COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL DECISION

on the conclusion of the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia

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Proposal for a

COUNCIL DECISION

on the conclusion of the Agreement on Mutual Recognition in relation to Conformity Assessment between the European Community and New Zealand

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(presented by the Commission)

EXPLANATORY MEMORANDUM

I. Introduction

On the basis of negotiating directives issued by the Council on 21.9.92. the European Commission has negotiated and initialled agreements on the mutual recognition of conformity assessment (Mutual Recognition Agreements, or MRAs) with Australia and New Zealand. Texts of the initialled Agreements are annexed.

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

I.1 Assessment of the Agreements

The Commission considers that the initialled Agreements are in conformity with the Council's negotiating directives, have taken account of changes requested by the 113 MRA Committee, which gave detailed advice to the Commission during the negotiations, and provide benefits to the European Community.

Sufficient confidence also exists between the Parties to the Agreements to allow them to proceed. As part of the negotiating process, a seminar was held in Brussels between 14-18 April between the Australian, New Zealand and Member States' regulatory authorities. The aim of this was to exchange information and establish mutual confidence in each Party's capacity to designate bodies to work to the other Party's requirements under the MRA. This seminar achieved the desired results and subsequently Member States have designated a considerable number of conformity assessment bodies (CABs). Once these bodies have been provisionally accepted by Australia and New Zealand subject to formal acceptance by decision of the Joint Committee, the Council will receive this list of CABs by way of a Commission Staff paper.

I.1.1 Framework Agreements

Each Agreement consists of a framework agreement and a series of sectoral annexes. The two framework agreements are identical in substance. An article-by-article assessment follows:

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

Article 1: Definitions : these are self-explanatory.

Article 2 : General Obligations : this sets out the obligation of each Party to accept the conformity assessment results carried out to its requirements by the other Party, according to the terms of the sectoral annexes. Notably, the provision establishes acceptance of product certifications and authorisations set out in the legislation of each Party. This Article, together with Article 3, establishes the link between the basic obligations of the Agreement and its sectoral annexes.

Article 3: Sectoral Coverage : this Article provides that the conformity assessment procedures to which the Agreement applies are specified in the individual sectoral annexes, and describes the content of the annexes.

Article 4: Origin : this Article provides that the Agreement will apply to products originating in the parties according to non-preferential origin rules. Article 4.3 provides for products of EFTA EEA origin to benefit from the Agreements where those countries have concluded parallel agreements with Australia and New Zealand, in accordance with Protocol 12 of the Agreement Establishing the European Economic Area.

Article 4.4 with Australia provides that where the Community has concluded an agreement on the same sectors with New Zealand, the provisions of the Agreement with Australia will also apply to products of New Zealand origin. A corresponding provision appears in the EC-New Zealand Agreement. These provisions mirror the arrangements for EFTA-EEA in Article 4.3, and will enable New Zealand products to be certified in Australia according to the MRA with Australia. The provision could not be used to allow products from third countries with whom no MRA existed from benefiting from the agreements.

It should be noted that in the event that a Party (e.g. New Zealand) terminated its Agreement with the EC, then its products would no longer be able to access the Community via another Agreement. The anti-circumvention objective of the origin provision is thus preserved.

Australia and New Zealand accepted an origin restriction only with great reluctance, and only on condition that its continuation could be reviewed in future. Accordingly, a Joint Joint Declaration was made (see section II.2 below) which requires the Parties in future to consider liberalisation of the origin rule to encompass products from third countries with whom the Parties have also concluded MRAs. Australia has already indicated, in the light of the MRAs recently initialled with USA and Canada - and which contain no such origin rule - its intention to revisit this issue at the first meeting of the Joint Committee of the Parties after the MRA has entered into force. New Zealand will act likewise.

Article 5: Conformity Assessment Bodies : this Article obliges each Party to recognise the competence of bodies designated by the other Party and included in the MRA.

Article 6 : Designating Authorities : this is a key provision requiring designating authorities to have the necessary formal powers over the bodies they designate. This article thus provides a treaty guarantee that New Zealand or Australia have the necessary authority to designate, suspend or withdraw bodies.

Article 7 : Verification of Designation Procedures : this Article provides for continued verification of competence and performance of designated bodies.

Article 8 : Verification of Compliance By Conformity Assessment Bodies : this Article establishes the right for one Party to verify the compliance of bodies in the other Party. As advised by Member States in the 113 Committee MRA Group, the right of verification has been closely circumscibed to prevent it from being carried out routinely or unilaterally.

Article 9 : Exchange of Information : a basic transparency provision..

Article 10 : Monitoring of the Agreement : this Article ensures that bodies of each Party remain coordinated so as to be able, continuously, to correctly interpret the regulatory requirements of the other Party.

Article 11 : Agreements with other countries : the Article confirms that the agreement does not create obligations in respect of conformity assessment carried out by other countries, unless otherwise agreed.

Article 12 : Joint Committee : this Article requires the establishment of a Joint Committee to administer the Agreement on behalf of the Parties. Duties of the Joint Committee include formally adopting changes to the Sectoral annexes to add or remove conformity assessment bodies, and discussing divergences of view. Article 12.6 sets out detailed procedures for designation of bodies and the right of the other Party to contest such designations according to certain rules. The Article does not give the Joint Committee the right to extend the scope and coverage of the agreement to include new sectors. This has to be mandated by the Parties. Article 12.8 does however provide that where one Party introduces additional certification procedures applying to a product already covered by the Agreement, these procedures will be subject to the MRA, to ensure that the level of market access under the MRA is not negatively affected.

Articles 13 and 14 : these are standard institutional and legal provisions. To be noted that the Agreement is of unlimited duration.

Article 15 : Final Provisions : among other things this Article spells out that the sectoral annexes shall be the means of implementing the mutual recognition obligations of Article 2 of the Agreement, and that amendments to the Agreement shall be mutually agreed by the Parties. Unilateral termination of a sector is not possible. This provides legal certainty.

Annex 1 on Procedures for the Designation and Monitoring of Conformity Assessment Bodies

This Annex sets out the disciplines to be observed in identifying, designating and monitoring competent bodies, and meets the requirements concerning competence of the third country bodies and the responsibilities of designating authorities. The text has been discussed and agreed by the 113 Committee Technical Group on Mutual Recognition. The provisions of this text are consistent with the technical competence criteria as well as the notification procedures applicable to Notified Bodies under the EC internal market Directives, the aim being to establish an approach which would require third country bodies to demonstrate at least the same competences as European Notified Bodies.

I.1.2 The Joint Declarations

The framework agreements and Annex 1 are accompanied by four Joint Declarations by the Parties, as follows:

Annex 2 of the Agreement: Joint Declaration Relating To Future Work. This

a) provides for future extension of the scope of the Pressure Equipment Annex to include, products falling within the scope of the draft Community Directive on Pressure Equipment,once this is in force.

b) confirms the intention to continue negotiations for a future sectoral annex on aircraft certification and continued airworthiness with a view to completing this work within 2 years. This sector was in the original list of sectors which Member States agreed should be subject to negotiations.

c) at the request of Australia and New Zealand, provides for the opening of further negotiations after two years on possible additional sectors.

Annex 3: Joint Declaration on Mutual Recognition in the Voluntary Sphere. This encourages the conclusion of mutual recognition arrangements in the voluntary sphere (eg the Parties' respective accreditation bodies) so as to support the Agreements.

Annex 4: Joint Declaration on Further Harmonisation. This gives encouragement to the Parties to consider greater harmonisation or convergence of their respective standards and technical requirements where appropriate. While not binding, this is a recognition of the additional value that harmonisation may bring. In particular, the Parties recognise the objective of establishing a single product evaluation procedure for those products and sectors where the respective requirements are harmonised.

Annex 5: Joint Declaration relating to the Review of Article 4. Inclusion of this Declaration was a condition for Australia and New Zealand to accept Article 4 of the Agreement on Rules of Origin. It permits liberalisation of the origin rule to encompass products from third countries with whom the Parties have concluded equivalent MRAs in the same sectors.

I.1.3 The Sectoral Annexes

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

a) whether the sectoral annex provides for genuine mutual recognition, i.e. whether all relevant conformity assessment procedures for a particular sector have been captured;

b) whether the sectoral arrangements include evaluation of conformity not only to Federal law in Australia, but also to sub-Federal regulations where they exist. New Zealand does not have a federal system so this issue does not apply to New Zealand;

c) the level of trade between the Community and Australia and New Zealand for the sectors and products covered;

d) the views expressed by Member States and European industry groups on the benefits of mutual recognition;

e) the precedential nature (if any) of arriving at a mutual recognition agreement with Australia and New Zealand in the sectors covered;

f) overall consistency with Community policy objectives in the field of standardisation, certification, designation of Conformity Assessment Bodies and the removal of technical barriers to trade.

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

The Commission draws Member States' attention to the trade figures for each covered sector which are attached to this note. These figures show that for every sector concerned, the Community has a considerable trade surplus with Australia and New Zealand, (typically a factor of 7:1) notwithstanding the different size of our respective economies. This is however not surprising given that third party certification (the subject of the MRA) applies most commonly to industrial products at the higher end of technology, in respect of which the Community is a major exporter.

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

a) the range of products within a sector subject to third party certification. Obviously, if in a given sector one Party has more comprehensive certification requirements, the trade facilitation benefits to the other i.e. exporting Party may be proportionately greater;

b) the complexity and accessibility of the conformity assessment requirements of each Party, including the extent to which each Party applies internationally recognised standards or technical requirements for the sector in question. Generally, this is not a major issue in the case of Australia and New Zealand which, being medium sized economies with limited domestic industry in the sectors covered, have adopted international standards, regulations and conformity systems.

The Commission notes that industrial groups consulted throughout the negotiations, such as Eurobit and Orgalime, while supporting the agreements, have not always been able to quantify the costs or time taken to obtain conformity assessment of their products in third countries, including Australia and New Zealand. It is therefore not feasible in every case to determine the precise extent of savings in time, cost or market opportunity of the

arrangements set out in these agreements. This may only be possible once the agreements have been in operation for some time. However, on the basis of a rough calculation taking into account a shortening lifecycle of products it is estimated that this Agreement would create cost saving opportunities for the exporting industry of around 40 MECU and an amount around 5 MECU in terms of cost savings to exporters to the EC, some part of which will be passed on to European importers and consumers.

What can be ascertained with certainty is whether we have addressed industry's concern that any agreement provide reciprocal levels of market access, in terms of conformity assessment procedures. In addition, it should be noted that export markets become more easiliy accessible to small and medium-size enterprises.

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

Pharmaceuticals Good Manufacturing Practice (GMP)

This annex establishes mutual recognition of each Party's inspections of pharmaceutical sites according to the GMP standards of each, which are effectively harmonised. At the request of some member States, the text explicitly recognises the harmonisation of each Party's GMP, permitting inspections to be carried out against each Party's domestic GMP standard in most cases.

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

European industry and Member States' inspection authorities (the Pharmaceuticals Inspections Committee) have been consulted at every step of the negotiation and support the arrangements negotiated. The Community is the major exporter to Australia and New Zealand, who themselves have a very limited production and export of pharmaceuticals (see attachment). The proposed arrangements also supersede and extend to all Member States the coverage of what were some limited arrangements between Australia and a number of Member States under the Pharmaceutical Inspection Convention.

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

For veterinary medicines, transitional arrangements have been proposed (Section V of the sectoral annex). Australia is putting in place a new system for veterinary GMP inspection which will only be fully operational from 1997 onwards. Accordingly, the agreement provides that Australian certificates of GMP will not be accepted by the Community until two years following entry into force of the MRA, and subject to our being satisfied with

the level of GMP inspections carried out by Australia. This may need practical verification. During this 2-year transitional period, the Community will however accept inspection reports from Australia and can choose not to carry out its own inspections. Australia will continue to recognise Community GMP certificates, where proof of compliance is requested, during the transitional period.

For New Zealand, a three year transitional period for veterinary medicines GMP has been established (Section V of the sectoral annex), during which NZ will ensure that its GMP inspection system is operational and meets Community requirements, and vice versa. Subject to adequate verification of this by each Party, EC and NZ certificates would be reciprocally recognised three years after the entry into force of the agreement. Existing arrangements for NZ to accept European GMP certificates (bilateral arrangements exist with the UK and Sweden) will be unaffected thanks to a standstill provision in the sectoral annex.

While providing mutual benefits to pharmaceutical companies, and some savings to inspection authorities, we consider that the MRA in this sector establishes a good precedent for other negotiations. The present agreement also establishes mechanisms for longer-term cooperation between respective inspection authorities which will not only ensure the agreement continues to be properly applied, but will stimulate further harmonisation initiatives in other fields of medicines controls, such as Good Clinical Practices.

Medical Devices

The sectoral annex provides for mutual recognition of certificates for medical devices subject to third party certification procedures in either Party, with a few specific exceptions. Coverage is therefore determined according to the two existing Community Directives for medical devices, and for Australia and New Zealand their domestic legislation in this field (both specific medical device legislation and in New Zealand's case legislation covering electrical risks for electromedical devices). The annex thus covers all conformity assessment procedures in the Parties, including final certification and approval.

Currently, the Community provides more comprehensive third party certification than either Australia or New Zealand, who regulate a narrower range of products. However, we note that:

- both Australia and New Zealand have very limited production and export of medical devices (see attachment), and much of that export is for devices at the lower end of the technology where the Community does not require third party certification;

- New Zealand is in the process of introducing comprehensive legislation which will follow closely the EC Directives. It has agreed to offer the EC access to the certification procedures of this legislation once it enters into force: this is stated in Section V of the Sectoral Annex. It is also New Zealand's stated intention to allow CE-marked products access to the New Zealand market without modification, although this cannot be legally guaranteed at this stage.

- Australia is intending to modernise its medical device legislation to correspond more closely to the European approach, which it regards as an internationally applicable model for legislation in this sector. At our request, Australia has agreed to bring such future legislation within the scope of the MRA (Section V:5 of the Sectoral Annex).

Of importance in the Sectoral Annex with Australia is that Australia recognises a priori the competence to certify to Australian requirements of all Notified Bodies under the two EC Directives for medical devices, in cases where the requirements themselves are equivalent between Australia and the EC (Section IV). This is a clear recognition of the *uniformity* of the EC regulatory system, which establishes a useful precedent.

Given the nature of the sector, it has been necessary to introduce in the sectoral annex specific procedures for cooperation between regulatory authorities on exchange of information and vigilance mechanisms. Effectively, Australia and New Zealand will participate in the Community system for medical device vigilance.

At Australia's request, the Agreement with Australia includes an 18-month transitional period for 10 particularly high-risk products.

Discussions with EC industry federations raised the following

- certification procedures in these countries are not regarded as a major trade barrier, and an MRA could imply the need to undergo in Europe additional procedures not currently demanded in Australia;

- third countries like Malaysia or Japan could use the MRA to have their products certified in Australia or New Zealand and then get free access to the EC market, without reciprocity for EC exporters to those third countries;

- harmonisation of standards and regulatory requirements for medical devices is a higher priority for industry than mutual recognition.

- the level of competence in Australia and New Zealand to evaluate products to EC requirements should not be taken for granted;

In discussions with industry we have taken care to address all these concerns. It has been explained that the MRA provides a trade facilitation mechanism which would be optional, not compulsory, for European exporters. It would only apply to products requiring third party pre-market assessment, and there is no question of the Agreement imposing certification to products which under current Australian or NZ rules do not require such conformity assessment. Coverage of more extensive Australian and New Zealand requirements in future has also been guaranteed.

Secondly the origin rule in the Agreement will prevent circumvention by unrelated third countries: what is classified as Australian origin today will continue to be of Australian origin once the MRA is in force.

Thirdly, the Commission recognises that standards harmonisation is a priority for industry, and considers that mutual recognition is an important flanking policy for harmonisation, and not an alternative to it. Partly as a result of hte MRA, Australia and are moving towards the quality systems approach of the European. The Commission and the European industry federations are together actively promoting this approach in the Asia-Pacific region, and our industry recognises that Australia is a good ally in promoting the European approach.

On technical competence, the sole designated body for Australia for the time being will be the government itself in the form of the Therapeutic Goods Administration (TGA), with which Community regulators are familiar. New Zealand will either use the TGA itself or designate only a limited number of bodies according to where it has competence and an industrial interest. Any additional proposals for designation by either Party will have to comply with Annex 1 of the Agreement, and be subject to review and agreement by the Community, under the procedures set out in Article 12 of the Agreement. Technical competence can thus be assured.

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

The Commission considers that the MRA in this sector sets the right precedents in terms of our long term objectives. All certification procedures are covered; a link between mutual recognition and harmonised procedures has been made; and significantly, Australia has decided to move from a system of regulation by a sole government regulator to one of accepting certificates of conformity from European bodies.

Electrical Safety

This Annex covers the testing and certification requirements set out in the EC's Low Voltage Directive and the corresponding Australian and New Zealand legislation. The EC regime is based on manufacturer's self-declaration, i.e. there is no third party certification requirement under the Low Voltage Directive. The only recognition being granted to Australian or New Zealand certification bodies is according to Article 8:2 of the Directive where, should the compliance of a product already on the market be challenged by a Member State authority, a certificate of conformity from a recognised "competent body" can be used in attesting the product's conformity.

