by mutual arrangement by the Parties, ‘manufacture’ of a medical device does not include:
(i) restoration or renovation processes such as repairing, re-conditioning, overhauling or refurbishing; or	(i) restoration or renovation processes such as repairing, re-conditioning, overhauling or refurbishing; or
(ii) operations such as pressing, labelling, ticketing, packaging and preparation for sale, conducted alone or in combination with each other; or	(ii) operations such as pressing, labelling, ticketing, packaging and preparation for sale, conducted alone or in combination with each other; or
(iii) quality control inspections alone; or	(iii) quality control inspections alone; or
(iv) sterilisation alone.	(iv) sterilisation alone.

▼M1

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Union with which New Zealand-designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Union-designated conformity assessment bodies will assess compliance
— Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended — Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended — and any European Union legislation adopted on the basis of these Directives	— Radiocommunications Act 1989 and Regulations made pursuant to that Act — Electricity Act 1992 and Regulations made pursuant to that Act — Medicines Act 1981 — Medicines Regulations 1984 — Medicines (Database of Medical Devices) Regulations 2003 — and any legislation adopted on the basis of, or that amends, the above legislation

SECTION II

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES UNDER THIS SECTORAL ANNEX

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
— Ministry of Health	— *Belgium* Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie Agence Fédérale des Médicaments et des Produits de Santé – Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten — *Bulgaria* Държавна агенция за метрологичен и технически надзор — *Czech Republic* Úřad pro technickou normalizaci, metrologii a státní zkušebnictví — *Denmark* Indenrigs- og Sundhedsministeriet Lægemiddelstyrelsen — *Germany* ZLG — Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, Bonn

▼**M1**

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
	ZLS — Zentralstelle der Länder für Sicherheitstechnik, München
	— *Estonia*
	Majandus- ja Kommunikatsiooniministeerium
	— *Ireland*
	Department of Health
	Irish Medicines Board
	— *Greece*
	Υπουργείο Υγείας και Κοινωνικής Αλληλεγγύης
	Εθνικός Οργανισμός Φαρμάκων
	— *Spain*
	Ministerio de Sanidad, Política Social e Igualdad
	Agencia Española de Medicamentos y Productos Sanitarios
	— *France*
	Ministère de la Santé
	Agence Française de Sécurité Sanitaire des produits de Santé
	Agence Nationale du Médicament Vétérinaire
	— *Italy*
	Ministero della Salute – Dipartimento dell' Innovazione – Direzione Generale Farmaci e Dispositivi Medici
	— *Cyprus*
	The Drugs Council, Pharmaceutical Services (Ministry of Health)
	Veterinary Services (Ministry of Agriculture)
	— *Latvia*
	Zāļu valsts aģentūra
	Veselības ministrija
	— *Lithuania*
	Lietuvos Respublikos sveikatos apsaugos ministerija
	— *Luxembourg*
	Ministère de la Santé
	Division de la Pharmacie et des Médicaments
	— *Hungary*
	Országos Gyógyszerészeti Intézet

▼**M1**

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
	— *Malta* Direttorat tal-Affarijiet Regolatorji, Awtorità Maltija dwar l-i*Standards* — *Netherlands* Ministerie van Volksgezondheid, Welzijn en Sport Inspectie voor de Gezondheidszorg — *Austria* Bundesministerium für Gesundheit Bundesamt für Sicherheit im Gesundheitswesen — *Poland* Ministerstwo Zdrowia Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych — *Portugal* INFARMED:I.P. (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.) — *Romania* Ministerul Sănătății – Departament Dispozitive Medicale — *Slovenia* Ministrstvo za zdravje Javna agencija Republike Slovenije za zdravila in medicinske pripomočke — *Slovakia* Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky — *Finland* Sosiaali- ja terveysministeriö Sosiaali- ja terveysalan lupa- ja valvontavirasto (Valvira) — *Sweden* Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Medicines and Healthcare products Regulatory Agency

▼M1

SECTION III

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Union's requirements	The procedures to be followed by the European Union in designating conformity assessment bodies to assess products against New Zealand's requirements
Conformity assessment bodies to be designated for the purposes of this Sectoral Annex will meet the requirements of the Directives listed in Section I, taking into account Annex II to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, as amended, and be designated on the basis of the procedures defined in the Annex to this Agreement. This may be demonstrated through: (a) Product certification bodies operating according to the requirements of EN 45011 or ISO Guides 28 and 40, and either: — accredited by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ), or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement. (b) Quality System certification bodies operating according to the requirements of EN 45012 or ISO Guide 62, and either: — accredited by JAS-ANZ, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement. (c) Inspection bodies operating according to the requirements of ISO/IEC 17020, and either: — accredited by the Testing Laboratory Registration Council of New Zealand or any other body established by law in New Zealand which replaces it and which has the same functions, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement.	1. The procedures for designating conformity assessment bodies will be consistent with the principles and procedures set out in the Annex to this Agreement. 2. The following procedures are deemed to be consistent with those set out in the Annex to this Agreement: (a) Certification bodies: — accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement (MLA) for certification of products, — members of the Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE) CB Scheme, — accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or — able to demonstrate competence by other means in accordance with Section A and B of the Annex to this Agreement. (b) Testing laboratories: — accredited by accreditation bodies which are signatories to the EA MLA for calibration and testing laboratories, — recognised within the IECEE CB Scheme, or — able to demonstrate competence by other means in accordance with Section A and B of the Annex to this Agreement.

▼M1

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Union's requirements	The procedures to be followed by the European Union in designating conformity assessment bodies to assess products against New Zealand's requirements
Pursuant to point 5.2 of Section IV, designation for high-risk devices listed in point 5.1 of that Section will occur on the basis of a confidence-building programme.	Pursuant to point 5.2 of Section IV, designation for high-risk devices listed in point 5.1 of that Section will occur on the basis of a confidence-building programme.

