COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL DECISION

on the signature on behalf of the Community of an Agreement between the European Community and Japan on Mutual Recognition in relation to Conformity Assessment

Proposal for a

COUNCIL DECISION

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. The Agreement

On the basis of the negotiating directives issued by the Council on 21.9.92. the European Commission has negotiated and initialled an agreement on the mutual recognition of conformity assessment (Mutual Recognition Agreement, or MRA) with Japan. A Text of the Agreement initialled in December 2000 is annexed.

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

I.1 Assessment of the Agreement

The Commission considers that the initialled Agreement is in conformity with the Council's negotiating directives, takes account of the views expressed by the 133 MRA Working Group, which gave detailed advice to the Commission during the negotiations, and provides benefits to the European Community.

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

I.1.1 Framework Agreement

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

Pre-amble : This sets out the principal objective of the mutual recognition agreement, which is thefacilitation of trade between the parties.

Article 1: Definitions: these are self-explanatory. One should note, however, that there are separate sets of definitions for the GMP and GLP annexes.

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 of each Party. This Article also 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: 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 Japan has the necessary authority to designate, suspend or withdraw bodies.

Article 5: Verification of Compliance By Conformity Assessment Bodies: this Article establishes the right for one Party to challenge the compliance of bodies in the other Party. Verification will be carried out by the Party in whose territory the CAB is located. This article also ensures that bodies of each Party are monitored so as to be able, continuously, to correctly interpret the regulatory requirements of the other Party.

Articles 6 and 7: A CAB will be suspended where disagreement over its status has been confirmed by the Joint Committee, unless otherwise decided by that Committee. As advised by Member States in the 133 Committee MRA Group, the right of verification has been closely circumscribed to prevent it from being carried out routinely or unilaterally.

Article 8: 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. This article also contains provisions on exchange of information.

Article 9 sets out detailed procedures for designation of bodies and the right of the other Party to contest such designations according to certain rules.

Article 10: Safeguards: this Article provides that an importing Party retains all powers under its domestic law, and within its territory, to take measures to protect health, safety or the environment. These powers must be exercised in accordance with the principle of non-discrimination. This article also provides for emergency verification of GMP and GLP facilities.

Article 8, 9 and 15: Market Access: New conformity assessment procedures applying to covered products or requirements will be brought within the scope of the Agreement, unless jointly decided otherwise, so as to preserve negotiated market access benefits.

Article 11: Agreements with other countries: this Article provides that Mutual Recognition Agreements between Parties to this Agreement and other countries shall have no force in regard to the other Party to this Agreement.

Article 13: Confidentiality Clause: this is a standard clause

Articles 12 and 14: these are standard institutional and legal provisions. It should be noted that the Agreement is of unlimited duration, and that there is no scope for a Party unilaterally to terminate an individual sectoral annex.

I.1.2 The Sectoral Annexes

In the following, an assessment is given 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) the level of trade between the Community and Japan for the sectors and products covered;

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

d) the precedential nature (if any) of arriving at a mutual recognition agreement with Japan in the sectors covered;

e) overall consistency with Community policy objectives in the field of standardisation, certification, designation of conformity assessment bodies and the removal of technical barriers to trade.

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

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

A priori, this may indicate that the trade facilitation benefits of the Mutual Recognition should accrue to both the Community and Japan. 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 Japan which has adopted international standards and regulations fairly systematically.

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

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

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

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

Pharmaceuticals Good Manufacturing Practice (GMP)

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

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

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

The scope of the Agreement is as broad as possible and covers all medicinal products, which have undergone one or a series of manufacturing processes, e.g. fabrication, repackaging, labelling, testing, wholesaling to which GMP applies. Veterinary immunologicals are not covered.

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

The Agreement also lists the applicable legislation and relevant certifying authorities. It sets up a Joint Sub Committee to oversee preparatory work which must be completed and agreed before this sectoral annex can come into effect; This is the equivalent of confidence building period.

While providing mutual benefits to pharmaceutical companies, and some savings to inspection authorities, the present agreement also establishes mechanisms for longer-term cooperation between respective inspection authorities which will not only ensure the agreement continues to be properly applied, but will stimulate further harmonisation initiatives in other fields of medicines controls, such as Good Clinical and Laboratory Practices

Industrial Chemicals, Good Laboratory practice (GLP)

This annex establishes mutual recognition of studies and data generated therefrom produced by the test facilities of the other Party provided that these facilities are recognised to be in conformity with the OECD principles of Good Laboratory Practice and participate in the compliance monitoring programme of that party. To that end the Parties also recognise the equivalence of each other’s compliance monitoring programmes. Recognition of inspection results and the ensuing compliance with the GLP principles removes the need for companies in each Party to be inspected by the authorities of the other Party. Both Parties have accepted the decisions and recommendations of the OECD Council on Mutual Acceptance of Data (MAD) in 1981 and on compliance monitoring for Good Laboratory Practice in 1989 and have co-operated closely in the relevant OECD Working Group.