Both the Australian and New Zealand legislation demands third party conformity assessment for "declared articles": sixty-plus different electrical products in Australia. Under the agreement, these products can be tested and certified in Europe prior to export. The Australian standards for such products are largely harmonised to IEC standards, but the common legal requirements and approval procedures are currently applied through legislation of the Australian States and Territories (i.e. sub-Federal level). This legislation is listed in the Sectoral Annex. However, under the 1992 Mutual Recognition Act of Australia, products approved for marketing in one State must be accepted in all other states, to ensure free circulation. The agreement thus ensures that products certified in Europe to any or all sub-Federal legislation can access Australia without any further procedures, in accordance with the Council's negotiating directives.

Section IV of the annexes sets out the designation criteria and procedures for conformity assessement bodies, based on existing internationally accepted standards and guides.

European industry groups have been consulted on the proposed MRA and have expresses support provided that we ensure that any agreement provide for reciprocity of market access, and not lead to the introduction of new and more onerous requirements. Given the existing openness of the EC regime, and the fact that the necessary Australian legislation is covered under the sectoral annex, these requirements have clearly been met.

For New Zealand, its Electricity Act and subsidiary regulations require type testing for a smaller number of electrical products by recognised bodies. Comparable to the EC's low Voltage Directive, the NZ regime also provides for the production of test reports in respect of other electrical products as attestation of conformity under post-market surveillance procedures.

It should be noted that Australia and New Zealand are currently harmonising their electrical safety standards, conformity assessment procedures and marking requirements to create a common set of standards, technical requirements and mark. A draft standard on common rules and procedures, marking and third party certification requirements is being finalised. Once adopted, the amended regulations will enable EC products to be approved once for both markets under a common procedure and a single mark.

Electromagnetic Compatibility (EMC)

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

Australia has recently set up a new EMC regulation based on the approach of Directive 89/336/EEC, and this will be opened up to EC certification bodies through the MRA upon its entry into force.

The sectoral annex applies to all products for which under either legislation a third party conformity assessment procedure is called for, with the exclusion of radiocommunications equipment not connected to public networks. The annex with New Zealand foresees the designation by New Zealand of "competent bodies" according to the provisions of Article 10.2 of the EMC Directive. The Community in turn can designate certification bodies to certify EMC compliance where applicable of products falling under the Electricity Act and Regulations, and testing laboratories for products regulated under the Radiocommunications Act and regulations, for which lodging of a test report from a recognised laboratory is required for specific categories of radiocommunications equipment upon entering the market. Section IV of the annexes sets out the criteria and procedures for designating conformity assessment bodies, and are based on existing international standards.

Pressure Vessels

Product coverage of the sectoral annex is limited, on the Community's side, to those products regulated under Directive 87/404/EEC on Simple Pressure Vessels, and the same product range under the corresponding Australian States and Territories laws, which apply a common body of standards and technical requirements. Only some S&T laws impose third party certification. Australia has not agreed to include at this stage other categories of pressure equipment beyond the coverage of the EC Directive, but will do so once the draft EC Directive on Pressure equipment has entered into force, and has been included in the scope of this Sectoral Annex (see Joint Declaration No 1).

New Zealand has agreed that EC bodies can test and certify all categories of pressure vessels subject to third party assessment under its law: i.e. the coverage "offered" by New Zealand is wider than the EC's coverage.

The sectoral annexes now set out in detail the standards and procedures to be observed in designating Conformity Assessment Bodies (Section IV of the annexes). In the case of Australia and New Zealand their requirements are based on international standards such as the relevant ISO Guides. In addition, Australia recognises that simple pressure vessels certified under Directive 87/404/EEC may meet Australian requirements (Section IV of the Sectoral annex).

For both agreements, it has been proposed to open negotiations on expanding coverage to include other categories of pressure equipment to which the forthcoming EC directive on pressure equipment will apply, and which are also regulated under Australian law.

As the attached trade statistics show, the EC holds a considerable trade surplus for the products covered in the present sectoral annex. In view of the systematic use of third party certification procedures for these products in Australia and New Zealand, and their application of international and European standards for these products, the MRA should improve the ease by which European products can be approved for these markets. In the case of New Zealand, the capacity to certify to specific seismic requirements will be needed. The relevant European industry organisations were given the opportunity to comment on the proposed scope of the annex and did not raise any objections.

Telecommunications Terminal Equipment

Both sectoral annexes apply to all telecommunications terminal equipment (TTE) regulated under the relevant Community Directives and the corresponding Australian and New Zealand legislation. The scope offered by the EC does not however extend to analogue network equipment as long as it has not been harmonised at Community level. The scope being offered by Australia and New Zealand, which includes all analogue interfaces, is thus broader.

In both the cases of Australia and New Zealand third party certification against network harm is required. To the extent that requirements in respect of electrical safety and EMC exist, these are covered under the electrical safety and EMC sectoral annexes.

Both Community legislation and Australian and New Zealand legislation allow the ***option*** of presenting test reports to the domestic certification body as part of the product type approval procedure. Accordingly, the sectoral annexes provide for certification upon presentation of test reports, as well as the full delegation to the exporting party of the certification and approval procedure itself.

The sectoral annexes detail the criteria and procedures for designation of conformity assessment bodies of each Party, in Section IV. Australian and New Zealand criteria are transparent and refer to international standards. EC bodies will readily be able to comply with them.

It is noted that through the agreement Australia has agreed to delegate its sole regulatory authority by allowing European bodies to certify to Australian requirements.

European industry organisations have been consulted extensively on the MRA negotiations and have supported the objectives provided that access to all Australian and New Zealand conformity assessment, including product approvals, is achieved. In this connection, the agreements do provide for reciprocal recognition of all conformity assessment procedures including final certification without further product assessment by the importing party.

Machinery

The proposed sectoral annex covers a range of identified products subject to third party conformity assessment under the Machinery Directive 89/392/EEC and noise emissions legislation, and the corresponding Australian and NZ legislation. Tower and mobile cranes have been proposed because, while not subject to the EC machinery Directive, they are subject to third party assessment in all three parties and represent not insignificant trade (EC export to Australia and New Zealand).

Section IV of the Sectoral Annex details the criteria and procedures to be followed by both Parties in designating conformity assessment bodies under the Agreement.

In consultations with Orgalime and sector-specific industry federations on the proposed MRA, support has been given, especially as concerns wood-working machinery, with emphasis being placed on the fact that any MRA should create a level playing field for EC exporters (the problems at sub-Federal level having been a concern). In the case of Australia, internationally-derived national machinery standards are called up in the States and Territories legislation, which has been covered under the agreement. Market access is thus assured.

Other industry representatives have underlined the need for Australian and NZ bodies to participate adequately in coordination exercises with EC notified bodies to ensure harmonious application of requirements. We agree this will be necessary, while noting at the same time that the Australian and New Zealand requirements are close to international and European ones, and the accreditation systems in both countries have extensive experience in accrediting competent testing and inspection bodies to work to such requirements.

Vehicles

Following agreement within the 113 Committee to negotiate this sector with Australia, a sectoral annex for automotive products has now been agreed. This provides for reciprocal recognition of tests and conformity of production inspections in those fields where EC and Australian legislation is based on corresponding UN-ECE Regulations, or is otherwise equivalent. In addition, Australia will recognise approvals carried out by Community bodies. The scope of the annex will be expanded to the extent that the Parties both adopt further UN-ECE rules.

The annex includes a standstill provision (Section V) to ensure that any existing arrangements through which Australia recognises EC conformity assessment will not be adversely affected. The sectoral annex also contains a review clause allowing its continuation or amendment to be considered in the light of the Parties' international commitments, especially Australia's participation in the UN-ECE 1958 Agreement on harmonisation and mutual recognition of approvals.

I.1.4 Relations with EFTA States, Members of the European Economic Area

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

The EFAT/EEA States are in the final stage of the process of negotiating with Australia and New Zealand a parallel mutual recognition agreement equivalent to those to be concluded between the Community and these countries.

I.1.5 Overall Appreciation

The Commission considers that the proposed MRAs create an acceptable balance of benefits for all parties. In all sectors the Community has secured effective market access - in terms of access to all mandatory procedures of the other party. Australia and New Zealand have accepted the Community's approach of reciprocally recognising not only testing, but also certificates and approvals of conformity to the other's requirements, including where applied through sub-Federal legislation. Given the extent to which regulatory powers are today held by single regulatory agencies in these countries, this is a significant development, and establishes a good precedent for other MRA negotiations. The agreements will allow Community exporters, if they so choose, to test and certify their products to Australian and New Zealand requirements prior to export, and then access those markets without any further conformity assessment requirements. This will facilitate Community exports. European industry federations have been consulted on the agreements and have supported them.

Since Australia and New Zealand base both their product standards and regulations, and criteria for accepting Community bodies on established international or European norms, this will enable European conformity assessment bodies to participate in the agreement and offer their services to European exporters. The Commission has received a large number of EC conformity assessment bodies that would be interested to work in the

framework of these Agreements, and this indicates both their technical capacity and economic interest in the Agreements. Those which have provided sufficient information will be provisionally agreed by Australia and New Zealand, subject to confirmation by the Joint Committee. The Council will receive the list of these CABs by way of a Commission Staff paper in the near future.

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

In terms of the benefits of the agreements to Australia and New Zealand, the MRAs will certainly facilitate their access to the Community market. In view of the significant trade imbalance between the Community and Australia and New Zealand, these two countries expect the practical trade benefits of the MRA to be modest. Australia and New Zealand however regard the MRAs as a means not only to develop closer industrial relations with Europe, but also to create a good precedent for their efforts within the APEC framework to develop mutual recognition agreements.

II. The Draft Council Decision

A proposal for a Council decision for each of the two Agreements is annexed. Each decision is identical in substance and has two objectives:

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

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

On this second aspect, it is noted that in Article 12 of each Agreement, a Joint Committee of the Parties operates. This Joint Commitee is responsible for the management of the Agreement and has the delegated power to amend existing sectoral annexes. Such right of amendment is restricted only to procedural issues concerned with implementation, essentially: amending the references to the regulations applicable to covered sectors; amending the annexes further to decisions to recognise, suspend, remove, or alter the scope of activity of conformity assessment bodies or designating authorities in the Agreements. The Joint Committee does not have the power to amend the framework agreement, to delete sectoral annexes or to add new sectoral annexes. These remain the responsibility of the Parties as such.

It is accordingly proposed that:

a) the Commission, assisted by the 113 Committee (Technical Group on Mutual Recognition) should represent the Community in the Joint Committee, and that the Community position in that Joint Committee in case of changes to the annexes and other sectoral questions be determined, in conformity with Article 228, paragraph 4 of the Treaty, by the Commission following consultation of one of the committees established by the corresponding technical directives.

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

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

Annex 1

EU TRADE WITH AUSTRALIA AND NEW ZELAND 1996 (000 ecu)

IMPORT

Products	Australia	%	New Zealand	%
Pharmaceuticals	87 025	1.7	9 924	0.5
Medical Devices	44 130	0.8	8 359	0.4
Telephonic & telegraphic Equipment	32 859	0.6	2 936	0.2
Electrical Equipment	208 007	4.0	41 488	2.2
Pressure Vessels	86 890	1.7	20 676	1.1
Machinery	1 719	0.0	474	0.0
Motor Vehicles & Components	45 323	0.9		
TOTAL	505 953	9.7	83 857	4.4
IMPORT TOTAL	5 230 268	100.0	1 885 310	100.0

EXPORT

Products	Australia	%	New Zealand	%
Pharmaceuticals	628 785	5.5	87 593	4.6
Medical Devices	163 712	1.4	20 534	1.1
Telephonic & telegraphic Equipment	221 401	1.9	28 626	1.5
Electrical Equipment	1 552 863	13.5	188 358	10.0
Pressure Vessels	319 016	2.8	68 488	3.6
Machinery	182 178	1.6	32 622	1.7
Motor Vehicles & Components	937 726	8.2		
TOTAL	4 005 683	34.8	426.222	30.6
EXPORT TOTAL	11 503 638	100.0	1 885 817	100.0

SOURCE:

Pharmaceuticals: (ch 30)
Medical Devices: (ch 9018, 9019, 9020 , 9021, 9022)
Telephonic & telegraphic Equipment: (ch 8517)
Electrical Equipment: (ch 85)
Pressure Vessels: (ch 7311, 7613, 8402-8406, 8410, 8411, 8413, 8414)
Machinery: (ch 8408, 8426, 8462-65)
Motor Vehicles & Components:(ch 8703, 8708)

Source: COMEXT

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

JS/0126 (ACC)

The Council of the European Union,

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

Having regard to the proposal of the Commission,

Whereas the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia has been negotiated and should be approved,

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

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

Decides:

Article 1

The Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia, including its Annexes and the Joint Declarations attached to it are hereby approved on behalf of the European Community.

The text of the Agreement, the Annexes and the Joint Declarations is attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Community, transmit the note provided for in Article 14 of the Agreement. (1)

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

Article 3

1. The Commission shall represent the Community in the Joint Committee provided for in Article 12 of the Agreement, assisted by the special committee established under Article 113 of the EC Treaty (Technical Group on Mutual Recognition). The Commission shall proceed, after consultation with this special committee, to the appointments, notifications, exchange of information and requests for verifications referred to in Article 8 paragraph 2 and Article 12, paragraph 4, letter c), d) and e) of the Agreement.

2. The position to be taken by the Community in regard of decisions to be taken by the Joint Committee shall be determined with regard to amendments of Sections I to IV of the Sectoral Annexes (Article 12, paragraph 4, letter a) and b) and paragraph 6 of the Agreement) and verification of compliance in accordance with Article 8 and Article 12, paragraph 6, letter d) of the Agreement by the Commission following consultation of the above-mentioned special Committee.

3. In all other cases the position of the Community for a decision in the Joint Committee shall be determined by the Council, acting by qualified majority on a proposal from the Commission.

Done at Brussels,

For the Council
The President

AGREEMENT ON MUTUAL RECOGNITION

IN RELATION TO CONFORMITY ASSESSMENT,

CERTIFICATES AND MARKINGS

BETWEEN

AUSTRALIA AND THE EUROPEAN COMMUNITY

AGREEMENT ON MUTUAL RECOGNITION

IN RELATION TO CONFORMITY ASSESSMENT,

CERTIFICATES AND MARKINGS

BETWEEN

AUSTRALIA AND THE EUROPEAN COMMUNITY

The European Community and the Government of Australia, 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 Australia and New Zealand 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 Australian and New Zealand 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 Australia 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 standardization and related activities" and in EN 45020 (1993 edition) unless the context otherwise requires. 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;

   "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 Australia 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 Australia 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.

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 (Section I);

   (c) a list of the designated Conformity Assessment Bodies (Section II);

   (d) the Designating Authorities (Section III);

   (e) a set of procedures for the designation of Conformity Assessment Bodies (Section IV); and

   (f) additional provisions as required (Section V).

ARTICLE 4 : ORIGIN

1. This Agreement shall apply to products originating in the Parties to the Agreement according to the non-preferential rules of origin.

2. In case of conflicting rules, the non-preferential rules of the Party on whose territory the goods are marketed are determinative.

3. To the extent that the same products are also covered in a Sectoral Annex to the Agreement on Mutual Recognition in relation to conformity assessment between the European Community and New Zealand, the present Agreement shall also apply to products of New Zealand origin.

4. To the extent that the same products are also covered in a Sectoral Annex to an Agreement on Mutual Recognition in relation to conformity assessment between Australia and States Contracting Parties to both the Convention of the European Free Trade Association (EFTA) and the Agreement on the European Economic Area (EEA), the present Agreement shall also apply to products originating in any of these EFTA States.

ARTICLE 5 : CONFORMITY ASSESSMENT BODIES

In accordance with the terms of Annex 1 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.

ARTICLE 6 : DESIGNATING AUTHORITIES

1. The Parties shall ensure that the Designating Authorities responsible for designating the Conformity Assessment Bodies specified in the Sectoral Annexes shall have the necessary power and competence to designate, suspend, remove suspension and withdraw the designation of such bodies.

2. In making such designations and withdrawals, Designating Authorities shall, unless specified otherwise in the Sectoral Annexes, observe the procedures for designation set out in Article 12 and Annex 1 of this Agreement.

3. In case of suspension of a designation or removal of such a suspension, the Designating Authority of the Party concerned shall immediately inform the other Party and the Joint Committee. Conformity assessment carried out by a suspended Conformity Assessment Body before its suspension shall remain valid unless otherwise determined by its Designating Authority.

ARTICLE 7 : VERIFICATION OF DESIGNATION PROCEDURES

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

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 Annex 1. Existing systems for the accreditation of Conformity Assessment Bodies in the two Parties may be used for such comparison procedures.

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

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.

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

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.

6. Except when decided otherwise by the Joint Committee, the contested Conformity Assessment Body, where it is included in Section II of a Sectoral Annex, will be suspended by the competent Designating Authority from the time disagreement has been established in the Joint Committee until agreement has been reached in the Joint Committee on the status 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.

2. Consistent with their obligations under the World Trade Organisation 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 where considerations of safety, health and environmental protection warrant more urgent action, notify the other Party of the new provisions at least 60 days before their entry into force.

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 to this Agreement.

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 sub-committees.

3. The Joint Committee will meet at least once a year unless it decides otherwise. If required for the effective functioning of this Agreement, and at the request of either Party, an additional meeting or meetings will 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 to give effect to the decision by a Designating Authority to designate a particular Conformity Assessment Body;

   b) Amending the Sectoral Annexes to give effect to the decision by a Designating Authority to withdraw designation of a particular Conformity Assessment Body;

   c) Exchanging information concerning the procedures used by either Party to ensure that the Conformity Assessment Bodies specified in the Sectoral Annexes maintain the necessary level of competence;

   d) In accordance with the provisions of 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 ;

   e) 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;

   f) Resolving any questions relating to the application of this Agreement and its Sectoral Annexes; and

   g) Facilitating the extension of this Agreement to further sectors.