SECTION IV

ADDITIONAL PROVISIONS

1. **New legislation**

The Parties note New Zealand's intention to introduce new legislation concerning medical devices, and jointly decide that the provisions of this Sectoral Annex will apply to this legislation upon its entry into force in New Zealand.

The Parties jointly declare their intention to extend the scope of this Sectoral Annex to in vitro diagnostic devices as soon as New Zealand's new legislation concerning medical devices is in place.

2. **Exchange of information**

The Parties will inform each other of incidents in the context of the medical device vigilance procedure, or with regard to matters concerning product safety. The Parties will also inform each other of:

— certificates withdrawn, suspended, restricted or revoked, and

— any legislation or amendment to existing legislation adopted on the basis of the legal texts listed in Section I.

The contact points through which the information can be passed are:

New Zealand:	The Manager Medicines and Medical Devices Safety Authority (Medsafe) PO Box 5013 Wellington New Zealand Tel. 64-4-819 6874 Fax 64-4-819 6806 and Group Manager Energy Safety and Radio Spectrum Management Ministry of Economic Development (MED) P.O. Box 1473 Wellington New Zealand Tel. 64-4-472-0030 Fax 64-4-471-0500

▼**M1**

European Union	European Commission Directorate-General for Health and Consumers Rue de la Loi/Wetstraat 200 B-1049 Brussels Tel. 32-2-299 11 11

The Parties may exchange information on the consequences of the establishment of the European Database on Medical Devices (Eudamed).

In addition, the Medicines and Medical Devices Safety Authority will advise of any certificates issued.

3. **Subcontracting**

Where required by New Zealand legislative, regulatory and administrative provisions, European Union conformity assessment bodies subcontracting all or part of the testing will subcontract only to testing laboratories accredited in accordance with point 2 of Section III.

4. **Recording of approvals granted**

In addition to the requirements imposed by the Annex to this Agreement on the designation of a conformity assessment body, the relevant European Union designating authority will provide to New Zealand, in respect of each designated conformity assessment body, details of the method that such conformity assessment body intends to adopt to record the fact that an approval required by the Secretary under the Electricity Act 1992 (and Regulations made pursuant to that Act) for fittings or appliances to be sold or offered for sale in New Zealand has been granted.

5. **Confidence-building with respect to high-risk devices**

5.1. A confidence-building process for the purpose of strengthening confidence in the designating systems of each of the Parties will apply for the following medical devices:

— active implantable devices as defined in the legislation referred to in Section I;

— devices that are classified as class III devices under the legislation referred to in Section I;

— medical devices that are implantable intra-ocular lenses;

— medical devices that are intra-ocular visco elastic fluids, and

— medical devices that are a barrier indicated for contraception or prevention of the sexual transmission of disease.

5.2. The Parties will establish a detailed programme to this effect involving the Medicines and Medical Devices Safety Authority and the European Union's competent authorities.

5.3. The confidence-building period will be reviewed after two years commencing from the date this Sectoral Annex, as amended, becomes effective.

▼M1

5.4. Additional specific requirements for regulatory progress:

5.4.1. In pursuance of Articles 2, 7(1), 8(1) and 9(1) of this Agreement, either Party may request additional specific requirements in relation to the conformity assessment bodies for the purposes of demonstration of experience in the evolving regulatory systems.

5.4.2. These specific requirements may include training, observed conformity assessment body audits, visits and information and document exchange, including audit reports.

5.4.3. These requirements may likewise be applicable in relation to the designation of a conformity assessment body in accordance with this Agreement.

6. **Joint Sectoral Group**

A Joint Sectoral Group made up of representatives of the Parties will be established under this Sectoral Annex. It will be responsible for the effective functioning of this Sectoral Annex. It will report to the Joint Committee as the latter will determine.

The Joint Sectoral Group will determine its own rules of procedure. It will take its decisions and adopt its recommendations by consensus. It may decide to delegate its tasks to subgroups.

7. **Divergence of views**

Both Parties will use their best endeavours to resolve any divergence of views concerning, inter alia, compliance of manufacturers and conclusions of conformity assessment reports. Unresolved divergences of view will be referred to the Joint Sectoral Group.

Appendix

The provisions of this Sectoral Annex will not apply to the following devices:

— medical devices that contain or are manufactured using cells, tissues or tissue derivatives of animal origin that have been rendered non-viable, where the safety with regard to viruses or other transferable agents requires validated methods for elimination or viral inactivation in the course of the manufacturing process;

— medical devices that contain tissues, cells or substances of microbial, bacterial or recombinant origin and are intended for use in or on the human body;

— medical devices incorporating tissues or tissue derivatives of human origin;

— medical devices incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;

— medical devices that incorporate, or intend to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device, and

▼**M1**

— medical devices that are intended by the manufacturer specifically to be used for chemical disinfection of another medical device, except for sterilisers using dry heat, moist heat or ethylene oxide.

Both Parties may decide by common arrangement to extend the application of this Sectoral Annex to the aforementioned medical devices.