The Parties will exchange annually lists of recognised test facilities which specify the area of expertise of each test facility for which GLP compliance has been established. Only the

studies and data generated therefrom in the areas for which compliance with GLP is certified will have to be recognised.

The studies and data generated therefrom are used by the parties for administrative purposes during the evaluation process before the marketing and use of the substances for which the studies have been carried out. The MRA thus reduces the costs and time delays due to the testing of chemical substances and preparations and facilitates market access. The Annex covers all non-clinical health and environmental safety studies for the products which are explicitly specified: industrial chemicals, pesticides, medicinal products, veterinary drugs, food additives, animal feed additives, cosmetics. The Commission considers that the MRA is to the advantage of manufacturers and Exporters of the Community intending to placing their products on the Japanese market.

The proposed arrangement also supersedes and extends to all Member States the coverage of what were some limited 'memoranda of understanding' between some individual Japanese ministries and a number of Member States for certain chemical products.

Electrical Safety

This Annex covers the testing and certification requirements set out in the EC's Low Voltage Directive and corresponding Japanese legislation and regulations.

European industry groups have been consulted on the proposed MRA and have expressed support provided that we ensure that any agreement provide for reciprocity of market access and not lead to the introduction of new and more onerous requirements. Given the existing openness of the EC regime, and the fact that the necessary Japanese legislation is covered under the sectoral annex, these requirements have clearly been met. While manufacturers self certification exists in the EC third party certification is required for certain categories of products in Japan. As a result of the Agreement one certificate issued by a designated European CAB will now suffice. There are therefore clear advantages in the Agreement from an EC perspective.

Electromagnetic Compatibility (EMC)

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

Each Party agrees to recognise all of the other Party's reports, certificates and Technical Construction Files, as required under their respective legislation, without any further assessment of the products. Both Parties also agree to recognise each other's suppliers declaration of compliance as required under their respective legislation.

Telecommunications Terminal Equipment

There is a special annex on Telecommunications equipment but both sectoral annexes on electrical safety and electromagnetic compatibility also apply. These annexes apply to all telecommunications terminal equipment (TTE) regulated under the relevant Community RTTE Directive and the corresponding Japanese legislation.

The Agreement provides for recognition of the conformity assessment certificates of Conformity Assessment Bodies designated by the Parties in so far as applicable. The

Conformity Assessment Bodies will be required to comply with the criteria and standards set out in the regulatory requirements of the other Party (a list of Designating and Approval Bodies and Designated Bodies with an indication of the products and procedures for which the latter have been designated, have or will be set out in the sectoral annex).

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

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

In accordance with the general information and consultation procedures set out in the EEA Agreement and Protocol 12 of the said Agreement, the Commission has kept EFTA / EEA States regularly informed about developments in the negotiations and has informed them on the final result of the negotiations. Japan has not at this stage accepted to negotiate a similar agreement with EEA / EFTA.

I.1.4 Overall Appreciation

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

The Commission has received indications that a large number of EC conformity assessment bodies would be interested to work in the framework of this Agreement, and this indicates both their technical capacity and economic interest in the Agreement.

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

II. The Draft Council Decisions

A proposal for two Council decisions on the signature and the conclusion of the Agreement is attached.

The legal basis for both decisions are Articles 133 and 300 of the Treaty.

The decision concerning the conclusion of the Agreement must also establish the appropriate Community procedure to enable the Commission, assisted by the 133 Committee (Mutual Recognition), to represent the Community in the Joint Committee and where appropriate in

the Joint Sub-Committee established by the Sectoral Annexes. It should furthermore provide that the Community position in that Joint Committee and in the Joint Sub-Committee in case of certain technical decisions, including in some cases the amendment of the annexes, be determined, in conformity with Article 300, paragraph 4 of the Treaty, by the Commission in consultation with the 133 Committee.

Such decisions are limited to issues concerned with implementation over time, in particular amending the references to the regulations applicable to covered sectors; amending the annexes further to decisions to recognise, suspend, remove, or alter the scope of activity of conformity assessment bodies or designating authorities in the Agreement. In all other cases, the position of the Community shall be established by the Council, acting on the basis of a proposal from the Commission.