5. Any amendments to Sectoral Annexes made in accordance with the provisions of this Article will be notified promptly in writing by the Chair of the Joint Committee to each Party.

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

   a) A Party proposing an amendment to a Sectoral Annex to give effect to a decision by a Designating Authority to designate or withdraw designation of a Conformity Assessment Body shall forward its proposal to the other Party in writing, adding supporting documentation to the request;

   b) A copy of the proposal and documentation shall be sent to the Chair of the Joint Committee;

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

   d) In the event, that under the provisions of Article 8, the other Party contests the technical competence or compliance of a Conformity Assessment Body within the afore-mentioned 60 day period, the Joint Committee may decide to carry out a verification of the Body concerned, in accordance with the provisions of that Article.

7. In the event that a designated Conformity Assessment Body is withdrawn from a Sectoral Annex, conformity assessment carried out by that Conformity Assessment Body before the date of effect of its withdrawal shall remain valid unless otherwise determined by the Joint Committee. In the case of the inclusion of a new Conformity Assessment Body, conformity assessment carried out by such a Conformity Assessment Body shall be valid from the date the Parties agree to its inclusion in the Sectoral Annex.

8. Where a Party introduces new or additional conformity assessment procedures affecting a sector covered by a Sectoral Annex, the Joint Committee will, 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, on the one hand, to the territories in which the Treaty establishing the European Community is applied, and under the conditions laid down in that Treaty and, on the other hand, to the territory of Australia.

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. Annex 1 to this Agreement forms an integral part of it.

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

3. The Parties shall conclude Sectoral Annexes, to which the provisions of Article 2 apply, which will provide the implementing arrangements for this Agreement.

4. Amendments to the Sectoral Annexes will be determined by the Parties through the Joint Committee.

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.

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;
   - the experience relevant to the applicable legislative, regulatory and administrative provisions;
   - the physical capability to perform the relevant conformity assessment activity;
   - an adequate management of the conformity assessment activities concerned; and
   - any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed on a continuous basis.

4. The technical 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.

(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.

D. Formal Designation

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

9. Designating Authorities shall inform their Party's representatives on the Joint Committee, established under this Agreement, of the Conformity Assessment Bodies to be included in or withdrawn from Section II of the Sectoral Annexes. Designation, suspension or withdrawal of designation of Conformity Assessment Bodies shall take place in accordance with the provisions of this Agreement and the rules of procedure of the Joint Committee.

10. When advising their Party's representative on the Joint Committee established under this Agreement, of the Conformity Assessment Bodies to be included in the Sectoral Annexes, the Designating Authority shall provide the following details in respect of each Conformity Assessment Body:

    (a) the name;

    (b) the postal address;

    (c) the facsimile (fax) number;

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

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

    (f) the designation procedure used to determine competence.

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 reasonaole cost.

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

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

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 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 the 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, Australia and the European Community 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.

Annex 3

Joint Declaration
on mutual recognition in the voluntary sphere

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

Annex 4

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.

[redacted]

Joint Declaration
relating to the review of Article 4

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.

AUSTRALIA- EUROPEAN COMMUNITY

MUTUAL RECOGNITION AGREEMENT

OF

CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SECTORAL ANNEX

MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

AUSTRALIA- EUROPEAN COMMUNITY

SECTORAL ANNEX - MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

SCOPE AND COVERAGE

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

   For medicinal products covered by this Sectoral Annex, each Party shall 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 shall be recognised by the other Party without re-control at import.

   "Medicinal products" means all products regulated by the pharmaceutical legislation in the European Community and Australia as listed in the Appendix to this Annex. 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 homeopathic 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 Community).

2. With respect to medicinal products covered by the legislation of one Party but not the other, the manufacturing company can request, for the purpose of this Agreement, an inspection be made by the locally competent inspection service. This provision shall apply *inter alia* to the manufacture of active pharmaceutical ingredients and intermediate products and products intended for use in clinical trials, as well as agreed pre-marketing inspections. Operational arrangements are detailed under Section III, item 3 b.

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 shall certify that the manufacturer:

   - 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, and which are listed in Appendix 1 to this Sectoral Annex. In case different GMP requirements would be used as a reference (in line with the provisions in Section 3, 3 b), this is to be mentioned in the certificate.

   The certificates shall also identify the site(s) of manufacture (and contract testing laboratories, if any). The format of certificate is attached as Appendix 2; it may be modified by the Joint Committee, as established in Article 12 of the Agreement.

   Certificates shall 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 days.

Batch certification

4. Each batch exported shall 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 shall attest that the batch meets its specifications and shall 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 shall take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate shall detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It shall contain a statement that the batch processing and packaging records were reviewed and found in conformity with GMP. The batch certificate shall be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Community the "qualified person" referred to in article 21 of Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. In Australia, the responsible persons are for manufacturing quality control as specified in the Therapeutic Goods Regulation 19(b) under the Therapeutic Goods Act 1989:

SECTION I: LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

Subject to Section 3 "Operational provisions", general GMP inspections shall be carried out against the GMP requirements of the exporting Party. The legislative, regulatory and administrative requirements are listed in the Appendix.

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

SECTION II: OFFICIAL INSPECTION SERVICES

For Australia:

Therapeutic Goods Administration (TGA)
Department of Health and Family Services
PO Box 100
Woden ACT 2606
Australia

Tel.: 61-6-232 8632
Fax : 61-6-232 8659

For the European Community:

BELGIUM

Inspection générale de la Pharmacie
Cité administrative de l'Etat
Quartier Vésale
Algemene Farmaceutische Inspectie
Rijksadministratief Centrum
Vesalius Gebouw
B-1010 BRUXELLES — Tel. : 32-2-210 4924
BRUSSEL — Fax : 32-2-210 4880

DENMARK

Sundhedsstyrelsen -Medicines Division
Frederikssundsvej 378
DK-2700 BRØNSHØJ — Tel. : 45-44-889 320
Fax : 45-42-847 077

GERMANY

Bundesministerium für Gesundheit
Am Propsthof 78a
D-53108 BONN — Tel. : 49-228-941 2340
Fax : 49-228-941 4923

for immunologicals :
Paul-Ehrlich-Institut, Federal Agency for Sera & Vaccines
Postfach
D-63207 LANGEN — Tel. : 49-6103-77 1010
Fax : 49-6103-77 1234

GREECE

Εθνικός Οργανισμός Φαρμάκου
National Drug Organization (E.O.F.)
Mesogion 284
GR-ATHENS 15562 — Tel. : 30-1-654 5530
Fax : 30-1-654 9591

SPAIN

Ministerio de Sanidad y Consumo
Subdirección General de Control Farmaceutico
Paseo del Prado 18-20
E-28014 MADRID
Tel. : 34-1-596 4068
Fax : 34-1-596 4069

FRANCE

for medicinal products for human use :
Agence du Médicament
143-145 boulevard Anatole France
F-93200 SAINT-DENIS
Tél. : 33-1-4813 2000
Fax : 33-1-4813 2478

for veterinary medicinal products :
Agence Nationale du Médicament Vétérinaire
la Haute Marche - Javené
F - 35133 FOUGERES.
Tel.: +33-9994 7878
Fax : +33-9994 7899

IRELAND

National Drugs Advisory Board
63-64 Adelaide Road
IRL-DUBLIN 2
Tel. : 353-1-676.4971 - 7
Fax : 353-1-676.7836

ITALY

Ministero della Sanità
Direzione Generale del Servicio Farmaceutico
Viale della Civiltà Romana 7
I-00144 ROMA
Tel. : 39-6-5994 3676
Fax : 39-6-5994 3365

LUXEMBOURG

Division de la Pharmacie et des Médicaments
10 rue C.M. Spoo
L-2546 LUXEMBOURG
Tel. : 352-478 5590 / 93
Fax : 352-22 44 58

NETHERLANDS

Ministerie van Volksgezondheid, Welzijn, en Sport
Inspectie voor de Gezondheidszorg
Postbus 5850
NL-2280 HW RIJSWIJK
Tel. : 31-70-340 6839
Fax : 31-70-340 7159

AUSTRIA

Bundesministerium für Gesundheit und Konsumentenschutz
Radetzkystraße 2
A-1031 WIEN
Tel. : 43-1-711 724 642
Fax : 43-1-714 92 22

PORTUGAL

Instituto Nacional da Farmácia e do Medicamento - INFARMED
Av. do Brasil, 53
P - 1700 LISBOA
Tel. : 351-1-795 7836
Fax : 351-1-795 9116

FINLAND

National Agency for Medicines
P.O. Box 278
FIN-00531 HELSINKI
Tel. : 358-0-396 72 112
Fax : 358-0-714 469

SWEDEN

Läkemedelsverket - Medical Products Agency
Husargatan 8, P.O. Box 26
S - 751 03 UPPSALA
Tel. : 46-18-174 600
Fax : 46-18-548 566

UNITED KINGDOM

for human and veterinary (non immunologicals) :
Medicines Control Agency
1 Nine Elms Lane
GB-LONDON SW8 5NQ
Tel. : 44-171-273 0500
Fax : 44-171-273 0676

for veterinary immunologicals :
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone
GB - SURREY KT15 3NB
Tel. : 44-1932-336911
Fax : 44-1932-336618

SECTION III : OPERATIONAL PROVISIONS

1. Transmission of inspection reports

Upon reasoned request, the relevant inspection services shall forward a copy of the last inspection report of the manufacturing or control site, in case analytical operations are contracted out. The request may concern a "full inspection report" or a "detailed report" (see item 2 below). Each Party shall 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 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 shall be inspected against the applicable GMP of the exporting Party (see Appendix 1);

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 shall 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 Committee.

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) shall be provided in confidence to the inspectorate.

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 Agreement.

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 the Agreement, the Parties shall exchange any information necessary for the mutual recognition of inspections.

In addition, the relevant Authorities in Australia and in the European Community shall keep each other informed of any new technical guidance or inspection procedure. Each Party shall consult the other before their adoption and will endeavour to proceed towards their approximation.

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 shall 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 Community, the official batch release procedure for medicinal products for human use is specified, in document "Administrative EC Batch Release Procedure III/3859/92" and different specific batch release procedures. For Australia, 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 the Agreement, training sessions for inspectors, organised by the Authorities, shall be accessible to inspectors of the other Party. The Parties to the Agreement will keep each other informed of these sessions.

10. Joint Inspections

In accordance with the general provisions of the Agreement, and by mutual agreement 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 shall be agreed through procedures approved by the Joint Committee.

11. Alert system

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

The Parties shall 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, are communicated to each other with the appropriate degree of urgency.

12. Contact points

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

for Australia:
for medicinal products for human use:
the Chief GMP Auditor
Therapeutic Goods Administration
Department of Health and Family Services
PO Box 100
Woden ACT 2606
Australia
Tel: 61-6-232-8632
Fax: 61-6-232-8659

for medicinal products for use in animals:
the GMP Licensing Scheme Manager
National Registration Authority
PO Box E 240
Parkes ACT 2600
Australia
Tel: 61-6-272-5158
Fax: 61-6-272-4753

for the European Community:
the Director of the European Agency for the Evaluation of Medicinal Products
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom
Tel: 44-171-418 8400
Fax: 44-171-418 8416

13. Divergence of views

Both Parties shall 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 Committee.

SECTION IV : TRANSITIONAL ARRANGEMENTS FOR VETERINARY MEDICINAL PRODUCTS

The Parties note that the current GMP requirements for veterinary medicinal products in Australia are not equivalent to those that apply in the European Union. Therefore, Australian veterinary medicinal products manufacturers will be inspected by Therapeutic Goods Administration on behalf of the veterinary National Registration Authority, according to the TGA reference GMP and relevant additional EU GMP for veterinary medicinal products.

During a two year transitional period, TGA inspection reports will be routinely sent to the importing Party, which may accept them or decide to carry out an inspection itself. If accepted, the European Community will recognise Australian manufacturers' certifications of batch conformity.

Two years after the entry into force of the Agreement, the European Community shall, subject to satisfactory verification of Australia's GMP inspection programme, recognise the conclusions of inspections carried out by the TGA and Australian manufacturers' certifications of batch conformity.

Should the National Registration Authority (NRA) begin to carry out inspections itself, inspection reports will also be routinely transmitted to the importing Party until there has been a satisfactory verification of the NRA GMP inspection programme.

APPENDIX 1

LIST OF APPLICABLE LEGISLATIVE, REGULATORY & ADMINISTRATIVE PROVISIONS

For the European Community:

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 81/851/EEC of 6 November 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products as widened and amended.

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products

Council Regulation No (EEC) 2309/93 of 23 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use & Guide to Good Distribution Practice

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV

For Australia:

For products for human use:

Therapeutic Goods Act 1989, and regulations, Orders and Determinations thereunder, including Orders setting standards such as labelling, the Determination establishing manufacturing Principles.

¨ Therapeutic Goods Act 1989
¨ Therapeutic Goods Regulations
¨ Therapeutic Goods (Charges) Act 1989
¨ Therapeutic Goods (Charges) Regulations
¨ Therapeutic Goods (Excluded Goods) Order No. 1 of 1992
¨ Therapeutic Goods (Goods that are not Therapeutic Devices) Order No. 1 of 1992
¨ Therapeutic Goods (Manufacturing Principles) Determinations.
¨ Australian Code of Good Manufacturing Practice for Therapeutic Goods - Medicinal Products, August 1990, including:
  - Appendix A: Guidelines for Sterilisation by Irradiation, October 1993
  - Appendix C: Guidelines on Tests for Sterility, July 1991
  - Appendix D: Guidelines for laboratory Instrumentation, November 1991
  - Appendix E: Guidelines for Industrial Ethylene Oxide Sterilisation of Therapeutic Goods, April 1986
  - Appendix F: Guidelines for Estimation of Microbial Count in Process Water, August 1990
  - Appendix G: Guidelines for Good Manufacturing Practice for Investigational Medicinal Products, June 1993
¨ Australian Code of Good Manufacturing Practice - Blood and Blood products (including technical annexes 1-7), July 1992
¨ Australian Code of Good Manufacturing Practice for Therapeutic Goods - Sunscreen Products, February 1994
¨ Australian Code of Good Manufacturing Practice for Therapeutic Goods - Medicinal Gases, July 1992

and for products for veterinary use:

Legislation - Commonwealth:

- Agricultural and Veterinary Chemicals (Administration) Act, 1992
- Agricultural and Veterinary Chemicals Act, 1993
- Agricultural and Veterinary Chemicals Code Act, 1993
- Agricultural and Veterinary Chemicals (Consequential Amendments) Act, 1993

Legislation - New South Wales:

- Stock Foods and Medicines Act, 1940
- Public Health Act, 1961
- Poison Act, 1966
- Pesticides and Allied Chemicals Act, 1979

Legislation - Victoria:

- Animal Preparations Act, 1987
- Health Act, 1958
- Drugs, Poisons and Controlled Substances Act, 1981

Legislation - Queensland:

- Agricultural Standards Act, 1952-1981
- Stock Act, 1915-1976
- Health Act, 1937-1987

Legislation - South Australia:

- Stock Medicines Act, 1939-1978
- Stock Foods Act, 1941
- Dangerous Drugs Act, 1986
- Controlled Substances Act, 1984
- Stock Diseases Act, 1934

Legislation - Western Australia:

- Veterinary Preparations and Animal Feeding Stuffs Act, 1976–1982
- Poisons Act, 1964-1981
- Health (Pesticides) regulations, 1956

Legislation - Tasmania:

- Veterinary Medicines Act, 1987
- Poisons Act, 1971
- Public Health Act, 1962
- Pesticides Act, 1968

Legislation - Northern Territory:

- Poisons and Dangerous Drugs Act, 1983
- Therapeutic Goods and Cosmetics Act, 1986
- Stock Diseases Act, 1954

APPENDIX 2

CERTIFICATE OF PHARMACEUTICAL MANUFACTURER IN THE FRAMEWORK OF THE AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS BETWEEN AUSTRALIA AND THE EUROPEAN COMMUNITY, SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

As requested by the Competent Authorities of Australia / ..... (*) on ..../..../.... (date) (reference: .....), the Competent Authority of ..... confirms the following:

The company .....,
whose legally registered address is: .....
.....
.....
has been authorised, under the Therapeutic Goods Act 1989 / Directive 75/319/EEC, Article 16, and Directive 81/851/EEC, Article 24, transposed in the national legislation of ..... (*), under the authorisation reference number .....,
covering the following site(s) of manufacture (and contract testing laboratories, if any):
1 .....
.....
2 .....
.....
3 .....
.....
to carry out the following manufacturing operations:

+ complete manufacture (**)

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

for the following medicinal product: .....

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

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on ..../..../.... (date), it is considered that the company complies with the Good Manufacturing Practice requirements referred to in the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community.