▼B

SECTORAL ANNEX ON TELECOMMUNICATIONS TERMINAL EQUIPMENT TO THE EUROPEAN COMMUNITY-NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The provisions of this Sectoral Annex will apply to the following:

Products for export to the European	Products for export to New Zealand
Community Any product falling under the scope of Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity. In general terms, that Council Directive covers: (a) terminal equipment intended to be connected to the public telecommunications networks. The terminal equipment may be connected directly or indirectly to the termination of the public telecommunications network; and (b) satellite earth station equipment, which is capable of being used either for transmission only, or for transmission and reception, or for reception only, of radio communications signals by means of satellites or other space-based systems. Purpose-built satellite earth station equipment used as part of the public switched telecommunications network is excluded. This list of product groups may be extended to include other European Community common technical regulations in this sector as they become available.	Any product intended for connection to the public and leased networks operated by Telecom New Zealand Limited and its subsidiary companies. In general terms, the product range covered includes: (a) single-line and multi-line TTE intended for connection to the public switched telecommunications network or leased lines, whether for voice or data transmission, including PABX and like switching systems; (b) ISDN Basic Rate Access (connecting at the S/T interface); (c) ISDN Primary Rate Access (connecting at the S/T interface); (d) AMPS and D-AMPS cellular telephones; (e) Cordless telephones, CT-1, CT-2 and CT-3; (f) Bandwidth Management Systems; (g) Trunked Mobile Radio Terminals; (h) Power supplies (where supplied as separate items for use with any appropriate items of TTE); (i) Telex TTE; and (j) Jackpoints and associated cable and hardware used in residential premises. The provisions of this Sectoral Annex may be extended to include the products intended for connection to the public and leased networks operated by other network operators designated pursuant to the Telecommunications Act 1997 at the request of the New Zealand Government.

▼B

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
— Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity	— Telecommunications Act 1987 — Telecom New Zealand Limited Permit to Connect (PTC) and Telecom Network Advisory (TNA) specifications — Radiocommunications Act 1989 — Radiocommunications (Radio) Regulations 1993 — Electricity Act 1992 — Electricity Regulations 1997
— Commission Decision 95/290/EC of 17 July 1995 on a common technical regulation for public land-based European radio message system (ERMES) receiver requirement	
— Commission Decision 95/525/EC of 28 November 1995 on a common technical regulation for attachment requirements for terminal equipment for digital European cordless telecommunications (DECT), public access profile (PAP) applications	
— Commission Decision 96/629/EC of 23 October 1996 on a common technical regulation for telephony application requirements for public pan-European cellular digital land-based mobile communications, Phase II	
— Commission Decision 96/630/EC of 23 October 1996 on a common technical regulation for the general attachment requirements for public pan-European cellular digital land-based mobile communications, Phase II	
— Commission Decision 97/346/EC of 20 May 1997 on a common technical regulation for the pan-European integrated services digital network (ISDN) basic access	
— Commission Decision 97/347/EC of 20 May 1997 on a common technical regulation for the pan-European integrated services digital network (ISDN) primary rate access	

▼B

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
— Commission Decision 97/486/EC of 9 July 1997 on a common technical regulation for the general attachment requirements for terminal equipment to interface to open network provision (ONP) two-wire analogue leased lines	
— Commission Decision 97/487/EC of 9 July 1997 on a common technical regulation for the attachment requirements for terminal equipment to interface to open network provision (ONP) four-wire analogue leased lines	
— Commission Decision 97/520/EC of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 2 048 kbit/s digital unstructured ONP leased lines (Amendment 1)	
— Commission Decision 97/521/EC of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 2 048 kbit/s digital structured ONP leased lines	
— Commission Decision 97/522/EC of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 64 kbit/s digital unrestricted ONP leased lines (Amendment 1)	
— Commission Decision 97/523/EC of 9 July 1997 on a common technical regulation for the general terminal attachment requirements for digital enhanced cordless telecommunications (DECT) (edition 2)	
— Commission Decision 97/524/EC of 9 July 1997 on a common technical regulation for the telephony application requirements for digital enhanced cordless telecommunications (DECT) (edition 2)	

▼B

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
— Commission Decision 97/525/EC of 9 July 1997 on a common technical regulation for the attachment requirements for terminal equipment for digital enhanced cordless telecommunications (DECT) generic access profile (GAP) applications	
— Commission Decision 97/526/EC of 9 July 1997 on a common technical regulation for the general attachment requirements for public pan-European cellular digital land-based mobile communications (edition 2)	
— Commission Decision 97/527/EC of 9 July 1997 on a common technical regulation for the telephony application requirements for public pan-European cellular digital land-based mobile communications (edition 2)	
— Commission Decision 97/528/EC of 9 July 1997 on a common technical regulation for the general attachment requirements for mobile stations intended to be used with Phase II public digital cellular telecommunications networks operating in the DCS 1800 band	
— Commission Decision 97/529/EC of 9 July 1997 on a common technical regulation for the telephony application requirements for mobile stations intended to be used with Phase II public digital cellular telecommunications networks operating in the DCS 1800 band	
— Commission Decision 97/544/EC of 9 July 1997 on a common technical regulation for terminal equipment to be connected to public circuit switched data networks and ONP leased circuits using a CCITT Recommendation X.21 type interface	
— Commission Decision 97/545/EC of 9 July 1997 on a common technical regulation for the general attachment requirements for data terminal equipment (DTE) to connect to packet switched public data networks (PSPDNs) offering CCITT Recommendation X.25 interfaces	

▼B

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
— Commission Decision 97/639/EC of 19 September 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 34 Mbit/s digital unstructured and structured leased lines — Commission Decision 97/751/EC of 31 October 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 140 Mbit/s digital unstructured and structured leased lines	

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The conformity assessment bodies designated by New Zealand to assess products against the European Community's legislative, regulatory and administrative requirements	The conformity assessment bodies designated by the European Community to assess products against New Zealand's legislative, regulatory and administrative requirements
The designated conformity assessment bodies are: [Name and details to be inserted] [Note: Further names to be added as required]	The designated conformity assessment bodies are: [Name and details to be inserted] [Note: Further names to be added as required]