The Commission therefore proposes that the Council adopts the appended decisions.

2001/0036 (ACC)

Proposal for a

COUNCIL DECISION

on the signature on behalf of the Community of an Agreement between the European Community and Japan on Mutual Recognition in relation to Conformity Assessment

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133, in conjunction with the first sentence of the first subparagraph of Article 300 (2) thereof,

Having regard to the proposal from the Commission[1],

Whereas subject to its possible conclusion at a later date, the Agreement on Conformity Assessment initialled in Brussels on 11 December 2000 should be signed,

HAS DECIDED AS FOLLOWS:

Sole Article

Subject to a possible conclusion at a later date, the President of the Council is hereby authorised to designate the person empowered to sign, on behalf of the Community, the Agreement with Japan on Mutual Recognition in regard to Conformity Assessment.

Done at Brussels, […]

For the Council
The President
[…]

[1] OJ C […], […], p. […].

2001/0037 (ACC)

Proposal for a

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

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 in conjunction with Article 300, paragraph (2), first subparagraph, first sentence, paragraph (3), first subparagraph, first sentence, and paragraph (4) thereof,

Having regard to the proposal of the Commission,

Whereas:

(1) The Agreement on Mutual Recognition in relation to Conformity Assessment between the European Community and Japan, initialled on 11 December 2000, has been negotiated and should be approved,

(2) This Agreement has been signed, on behalf of the European Community, on […] subject to its possible conclusion at a later date, in accordance with Decision …/…/EC of the Council of […],

(3) Certain tasks for implementation have been attributed to the Joint Committee established by the Agreement, involving in certain cases the power to amend the Sectoral Annexes thereto;

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

HAS DECIDED AS FOLLOWS:

Article 1

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

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

Article 2

The President of the Council shall, on behalf of the Community, transmit the note provided for in Article 14 of the Agreement[2].

Article 3

1. The Commission shall represent the Community in the Joint Committee (art. 8) and in any Sub-Committees (art. 8.2) that are established under it, assisted by the special committee designated by the Council. The Commission shall proceed, after consultation with this committee, to the proposals for registrations, provision of lists of facilities, terminations, suspensions, withdrawals, appointments of experts, notifications, exchange of information, and requests for verifications referred to in Articles 5, 6, 7, 8, 9, 10 of the Agreement and the equivalent provisions of its Sectoral Annexes.

2. The position to be taken by the Community in the Joint Committee or if appropriate by any Sub-Committees shall be determined by the Commission following consultation of the above mentioned special committee, with regard to:

   a) adoption of the rules of procedure, in accordance with article 8.2;

   b) registration of CABs in accordance with art. 9.1;

   c) verification of the compliance of conformity assessment bodies and related decisions, in accordance with articles 5 and 7 of the Agreement;

   d) verification of facilities in accordance with articles 5, 7 and 10 of the Agreement;

   e) the transitional arrangements associated with implementation of the Agreement (art. 2.9 of sectoral annex on GMP);

   f) definition of emergencies in accordance with article 10.2 (b).

3. In all other cases the position to be taken by the Community in the Joint Committee or a Sub-Committee shall be determined by the Council, acting by a qualified majority on a proposal from the Commission.

Done at Brussels,

For the Council
The President

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

Draft

Agreement on Mutual Recognition between

Japan and the European Community

AGREEMENT ON MUTUAL RECOGNITION
BETWEEN
JAPAN AND THE EUROPEAN COMMUNITY

The European Community and Japan (hereinafter referred to as "the Parties");

Considering the traditional friendly relations that exist between Japan and the European Community;

Recognising the significance of mutual recognition of the results of conformity assessment procedures in facilitating market access and promoting trade between the Parties;

Considering the common interest in enhancing product quality, with a view to ensuring the health and safety of the public and protecting the environment;

Recognising the OECD principles of Good Laboratory Practice (GLP);

Recalling that long and fruitful cooperative activities of Japan and the European Community have made contributions to international development and harmonisation of Good Manufacturing Practice (GMP) requirements;

Being aware of the positive contribution that mutual recognition agreements can make to encouraging international harmonisation of standards; and

Bearing in mind the obligations of the Parties as Members of the World Trade Organisation, and being conscious, inter alia, of their obligations under the Agreement on Technical Barriers to Trade (hereinafter referred to as the “WTO Agreement on Technical Barriers to Trade”) included in Annex 1A, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the “WTO Agreement on Trade-Related Aspects of Intellectual Property Rights”) included in Annex 1C of the Marrakesh Agreement Establishing the World Trade Organisation (hereinafter referred to as the “WTO Agreement”);