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

For the Competent Authority,

(Name and signature of the officer responsible)

(*) : insert European Community Member State or European Community as required
(**): delete that which does not apply

AUSTRALIA - EUROPEAN COMMUNITY

MUTUAL RECOGNITION AGREEMENT

OF

CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SECTORAL ANNEX

MEDICAL DEVICES

AUSTRALIA - EUROPEAN COMMUNITY

SECTORAL ANNEX - MEDICAL DEVICES

SCOPE AND COVERAGE

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

Products for export to the European Community	Products for export to Australia
· All medical devices subject to third party conformity assessment procedures, both product related and quality system related, provided for in the Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, but excluding the following products: · radioactive materials to the extent these may be considered medical devices, and · medical devices incorporating tissues of animal origin. However, medical devices (a) incorporating refined derivatives of animal derived waxes, heparin and gelatine which conform to pharmacopoeial standards and sintered hydroxyapatite, or (b) incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, will be included within the scope of this Sectoral Annex.	· All medical devices subject, under the Australian Therapeutic Goods Act 1989 and Therapeutic Goods Regulations, to third party conformity assessment procedures, both product related and quality system related, apply; but excluding the following products: · radioactive materials to the extent these may be considered medical devices. · medical devices incorporating tissues of animal origin. However, medical devices (a) incorporating refined derivatives of animal derived waxes, heparin and gelatine which conform to pharmacopoeial standards and sintered hydroxyapatite, or (b) incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, will be included within the scope of this Sectoral Annex.

SECTION I: LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which Australian designated Conformity Assessment Bodies shall assess compliance	**The legislative, regulatory and administrative requirements of Australia to which European Community designated Conformity Assessment Bodies shall assess compliance**
· Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC), as amended · Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended	· Therapeutic Goods Act 1989 · Therapeutic Goods (Charges) Act 1989 · Therapeutic Goods Regulations · Therapeutic Goods (Charges) Regulations · Therapeutic Goods (Excluded Goods) Order No. 1 of 1992 · Therapeutic Goods (Goods that are not therapeutic devices) Order No. 1 of 1992 · Therapeutic Goods (Manufacturing Principles) Determinations - European Standard EN 46001: 1993, specification for Application of EN 29001 (BS 5750 : Part 1) to the manufacture of medical devices

SECTION II: DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess product against the European Community's legislative and regulatory requirements	**The Conformity Assessment Bodies designated by the European Community to assess product against Australia's legislative and regulatory requirements**
The Therapeutic Goods Administration of the Department of Health and Family Services, in respect of the conformity assessment procedures required under the Community legislation cited in Section I, for all medical devices and for all modules for the various phases of the conformity assessment procedures applicable to such devices.	The designated Conformity Assessment Bodies are: [Names and details to be inserted] [Further names to be added as required]

SECTION III : AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
· Department of Health and Family Services	• **Belgium** Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie • **Denmark** Sundhedsministeriet • **Germany** Bundesministerium für Gesundheit • **Greece** Υπουργείο Υγείας και Πρόνοιας Ministry of Health • **Spain** Ministerio Sanided y Consumo • **France** Ministère du Travail et des Affaires Sociales • **Ireland** Department of Health • **Italy** Ministero Sanita • **Luxembourg** Ministère de la Santé • **Netherlands** Ministerie van Volksgezondheid, Welzijn en Sport

	• **Austria** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Ministerio da Saude • **Finland** Sosiaali- ja terveysministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) • **United Kingdom** Department of Health

SECTION IV: PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess product against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product against Australia's requirements
The Conformity Assessment Bodies listed in Section II must meet the requirements of the Directives listed in Section I, taking into account Council Decision 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 (93/465/EEC), and be designated on the basis of the procedures defined in Annex 1 to the Agreement. This may be demonstrated through: • Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guide 28 and 40; • Quality System Certification Bodies operating according to the requirements of EN 45012 or ISO Guide 62; • Inspection Bodies operating according to the requirements of EN 45004 or ISO Guide 39.	Conformity Assessment Bodies will be designated in accordance with the procedures set out in Annex 1 of this Agreement. Conformity Assessment Bodies which are Notified Bodies under Annex XI of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Annex VIII of Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) in conjunction with Council Decision 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 (93/465/EEC) shall be presumed competent to carry out conformity assessment to Australian requirements for those devices and procedures for which they have been correspondingly notified by their competent authorities in Europe.

SECTION V: ADDITIONAL PROVISIONS

1. Transitional period for certain high risk devices

1.1. A transitional period, for the purpose of strengthening confidence in the designating systems of each of the Parties will apply for the Medical Devices specified in Schedule 3 of the Therapeutic Goods Regulations and medical devices directives (90/385/EEC and 93/42/EEC) and listed below:

- active implantable devices
- intra-uterine contraceptive devices
- heart valves
- intra-ocular lenses
- intra-ocular visco elastic fluids
- powered drug infusion pumps
- implantable breast prostheses (other than those containing only saline or water)
- barrier contraceptive devices (excluding condoms)
- instrument grade disinfectants.

1.2. The Parties will establish a detailed programme to this effect involving the Therapeutic Goods Administration and European Community's Competent Authorities.

1.3. This confidence building period will be completed within 18 months from the date of entry into force of the Agreement.

2. Medical Devices incorporating Medicinal Substances

2.1. In order to meet European Community requirements, the following procedures shall apply to medical devices incorporating medicinal substances referred to in Article 1, paragraph 4 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices:

(a) if a medical device incorporates a substance with ancillary medicinal action and which is already established by monographs of the European Pharmacopoeia, the consultation required under Annex 2 or 3 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices will be carried out with the Australian competent authority;

(b) if a medical device incorporates a substance with ancillary medicinal action other than one specified in the European Pharmacopoeia, the Therapeutic Goods Administration shall carry out such consultation with one of the competent authorities within the European Community responsible for authorising the placing on the market of medicinal products.

2.2. In order to meet Australian requirements, the following procedures shall apply to medical devices incorporating medicinal substances referred to in Article 1, paragraph 4 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices:

(a) if a medical device incorporates a substance with ancillary medicinal action and which is already established by monographs of the European Pharmacopoeia, the consultation required under Annex 2 or 3 of Council Directive 92/42/EEC of 14 June 1993 concerning medical devices will be carried out with the European Community competent authority;

(b) if a medical device incorporates a substance with ancillary medicinal action other than one specified in the European Pharmacopoeia, consultation shall take place with the Department of Health and Family Services before taking a decision.

3. Registration and Listing Procedures

3.1. The Parties recognise that Australian procedures under the Therapeutic Goods Act for the registration or listing of products for market surveillance purposes, and corresponding European Community procedures, are unaffected by this Agreement.

3.2. Within the framework of this Agreement, the Australian Regulatory Authority will within five (5) working days register a product from the European Community upon receipt of an application accompanied by the designated fee without further assessment of the product.

3.3. Any fees attached to registration by either Party will be related only to the costs of medical device registration, enforcement and post-market surveillance activities of the Parties in this sector.

4. Exchange of Information

The Parties agree to inform each other of incidents in the context of medical device vigilance procedure, or with regard to matters concerning product safety, and shall establish contact points for this purpose.

5. In order to facilitate the application of this Sectoral Annex, the Parties will establish a guidance document setting out the procedures and requirements which are equivalent under the legislation of the two Parties, as well as modalities to facilitate registration requirements.

6. New legislation

The Parties note the possibility of Australia introducing new legislation concerning medical devices, and agree that any new arrangements will respect the principles on which the Mutual Recognition Agreement is based, notably Article 2 of the Agreement.

7. Divergence of Views

Both Parties shall use their best endeavours to resolve any divergence of views concerning compliance of manufacturers and conclusions of conformity assessment reports. Unresolved divergencies of view will be referred to the Joint Committee as established in Article 12 of the Agreement.

AUSTRALIA - EUROPEAN COMMUNITY

MUTUAL RECOGNITION AGREEMENT

OF

CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SECTORAL ANNEX

TELECOMMUNICATIONS TERMINAL EQUIPMENT

AUSTRALIA - EUROPEAN COMMUNITY

SECTORAL ANNEX - TELECOMMUNICATIONS TERMINAL EQUIPMENT

SCOPE AND COVERAGE

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

Products for export to the European Community	Products for export to Australia
Any product falling under the scope of Council Directive 91/263/EEC of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity, as supplemented by Council Directive 93/97/EEC of 29 October 1993 supplementing Directive 91/263/EEC in respect of satellite earth station equipment In general terms, these Council Directives cover: (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 telecommunications network is excluded.	Any product defined as customer equipment in the Telecommunications Act 1991. In general this is equipment whose parameters are defined in AUSTEL Technical Standards as determined under the above Act. A schedule of these standards at the date of this Agreement is attached and includes analogue and digital equipment and satellite earth station equipment as applicable.

This list of product groups may be extended to include other European common technical regulations in this sector as they become available.	

SECTION I : LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia to which European Community designated Conformity Assessment Bodies shall assess compliance
• Council Directive 91/263/EEC of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity, as amended • Council Directive 93/97/EEC of 29 October 1993, supplementing Directive 91/263/EEC in respect of satellite earth station equipment, as amended • Commission Decision of 21 December 1993 on a common technical regulation for the general attachment requirements for public pan-European cellular digital land-based mobile communications (94/11/EC) • Commission Decision of 21 December 1993 on a common technical regulation for the telephony application requirements for public pan-European cellular digital land-based mobile communications (94/12/EC) • Commission Decision of 18 July 1994 on a common technical regulation for attachment requirements for terminal equipment interface for ONP 2048 kbit/s digital unstructured leased line (94/470/EC)	• Telecommunications Act 1991 • Radiocommunications Act 1993 • Telecommunications Regulations, Statutory Rules 1989, No. 152 • Telecommunications Regulations (Amendment), Statutory Rules, No. 370 • Telecommunications (Applications and Fees) Regulations, Statutory Rules, No. 359 • Telecommunications Regulations (Amendment), Statutory Rules, No. 425

· Commission Decision of 18 July 1994 on a common technical regulation for general terminal attachment requirements for Digital European Cordless Telecommunications (DECT) (94/471/EC) · Commission Decision of 18 July 1994 on a common technical regulation for telephony application requirements for Digital European Cordless Telecommunications (DECT) (94/472/EC) · Commision Decision of 18 November 1994 on a common technical regulation for the pan-European integrated services digital network (ISDN) primary rate access (94/796/EC) · Commision Decision of 18 November 1994 on a common technical regulation for the pan-European integrated services digital network (ISDN) basic access (94/797/EC) · Commision Decision of 9 December 1994 on a common technical regulation for attachment requirements for terminal equipment interface for ONP 64 kbit/s digital unstructured leased line (94/821/EC) · Commision Decision of 17 July 1995 on a common technical regulation for public land-based European radio message system (ERMES) receiver requirements (95/290/EC)	

· Commission Decision 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 (95/525/EEC) · Commission Decision of 28 November 1995 on a common technical regulation for Integrated Services Digital Network (ISDN); Telephony 3,1 kH³ teleservice, attachment requirements for handset terminals (95/526/EEC) · Commission Decision of 10 January 1996 on a common technical regulation for access to packet switched public data networks (PSPDNs) using CCITT recommendation X.25 interfaces (96/71/EC)	

SECTION II : DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess product against the European Community's legislative and regulatory requirements	**The Conformity Assessment Bodies designated by the European Community to assess product against Australia's legislative and regulatory 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 : AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the Government of Australia: (a) For Certification Bodies: · the Joint Accreditation System of Australia and New Zealand (JAS-ANZ), and, (b) For Testing Laboratories and Inspection Bodies: · the National Association of Testing Authorities, Australia (NATA)	· **Belgium** Institut Belge des services postaux et des télécommunications Belgisch instituut voor postdiensten en telecommunicatie · **Denmark** Telestyrelsen · **Germany** Ministerium für Post und Telekommunikation · **Greece** Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications · **Spain** Ministerio de Fomento · **France** Ministère de l'Industrie, de la Poste et des Télécommunications · **Ireland** Department of Transport, Energy and Communications · **Italy** Ispettorato Generale TLC · **Luxembourg** Administration des Postes et Télécommunications

	· **Netherlands** Ministerie van Verkeer en Waterstaat · **Austria** Bundesministerium fur wirtschaftliche Angelegenheiten · **Portugal** Instituto des Comunicaçôes de Portugal · **Finland** Liikenneministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) · **UK** Department of Trade and Industry

SECTION IV : PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess product against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product against Australia's requirements
The Conformity Assessment Bodies listed in Section II must meet the requirements of the Directives listed in Section I, taking into account Council Decision 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 (93/465/EEC), and be designated on the basis of the procedures defined in Annex I to the Agreement. This may be demonstrated through: a) Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guide 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 Annex I.	The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in Annex I to the Agreement. (a) Testing Laboratories: The following procedures are deemed to be consistent with those set out in Annex I: · accreditation by an accreditation body which is a signatory to the European cooperation for Accreditation of Laboratories (EAL) Multilateral Agreement, or · able to demonstrate competence under an equivalent accreditation scheme.

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 Annex I. c) Testing Laboratories operating according to the requirements of EN 45001 or ISO Guide 25, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of Annex I.	(b) Certification Bodies: The following procedures are deemed to be consistent with those set out in Annex I: · accreditation by an Accreditation Body which is a signatory to the European Accreditation of Certification Multilateral Agreement; · accreditation by an Accreditation Body with which JAS-ANZ has a Mutual Recognition Agreement; or · able to demonstrate competence under an equivalent accreditation scheme

SECTION V : ADDITIONAL PROVISIONS

1. In accordance with Part 12 of the Telecommunications Act 1991, AUSTEL is required to issue a permit to connect customer equipment to any of the Australian telecommunications networks prior to the connection of that customer equipment.

   Within the framework of this Agreement, AUSTEL will use its best endeavours, with five (5) working days and in any case no longer than 10 days to issue such a permit (to an intending Australian importer of that equipment) for a product from a source within the European Community upon receipt of a complete application covering a compliant product, under a Statement or Certificate of Compliance permit application process, which includes providing a Declaration of Conformity for ongoing equipment supply.

   The Parties note that Australian legislation has been foreshadowed which would, except for non-standard equipment, remove this requirement for a Permit with effect from 1 July 1997. The foreshadowed legislation is intended to replace the Permit (product registration process) with a supplier registration process. The legislation is subject to the formal approval of the Australian Government and the Parliament.

2. It is agreed by both Parties that the relevant Council Directives and Australian legislative and regulatory requirements allow mutual recognition of separate elements of the conformity assessment process. Accordingly each Party shall accept test reports issued by Conformity Assessment Bodies designated by the other Party as meeting its requirements in this regard.

3. Where the legislative regulatory or administrative provisions of either Party require it, Conformity Assessment Bodies subcontracting all or part of the testing must subcontract only to Testing Laboratories accredited in accordance with clause (a) in Section IV above.

4. 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 requirements designed for use within certain voltage limits and Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/EEC), the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility shall apply.

AUSTEL TECHNICAL STANDARDS

TS 001
TS 002
TS 003
TS 004
TS 005
TS 006
TS 007
TS 008
TS 009
TS 012
TS 013.1
TS 013.2
TS 014
TS 015
TS 016
TS 018
TS 019
TS 020
TS 021.1
TS 021.2
TS 021.3
TS 023
TS 024
TS 028

AUSTRALIA - EUROPEAN COMMUNITY

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OF

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SECTORAL ANNEX

LOW VOLTAGE EQUIPMENT

AUSTRALIA - EUROPEAN COMMUNITY

SECTORAL ANNEX - LOW VOLTAGE EQUIPMENT

SCOPE AND COVERAGE

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

- 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.

- Electrical products which are within the scope of Australian State and Territory legislation for the safety of low voltage electrical equipment.

SECTION I: LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia to which European Community designated Conformity Assessment Bodies shall 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	**New South Wales** · Electricity Act 1945 · Electricity (Equipment Safety) Regulation 1994 **Victoria** · State Electricity Commission Act 1958 · Electricity Industry Act 1993 **Queensland** · Electricity Act 1994 · Electricity Regulation 1994 **Western Australia** · Electricity Act 1945 · Electricity Act Regulations 1947 **South Australia** · Electrical Products Act 1988 **Tasmania** · Hydro Electric Commission Act 1944 **Australian Capital Territory** · Electricity Act 1971 **Northern Territory** · Power and Water Authority Act 1987 · Electricity By-Laws

SECTION II: DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess product against the European Community's legislative and regulatory requirements	**The Conformity Assessment Bodies designated by the European Community to assess product against Australia's legislative and regulatory 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 : AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the Government of Australia: a) For Certification Bodies: • The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) b) For Testing Laboratories and Inspection Bodies: • the National Association of Testing Authorities, Australia (NATA)	• **Belgium** Ministère des Affaires Economiques Ministerie van Economische Zaken • **Denmark** Bygge- og Boligstyrelsen • **Germany** Bundesministerium für Arbeit und Sozialordnung • **Greece** Υπουργείο Ανάπτυξης Ministry of Development • **Spain** Ministerio de Industria y Energia • **France** Ministère de l'Industrie, de la Poste et des Télécommunications • **Ireland** Department of Enterprise and Employment

	• **Italy** Ministero dell' Industria, del Commercio e dell' Artigianato • **Luxembourg** Ministère des Transports • **Netherlands** Ministerie van Economische Zaken • **Austria** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Under the authority of the Government of Portugal: Instituto Português da Qualidade • **Finland** Kauppa- ja teollisuusministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) • **UK** Department of Trade and Industry

SECTION IV: PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess product against the European Community's requirements	**The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product against Australia's requirements**
The Conformity Assessment Bodies listed in Section II must meet the requirements of the Directives listed in Section I, taking into account Council Decision 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 (93/465/EEC), and are designated on the basis of the procedures defined in Annex 1 to the Agreement. This may be demonstrated through: a) Inspection Bodies operating in accordance with the requirements of EN 45004 or ISO Guide 39, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of Annex 1 b) Testing Laboratories operating according to the requirements of EN 45001 or ISO Guide 25, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of Annex I.	The following procedures are deemed to be consistent with the procedures set out in Annex 1 to the Agreement: (a) Testing Laboratories · accredited by accreditation bodies which are signatories to the European cooperation for Accreditation of Laboratories Multilateral Agreement · recognised within the IECEE CB Scheme, or · able to demonstrate competence under an equivalent accreditation scheme. (b) Certification Bodies · accredited by accreditation bodies which are signatories to the European Accreditation of Certification Multilateral Agreement · membership of the IECEE CB Scheme · accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or · able to demonstrate competence under an equivalent accreditation scheme.