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Community
Under the authority of the New Zealand Government: (a) For Certification Bodies: — The Joint Accreditation System of Australia and New Zealand (JAS-ANZ), and (b) For Testing Laboratories and Inspection Bodies: — The Testing Laboratory Registration Council of New Zealand.	— *Belgium* Institut belge des services postaux et des télécommunications Belgisch instituut voor postdiensten en telecommunicatie — *Denmark* Telestyrelsen — *Germany* Bundesministerium für Wirtschaft — *Greece* Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications

▼B

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Community
	— *Spain* Ministerio de Fomento — *France* Ministère de l'économie, des finances et de l'industrie Direction des postes et télécommunication Service des télécommunications Ministère de l'économie, des finances et de l'industrie Secrétariat d'État à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation — *Ireland* Department of Transport, Energy and Communications — *Italy* Ispettorato Generale TLC — *Luxembourg* Administration des Postes et Télécommunications — *Netherlands* De Minister van Verkeer en Waterstaat — *Austria* Bundesministerium für Wissenschaft und Verkehr — *Portugal* Instituto das Comunicações de Portugal — *Finland* Liikenneministeriö/Trafikministeriet Telehallintokeskus/Teleförvaltningscentralen — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *UK* Department of Trade and Industry

▼B

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against New Zealand's requirements
The conformity assessment bodies listed in Section II will meet the requirements of the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives and be designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through: (a) Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guides 28 and 40, and either: — accredited by JAS-ANZ, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (b) Quality System Certification Bodies operating according to the requirements of EN 45012 or ISO Guide 62, and either: — accredited by JAS-ANZ, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (c) Testing laboratories operating according to the requirements of EN 45001 or ISO Guide 25, and either: — accredited by The Testing Laboratory Registration Council of New Zealand, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	1. The procedures for designating conformity assessment bodies will be consistent with the principles and procedures set out in the Annex to the Agreement. 2. The following procedures are deemed to be consistent with those set out in the Annex to the Agreement: (a) Testing Laboratories: — accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (b) Certification Bodies: — accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification, — accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.

▼B

SECTION V

ADDITIONAL PROVISIONS

1. The Parties note that under the Telecommunications Act 1987, no person can connect any additional line, apparatus or equipment to any part of a network, or connect to any line, apparatus or equipment connected to any part of a network owned by a network operator, without the agreement of that network operator. Under the Act, network operators have the right to specify conditions under which telecommunications terminal equipment may be connected to their network.

2. Telecommunications terminal equipment offered for sale for connection to the Telecom New Zealand Limited ('Telecom') network is required to bear a Telepermit label incorporating a Registered Telecom trade mark, prepared to the format specified by Telecom, also showing the brand and model of the product and the number allocated to that product. Telepermit labels may be attached by the manufacturer in the country of origin.

3. The manufacturer or New Zealand importer applies to Telecom for a Telepermit and the right to label conforming products, and contracts with Telecom to continue to supply only such product which complies with Telecom's requirements.

4. The Parties note that equipment suppliers are required to lodge with Telecom a copy of the certificate of compliance and supporting test reports when the product is placed on the market. Compliance with Telecom's requirements may be verified by Telecom through post-marketing surveillance.

5. Where required by New Zealand legislative, regulatory and administrative provisions, European Community Conformity Assessment Bodies subcontracting all or part of the testing will subcontract only to testing laboratories accredited in accordance with clause 2 in Section IV of this Sectoral Annex.

6. In respect of telecommunications terminal equipment which is subject to the provisions of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility will apply.

▼B

SECTORAL ANNEX ON LOW VOLTAGE EQUIPMENT TO THE EUROPEAN COMMUNITY-NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The provisions of this Sectoral Annex will apply to the following types of low voltage equipment:

Products for export to the European Community	Products for export to New Zealand
All products falling within the scope of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits.	Low voltage equipment which is a 'Declared Article' within the meaning of Regulation 90 of the New Zealand Electricity Regulations 1997.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, as amended.	Electricity Act 1992 Electricity Regulations 1997

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The conformity assessment bodies designated by New Zealand to assess products against the European Community's legislative, regulatory and administrative requirements	The conformity assessment bodies designated by the European Community to assess products against New Zealand's legislative, regulatory and administrative requirements
The designated conformity assessment bodies are: [Name and details to be inserted] [Note: Further names to be added as required]	The designated conformity assessment bodies are [Name and details to be inserted] [Note: Further names to be added as required]

▼B

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by New Zealand	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the New Zealand Government: (a) For certification bodies: — The Joint Accreditation System of Australia and New Zealand (JAS-ANZ), and (b) For Testing Laboratories and Inspection Bodies: — The Testing Laboratory Registration Council of New Zealand.	— *Belgium* Ministère des affaires economiques Ministerie van Economische Zaken — *Denmark* Boligministeriet — *Germany* Bundesministerium für Arbeit und Sozialordnung — *Greece* Υπουργείο Ανάπτυξης Ministry of Development — *Spain* Ministerio de Industria y Energía — *France* Ministère de l'économie, des finances et de l'industrie Secrétariat d'État à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation — *Ireland* Department of Enterprise and Employment — *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato — *Luxembourg* Ministère des transports — *Netherlands* Staat der Nederlanden — *Austria* Bundesministerium für Wirtschaftliche Angelegenheiten — *Portugal* Under the authority of the Government of Portugal: Instituto Português da Qualidade — *Finland* Kauppa- ja teollisuusministeriö/ Handels- och industriministeriet

▼B

For the Conformity Assessment Bodies designated by New Zealand	For the Conformity Assessment Bodies designated by the European Community
	— *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *UK* Department of Trade and Industry