Have agreed as follows:

ARTICLE 1

1. For the purposes of this Agreement:

(a) the term "conformity assessment procedure" means any procedure to determine, directly or indirectly, whether products or processes fulfil relevant technical requirements set out in the applicable laws, regulations and administrative provisions of a Party;

(b) the term "conformity assessment body" means a body which conducts conformity assessment procedure, and the term “registered conformity assessment body” means the conformity assessment body registered pursuant to Article 9 of this Agreement;

(c) the term "designation" means the designation of conformity assessment bodies by a Designating Authority of a Party pursuant to the applicable laws, regulations and administrative provisions of that Party;

(d) the term "Designating Authority" means an authority of a Party with the power to designate, monitor, withdraw the designation of, suspend the designation of, and withdraw the suspension of the designation of the conformity assessment bodies in its territory that conduct conformity assessment procedures based upon requirements set out in the applicable laws, regulations and administrative provisions of the other Party;

(e) the term “criteria for designation” means the criteria which conformity assessment bodies of a Party are required to fulfil in order to be designated by the Designating Authority of that Party, and other relevant conditions which designated conformity assessment bodies are required to continuously fulfil after the designation, as set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex;

(f) the term “confirmation” means the confirmation of the compliance of manufacturing facilities or test facilities (hereinafter referred to as “facilities”) with the criteria for confirmation by a Competent Authority of a Party pursuant to the applicable laws, regulations and administrative provisions of that Party;

(g) the term “Competent Authority” means an authority of a Party with the power to conduct inspection or study audits on facilities in its territory to confirm their compliance with the criteria for confirmation set out in the applicable laws, regulations and administrative provisions of that Party;

(h) the term “criteria for confirmation” means the criteria which a facility of a Party is required to continuously fulfil in order to be confirmed by the Competent Authority of the Party, as set out in the applicable laws, regulations and administrative provisions of that Party specified in the relevant Sectoral Annex; and

(i) the term “verification” means an action to verify in the territories of the Parties, by such means as audits or inspections, compliance with the criteria for designation or the criteria for confirmation by a conformity assessment body or a facility respectively.

2. Any term used in this Agreement, unless otherwise defined herein, has the meaning assigned to it in the ISO / IEC Guide 2: 1996 Edition, “Standardisation and related activities – General vocabulary”.

ARTICLE 2

1. Each Party shall accept, in accordance with the provisions of this Agreement, the results of conformity assessment procedures required by the applicable laws, regulations and administrative provisions of that Party specified in the relevant Sectoral Annex, including certificates and marks of conformity, that are conducted by the registered conformity assessment bodies of the other Party.

2. Each Party shall accept, in accordance with the provisions of this Agreement:

a) the confirmation of facilities conducted by the Competent Authorities of the other Party based upon the results of verification and in accordance with the criteria for confirmation stipulated in the laws, regulations and administrative provisions of that other Party as specified in the relevant Sectoral Annex; and

b) the data generated by confirmed facilities of the other Party.

ARTICLE 3

1. This Agreement applies to designation of conformity assessment bodies, conformity assessment procedures for products or processes, and to confirmation of facilities and data generated by them, covered by its Sectoral Annexes. Sectoral Annexes may consist of Part A and Part B.

2. Part A of Sectoral Annexes shall include, inter alia, provisions on scope and coverage.

3. Part B of Sectoral Annexes shall set out the following matters:

(a) the applicable laws, regulations and administrative provisions of each Party concerning the scope and coverage;

(b) the applicable laws, regulations and administrative provisions of each Party stipulating the requirements covered by this Agreement, all the conformity assessment procedures covered by this Agreement to satisfy such requirements and the criteria for designation of conformity assessment bodies, or the applicable laws, regulations and administrative provisions of each Party stipulating the criteria for confirmation of the facilities covered by this Agreement; and

(c) the list of Designating Authorities or Competent Authorities.

ARTICLE 4

1. Each Party shall ensure that Designating Authorities have the necessary power to designate, monitor (including verification), withdraw the designation of, suspend the designation of and withdraw the suspension of the designation of the conformity assessment bodies that conduct conformity assessment procedures based upon the requirements set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex.

2. Each Party shall ensure that Competent Authorities have the necessary power to conduct, in accordance with its applicable laws, regulations and administrative provisions, verification of facilities to confirm their compliance with the criteria for confirmation set out in the applicable laws, regulations and administrative provisions of that Party specified in the relevant Sectoral Annex.