SECTION V: ADDITIONAL PROVISIONS

1. In accordance with Australian legislation set out in Section 1 of this Annex, certain types of electrical equipment (the Declared Articles list) are required to be registered before they can be placed on the market.

   Within the framework of this Agreement, the Australian State and Territory Regulatory Authorities will within five (5) working days register a product from the European Community upon receipt of an application accompanied by the designated fee without further assessment of the product.

   The designated fee will be related to the costs of the electrical equipment registration, enforcement and post-market surveillance activities of the Australian regulatory authorities.

2. The Parties note that a Regulatory Compliance Mark (RCM) is to be introduced in Australia in August 1996. The adoption of the RCM, together with changes to Australian regulatory requirements, may result in due course in the removal of the arrangements described in paragraph 1 above. Any conditions for use of the RCM will respect the principles of the Mutual Recognition Agreement, notably Article 2 of the Agreement.

3. Where the legislative regulatory or administrative provisions of either Party require it, Conformity Assessment Bodies subcontracting all or part of the testing must subcontract only to Testing Laboratories accredited in accordance with clause (a) in Section IV above.

4. 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 Australia will be accepted by European Community authorities in the same way that reports from European Community Notified Bodies are accepted. That is, Conformity Assessment Bodies in Australia will be recognised under Article 11 of the Council Directive as "bodies which may make a report in accordance with Article 8."

AUSTRALIA - EUROPEAN COMMUNITY

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SECTORAL ANNEX

ELECTROMAGNETIC COMPATIBILITY

AUSTRALIA - EUROPEAN COMMUNITY

SECTORAL ANNEX - ELECTROMAGNETIC COMPATIBILITY

SCOPE AND COVERAGE

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

- Electromagnetic compatibility of equipment as defined in Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, but excluding radiocommunications equipment which is not connected to the public switched telecommunication networks, and

- Electromagnetic compatibility of equipment regulated under the Australian Radiocommunications Act 1992.

SECTION I: LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia to which European Community designated Conformity Assessment Bodies shall 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 1992

SECTION II: DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess product against the European Community's legislative and regulatory requirements	**The Conformity Assessment Bodies designated by the European Community to assess product against Australia's legislative and regulatory 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 : AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the Government of Australia: (a) For Certification Bodies: · the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) (b) For Testing Laboratories and Inspection Bodies: · the National Association of Testing Authorities, Australia (NATA)	• **Belgium** Ministère des Affaires Economiques Ministerie van Economische Zaken • **Denmark** Telestyrelsen • **Germany** Bundesministerium für Post und Telekommunikation • **Greece** Υπουργειο Μεταφορών καί Επικοινωνιών Ministry of Transport and Communications • **Spain** for telecommunications equipment: Ministerio de Fomento for other equipment: Ministerio de Industria y Energia • **France** Ministère de l'Industrie, de la Poste et des Télécommunications • **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** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Under the authority of the Government of Portugal: Instituto Português de Comunicaçôes de Portugal • **Finland** Kauppa- ja teollisuusministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) • **UK** Department of Trade and Industry

SECTION IV: PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess product against the European Community's requirements	**The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product against Australia's requirements**
The Conformity Assessment Bodies listed in Section II must meet the requirements of the Directives listed in Section I, taking into account Council Decision 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 (93/465/EEC), and are designated on the basis of the procedures defined in Annex 1 to the Agreement. This may be demonstrated through: a) For the purposes of Article 10.5 of the 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 45004 or ISO Guide 39, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of Annex 1.	The following procedures are deemed to be consistent with the procedures set out in Annex 1 to the Agreement: a) Testing Laboratories operating according to the requirements of ISO Guide 25 or EN 45001, and either: • accredited by accreditation bodies which are signatories to the European cooperation for Accreditation of Laboratories Multilateral Agreement, or • able to demonstrate competence under an equivalent accreditation scheme. b) Inspection Bodies operating according to the requirements of ISO Guide 39 or EN45004 and either: • accredited by accreditation bodies which are signatories to a European Multilateral Agreement, or • able to demonstrate competence under an equivalent accreditation scheme.

b) For Competent Bodies according to Article 10.2 of the 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 45001 or ISO Guide 25, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of Annex 1.	

SECTION V: ADDDITIONAL PROVISIONS

The European Community and Australia agree that

1. reports and certificates prepared by European Community Competent Bodies will be accepted by Australian regulatory authorities and

2. reports and certificates prepared by designated Conformity Assessment Bodies in Australia will also be accepted by European Community authorities on the same basis as reports and certificates prepared by European Community Competent Bodies.

3. Where the legislative regulatory or administrative provisions in either Party require it, Conformity Assessment Bodies subcontracting all or part of the testing must subcontract only to testing laboratories accredited in accordance with clause (a) in Section IV above.

4. The Parties note the Australian requirement for its Competent Bodies to be members of the Australian Association of Competent Bodies and the Commission's current consideration of a proposal to establish a Technical Secretariat for Notified Bodies and Competent Bodies under the Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility to promote the coordination activities of these Bodies under this Directive.

   The Parties also note the European Commission's intention to encourage Competent Bodies to participate in coordination activities.

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SECTORAL ANNEX

MACHINERY

AUSTRALIA - EUROPEAN COMMUNITY

SECTORAL ANNEX - MACHINERY

SCOPE AND COVERAGE

The provisions of this Sectoral Annex shall apply to the products listed in 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, plus tower cranes and mobile cranes.

SECTION I : LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia to which European Community designated Conformity Assessment Bodies shall 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 · Directives setting out noise limitation requirements for tower cranes as follows: - Council Directive 79/113/EEC of 19 December 1978 on the appoximation of the laws of the Member States relating to the determination of the noise emission of construction plant and equipment, as amended - 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 - 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	The following legislative, regulatory and administrative requirements cover the conformity assessment procedures for the use of products covered by this Annex. **New South Wales** **Victoria** · Occupational Health and Safety Act 1985[1] · Occupational Health and Safety (Plant) Regulations 1995[1] · Code of Practice for Plant 1995[1] · Equipment (Public Safety) Act 1994[1] · Equipment (Public Safety) (General) Regulations 1995[1] **Queensland** · Workplace Health & Safety Act 1995 · Workplace Health & Safety Regulation 1995 · Workplace Health & Safety (Plant) Code of Practical Approval Notice 1993 **Western Australia** **South Australia** · Occupational Health, Safety & Welfare Act 1986 · Occupational Health, Safety & Welfare Regulations 1995 **Tasmania** **Australian Capital Territory** **Northern Territory** [1]There are no mandatory conformity assessment requirements under this legislation.

SECTION II : DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess products against the European Community's legislative and regulatory requirements	The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative and regulatory requirements
[Name and details to be inserted] [Note : Further names and details to be added as required]	[Name and details to be inserted] [Note : Further names and details to be added as required]

SECTION III : AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the Government of Australia: a) For Certification Bodies: • the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) b) For Testing Laboratories and Inspection Bodies: • the National Association of Testing Authorities, Australia (NATA)	• **Belgium** Ministère de l'Emploi et du Travail Ministerie van Tewerkstelling en Arbeid • **Denmark** Direktoratet for Arbejdstilsynet • **Germany** Bundesministerium für Arbeit und Sozialordnung • **Greece** Υπουργείο Ανάπτυξης Ministry of Development • **Spain** Ministerio de Industria, Comercio y Turismo • **France** Ministère du Travail et des Affaires Sociales et Ministère de l'Industrie, de la Poste et des Télécommunications • **Ireland** Department of Enterprise and Employment

	• **Italy** Ministero dell' Industria, del Commercio e dell' Artigianato • **Luxembourg** Ministère des Transports • **Netherlands** Ministerie van Sociale Zaken en Werksgelegenheid • **Austria** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Under the authority of the Government of Portugal: Instituto Português da Qualidade • **Finland** Työministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) • **UK** Department of Trade and Industry

SECTION IV : PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess product against the European Community's requirements	**The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product against Australia's requirements**
The Conformity Assessment Bodies listed in Section II must meet the requirements of the Directives listed in Section I, taking into account Council Decision 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 (93/465/EEC), and are designated on the basis of the procedures defined in Annex 1 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 according to the requirements of EN 45004 or ISO Guide 39, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of Annex 1.	In accordance with the specific requirements set out in the legislation, regulations and administrative provisions listed in Section 1, and where these make compliance with Australian standards for plant mandatory, the Conformity Assessment Bodies listed in Section II are designated by the Designating Authorities specified in Section III in accordance with the following criteria: · Design Verification for compliance with technical standards may not be required under all legislation listed in Section 1 · If design verification is required it must be conducted by a design verifier who has not been involved in the machinery design and who has acquired through training, qualification, or experience, or a combination of these, the knowledge and skills enabling that person to perform this task.

b) For the purpose of Directives setting out noise limitation requirements for tower cranes: 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 Annex 1.	Where the designer and design verifier are employed or engaged by the same person the whole of the design process must, if the legislation requires, operate: a) within a quality system meeting requirements of ISO9001 and be certified by a Quality Systems Certification Body operating according to the requirements of ISO Guide 62 or EN 45012, and either: • accredited by an accreditation body which is a signatory to the European Accreditation of Certification (EAC) Multilateral Agreement, or • accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, and b) in conformity with EN 45004 or ISO Guide 39 and accredited by an accreditation body meeting the requirements of ISO Guide 58 or EN 45002/3. For Victoria there are no mandatory conformity assessment requirements under the legislation listed in Section I other than that the design must be verified by someone who did not participate in the design of the plant subject to design verification.

SECTION V : ADDITIONAL PROVISIONS

1. 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 requirements designed for use within certain voltage limits and Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/EEC), the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility shall apply.

2. Upon the date of application of the provisions of the European Parliament and Council Directive 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 Australia which have been designated to issue type-approvals according to this Directive shall, 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.

3. 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 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.

AUSTRALIA - EUROPEAN COMMUNITY

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SECTORAL ANNEX

PRESSURE EQUIPMENT

[redacted]

AUSTRALIA - EUROPEAN COMMUNITY

SECTORAL ANNEX - PRESSURE EQUIPMENT

SCOPE AND COVERAGE

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

Products for export to the European Community	Products for export to Australia
Products in 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.	Products in 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 and which are subject to the Australian legislative and regulatory requirements listed in Section I of this Sectoral Annex.

SECTION I : LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia to which European Community designated Conformity Assessment Bodies shall 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	The following legislative, regulatory and administrative requirements cover the conformity assessment procedures for the use of products covered by this Sectoral Annex. **New South Wales** **Victoria** · Occupational Health and Safety Act 1985[1] · Occupational Health and Safety (Plant) Regulations 1995[1] · Code of Practice for Plant · Equipment (Public Safety) Act 1994[1] · Equipment (Public Safety) (General) Regulations 1995[1] **Queensland** · Workplace Health & Safety Act 1995 · Workplace Health & Safety Regulation 1995 · Relevant Compliance Standards · Relevant Advisory Standards **Western Australia** [1] There are no mandatory conformity assessment requirements under this legislation.

	South Australia · Occupational Health, Safety & Welfare Act 1986 · Occupational Health, Safety & Welfare Regulations 1995 **Tasmania** **Australian Capital Territory** **Northern Territory**

SECTION II : DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess product against the European Community's legislative and regulatory requirements	**The Conformity Assessment Bodies designated by the European Community to assess product against Australia's legislative and regulatory requirements**
The designated CABs are: [Name and details to be inserted] [Note : Further names to be added as required]	The designated CABs are: [Name and details to be inserted] [Note : Further names to be added as required]

SECTION III : AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the Government of Australia: (a) For Certification Bodies · the Joint Accreditation System of Australia and New Zealand (JAS-ANZ), and (b) For Testing Laboratories and Inspection Bodies: · the National Association of Testing Authorities, Australia (NATA)	· **Belgium** Ministère de l'Emploi et du Travail Ministerie van Tewerkstelling en Arbeid • **Denmark** Direktoratet for Arbejdstilsynet • **Germany** Bundesministerium für Arbeit und Sozialordnung • **Greece** Υπουργείο Ανάπτυξης Ministry of Development • **Spain** Ministerio de Industria, Comercio y Turismo • **France** Ministère de l'Industrie, de la Poste et des Télécommunications • **Ireland** Department of Enterprise and Employment

	• **Italy** Ministero dell' Industria, del Commercio e dell' Artigianato • **Luxembourg** Ministère des Transports • **Netherlands** Ministerie van Sociale Zaken en Werksgelegenheid • **Austria** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Under the authority of the Government of Portugal: Instituto Português da Qualidade • **Finland** Kauppa- ja teollisuusministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) • **UK** Department of Trade and Industry

SECTION IV : PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess product against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product against Australia's requirements
The Conformity Assessment Bodies listed in Section II must meet the requirements of the Directives listed in Section I, taking into account Council Decision 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 (93/465/EEC), and are designated on the basis of the procedures defined in Annex 1 to the Agreement. This may be demonstrated through: a) Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guide 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 Annex 1. 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 Annex 1.	1. Where the laws and regulations listed in Section I make compliance with AS 3920.1 and Australian standards for pressure equipment mandatory, the Conformity Assessment Bodies listed in Section II are designated by the Designating Authorities specified in Section III in accordance with the following criteria: · Design Verification Bodies complying with AS 3920.1 and a) operating within a quality system meeting the requirements of ISO 9001 and certified by a Quality Systems Certification Body operating according to the requirementsof ISO Guide 62 or EN 45012 and either: • accredited by an accreditation body which is a signatory to the European Accreditation of Certification Multilateral Agreement • accredited by an accreditation body with whom JAS-ANZ has a mutual recognition agreement, or • able to demonstrate competence under an equivalent accreditation scheme, and

c) Inspection Bodies operating according to the requirements of EN 45004 or ISO Guide 39 and either

- accredited by NATA, or
- able to demonstrate competence by other means in accordance with Sections A or B of Annex 1.

b) operating in conformity with EN 45004 or ISO Guide 39 and accredited by an accreditation body meeting the requirements of ISO Guide 58 or EN 45002/3

- Inspection Bodies complying with AS 3920.1 and operating according to the requirements of ISO Guide 39 or EN45004 and either:
  - accredited by an accreditation body which is a signatory to a European Multilateral Agreement, or
  - able to demonstrate competence under an equivalent accreditation scheme
- Testing Laboratories operating according to the requirements of ISO Guide 25 or EN45001 and either:
  - accredited by an accreditation body which is a signatory to the European cooperation for Accreditation of Laboratories (EAL) Multilateral Agreement, or
  - able to demonstrate competence under an equivalent accreditation scheme.
- Quality Systems Certification Bodies complying with AS 3920.1 and operating according to the requirements of ISO Guide 62 or EN 45012, and either:
  - accredited by an accreditation body which is a signatory to the European Accreditation of Certification (EAC) Multilateral Agreement, or
  - accredited by an accreditation body with whom JAS-ANZ has a mutual recognition agreement, or
  - able to demonstrate competence under an equivalent accreditation scheme.

	2. Where AS 3920.1 is not mandatory, i.e. it may be referred to in a Code of Practice/Advisory Standard as one means of compliance with the legislation listed in Section 1, a designer or a manufacturer may choose to follow Item 1 above. Alternatively, the designer or manufacturer may choose alternative conformity assessment procedures which will ensure that the pressure equipment complies with the performance duties of the relevant laws and regulations of the particular jurisdiction. It is noted that pressure equipment that complies with and has been subject to the conformity assessment process contained in 87/404/EEC of 25 June 1987 on the harmonisation of the laws of the Member States relating to simple pressure vessels may satisfy the obligations on designers and manufacturers as provided for in the legislation listed in Section I. 3. For Victoria there are no mandatory conformity assessment requirements under the legislation listed in Section I, other than that the design must be verified by someone who did not participate in the design of the plant subject to design verification.

SECTION V : ADDITIONAL PROVISIONS

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 requirements designed for use within certain voltage limits and Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/EEC), the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility shall apply.

AUSTRALIA - EUROPEAN COMMUNITY

MUTUAL RECOGNITION AGREEMENT

OF

CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SECTORAL ANNEX

AUTOMOTIVE PRODUCTS

AUSTRALIA - EUROPEAN COMMUNITY

SECTORAL ANNEX - AUTOMOTIVE PRODUCTS

SCOPE AND COVERAGE

In accordance with the terms of this Annex, Australia shall recognise and accept results of testing, conformity of production and approval procedures according to Regulations adopted in the context of the UN/ECE 1958 Agreement (UN/ECE Regulations), deemed to be equivalent to EC Directives, carried out in the European Community, where these Regulations are substantially equivalent to Australian regulatory provisions.

In accordance with the terms of this Annex, the European Community shall accept results of testing and conformity of production procedures carried out in Australia in accordance with the Council Directives for which there is a UN/ECE Regulation, which is fully or partially/conditionally applied by Australia and is recognised as substantially equivalent in Annex IV, Part 2 of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers, as last amended.