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against New Zealand's requirements
The Conformity Assessment Bodies listed in Section II will meet the requirements of the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives and be designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through:	1. The procedures for designating conformity assessment bodies will be consistent with the principles and procedures set out in the Annex to the Agreement. 2. The following procedures are deemed to be consistent with those set out in the Annex to the Agreement: Testing Laboratories:
(a) Inspection Bodies operating according to the requirements of EN 45004 or ISO Guide 39, and either:	— accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or
— accredited by the Testing Laboratory Registration Council of New Zealand, or	— recognised within the IECEE CB Scheme, or
— able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	— able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.
(b) Testing laboratories operating according to the requirements of EN 45001 or ISO Guide 25, and either:	
— accredited by the Testing Laboratory Registration Council of New Zealand, or	

▼B

The procedures to be followed by New Zealand in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against New Zealand's requirements
— able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	

SECTION V

ADDITIONAL PROVISIONS

1. Where required by New Zealand legislative, regulatory and administrative provisions, European Community Conformity Assessment Bodies subcontracting all or part of the testing will subcontract only to testing laboratories accredited in accordance with clause 2 in Section IV of this Sectoral Annex.

2. In the event of a challenge within the European Community under Article 8(2) of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, test reports issued by designated conformity assessment bodies in New Zealand will be accepted by authorities in the European Community in the same way that reports from European Community notified bodies are accepted.

   That is, conformity assessment bodies in New Zealand will be recognised under Article 11 of that Council Directive as ‘bodies which may make a report in accordance with Article 8’.

3. In addition to the requirements imposed by the Annex to the Agreement, on designation of a conformity assessment body, the relevant European Community designating authority will provide to New Zealand, in respect of each designated conformity assessment body, details of the method that that conformity assessment body intends to adopt to record the fact that an approval within the meaning of Regulation 90 of the Electricity Regulations 1997 has been granted.

▼B

SECTORAL ANNEX ON ELECTROMAGNETIC COMPATIBILITY TO THE EUROPEAN COMMUNITY-NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The provisions of this Sectoral Annex will apply to the following:

Products for export to the European Community	Products for export to New Zealand
Electromagnetic compatibility of equipment as defined in Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, but excluding radiocommunications equipment which is not connected to the public switched telecommunication networks.	Electromagnetic compatibility of equipment to the extent that it is regulated under and complies with the New Zealand legislation specified in Section I.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, as amended	— Radiocommunications Act 1989 — Radiocommunications (Radio) Regulations 1993 — Electricity Act 1992 — Electricity Regulations 1997

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The conformity assessment bodies designated by New Zealand to assess products against the European Community's legislative, regulatory and administrative requirements	The conformity assessment bodies designated by the European Community to assess products against New Zealand's legislative, regulatory and administrative requirements
The designated conformity assessment bodies are:	The designated conformity assessment bodies are:
[Name and details to be inserted]	[Name and details to be inserted]
[Further names to be added as required]	[Further names to be added as required]

▼B

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Community
Under the authority of the New Zealand Government: (a) For Certification Bodies: — The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) (b) For Testing Laboratories and Inspection Bodies: — The Testing Laboratory Registration Council of New Zealand	— *Belgium* Ministère des Affaires Economiques Ministerie van Economische Zaken — *Denmark* For telecommunications equipment: Telestyrelsen For other equipment: Danmarks Elektriske Materielkontrol (DEMKO) — *Germany* Bundesministerium für Wirtschaft — *Greece* Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications — *Spain* For telecommunications equipment: Ministerio de Fomento for other equipment: Ministerio de Industria y Energía — *France* Ministère de l'économie, des finances et de l'industrie Secrétariat d'État à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation — *Ireland* Department of Transport, Energy and Communications — *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato — *Luxembourg* Ministère des transports — *Netherlands* Ministerie van Verkeer en Waterstaat — *Austria* For telecommunications equipment: Bundesministerium für Wissenschaft und Verkehr For other equipment: Bundesministerium für Wirtschaftliche Angelegenheiten

▼B

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Community
	— *Portugal* Under the authority of the Government of Portugal: Instituto das Comunicações de Portugal — *Finland* For telecommunications equipment: Liikenneministeriö/Trafikministeriet For other equipment: Kauppa- ja teollisuusministeriö/ Handels- och industriministeriet — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *UK* Department of Trade and Industry

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against New Zealand's requirements
The conformity assessment bodies listed in Section II will meet the requirements of the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives, and are designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through:	1. The procedures for designating conformity assessment bodies will be consistent with the principles and procedures set out in the Annex to the Agreement. 2. The following procedures are deemed to be consistent with those set out in the Annex to the Agreement: Testing Laboratories:
(a) For the purposes of Article 10(5) of Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, Inspection Bodies operating according to the requirements of EN 45 004 or ISO Guide 39, and either:	— accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.

▼B

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against New Zealand's requirements
— accredited by the Testing Laboratory Registration Council of New Zealand, or	
— able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	
(b) For competent bodies according to Article 10(2) of Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, Testing Laboratories operating according to the requirements of EN 45 001 or ISO Guide 25, and either:	
— accredited by The Testing Laboratory Registration Council of New Zealand, or	
— able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	

SECTION V

ADDITIONAL PROVISIONS

1. Where required by New Zealand legislative, regulatory and administrative provisions, European Community conformity assessment bodies subcontracting all or part of the testing will subcontract only to testing laboratories accredited in accordance with clause 2 in Section IV of this Sectoral Annex.

2. In addition to the requirements imposed by the Annex to the Agreement, on designation of a conformity assessment body, the relevant European Community designating authority will provide to New Zealand, in respect of each designated conformity assessment body, details of the method that that conformity assessment body intends to adopt to record the fact that an approval within the meaning of Regulation 90 of the Electricity Regulations 1997 has been granted.