ARTICLE 5

1. Each Party shall ensure, through appropriate means such as audits, inspections or monitoring, that the registered conformity assessment bodies fulfil the criteria for designation set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex. When applying the criteria for designation of the conformity assessment bodies, Designating Authorities of a Party should take into account the bodies' understanding of and experience relevant to the requirements set out in the applicable laws, regulations and administrative provisions of the other Party.

2. Each Party shall, in accordance with its applicable laws, regulations and administrative provisions and through appropriate means such as study audits, inspections or monitoring, ensure that the confirmed facilities fulfil the criteria for confirmation set out in the applicable

laws, regulations and administrative provisions of that Party specified in the relevant Sectoral Annex.

3. Each Party may request the other Party, by indicating in writing a reasoned doubt on whether a registered conformity assessment body or a confirmed facility complies with the criteria for designation or the criteria for confirmation set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex, respectively, to conduct verification of the conformity assessment body or the facility in accordance with the laws, regulations and administrative provisions of that other Party.

4. Each Party may, upon request, participate as an observer in the verification of conformity assessment bodies conducted by the Designating Authorities or the verification of facilities conducted by the Competent Authorities of the other Party, with the prior consent of such conformity assessment bodies or such facilities respectively, in order to maintain a continuing understanding of that other Party's procedures for verification.

5. The Parties shall, in accordance with the procedures to be determined by the Joint Committee to be established pursuant to Article 8, exchange information on methods, including accreditation systems, used to designate the conformity assessment bodies and to ensure that the registered conformity assessment bodies fulfil the criteria for designation and on methods to ensure that the confirmed facilities fulfil the criteria for confirmation.

6. Each Party should encourage its registered conformity assessment bodies to cooperate with the conformity assessment bodies of the other Party.

ARTICLE 6

1. In case of suspension of the designation of a registered conformity assessment body, the Party whose Designating Authority has suspended the designation shall immediately notify the other Party and the Joint Committee to that effect. The registration of that conformity assessment body shall be suspended from the time of receipt of the notification by the co-chairman of that other Party on the Joint Committee. The other Party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body prior to the suspension of the designation.

2. In case of lifting of the suspension of the designation of a registered conformity assessment body, the Party whose Designating Authority has lifted the suspension of the designation shall immediately notify the other Party and the Joint Committee to that effect. The suspension of the registration of that conformity assessment body shall be lifted from the time of receipt of the notification by the co-chairman of that other Party on the Joint Committee. The other Party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body from the time of lifting of the suspension of the registration.

ARTICLE 7

1. Each Party may contest the compliance with the criteria for designation or the criteria for confirmation set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex by a registered conformity assessment body or a confirmed facility of the other Party, respectively. Such contestation shall be notified to the Joint Committee and to that other Party in writing with an objective explanation of the reason

for the contestation. The Joint Committee shall discuss such contestation within 20 days following the date on which such notification is made.

2. Where the Joint Committee decides to conduct a joint verification, it will be conducted in a timely manner by the Parties with the participation of the Designating Authority that designated the contested conformity assessment body and with the prior consent of the conformity assessment body. The result of such joint verification shall be discussed in the Joint Committee with a view to resolving the issue as soon as possible.

3. The registration of the contested conformity assessment body shall be suspended 15 days after the date on which the notification is made or on the date on which the Joint Committee decides to suspend the registration, whichever is the sooner. The registration of the contested conformity assessment body shall remain suspended until the Joint Committee decides to lift the suspension of the registration of the conformity assessment body. In the event of such suspension, the contesting Party shall accept the results of conformity assessment procedures conducted by that conformity assessment body prior to the date of suspension.

4. The Joint Committee will decide on the actions to be taken by a Party or Parties with a view to resolving issues concerning the contestation of facilities as soon as possible.

5. The contesting Party shall not be obliged to accept the confirmation of and the data generated by the contested facility from the date on which the co-chairman of the other Party on the Joint Committee receives the notification referred to in paragraph 1 above until the date on which the Joint Committee decides otherwise.

ARTICLE 8

1. A Joint Committee made up of representatives of both Parties shall be established on the date of the entry into force of this agreement, as a body responsible for the effective functioning of this Agreement.

2. The Joint Committee shall take decisions and adopt recommendations by consensus. It shall meet at the request of either Party under the co-chairmanship of both Parties. The Joint Committee may establish sub-committees and delegate specific tasks to such sub-committees. It shall adopt its rules of procedure.