In accordance with the terms of this Annex Parties shall recognise and accept results of testing and conformity of production procedures carried out by the other Party to that Party's requirements in areas where substantial equivalence between regulatory provisions of both Parties is established.

The provision of this Sectoral Annex shall apply to automotive products and vehicle components as specified in the following Regulations from the Economic Commission for Europe: 1, 3 - 8, 11, 12, 13 for N and O category vehicles, 14, 16 - 21, 23 - 25, 30, 37, 38, 43, 46, 48, 49, 51 and 83, in their latest applicable version as well as to EC Directives/ADRs on speed limiting devices, defrosting and demisting systems and windscreen wiper/washer systems, as last amended.

The scope and coverage of this Sectoral Annex will be adapted according to changes in the position on substantial equivalence between UN/ECE Regulations and the regulatory provisions in force in Australia and the European Community.

The regulatory requirements of the European Community to which Australian designated Conformity Assessment Bodies shall assess compliance	The regulatory requirements of Australia to which European Community designated Conformity Assessment Bodies shall assess compliance
The relevant testing and conformity of production procedures for the purpose of this Annex are those defined in the following Council Directives in amended form, as appropriate:	The relevant testing, conformity of production and approval procedures for the purpose of this Annex are those defined in the following law, Regulations and Australian Design Rules in their latest applicable version:
• Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers	• Motor Vehicles Standards Act 1989 and • Motor Vehicles Standards Regulations
• Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles	• Australian Design Rule 28/01 External noise of motor vehicles of 30 March 1994
• Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles	• Australian Design Rule 37/00 Emission control for light vehicles of 30 March 1994 • Australian Design Rule 37/01 Emission control for light vehicles of 12 December 1995 • Australian Design Rule 70/00 Exhaust emission control for diesel engined vehicles of 29 September 1993
• Council Directive 70/387/EEC of 27 July 1970 on the approximation of the laws of the Member States relating to the doors of motor vehicles and their trailers	• Australian Design Rule 2/00 Side door latches and hinges of 20 May 1992

• Council Directive 71/127/EEC of 1 March 1971 on the approximation of the laws of the Member States relating to the rear-view mirrors of motor vehicles	• Australian Design Rule 14/02 Rear vision mirrors of 20 May 1992
• Council Directive 71/320/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to the braking devices of certain categories of motor vehicles and their trailers	• Australian Design Rule 35/00 Commercial vehicle braking systems of 30 June 1993 • Australian Design Rule 38/00 Trailer brake systems of 17 July 1991 • Australian Design Rule 38/01 Trailer brake systems of 22 September 1994
• Council Directive 72/306/EEC of 2 August 1972 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in vehicles	• Australian Design Rule 30/00 Diesel engine exhaust smoke emission of 20 May 1992
• Council Directive 74/60/EEC of 17 December 1973 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (interior parts of the passenger compartment other than the interior rear-view mirrors, layout of controls, the roof or sliding roof, the backrest and rear part of the seats)	• Australian Design Rule 11/00 Internal sunvisors of 20 May 1992
• Council Directive 74/61/EEC of 17 December 1973 on the approximation of the laws of the Member States relating to devices to prevent the unauthorised use of motor vehicles	• Australian Design Rule 25/02 Anti-theft lock of 29 March 1995
• Council Directive 74/297/EEC of 4 June 1974 on the approximation of the laws of the Member States relating to interior fittings of motor vehicles (the behaviour of the steering mechanism in the event of an impact)	• Australian Design Rule 10/01 Steering column of 16 December 1992

• Council Directive 74/408/EEC of 22 July 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (strength of seat and their anchorage)	• Australian Design Rule 3/01 Seat anchorages of 20 May 1992 • Australian Design Rule 3/02 Seats and seat anchorages of 29 September 1993
• Council Directive 76/115/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to anchorages for motor-vehicle safety-belts	• Australian Design Rule 5/02 Anchorages for seat belts and child restraints of 30 June 1993 • Australian Design Rule 5/03 Anchorages for seat belts of 21 December 1994
• Council Directive 76/756/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to the installation of lighting and light-signalling devices on motor vehicles and their trailers	• Australian Design Rule 13/00 Installation of lighting and light-signalling devices on other than L-group vehicles of 12 December 1995
• Council Directive 76/757/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to reflex reflectors for motor vehicles and their trailers	• Australian Design Rule 47/00 Reflex reflectors of 20 May 1992
• Council Directive 76/758/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to end-outline marker lamps	• Australian Design Rule 49/00 Front & rear position (side) lamps, stop lamps & end-outline marker lamps of 20 May 1992
• Council Directive 76/759/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to direction indicator lamps for motor vehicles and their trailers	• Australian Design Rule 6/00 Direction indicator lamps of 20 May 1992
• Council Directive 76/760/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to the rear registration plate lamps for motor vehicles and their trailers	• Australian Design Rule 48/00 Rear registration plate illuminating devices of 20 May 1992

• Council Directive 76/761/EEC of 27 July 1976 on the approximation of the laws of the Member Sates relating to motor-vehicle headlamps which function as main-beam and/or dipped-beam headlamps and to incandescent electric filament lamps for such headlamps	• Australian Design Rule 46/00 Headlamps of 20 May 1992 • Australian Design Rule 51/00 Filament globes of 12 December 1995
• Council Directive 76/762/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to front fog lamps for motor vehicles and filament lamps for such lamps	• Australian Design Rule 50/00 Front fog lamps of 20 May 1992
• Council Directive 77/538/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to rear fog lamps for motor vehicles and their trailers	• Australian Design Rule 52/00 Rear fog lamps of 20 May 1992
• Council Directive 77/539/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to reversing lamps for motor vehicles and their trailers	• Australian Design Rule 1/00 Reversing lamps of 20 May 1992
• Council Directive 77/541/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to safety-belts and restraint systems for motor vehicles	• Australian Design Rule 4/01 Seat belts of 30 March 1994 • Australian Design Rule 4/02 Seat belts of 21 December 1994
• Council Directive 78/317/EEC of 21 December 1977 on the approximation of the laws of the Member States relating to the defrosting and demisting systems of glazed surfaces of motor vehicles	• Australian Design Rule 15/01 Demisting of windscreen of 20 May 1992
• Council Directive 78/318/EEC of 21 December 1977 on the approximation of the laws of the Member States relating to the wiper and washer systems of motor vehicles	• Australian Design Rule 16/01 Windscreen wipers and washers of 20 May 1992

• Council Directive 78/932/EEC of 16 October 1978 on the approximation of the laws of the Member States relating to head restraints of seats of motor vehicles	• Australian Design Rule 22/00 Head restraints of 12 December 1995
• Council Directive 88/77/EEC of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles	• Australian Design Rule 70/00 Exhaust emission control for diesel engined vehicles of 29 September 1993
• Council Directive 92/22/EEC of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers	• Australian Design Rule 8/00 Safety glazing material of 20 May 1992 • Australian Design Rule 8/01 Safety glazing material of 12 December 1995
• Council Directive 92/23/EEC of 31 March 1992 relating to tyres for motor vehicles and their trailers and to their fitting	• Australian Design Rule 23/01 Passenger car tyres of 12 December 1995
• Council Directive 92/24/EEC of 31 March 1992 relating to speed limitation devices or similar speed limitation on-board systems of certain categories of motor vehicles	• Australian Design Rule 65/00 Maximum road speed limiting for heavy goods vehicles & vehicle omnibuses of 18 July 1990

SECTION II: DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess product against the European Community's regulatory requirements	The Conformity Assessment Bodies designated by the European Community to assess product against Australia's regulatory requirements
Federal Office of Road Safety P O Box 594 Canberra ACT 2601 Australia	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names to be added as required]

SECTION III: AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY OF ASSESSMENT BODIES

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
The Administrator of Vehicle Standards delegated by the Australian Minister for Transport under the provisions of the Motor Vehicle Standards Act 1989.	• **Belgium** Ministère des Communications et de l'Infrastructure Ministerie van Verkeer en Infrastructuur • **Denmark** Road Safety and Transport Agency • **Germany** Kraftfahrt-Bundesamt • **Greece** Υπουργείο Μεταφορών Ministry of Transport • **Spain** Ministerio de Industria, Comercio y Turismo • **France** Ministère des Transports • **Ireland** Department of Enterprise and Employment

	• **Italy** Ministero dei Trasporti • **Luxembourg** Ministère des Transports • **Netherlands** Rijksdienst voor het Wegverkeer • **Austria** Bundesministerium für öffentliche Wirtschaft und Verkehr • **Portugal** Direcção-General de Viação • **Finland** Liikenneministeriö • **Sweden** Vägverket • **UK** Vehicle Certification Agency

SECTION IV: PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess product against the European Community's regulatory requirements	**The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product against Australia's regulatory requirements**
The principles set out in Annex I to the Agreement For Testing Laboratories: • The Administrator of Vehicle Standards may authorise officers from the Federal Office of Road Safety to supervise testing of vehicle components and vehicle systems specified in Section I of this Sectoral Annex. • The Administrator of Vehicle Standards, following advice from the National Association of Testing Authorities, Australia (NATA) may designate laboratories to conduct tests on the vehicle and vehicle components specified in Section I of this Sectoral Annex.	The principles set out in Annex I to the Agreement For Testing Laboratories: The following procedures are deemed to be consistent with the procedures set out in Annex I: • Technical Services appointed under the provisions of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers, as amended by Council Directive 92/53/EEC, to conduct tests specified in the Australian Design Rules for Motor Vehicles and Trailers, • laboratories accredited under national accreditation systems or recognised under the provisions of the European Cooperation for Accreditation of Laboratories (EAL) Multilateral Agreement • bodies able to demonstrate competence and designated by the authorities listed in Section III

Conformity of Production: The following procedures are deemed to be consistent with the procedures set out in Annex I to the Agreement. • The Administrator of Vehicle Standards may authorise suitably qualified officers of the Federal Office of Road Safety to conduct conformity assessments of vehicle component manufacturers in accordance with the requirements of Annex X of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers. • Further, the Administrator of Vehicle Standards may designate conformity assessment bodies that have been accreditated by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) to conduct assessments in accordance with the requirements of Annex X of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers	Conformity of Production: The following procedures are deemed to be consistent with the procedures set out in Annex I to the Agreement • A certification body complying with harmonised standard EN45012, and either qualified as such by the approval authority of a Member State itself, or accredited as such by a national accreditation organisation of a Member State and recognised by that Member State's approval authority to conduct assessments to the ISO 9001 quality management standard as defined in Administrator's Circular 0-13-2.

SECTION V: ADDITIONAL PROVISIONS

1. Lighting

The Parties note that for certain Australian Design Rules concerned with vehicle lighting and included in Section I of this Sectoral Annex, i.e. Australian Design Rules 49/00, 6/00, 48/00, 50/00, 52/00 and 1/00, it is a requirement to test with filament globes complying with Australian Design Rule 51/00 which is considered equivalent to UN/ECE Regulation 37.

2. Standstill

In areas not covered by the Sectoral Annex, the Parties agree not to introduce changes to their certification arrangements other than those introduced by the establishment of this Agreement, which would make these arrangements less favourable in their effect than those currently prevailing.

3. Review

This Sectoral Annex shall be reviewed two years after its entry into force in the light of developments in relation to international standardisation in the area of vehicles and parts, in particular as far as Australia and the European Community are concerned.

4. Extension

The Parties shall advise one another of adoption of requirements that align with Regulations from the Economic Commission for Europe. Where notification has been received that both Australia and the European Community have adopted a UN/ECE Regulation, the Joint Committee, established underArticle 12 of the Agreement, shall adopt appropriate amendments for inclusion in the listing given in Section I of this Sectoral Annex.

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

98/0127 (ACC)

The Council of the European Union,

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

Having regard to the proposal of the Commission,

Whereas the Agreement on Mutual Recognition in relation to Conformity Assessment between the European Community and New Zealand has been negotiated and should be approved,

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

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

Decides:

Article 1

The Agreement on Mutual Recognition in relation to Conformity Assessment between the European Community and New Zealand, including its Annexes and the Joint Declarations attached to it are hereby approved on behalf of the European Community.

The text of the Agreement, the Annexes and the Joint Declarations is attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Community, transmit the note provided for in Article 14 of the Agreement. (1)

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

Article 3

1. The Commission shall represent the Community in the Joint Committee provided for in Article 12 by the Commission, assisted by the special committee established under Article 113 of the EC Treaty (Technical Group on Mutual Recognition). The Commission shall proceed, after consultation with this special Committee, to the appointments, notifications, exchange of information and requests for verifications referred to in Article 8, paragraph 2 and Article 12, paragraph 4, letter c), d) and e) of the Agreement.

2. The position to be taken by the Community in regard of decisions to be taken by the Joint Committee shall be determined with regard to amendments of Sections I to IV of the Sectoral Annexes (Article 12, paragraph 4, letter a) and b) and paragraph 6 of the Agreement) and verification of compliance in accordance with Article 8 and Article 12, paragraph 6, letter d) of the Agreement by the Commission following consultation of the above-mentioned special Committee.

3. In all other cases the position of the Community for a decision in the Joint Committee shall be determined by the Council, acting by qualified majority on a proposal from the Commission.

Done at Brussels,

For the Council
The President

AGREEMENT ON MUTUAL RECOGNITION

IN RELATION TO CONFORMITY ASSESSMENT

BETWEEN

NEW ZEALAND AND THE EUROPEAN COMMUNITY

AGREEMENT ON MUTUAL RECOGNITION

IN RELATION TO CONFORMITY ASSESSMENT

BETWEEN

NEW ZEALAND AND THE EUROPEAN COMMUNITY

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 standardization and related activities" and in EN 45020 (1993 edition) unless the context otherwise requires. 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;

   "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.

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 (Section I);

   (c) a list of the designated Conformity Assessment Bodies (Section II);

   (d) the Designating Authorities (Section III);

   (e) a set of procedures for the designation of Conformity Assessment Bodies (Section IV); and

   (f) additional provisions as required (Section V).

ARTICLE 4 : ORIGIN

1. This Agreement shall apply to products originating in the Parties to the Agreement according to the non-preferential rules of origin.

2. In case of conflicting rules, the non-preferential rules of the Party on whose territory the goods are marketed are determinative.

3. To the extent that the same products are also covered in a Sectoral Annex to the Agreement on Mutual Recognition in relation to conformity assessment between the European Community and Australia, the present Agreement shall also apply to products of Australian origin.

4. To the extent that the same products are also covered in a Sectoral Annex to an Agreement on Mutual Recognition in relation to conformity assessment between New Zealand and States Contracting Parties to both the Convention of the European Free Trade Association (EFTA) and the Agreement on the European Economic Area (EEA), the present Agreement shall also apply to products originating in any of these EFTA States.

ARTICLE 5 : CONFORMITY ASSESSMENT BODIES

In accordance with the terms of Annex 1 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.

ARTICLE 6 : DESIGNATING AUTHORITIES

1. The Parties shall ensure that the Designating Authorities responsible for designating the Conformity Assessment Bodies specified in the Sectoral Annexes shall have the necessary power and competence to designate, suspend, remove suspension and withdraw the designation of such bodies.

2. In making such designations and withdrawals, Designating Authorities shall, unless specified otherwise in the Sectoral Annexes, observe the procedures for designation set out in Article 12 and Annex 1 of this Agreement.

3. In case of suspension of a designation or removal of such a suspension, the Designating Authority of the Party concerned shall immediately inform the other Party and the Joint Committee. Conformity assessment carried out by a suspended Conformity Assessment Body before its suspension shall remain valid unless otherwise determined by its Designating Authority.

ARTICLE 7 : VERIFICATION OF DESIGNATION PROCEDURES

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

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 Annex 1. Existing systems for the accreditation of Conformity Assessment Bodies in the two Parties may be used for such comparison procedures.

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

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.

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

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.

6. Except when decided otherwise by the Joint Committee, the contested Conformity Assessment Body, where it is included in Section II of a Sectoral Annex, will be suspended by the competent Designating Authority from the time disagreement has been established in the Joint Committee until agreement has been reached in the Joint Committee on the status 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.

2. Consistent with their obligations under the World Trade Organisation 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 where considerations of safety, health and environmental protection warrant more urgent action, notify the other Party of the new provisions at least 60 days before their entry into force.

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 to this Agreement.

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 sub-committees.

3. The Joint Committee will meet at least once a year unless it decides otherwise. If required for the effective functioning of this Agreement, and at the request of either Party, an additional meeting or meetings will 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 to give effect to the decision by a Designating Authority to designate a particular Conformity Assessment Body;

   b) Amending the Sectoral Annexes to give effect to the decision by a Designating Authority to withdraw designation of a particular Conformity Assessment Body;

   c) Exchanging information concerning the procedures used by either Party to ensure that the Conformity Assessment Bodies specified in the Sectoral Annexes maintain the necessary level of competence;

   d) In accordance with the provisions of 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 ;

   e) 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;

   f) Resolving any questions relating to the application of this Agreement and its Sectoral Annexes; and

   g) Facilitating the extension of this Agreement to further sectors.

5. Any amendments to Sectoral Annexes made in accordance with the provisions of this Article will be notified promptly in writing by the Chair of the Joint Committee to each Party.

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

   a) A Party proposing an amendment to a Sectoral Annex to give effect to a decision by a Designating Authority to designate or withdraw designation of a Conformity Assessment Body shall forward its proposal to the other Party in writing, adding supporting documentation to the request;

   b) A copy of the proposal and documentation shall be sent to the Chair of the Joint Committee;

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

   d) In the event, that under the provisions of Article 8, the other Party contests the technical competence or compliance of a Conformity Assessment Body within the afore-mentioned 60 day period, the Joint Committee may decide to carry out a verification of the Body concerned, in accordance with the provisions of that Article.