▼B

SECTORAL ANNEX ON MACHINERY TO THE EUROPEAN COMMUNITY-NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The provisions of this Sectoral Annex will apply to the following:

Products for export to the European Community	Products for export to New Zealand
— Any product falling under Annex IV of Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery,	Any machinery that falls within the scope of the Health and Safety in Employment Act 1992.
— tower cranes, and	For the avoidance of doubt, this Sectoral Annex will include tower cranes, port-type container cranes and mobile cranes including truck-mounted cranes with a lifting capacity exceeding five (5) tonnes used for loading and unloading that vehicle.
— mobile cranes.	

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
— Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery, as amended	— Health and Safety in Employment Act 1992,
	— Health and Safety in Employment Regulations 1995,
— Directives setting out noise limitation requirements for tower cranes as follows:	— Health and Safety in Employment (Pressure Equipment, Cranes and Passenger Ropeways) Regulations 199[6] with, respect to tower cranes, port-type container cranes and mobile cranes ([1]),
— Council Directive 79/113/EEC of 19 December 1978 on the approximation of the laws of the Member States relating to the determination of the noise emission of construction plant and equipment, as amended,	— Health and Safety in Employment (Tractor Safety Frames) Regulations 199[6] in respect of safety frames fitted to agricultural tractors ([1]),
— Council Directive 84/532/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to common provisions for construction plant and equipment, as amended,	— Health and Safety in Employment (Mining Control) Regulations 199[6] ([1]), and
	— Health and Safety in Employment (Petroleum) Regulations 199[6] ([1]).

▼B

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
— Council Directive 84/534/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of tower cranes, as amended,	

([1]) These regulations have yet to be incorporated into the law of New Zealand.

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The conformity assessment bodies designated by New Zealand to assess products against the European Community's legislative, regulatory and administrative requirements	The conformity assessment bodies designated by the European Community to assess products against New Zealand's legislative, regulatory and administrative requirements
The designated conformity assessment bodies are:	The designated conformity assessment bodies are:
[Name and details to be inserted]	[Name and details to be inserted]
[Further names and details to be added as required]	[Further names and details to be added as required]

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Community
Under the authority of the New Zealand Government: (a) For Certification Bodies: — the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) (b) For Testing Laboratories and Inspection Bodies: — The Testing Laboratory Registration Council of New Zealand	— *Belgium* Ministère de l'Economie Ministerie van Economie *Denmark* Direktoratet for Arbejdstilsynet *Germany* Bundesministerium für Arbeit und Sozialordnung *Greece* Υπουργείο Ανάπτυξης Ministry of Development *Spain* Ministerio de Industria y Energía *France* Ministère de l'emploi et de la solidarité Direction des relations du travail

▼B

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Community
	Bureau CT5 Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation *Ireland* Department of Enterprise and Employment *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato *Luxembourg* Ministère des transports *Netherlands* Staat der Nederlanden — *Austria* Bundesministerium für wirtschaftliche Angelegenheiten *Portugal* Under the authority of the Government of Portugal: Instituto Português da Qualidade *Finland* Sosiaali- ja terveysministeriö/ Social- och hälsovårdsministerie *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) *UK* Department of Trade and Industry

▼B

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against New Zealand's requirements
The conformity assessment bodies listed in Section II will meet the requirements of the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives, and are designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through: (a) For the purpose of Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery: Inspection Bodies operating to the requirements of EN 45 004 or ISO Guide 39, and either — accredited by the Testing Laboratory Registration Council of New Zealand, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (b) For the purpose of Council Directives setting out noise limitation requirements for tower cranes: Product Certification Bodies operating according to the requirements of EN 45 011 or ISO Guides 28 and 40, and either: — accredited by JAS-ANZ, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	1. The procedures for designating conformity assessment bodies will be consistent with the principles and procedures set out in the Annex to the Agreement. 2. The following procedures are deemed to be consistent with those set out in the Annex to the Agreement: (a) For cranes: For Design Verification, conformity assessment bodies will: — operate in conformity with EN 45 004 or ISO Guide 39, and — operate a quality system conforming with ISO 9001, and — employ design verifiers who through qualifications, training and experience can demonstrate that they have the necessary skills and ability to fully understand and apply the detailed requirements of the legislation and standards in which they will operate and with which they are certifying compliance. For Inspection Bodies, Conformity Assessment Bodies will: — operate in conformity with EN 45 004 or ISO Guide 39, and — operate a quality system conforming with ISO 9001 or ISO 9002, and — employ engineers who through qualifications, training and experience can demonstrate that they have the necessary skills and ability to fully understand and apply the detailed requirements of the legislation and standards in which they will operate and with which they are certifying compliance.

▼B

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against New Zealand's requirements
	For Certification Bodies, the following procedures are deemed to be consistent with the procedures set out in the Annex to the Agreement: — accreditation by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification, — accreditation by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or — ability to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. For Testing Laboratories: The following procedures are deemed to be consistent with those set out in the Annex to the Agreement: — accreditation by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or — ability to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (b) For machinery other than cranes, either: — notified as Conformity Assessment Bodies in the European Community in accordance with the requirements established in Annex VII of Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery in conjunction with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives and are listed in Section II of this Sectoral Annex, or

▼B

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against New Zealand's requirements
	— procedures that will ensure that the machinery meets the performance-based risk protection requirements of the New Zealand legislation.

SECTION V

ADDITIONAL PROVISIONS

1. Where required by New Zealand legislative, regulatory and administrative provisions, European Community conformity assessment bodies subcontracting all or part of the testing will subcontract only to testing laboratories accredited in accordance with clause 2 in Section IV of this Sectoral Annex.