3. The Joint Committee may consider any matter related to the operation of this Agreement. In particular, it shall be responsible for and/or decide on:

(a) registration of a conformity assessment body, suspension of registration of a conformity assessment body, lifting of suspension of registration of a conformity assessment body, and termination of registration of a conformity assessment body;

(b) establishment and, unless otherwise decided, publication on a Sector by Sector basis, of lists of the registered conformity assessment bodies and the confirmed facilities;

(c) establishment of appropriate modalities of information exchange referred to in this Agreement; and

(d) appointment of experts from each Party for the joint verification referred to in paragraph 2 of Article 7 and sub-paragraph (c) of paragraph 1 of Article 9.

4. If any problem arises to the interpretation or application of this Agreement, the Parties shall seek an amicable solution through the Joint Committee.

5. The Joint Committee is responsible for coordinating and facilitating the negotiation of additional Sectoral Annexes.

6. Each Party shall provide the other Party and the Joint Committee, at least annually, with a list of the confirmed facilities.

7. Any decision made by the Joint Committee will be notified promptly in writing to each Party.

8. The Parties shall, through the Joint Committee:

(a) specify and communicate to each other the applicable articles or annexes contained in the laws, regulations and administrative provisions set out in the Sectoral Annexes;

(b) exchange information concerning the implementation of the applicable laws, regulations and administrative provisions specified in the Sectoral Annexes;

(c) notify each other of any scheduled changes in the laws, regulations and administrative provisions related to this Agreement prior to their entry into force; and

(d) notify each other of any scheduled changes concerning their Designating Authorities, Competent Authorities, the registered conformity assessment bodies and the confirmed facilities.

ARTICLE 9

1. The following procedure shall apply to the registration of a conformity assessment body:

(a) Each Party shall make a proposal that a conformity assessment body of that Party designated by its Designating Authority be registered under this Agreement, by presenting its proposal in writing, supported by necessary documents, to the other Party and the Joint Committee.

(b) The other Party shall consider whether the proposed conformity assessment body complies with the criteria for designation set out in the applicable laws, regulations and administrative provisions of that other Party specified in the relevant Sectoral Annex and indicate its position regarding the registration of that conformity assessment body within 90 days from the receipt of the proposal referred to in sub-paragraph (a) above. In such consideration, such other Party should assume that the proposed conformity assessment body complies with the aforementioned criteria. The Joint Committee shall take a decision whether to register the proposed conformity assessment body within 90 days from the receipt of the proposal.

(c) In the event that the Joint Committee cannot decide to register the proposed conformity assessment body, the Joint Committee may decide to conduct a joint verification or to request the proposing Party to conduct a verification of the proposed body with the prior consent of such body. After the completion of such verification, the Joint Committee may reconsider the proposal.

2. The proposing Party shall provide the following information in its proposal for registration of a conformity assessment body and keep such information up to date:

(a) the name and address of the conformity assessment body;

(b) the products or processes the conformity assessment body is authorised to assess;

(c) the conformity assessment procedures the conformity assessment body is authorised to conduct; and

(d) the designation procedure and necessary information used to determine the compliance of the conformity assessment body with the criteria for designation.

3. Each Party shall ensure that its Designating Authority withdraws the designation of a registered conformity assessment body when the Designating Authority considers that the conformity assessment body no longer complies with the criteria for designation set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex.

4. Each Party shall propose the termination of the registration of its conformity assessment body when that Party considers that the conformity assessment body no longer complies with the criteria for designation set out in the applicable laws, regulations and administrative provisions of the other Party specified in the relevant Sectoral Annex, or the Designating Authority of that Party withdraws the designation of a conformity assessment body. Proposals for terminating the registration of that conformity assessment body shall be made to the Joint Committee and the other Party. The registration of that conformity assessment body shall be terminated upon receipt of the proposal by the co-chairman of that other Party on the Joint Committee, unless otherwise determined by the Joint Committee.

5. In the case of a registration of a new conformity assessment body, the other Party shall accept the results of conformity assessment procedures conducted by that conformity assessment body from the date of the registration. In the event that the registration of a conformity assessment body is terminated, the other Party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body prior to the termination, without prejudice to paragraph 1 of Article 6 and paragraph 3 of Article 7.

ARTICLE 10

1. Nothing in this Agreement shall be construed to limit the authority of a Party to take measures it considers appropriate, for protecting health, safety or the environment or prevention of deceptive practices.

2. (a) The Competent Authority of a Party may conduct a verification on manufacturing facilities of the other Party with the prior consent of that other Party and of the manufacturing facilities concerned, for the purpose of deciding whether to continue to accept the confirmation of the manufacturing facilities concerned and the data generated by them pursuant to paragraph 2 of Article 2, where an emergency as defined in sub-paragraph (b) of this paragraph takes place. Such verification shall be carried out in a manner not inconsistent with the laws and regulations of that other Party and in accordance with the modalities to be decided pursuant to sub-paragraph (b) of this paragraph. The Party shall use the information obtained by its Competent Authority in connection with such verification only for the purpose above. The Competent Authority of that other Party may join such verification.