7. In the event that a designated Conformity Assessment Body is withdrawn from a Sectoral Annex, conformity assessment carried out by that Conformity Assessment Body before the date of effect of its withdrawal shall remain valid unless otherwise determined by the Joint Committee. In the case of the inclusion of a new Conformity Assessment Body, conformity assessment carried out by such a Conformity Assessment Body shall be valid from the date the Parties agree to its inclusion in the Sectoral Annex.

8. Where a Party introduces new or additional conformity assessment procedures affecting a sector covered by a Sectoral Annex, the Joint Committee will, 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. Annex 1 to this Agreement forms an integral part of it.

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

3. The Parties shall conclude Sectoral Annexes, to which the provisions of Article 2 apply, which will provide the implementing arrangements for this Agreement.

4. Amendments to the Sectoral Annexes will be determined by the Parties through the Joint Committee.

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.

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;
   - the experience relevant to the applicable legislative, regulatory and administrative provisions;
   - the physical capability to perform the relevant conformity assessment activity;
   - an adequate management of the conformity assessment activities concerned; and
   - any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed on a continuous basis.

4. The technical 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.

(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.

D. Formal Designation

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

9. Designating Authorities shall inform their Party's representatives on the Joint Committee, established under this Agreement, of the Conformity Assessment Bodies to be included in or withdrawn from Section II of the Sectoral Annexes. Designation, suspension or withdrawal of designation of Conformity Assessment Bodies shall take place in accordance with the provisions of this Agreement and the rules of procedure of the Joint Committee.

10. When advising their Party's representative on the Joint Committee established under this Agreement, of the Conformity Assessment Bodies to be included in the Sectoral Annexes, the Designating Authority shall provide the following details in respect of each Conformity Assessment Body:

    (a) the name;

    (b) the postal address;

    (c) the facsimile (fax) number;

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

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

    (f) the designation procedure used to determine competence.

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.

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.

Annex 2

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 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 the 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 the view to establishing mutual recognition arrangements in the voluntary sphere.

[redacted]

Annex 4

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.

[redacted]

Annex 5

Joint Declaration
relating to the review of Article 4

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.

NEW ZEALAND- EUROPEAN COMMUNITY

MUTUAL RECOGNITION AGREEMENT

OF

CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SECTORAL ANNEX

MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

NEW ZEALAND- EUROPEAN COMMUNITY

SECTORAL ANNEX - MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

SCOPE AND COVERAGE

1. The provisions of this Sectoral Annex cover all medicinal products which are industrially manufactured in New Zealand and the European Community, 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 or licences 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 Community and New Zealand as listed in the Appendix to this Annex. 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 homeopathic 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 Community).

2. With respect to medicinal products covered by the legislation of one Party but not the other, the manufacturing company can request, for the purpose of this Agreement, 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 agreed pre-marketing inspections. Operational arrangements are detailed under Section III, item 3 b.

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 supervising manufacturers of medicinal products will certify that the manufacturer:

   - 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, and which are listed in Appendix 1 to this Sectoral Annex. In case different GMP requirements would be used as a reference (in line with the provisions in Section 3, 3 b), 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 certificate is attached as Appendix 2; it may be modified by the Joint Committee, as established in Article 12 of the Agreement.

   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 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 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 Community the "qualified person" referred to in article 21 of Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. In New Zealand, the responsible persons are:

   - for pharmaceuticals for human use: the authorised person responsible for Quality Assurance named on the licence to manufacture (Medicines Act 1981); and

   - for animal remedies (veterinary medicines): the authorised person responsible for Quality Assurance named on the manufacturers licence (Animal Remedies Act 1967).

SECTION I: LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

Subject to Section III "Operational provisions", general GMP inspections will be carried out against the GMP requirements of the exporting Party. The legislative, regulatory and administrative requirements are listed in the Appendix 1.

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.

SECTION II: OFFICIAL INSPECTION SERVICES

For New Zealand:

for medicines for human use:
Ministry of Health
Therapeutics Section
P.O. Box 5013
Wellington
New Zealand
Tel.: 64-4-496-2081
Fax: 64-4-496-2229

for veterinary medicines:
Ministry of Agriculture
Agricultural Compounds Unit
P.O. Box 40063
Upper Hutt
New Zealand
Tel.: 64-4-528-0126
Fax : 64-4-528-1378

For the European Community :

BELGIUM

Inspection générale de la Pharmacie
Cité administrative de l'Etat
Quartier Vésale
Algemene Farmaceutische Inspectie
Rijksadministratief Centrum
Vesalius Gebouw
B-1010 BRUXELLES — Tel. : 32-2-210 4924
BRUSSEL — Fax : 32-2-210 4880

DENMARK

Sundhedsstyrelsen -Medicines Division
Frederikssundsvej 378
DK-2700 BRØNSHØJ — Tel. : 45-44-889 320
Fax : 45-42-847 077

GERMANY

Bundesministerium für Gesundheit
Am Propsthof 78a
D-53108 BONN — Tel. : 49-228-941 2340
Fax : 49-228-941 4923

for immunologicals :
Paul-Ehrlich-Institut, Federal Agency for Sera & Vaccines
Postfach
D 63207 LANGEN — Tel. : 49-6103-77 1010
Fax : 49-6103-77 1234

GREECE

Εθνικός Οργανισμός Φαρμάκου
National Drug Organization (E.O.F.)
Mesogion 284
GR-ATHENS 15562
Tel. : 30-1-654 5530
Fax : 30-1-654 9591

SPAIN

Ministerio de Sanidad y Consumo
Subdirección General de Control Farmaceutico
Paseo del Prado 18-20
E-28014 MADRID
Tel. : 34-1-596 4068
Fax : 34-1-596 4069

FRANCE

for medicinal products for human use :
Agence du Médicament
143-145 boulevard Anatole France
F-93200 SAINT-DENIS
Tél. : 33-1-4813 2000
Fax : 33-1-4813 2478

for veterinary medicinal products :
Agence Nationale du Médicament Vétérinaire
la Haute Marche - Javené
F - 35133 FOUGERES.
Tel.: +33-9994 7878
Fax : +33-9994 7899

IRELAND

National Drugs Advisory Board
63-64 Adelaide Road
IRL-DUBLIN 2
Tel. : 353-1-676.4971 - 7
Fax : 353-1-676.7836

ITALY

Ministero della Sanità
Direzione Generale del Servicio Farmaceutico
Viale della Civiltà Romana 7
I-00144 ROMA
Tel. : 39-6-5994 3676
Fax : 39-6-5994 3365

LUXEMBOURG

Division de la Pharmacie et des Médicaments
10 rue C.M. Spoo
L-2546 LUXEMBOURG
Tel. : 352-478 5590 / 93
Fax : 352-22 44 58

NETHERLANDS

Ministerie van Volksgezondheid, Welzijn en Sport
Inspectie voor de Gezondheidszorg
Postbus 5406
NL-2280 HW RIJSWIJK
Tel. : 31-70-340 7911
Fax : 31-70-340 5177

AUSTRIA

Bundesministerium für Gesundheit und Konsumentenschutz
Radetzkystraße 2
A-1031 WIEN
Tel. : 43-1-711 724 642
Fax : 43-1-714 92 22

PORTUGAL

Instituto Nacional da Farmácia e do Medicamento - INFARMED
Av. do Brasil, 53
P - 1700 LISBOA
Tel. : 351-1-795 7836
Fax : 351-1-795 9116

FINLAND

National Agency for Medicines
P.O. Box 278
FIN-00531 HELSINKI
Tel. : 358-0-396 72 112
Fax : 358-0-714 469

SWEDEN

Läkemedelsverket - Medical Products Agency
Husargatan 8, P.O. Box 26
S - 751 03 UPPSALA
Tel. : 46-18-174 600
Fax : 46-18-548 566

UNITED KINGDOM

for human and veterinary (non immunologicals) :
Medicines Control Agency
1 Nine Elms Lane
GB-LONDON SW8 5NQ
Tel. : 44-171-273 0500
Fax : 44-171-273 0676

for veterinary immunologicals :
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone
GB - SURREY KT15 3NB
Tel. : 44-1932-336911
Fax : 44-1932-336618

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 site 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 item 2 below). 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 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 country (see Appendix 1);

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 country. 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 Committee.

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.

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 Agreement except as provided for in paragraph 6 below.

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 the Agreement, the Parties will exchange any information necessary for the mutual recognition of inspections.

In addition, the relevant Authorities in New Zealand and in the European Community will keep each other informed of any new technical guidance or inspection procedure. Each Party will consult the other before their adoption and will endeavour to proceed towards their approximation.

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 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 Community, the official batch release procedure for medicinal products for human use is specified, in document "Administrative EC Batch Release Procedure III/3859/92" and different specific batch release procedures. 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 the Agreement, training sessions for inspectors, organised by the Authorities, will be accessible to inspectors of the other Party. The Parties to the Agreement will keep each other informed on these sessions.

10. Joint Inspections

In accordance with the general provisions of the Agreement, and by mutual agreement 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 agreed through procedures approved by the Joint Committee.

11. Alert system

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

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, are communicated to each other with the appropriate degree of urgency.

12. Contact points

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

for New Zealand:
for medicinal products for human use:
Ministry of Health
Therapeutics Section
PO Box 5013
Wellington
New Zealand
Tel.: 64-4-496-2000
Fax: 64-4-496-2340

for medicinal products for use in animals:
Ministry of Agriculture
Agricultural Compounds Unit
PO Box 40063
Upper Hutt
New Zealand
Tel.: 64-4-528 4794
Fax: 64-4-528 6089

for the European Community:
the Director of the European Agency for the Evaluation of Medicinal Products
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom
Tel.: 44-171- 418 8400
Fax : 44-171- 418 8416

13. 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 Committee.

SECTION IV : TRANSITIONAL ARRANGEMENTS FOR VETERINARY MEDICINAL PRODUCTS

In respect of veterinary medicinal products, the European Community will, subject to satisfactory verification of New Zealand's GMP inspection programme, recognise the conclusions of New Zealand GMP inspections and of New Zealand Manufacturers' certifications of batch conformity, three years after the entry into force of the Agreement. New Zealand will, subject to satisfactory verification of the European Community's GMP inspection programme, recognise the conclusions of the European Community's inspections and of the European Community's Manufacturers' certifications of batch conformity three years after the entry into force of the Agreement. During this three year period, joint inspections, carried out in accordance with Section III, item 10 of this Sectoral Annex, may be authorised as a means to build further confidence between the Parties regarding the application and interpretation of their respective requirements.

The terms of any existing recognition arrangements concerning imports into New Zealand will remain valid during this three year period.

APPENDIX 1

LIST OF APPLICABLE LEGISLATIVE, REGULATORY & ADMINISTRATIVE PROVISIONS

For the European Community:

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 81/851/EEC of 6 November 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products as widened and amended.

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products

Council Regulation No (EEC) 2309/93 of 23 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use & Guide to Good Distribution Practice

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV

For New Zealand:

Medicines Act 1981

Medicines Regulations 1984

New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Parts 1, 2, 4 and 5

Animal Remedies Act 1967

Animal Remedies Regulations 1980

Code of GMP for Animal Remedies 1994

APPENDIX 2

CERTIFICATE OF PHARMACEUTICAL MANUFACTURER IN THE FRAMEWORK OF THE AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS BETWEEN NEW ZEALAND AND THE EUROPEAN COMMUNITY, SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

As requested by the Competent Authorities of New Zealand / ..... (*) on ..../..../.... (date) (reference: .....), the Competent Authority of ..... confirms the following:

The company .....,
whose legally registered address is: .....
.....
.....
has been authorised, under the Medicines Act 1981 and Medicines Regulations 1984 / Directive 75/319/EEC, Article 16, and Directive 81/851/EEC, Article 24, transposed in the national legislation of ..... (*), under the authorisation reference number .....,
covering the following site(s) of manufacture (and contract testing laboratories, if any):
1 .....
.....
2 .....
.....
3 .....
.....
to carry out the following manufacturing operations:

+ complete manufacture (**)

+ partial manufacture (**), i.e. (detail of manufacturing operations authorised):
.....
.....
for the following medicinal product: .....

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

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on ..../..../.... (date), it is considered that the company complies with the Good Manufacturing Practice requirements referred to in the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between New Zealand and the European Community.

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

For the Competent Authority,

(Name and signature of the officer responsible)

(*) : insert European Community Member State or European Community as required
(**): delete that which does not apply

NEW ZEALAND - EUROPEAN COMMUNITY

MUTUAL RECOGNITION AGREEMENT

OF

CONFORMITY ASSESSMENT, CERTIFICATES AND

MARKINGS

SECTORAL ANNEX

MEDICAL DEVICES

NEW ZEALAND - EUROPEAN COMMUNITY
SECTORAL ANNEX - MEDICAL DEVICES

SCOPE AND COVERAGE

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

Products for export to the European Community	Products for export to New Zealand
• All medical devices subject to third party conformity assessment procedures, both product related and quality system related, provided for in the Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, but excluding the following products: • radioactive materials to the extent these may be considered medical devices, and • medical devices incorporating tissues of animal origin. However, medical devices: (a) incorporating refined derivatives of such tissues; or (b) incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, will be included within the scope of this Sectoral Annex.	• All medical devices defined as such under the New Zealand legislation listed in Section I of this Sectoral Annex, and to which third party conformity assessment procedures, both product related and quality systems related, apply, but excluding the following products: • radioactive materials to the extent these may be considered medical devices, and • medical devices incorporating tissues of animal origin. However, medical devices (a) incorporating refined derivatives of such tissues, or (b) incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, will be included within the scope of this Sectoral Annex.

SECTION I : LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which New Zealand designated Conformity Assessment Bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand to which European Community designated Conformity Assessment Bodies will assess compliance
• Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC), as amended • Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended	• Radiocommunications Act 1989 • Radiocommunications (Radio) Regulations 1993 • Electricity Act 1992 • Electricity Regulations 1993

SECTION II : DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by New Zealand to assess product against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess product against New Zealand's legislative, regulatory and administrative requirements
The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names to be added as required]	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [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
• Ministry of Health	• **Belgium** Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie • **Denmark** Sundhedsministeriet • **Germany** Bundesministerium für Gesundheit • **Greece** Υπουργείο Υγείας και Πρόνοιας Ministry of Health • **Spain** Ministerio Sanided y Consumo • **France** Ministère de la Santé • **Ireland** Department of Health • **Italy** Ministero Sanita • **Luxembourg** Ministère de la Santé • **Netherlands** Ministerie van Volksgezondheid, Welzijn en Sport

	• **Austria** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Ministerio da Saude • **Finland** Sosiaali- ja terveysministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) • **United Kingdom** Department of Health

SECTION IV : PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating Conformity Assessment Bodies to assess product against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product 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 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 (93/465/EEC), and be designated on the basis of the procedures defined in Annex 1 to the Agreement. This may be demonstrated through: a) Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guide 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 Annex 1.	1. The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in Annex 1 to the Agreement. 2. The following procedures are deemed to be consistent with those set out in Annex 1: (a) Certification Bodies: • accredited by accreditation bodies which are signatories to the European Accreditation of Certification (EAC) Multilateral Agreement, • members of the 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 Annex 1.

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 Annex 1. c) Inspection Bodies operating according to the requirements of EN 45004 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 Annex 1.	(b) Testing Laboratories: • accredited by accreditation bodies which are signatories to the European cooperation for Accreditation of Laboratories (EAL) Multilateral Agreement, • recognised within the IECEE CB Scheme, or • able to demonstrate competence by other means in accordance with Section A and B of Annex 1.

SECTION V : ADDITIONAL PROVISIONS

1. Medical Devices incorporating medicinal substances

In order to meet European Community requirements, the following procedures will apply to medical devices incorporating medicinal substances referred to in Article 1, paragraph 4 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices:

(a) if a medical device incorporates a substance which is already established by monographs of the European Pharmacopoeia, the consultation required under Annex 2 or 3 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices will be carried out with the Therapeutics Section of the New Zealand Ministry of Health;

(b) if a medical device contains a substance other than one specified in the European Pharmacopoeia, the Ministry of Health will carry out such consultation with one of the competent authorities within the European Community responsible for authorising the placing on the market of medicinal products.

2. New legislation

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

3. Exchange of information

The Parties agree to inform each other of incidents in the context of medical device vigilance procedure, or with regard to matters concerning product safety. The contact points through which the information can be passed are:

(i) New Zealand:

The Manager
Therapeutics Section
Ministry of Health
P.O. Box 5013
Wellington
New Zealand
Tel.: 64-4-496-2081
Fax: 64-4-496-2229
and
The Chief Electrical Engineer
Ministry of Commerce
P.O. Box 1473
Wellington
New Zealand
Tel.: 64-4-472-0030
Fax: 64-4-471-0500

(ii) European Community:

European Commission
Directorate-General Industry
The Head of Unit III.D.2
Rue de la Loi 200
B-1049 Brussels
Tel.: 32-2-299.11.11
Fax: 32-2-296.70.13

4. Sub-Contracting

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

5. Recording of approvals granted

In addition to the requirements imposed by Annex 1 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 1993 has been granted.

6. Divergence of views

Both Parties will use their best endeavours to resolve any divergence of views concerning compliance of manufacturers and conclusions of conformity assessment reports. Unresolved divergencies of view will be referred to the Joint Committee as established in Article 12 of the Agreement.