2. In respect of machinery which is subject to the provisions of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility will apply.

3. Upon the date of application of the provisions of the Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, at present European Commission proposal COM(95) 350, bodies in New Zealand which have been designated to issue type approvals according to this Directive will, either directly or through the authority responsible for their designation, fulfil the notification and other obligations placed upon approval authorities under the relevant provisions of this Directive.

4. It is noted further that this proposed Directive makes reference to the conformity assessment requirements set out in Council Directive 92/53/EEC of 18 June 1992 amending Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers. It is recognised that under the provisions of this Directive, a manufacturer cannot be accredited as a testing laboratory. However, it is permissible for a testing laboratory to use outside equipment, subject to the approval of the Designating Authority.

▼B

SECTORAL ANNEX ON PRESSURE EQUIPMENT TO THE EUROPEAN COMMUNITY-NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The provisions of this Sectoral Annex will apply to the following types of pressure equipment:

Products for export to the European Community	Products for export to New Zealand
Products falling within the scope of Council Directive 87/404/EEC of 25 June 1987 on the harmonisation of the laws of the Member States relating to simple pressure vessels.	Pressure equipment subject to third-party conformity assessment procedures under the New Zealand statutes and regulations specified in Section I of this Sectoral Annex.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which New Zealand designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Community designated conformity assessment bodies will assess compliance
Council Directive 87/404/EEC of 25 June 1987 on the harmonisation of the laws of the Member States relating to simple pressure vessels, as amended.	— Health and Safety in Employment Act 1992, — Health and Safety in Employment Regulations 1995, and — Health and Safety in Employment (Pressure Equipment, Cranes and Passenger Ropeways) Regulations 199[6] ([1]).

([1]) These regulations have yet to be incorporated into the law of New Zealand.

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The conformity assessment bodies designated by New Zealand to assess products against the European Community's legislative, regulatory and administrative requirements	The conformity assessment bodies designated by the European Community to assess products against New Zealand's legislative, regulatory and administrative requirements
The designated conformity assessment bodies are: [Names and details to be inserted] [Note: Further names and details to be added as required]	The designated conformity assessment bodies are: [Names and details to be inserted] [Note: Further names and details to be added as required]

▼B

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Community
Under the authority of the New Zealand Government: (a) For Certification Bodies: — The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) (b) For Testing Laboratories and Inspection Bodies: — The Testing Laboratory Registration Council of New Zealand	— *Belgium* Ministère de l'Economie Ministerie van Economie — *Denmark* Direktoratet for Arbejdstilsynet — *Germany* Bundesministerium für Arbeit und Sozialordnung — *Greece* Υπουργείο Ανάπτυξης Ministry of Development — *Spain* Ministerio de Industria y Energía — *France* Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction de l'action régionale et de la petite et moyenne industrie Sous direction de la sécurité industrielle Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation — *Ireland* Department of Enterprise and Employment — *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato — *Luxembourg* Ministère des transports — *Netherlands* Staat der Nederlanden — *Austria* Bundesministerium für Wirtschaftliche Angelegenheiten — *Portugal* Under the authority of the Government of Portugal: Instituto Português da Qualidade

▼B

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Community
	— *Finland* Kauppa- ja teollisuusministeriö/ Handels- och industriministeriet — *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *UK* Department of Trade and Industry

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against New Zealand's requirements
The conformity assessment bodies listed in Section II will meet the requirements of the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives, and are designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through: (i) Product Certification Bodies operating according to the requirements of EN 45 011 or ISO Guides 28 and 40, and either: (a) accredited by JAS-ANZ, or (b) able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (ii) Quality System Certification Bodies operating according to the requirements of EN 45 012 or ISO Guide 62, and either: (a) accredited by JAS-ANZ, or	1. The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in the Annex to the Agreement. 2. The following procedures are deemed to be consistent with those set out in the Annex to the Agreement: (a) Design Verification: For Design Verification, conformity assessment bodies will: — operate in conformity with EN 45 004 or ISO Guide 39, and — operate a quality system conforming with ISO 9001, and — employ design verifiers who through qualifications, training and experience can demonstrate that they have the necessary skills and ability to fully understand and apply the detailed requirements of the legislation and standards in which they will operate and with which they are certifying compliance

▼B

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating conformity assessment bodies to assess products against New Zealand's requirements
(b) able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (iii) Inspection Bodies operating according to the requirements of EN 45 004 or ISO Guide 39, and either: (a) accredited by the Testing Laboratory Registration Council of New Zealand, or (b) able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	(b) Inspection bodies: For inspection bodies, conformity assessment bodies will: — operate in conformity with EN 45 004 Type A or ISO Guide 39, and — operate a quality system conforming with ISO 9001 or ISO 9002, and — employ engineers who through qualifications, training and experience can demonstrate that they have the necessary skills and ability to fully understand and apply the detailed requirements of the legislation and standards in which they will operate and with which they are certifying compliance. (c) Certification bodies: For certification bodies, conformity assessment bodies will be: — accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification, — accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (d) Testing laboratories: For testing laboratories, conformity assessment bodies will be: — accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.

▼B

SECTION V

ADDITIONAL PROVISIONS

1. Where required by New Zealand legislative, regulatory and administrative provisions, European Community conformity assessment bodies subcontracting all or part of the testing will subcontract only to testing laboratories accredited in accordance with clause 2 in Section IV of this Sectoral Annex.

2. In respect of pressure equipment which is subject to the provisions of Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility will apply.

3. In addition to the requirements imposed by the Annex to the Agreement, on designation of a conformity assessment body, the relevant designating authority will provide to New Zealand, in respect of each designated conformity assessment body, details of whether the conformity assessment body is carrying out design verification, or product inspection, or both.