(b) The definition of the emergency and the modalities of such verification referred to in sub-paragraph (a) of this paragraph will be decided by the Joint Committee as part of the preparatory work to be done in accordance with the provisions of the relevant Sectoral Annex.

ARTICLE 11

1. Without prejudice to paragraph 2 of Article 2, nothing in this Agreement shall entail mutual acceptance of the standards or technical regulations of the Parties.

2. Nothing in this Agreement shall be construed to entail an obligation upon a Party to accept the result of the conformity assessment procedures of any third country.

3. Nothing in this Agreement shall be construed so as to affect the rights and obligations that either Party has as a Member to the WTO Agreement, including the WTO Agreement on Technical Barriers to Trade and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.

ARTICLE 12

This Agreement shall apply to the territory of Japan and to the territories in which the Treaty establishing the European Community is applied under the conditions laid down in that Treaty.

ARTICLE 13

Neither Party shall disclose any information obtained under this Agreement as confidential, unless otherwise required under the laws or regulations of each Party.

ARTICLE 14

1. This Agreement shall enter into force on the first day of the second month following the date on which the Parties exchange diplomatic notes informing each other that their respective internal procedures necessary to give effect to this Agreement have been completed.

2. Either Party may terminate this Agreement by giving the other Party six months written notice.

ARTICLE 15

1. The Sectoral Annexes to this Agreement are an integral part of this Agreement.

2. In case of conflict between the provisions of Part A of a Sectoral Annex and Articles 1 to 15 of this Agreement, the provisions of Part A of the Sectoral Annex shall prevail.

3. Laws, regulations and administrative provisions, Designating Authorities or Competent Authorities may be added to, deleted from or changed in Part B of the Sectoral Annexes by agreement between the Parties, in conformity with their applicable domestic procedures. They shall not change the scope and coverage stipulated in paragraph 1 of Part A of each Sectoral Annex unless they amend this Agreement.

4. If a Party introduces new or additional conformity assessment procedures within the same product coverage to satisfy the requirements set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex, the relevant lists contained in Part B of that Sectoral Annex shall be changed to set out the applicable laws, regulations and administrative provisions stipulating such new or additional conformity assessment procedures, in accordance with the procedures set out in paragraph 3 of Article 15.

This Agreement and its Annexes are drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Japanese, Portuguese, Spanish and Swedish languages. In case of divergence the English and Japanese versions shall prevail over the other language versions.

IN WITNESS WHEREOF, the undersigned, being duly authorised, have signed this Agreement.

Done at ……, this ……day of ……

For the Council
The President

ANNEX

SECTORAL ANNEX

ON

TELECOMMUNICATIONS TERMINAL EQUIPMENT

AND

RADIO EQUIPMENT

Part A

SCOPE AND COVERAGE

1. This Sectoral Annex applies to conformity assessment procedures for all telecommunications terminal equipment and radio equipment, which in European Community and Japan respectively are subject to conformity assessment procedures conducted by the conformity assessment body, as set out in the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex.

2. It is understood that the term “amendment” referred to in Part B of this Sectoral Annex includes the following cases that:

(a) a Party entirely or partially changes its applicable laws, regulations and / or administrative provisions listed in Part B of this Sectoral Annex, whether those names are changed or not;

(b) a Party terminates its applicable laws, regulations and /or administrative provisions listed in Part B of this Sectoiral Annex and adopts new laws, regulations and / or administrative provisions substituting the previous laws, regulations and / or administrative provisions, whether the previous names are changed or not; and

(c) a Party incorporates the whole or relevant part of its applicable laws, regulations and / or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and / or administrative provisions.