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SECTORAL ANNEX

TELECOMMUNICATIONS TERMINAL EQUIPMENT

NEW ZEALAND - EUROPEAN COMMUNITY SECTORAL ANNEX - TELECOMMUNICATIONS TERMINAL EQUIPMENT

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 the scope of Council Directive 91/263/EEC of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity, as supplemented by Council Directive 93/97/EEC of 29 October 1993 supplementing Directive 91/263/EEC in respect of satellite earth station equipment. In general terms, these Council Directives cover: (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	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),

(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 common technical regulations in this sector as they become available.	(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 1987 at the request of the New Zealand Government.

SECTION I : LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which New Zealand designated Conformity Assessment Bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand to which European Community designated Conformity Assessment Bodies will assess compliance
• Council Directive 91/263/EEC of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity, as amended • Council Directive 93/97/EEC of 29 October 1993 supplementing Directive 91/263/EEC in respect of satellite earth station equipment, as amended • Commission Decision of 21 December 1993 on a common technical regulation for the general attachment requirements for public pan-European cellular digital land-based mobile communications (94/11/EC) • Commission Decision of 21 December 1993 on a common technical regulation for the telephony application requirements for public pan-European cellular digital land-based mobile communications (94/12/EC) • Commission Decision of 18 July 1994 on a common technical regulation for attachment requirements for terminal equipment interface for ONP 2048 kbit/s digital unstructured leased line (94/470/EC)	• 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 1993

• Commission Decision of 18 July 1994 on a common technical regulation for general terminal attachment requirements for Digital European Cordless Telecommunications (DECT) (94/471/EC) • Commission Decision of 18 July 1994 on a common technical regulation for telephony application requirements for Digital European Cordless Telecommunications (DECT) (94/472/EC) • Commision Decision of 18 November 1994 on a common technical regulation for the pan-European integrated services digital network (ISDN) primary rate access (94/796/EC) • Commision Decision of 18 November 1994 on a common technical regulation for the pan-European integrated services digital network (ISDN) basic access (94/797/EC) • Commision Decision of 9 December 1994 on a common technical regulation for attachment requirements for terminal equipment interface for ONP 64 kbit/s digital unstructured leased line (94/821/EC) • Commision Decision of 17 July 1995 on a common technical regulation for public land-based European radio message system (ERMES) receiver requirements (95/290/EC)	

• Commission Decision 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 (95/525/EC) • Commission Decision of 28 November 1995 on a common technical regulation for Integrated Services Digital Network (ISDN); Telephony 3,1 kHz teleservice, attachment requirements for handset terminals (95/526/EC) • Commission Decision of 10 January 1996 on a common technical regulation for access to packet switched public data networks (PSPDNs) using CCITT recommendation X.25 interfaces (96/71/EC)	

SECTION II : DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by New Zealand to assess product against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess product 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** Ministerium für Post und Telekommunikation • **Greece** Υπουργείο Μεταφορών καί Επικοινωνιών Ministry of Transport and Communications • **Spain** Ministerio de Fomento • **France** Ministère de l'Industrie, de la Poste et des Télécommunications • **Ireland** Department of Transport, Energy and Communications • **Italy** Ispettorato Generale TLC • **Luxembourg** Administration des Postes et Télécommunications

	• **Netherlands** Ministerie van Verkeer en Waterstaat • **Austria** Bundesministerium fur wirtschaftliche Angelegenheiten • **Portugal** Instituto des Comunicaçôes de Portugal • **Finland** Liikenneministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) • **UK** Department of Trade and Industry

SECTION IV : PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed in designating Conformity Assessment Bodies to assess product against the European Community's requirements	The procedures to be followed in designating Conformity Assessment Bodies to assess product 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 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 (93/465/EEC), and be designated on the basis of the procedures defined in Annex to the Agreement. This may be demonstrated through: a) Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guide 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 Annex 1.	1. The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in Annex 1 to the Agreement. 2. The following procedures are deemed to be consistent with those set out in Annex 1: (a) Testing Laboratories: • accredited by accreditation bodies which are signatories to the European cooperation for Accreditation of Laboratories (EAL) Multilateral Agreement, or • able to demonstrate competence by other means in accordance with Section A and B of Annex 1.

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 Annex 1. 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 Annex 1.	b) Certification Bodies: • accredited by accreditation bodies which are signatories to the European Accreditation of Certification (EAC) Multilateral Agreement, • 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 Annex 1.

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 sub-contract 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 requirements designed for use within certain voltage limits and Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/EEC), the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility will apply.

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SECTORAL ANNEX

LOW VOLTAGE EQUIPMENT

NEW ZEALAND - EUROPEAN COMMUNITY
SECTORAL ANNEX - LOW VOLTAGE EQUIPMENT

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 exports 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 1993.

SECTION I : LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which New Zealand designated Conformity Assessment Bodies will assess compliance	**The legislative, regulatory and administrative requirements of New Zealand to 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 1993

SECTION II : DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by New Zealand to assess product against the European Community's legislative, regulatory and administrative requirements	**The Conformity Assessment Bodies designated by the European Community to assess product against New Zealand's legislative, regulatory and administrative requirements**
The designated Conformity Assessment Bodies are: [Name and details to be to be inserted] [Note: Further names to be added as required]	The designated Conformity Assessment Bodies are: [Name and details to be 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) (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** Bygge- og Boligstyrelsen • **Germany** Bundesministerium für Arbeit und Sozialordnung • **Greece** Υπουργείο Ανάπτυξης Ministry of Development • **Spain** Ministerio de Industria y Energia • **France** Ministère de l'Industrie, de la Poste et des Télécommunications • **Ireland** Department of Enterprise and Employment

	• **Italy** Ministero dell' Industria, del Commercio e dell' Artigianato • **Luxembourg** Ministère des Transports • **Netherlands** Ministerie van Volksgezondheid, Welzijn en Sport • **Austria** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Under the authority of the Government of Portugal: Instituto Português da Qualidade • **Finland** Kauppa- ja teollisuusministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (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 product against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product 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 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 (93/465/EEC), and are designated on the basis of the procedures defined in Annex 1 to the Agreement. This may be demonstrated through: a) Inspection Bodies operating according to the requirements of EN 45004 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 Annex 1 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 • able to demonstrate competence by other means in accordance with Sections A and B of Annex 1.	1. The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in Annex 1 to the Agreement. 2. The following procedures are deemed to be consistent with those set out in Annex 1: Testing Laboratories: • accredited by accreditation bodies which are signatories to the European cooperation for Accreditation of Laboratories (EAL) Multilateral Agreement, or • recognised within the IECEE CB Scheme, or • able to demonstrate competence by other means in accordance with Section A and B of Annex 1.

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 sub-contract 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 the Council Directive as "bodies which may make a report in accordance with Article 8".

3. In addition to the requirements imposed by Annex 1 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 1993 has been granted.

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SECTORAL ANNEX

ELECTROMAGNETIC COMPATIBILITY

NEW ZEALAND - EUROPEAN COMMUNITY
SECTORAL ANNEX - ELECTROMAGNETIC COMPATIBILITY

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 to which New Zealand designated Conformity Assessment Bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand to 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 1993

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] [Further names to be added as required]	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [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) (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** Telestyrelsen • **Germany** Bundesministerium für Post und Telekommunikation • **Greece** Υπουργειο Μεταφορών καί Επικοινωνιών Ministry of Transport and Communications • **Spain** for telecommunications equipment: Ministerio de Fomento for other equipment: Ministerio de Industria y Energia • **France** Ministère de l'Industrie, de la Poste et des Télécommunications • **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** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Under the authority of the Government of Portugal: Instituto Português de Comunicaçôes de Portugal • **Finland** Kauppa- ja teollisuusministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (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 product against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product 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 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 (93/465/EEC), and are designated on the basis of the procedures defined in Annex 1 to the Agreement. This may be demonstrated through: a) For the purposes of Article 10.5 of the 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 45004 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 Annex 1.	1. The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in Annex 1 to the Agreement. 2. The following procedures are deemed to be consistent with those set out in Annex 1: Testing Laboratories: • accredited by accreditation bodies which are signatories to the European cooperation for Accreditation of Laboratories (EAL) Multilateral Agreement, or • able to demonstrate competence by other means in accordance with Section A and B of Annex 1.

b) For Competent Bodies according to Article 10.2 of the 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 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 Annex 1.	

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 sub-contract 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 Annex 1 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 1993 has been granted.

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SECTORAL ANNEX

MACHINERY

NEW ZEALAND - EUROPEAN COMMUNITY
SECTORAL ANNEX - MACHINERY

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, • tower cranes, and • mobile cranes.	Any machinery that falls within the scope of the Health and Safety in Employment Act 1992. 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.

SECTION I : LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community to which New Zealand designated Conformity Assessment Bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand to 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 • Directives setting out noise limitation requirements for tower cranes as follows: - 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 - 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 - 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	• Health and Safety in Employment Act 1992; • Health and Safety in Employment Regulations 1995; • Health and Safety in Employment (Pressure Equipment, Cranes and Passenger Ropeways) Regulations 199[6] in respect to tower cranes, port type container cranes and mobile cranes;[1] • Health and Safety in Employment (Tractor Safety Frames) Regulations 199[6] in respect of safety frames fitted to agricultural tractors;[1] • Health and Safety in Employment (Mining Control) Regulations 199[6];[1] and • Health and Safety in Employment (Petroleum) Regulations 199[6].[1] [1] These regulations have yet to be passed into the law of New Zealand.

SECTION II : DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by New Zealand to assess product against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess product against New Zealand's legislative, regulatory and administrative requirements
The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names and details to be added as required]	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [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 Commission
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'Emploi et du Travail Ministerie van Tewerkstelling en Arbeid • **Denmark** Direktoratet for Arbejdstilsynet • **Germany** Bundesministerium für Arbeit und Sozialordnung • **Greece** Υπουργείο Ανάπτυξης Ministry of Development • **Spain** Ministerio de Industria, Comercio y Turismo • **France** Ministère du Travail et des Affaires Sociales et Ministère de l'Industrie, de la Poste et des Télécommunications • **Ireland** Department of Enterprise and Employment

	• **Italy** Ministero dell' Industria, del Commercio e dell' Artigianato • **Luxembourg** Ministère des Transports • **Netherlands** Ministerie van Volksgezondheid, Welzijn en Sport • **Austria** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Under the authority of the Government of Portugal: Instituto Português da Qualidade • **Finland** Työministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (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 product against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to Assess product 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 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 (93/465/EEC), and are designated on the basis of the procedures defined in Annex 1 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 45004 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 Annex 1.	1. The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in Annex 1 to the Agreement. 2. The following procedures are deemed to be consistent with those set out in Annex 1: (a) For cranes: For Design Verification, Conformity Assessment Bodies will: • operate in conformity with EN 45004 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)	For the purpose of Council Directives setting out noise limitation requirements for tower cranes: Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guide 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 Annex 1.	For Inspection Bodies, Conformity Assessment Bodies will: • operate in conformity with EN 45004 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. For Certification Bodies the following procedures are deemed to be consistent with the procedures set out in Annex 1: • accreditation by an accreditation body which is a signatory to the European Accreditation of Certification (EAC) Multilateral Agreement, • accreditation 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 Annex 1.

	For Testing Laboratories: The following procedures are deemed to be consistent with those set out in Annex 1: • accreditation by an accreditation body which is a signatory to the European cooperation for Accreditation of Laboratories (EAL) Multilateral Agreement, or • able to demonstrate competence by other means in accordance with Section A and B of Annex 1. (b) For machinery other than cranes, either: • notified as a 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 Directive 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 (93/465/EEC) and are listed in Section II of this Sectoral Annex, or • 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 sub-contract 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 requirements designed for use within certain voltage limits and Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/EEC), 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 European Parliament and Council Directive 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 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.

NEW ZEALAND - EUROPEAN COMMUNITY

MUTUAL RECOGNITION AGREEMENT

OF

CONFORMITY ASSESSMENT, CERTIFICATES AND

MARKINGS

SECTORAL ANNEX

PRESSURE EQUIPMENT

NEW ZEALAND - EUROPEAN COMMUNITY
SECTORAL ANNEX - PRESSURE EQUIPMENT

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 in 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 to which New Zealand designated Conformity Assessment Bodies will assess compliance	The legislative, Regulatory and administrative requirements of New Zealand to 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 passed into the law of New Zealand.

SECTION II : DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by New Zealand to assess product against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess product 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]

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 Commission
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'Emploi et du Travail Ministerie van Tewerkstelling en Arbeid • **Denmark** Direktoratet for Arbejdstilsynet • **Germany** Bundesministerium für Arbeit und Sozialordnung • **Greece** Υπουργείο Ανάπτυξης Ministry of Development • **Spain** Ministerio de Industria; Comercio y Turismo • **France** Ministère de l'Industrie, de la Poste et des Télécommunications • **Ireland** Department of Enterprise and Employment

	• **Italy** Ministero dell' Industria, del Commercio e dell' Artigianato • **Luxembourg** Ministère des Transports • **Netherlands** Ministerie van Sociale Zaken en Werksgelegenheid • **Austria** Bundesministerium für wirtschaftliche Angelegenheiten • **Portugal** Under the authority of the Government of Portugal: Instituto Português da Qualidade • **Finland** Kauppa- ja teollisuusministeriö • **Sweden** Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (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 product against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess product 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 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 (93/465/EEC), and are designated on the basis of the procedures defined in Annex 1 to this Agreement. This may be demonstrated through: a) Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guide 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 Annex 1.	1. The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in Annex 1 to the Agreement. 2. The following procedures are deemed to be consistent with those set out in Annex 1: (a) Design Verification: For Design Verification, Conformity Assessment Bodies will: • operate in conformity with EN 45004 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) 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 Annex 1. c) Inspection Bodies operating according to the requirements of EN 45004 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 Annex 1.	(b) Inspection Bodies: For Inspection Bodies, Conformity Assessment Bodies will: • operate in conformity with EN 45004 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 European Accreditation of Certification (EAC) Multilateral Agreement, • accreditated 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 Annex 1. (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 of Laboratories (EAL) Multilateral Agreement, or • able to demonstrate competence by other means in accordance with Section A and B of Annex 1.

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 sub-contract 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 requirements designed for use within certain voltage limits and Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (89/336/EEC), 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 Annex 1 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.

Financial Statement 1998-2002

External trade relations - Mutual Recognition Agreement

1. TITLE

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

2. BUDGETARY HEADINGS: B7-8500 A-7010

3. LEGAL BASIS

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

4. DESCRIPTION OF OPERATION :

4.1 General objective:

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

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

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

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

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

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

5. CLASSIFICATION OF EXPENDITURE/REVENUE

5.1 Non-compulsory expenditure ("DNO")

5.2 Differentiated appropriation ("CD")

5.3 Type of revenue involved:
None

6. TYPE OF EXPENDITURE/REVENUE

- *100% subsidy: No*

- *subsidy for co-financing with other sources in the public or private sector?*

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

- *Interest subsidy: No*

- *Others*

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

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

Not relevant

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

No

7. FINANCIAL IMPACT ON APPROPRIATIONS FOR OPERATIONS

7.1 Method of calculating the total cost of the operation:

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

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

The costs of specific actions will be determined either:

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

A. Attendance at Joint Committee

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

B. Attendance at Joint Sectoral Groups

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

C. Workshops and Seminars

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

D. Verification actions

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

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

E. Production and dissemination of information

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

7.2 Breakdown by elements of the operation

"Trade Agreements with important Trading Partners"

For 1998, this involves the following calculation:

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

In Ecus
(current prices)

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

From the year 2000 on the estimates are for information.

7.3 Indication of the timetable for commitment and payment appropriations

1000 Ecus

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

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

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

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

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

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

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1. Specific objectives of the proposed operation, population targeted

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

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

- *Target population*

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

9.2. Reasons for the operation

- *Need for intervention from the Community budget*

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

- *Choice of methods of intervention*

  * *advantages over alternative measures (comparative advantages)*

  * *analysis of similar operations at Community or national level*

  * *results and expected multipliers*

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

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

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

- *Main factors of uncertainty which could affect the specific results of the operation.*

  * None

9.3 Monitoring and evaluation of the operation

- *Performance indicators selected*

  * *Output indicators*

  * *indicators of impact, following the objectives chosen*

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

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

- *Evaluation of results*

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

Details and frequency of the planned evaluation

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

10. ADMINISTRATIVE EXPENSES

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

10.1 Effect on the number of posts

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

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

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

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

For 1998 this involves the following calculation:

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

In ECU

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

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS

with special reference to small and medium-sized enterprises

Title of proposal

Proposal for a Council Decision on the conclusion of Agreements between the European Community and Australia and New Zealand on Mutual Recognition in relation to Conformity Assessment.

Reference number

The proposal

The legislation is necessary to conclude Agreements between the European Community and Australia and New Zealand on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings. These are agreements negotiated and initialled by the Commission in accordance with the mandate and negotiating directives provided by the Council on 21/9/92.

The impact on business

The business sectors affected are telecommunications terminal equipment, electrical equipment, machinery, pressure equipment, medicinal products, and medical devices, and in the case of Australia automotive products.

The Agreements permit certification of conformity with technical regulations on product safety, etc, to be conducted in Europe for exports destined for Australia and New Zealand. This avoids the necessity for further certification by Australian and New Zealand conformity assessment bodies before putting them on those markets.

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

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

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

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

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

Consultation

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

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