▼B

FINAL ACT

The plenipotentiaries of:

the EUROPEAN COMMUNITY, hereinafter referred to as 'the Community',

of the one part, and

the plenipotentiary of NEW ZEALAND,

of the other part,

meeting for the signature of the Agreement on Mutual Recognition in relation to Conformity Assessment between the European Community and New Zealand, hereinafter referred to as the 'Agreement', have adopted the following texts:

the Agreement including its Annex and the following Sectoral Annexes relating to:

1. Medicinal Products GMP Inspection and Batch Certification

2. Medical Devices

3. Telecommunications Terminal Equipment

4. Low Voltage Equipment

5. Electromagnetic Compatibility

6. Machinery

7. Pressure Equipment

The plenipotentiaries of the Community and the plenipotentiary of New Zealand have adopted the texts of the Joint Declarations listed below and annexed to this Final Act:

— Joint Declaration relating to future work on implementing arrangements for this Agreement,

— Joint Declaration on mutual recognition in the voluntary sphere,

— Joint Declaration relating to further developing harmonisation of technical regulations and conformity assessment procedures,

— Joint Declaration relating to the review of Article 4 of the Agreement.

Hecho en Wellington, el veinticinco de junio de mil novecientos noventa y ocho.

Udfærdiget i Wellington den femogtyvende juni nitten hundrede og otteoghalvfems.

Geschehen zu Wellington am fünfundzwanzigsten Juni neunzehnhundertachtundneunzig.

Έγινε στο Ουέλλιγκτον, στις είκοσι πέντε Ιουνίου χίλια εννιακόσια ενενήντα οκτώ.

Done at Wellington on the twenty-fifth day of June in the year one thousand nine hundred and ninety-eight.

Fait à Wellington, le vingt-cinq juin mil neuf cent quatre-vingt-dix-huit.

Fatto a Wellington, addì venticinque giugno millenovecentonovantotto.

▼B

Gedaan te Wellington, de vijfentwintigste juni negentienhonderd achtennegentig.

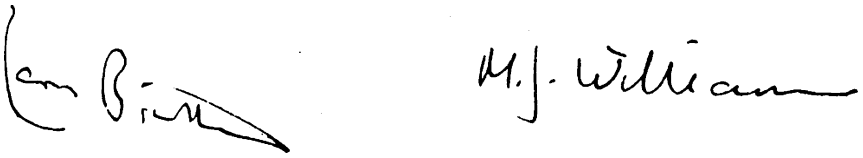
Feito em Wellington, em vinte e cinco de Junho de mil novecentos e noventa e oito.

Tehty Wellingtonissa kahdentenakymmenentenäviidentenä päivänä kesäkuuta vuonna tuhatyhdeksänsataayhdeksänkymmentäkahdeksan.

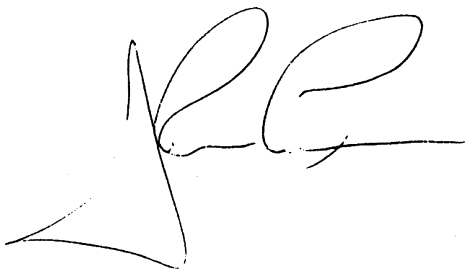
Som skedde i Wellington den tjugofemte juni nittonhundranittioåtta.

▼B

Por la Comunidad Europea
For Det Europæiske Fællesskab
Für die Europäische Gemeinschaft
Για την Ευρωπαϊκή Κοινότητα
For the European Community
Pour la Communauté européenne
Per la Comunità europea
Voor de Europese Gemeenschap
Pela Comunidade Europeia
Euroopan yhteisön puolesta
På Europeiska gemenskapens vägnar



Por Nueva Zelanda
For New Zealand
Für Neuseeland
Για τη Νέα Ζηλανδία
For New Zealand
Pour la Nouvelle-Zélande
Per la Nuova Zelanda
Voor Nieuw-Zeeland
Pela Nova Zelândia
Uuden-Seelannin puolesta
För Nya Zeeland



▼B

ANNEX

Joint Declaration relating to future work on implementing arrangements for this Agreement

1. *Pressure Equipment*

   The Parties will extend the scope of the Sectoral Annex on Pressure Equipment and start negotiations to that effect once the new Directive on this subject, at present being examined in the Council of the European Union and the European Parliament on the basis of a European Commission proposal, has entered into force.

2. *Aircraft certification and continued airworthiness*

   The Parties confirm their intention to continue negotiations in order to complete the Sectoral Annex in respect of aircraft certification and continued airworthiness, with a view to its establishment as an implementing arrangement for this Agreement no later than two years following its entry into force.

3. *Inclusion of other Sectoral Annexes*

   To build on this Agreement, the Parties will commence negotiations on the further extension of the sectoral coverage of the Agreement two years from the date that the Agreement enters into force.

Joint Declaration on mutual recognition in the voluntary sphere

The Parties will encourage their non-governmental bodies to cooperate with a view to establishing mutual recognition arrangements in the voluntary sphere.

Joint Declaration relating to further developing harmonisation of technical regulations and conformity assessment procedures

The Parties will give consideration to increasing the degree of harmonisation or equivalence of their respective technical regulations and conformity assessment procedures, where appropriate and where consistent with good regulatory practice. The Parties acknowledge that one objective could be the establishment where feasible of a single submission and evaluation procedure, applicable in both Parties, for the products covered by the Agreement.

Joint Declaration relating to the review of Article 4 of the Agreement

The Parties will consider a broadening of the provisions of Article 4 to include other countries once the Parties have concluded equivalent Agreements on Mutual Recognition in relation to conformity assessment in the same sectors with those other countries.