Part B

SECTION I

THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING TELECOMMUNICATIONS TERMINAL EQUIPMENT AND RADIO EQUIPMENT

EUROPEAN COMMUNITY	JAPAN
Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and amendments thereto.	Telecommunications Business Law (Law No. 86, 1984) and amendments thereto. Ordinance concerning Technical Conditions Compliance Approval and Certification of the Type for Terminal Equipment (Ordinance of the Ministry of Posts and Telecommunications No. 14, 1999) and amendments thereto. Radio Law (Law No. 131, 1950) and amendments thereto. Ordinance concerning Technical Regulations Conformity Certification of Specified Radio Equipment (Ordinance of the Ministry of Posts and Telecommunications No. 37, 1981) and amendments thereto

SECTION II

THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE REQUIREMENTS AND THE CONFORMITY ASSESSMENT PROCEDURES

EUROPEAN COMMUNITY	JAPAN
Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and amendments thereto. *For electrical safety*: Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits and amendments thereto, insofar as this Directive applies to equipment covered by this Sectoral Annex *For electromagnetic compatibility*: Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of Member States relating to electromagnetic compatibility and amendments thereto, insofar as this Directive applies to equipment covered by this Sectoral Annex	Telecommunications Business Law (Law No. 86, 1984) and amendments thereto. Ordinance concerning Terminal Facilities etc. (Ordinance of the Ministry of Posts and Telecommunications No. 31, 1985) and amendments thereto Ordinance concerning Technical Conditions Compliance Approval and Certification of the Type for Terminal Equipment (Ordinance of the Ministry of Posts and Telecommunications No. 14, 1999) and amendments thereto Radio Law (Law No. 131, 1950) and amendments thereto Ordinance concerning Regulating Radio Equipment (Ordinance of the Ministry of Posts and Telecommunications No. 18, 1950) and amendments thereto Ordinance concerning Technical Regulations Conformity Certification of Specified Radio Equipment (Ordinance of the Ministry of Posts and Telecommunications No. 37, 1981) and amendments thereto

SECTION III

DESIGNATING AUTHORITIES

EUROPEAN COMMUNITY	JAPAN
Designating Authorities of the European Community are the following authorities of the Member States of the European Community or authorities succeeding them. Belgium Institut belge des services postaux et des télécommunications Belgisch instituut voor postdiensten en telecommunicatie *For EMC aspects*: Ministère des Affaires Economiques Ministerie van Economische Zaken Denmark: Telestyrelsen Germany: Bundesministerium für Wirtschaft Greece: Ministry of Transport and Communications Spain: Ministerio de Fomento France: Ministère de l'économie, des finances et de l'industrie Ireland: Department of Transport, Energy and Communications Italy:	Designating Authorities of Japan are the following authorities or authorities succeeding them: *For Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and amendments thereto:* Ministry of Public Management, Home Affairs, Post and Telecommunication *For Council Directive 89/336/EC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits and amendments thereto:* Ministry of Public Management, Home Affairs, Posts and Telecommunications Ministry of Economy, Trade and Industry

Ministero dell'Industria, del Commercio e dell'Artigianato Luxembourg: Administration des Postes et Télécommunications Netherlands: De Minister van Verkeer en Waterstaat	
Austria: Bundesministerium für Wissenschaft und Verkehr Portugal: Instituto das Communicações de Portugal Finland: Liikennneministeriö/Trafikministeriet Sweden: *Under the authority of the Government of Sweden*: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) United Kingdom: Department of Trade and Industry	

SECTION IV:

THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE CRITERIA FOR DESIGNATION

The criteria to be applied by Japan in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The criteria to be applied by the European Community in designating Conformity Assessment Bodies to assess products against Japanese requirements
Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and amendments thereto Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, and amendments thereto Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto. Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives and amendments thereto, to be taken into account	Telecommunications Business Law (Law No. 86, 1984) and amendments thereto Ordinance concerning Technical Conditions Compliance Approval and Certification of the Type for Terminal Equipment (Ordinance of the Ministry of Posts and Telecommunications No. 14, 1999) and amendments thereto Radio Law (Law No. 131, 1950) and amendments thereto Ordinance concerning Technical Regulations Conformity Certification of Specified Radio Equipment (Ordinance of the Ministry of Posts and Telecommunications No. 37, 1981) and amendments thereto

SECTORAL ANNEX

ON

ELECTRICAL PRODUCTS

PART A

SCOPE AND COVERAGE

1. This Sectoral Annex applies to conformity assessment procedures for all electrical products which in European Community and Japan respectively are subject to conformity assessment procedures conducted by the conformity assessment body, as set out in the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex.

2. It is understood that the term “amendment” referred to in Part B of this Sectoral Annex includes the following cases that:

(a) a Party entirely or partially changes its applicable laws, regulations and / or administrative provisions listed in Part B of this Sectoral Annex, whether those names are changed or not;

(b) a Party terminates its applicable laws, regulations and /or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and / or administrative provisions substituting the previous laws, regulations and / or administrative provisions, whether the previous names are changed or not; and

(c) a Party incorporates the whole or relevant part of its applicable laws, regulations and / or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and / or administrative provisions.

PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING ELECTRICAL PRODUCTS	
European Community	**Japan**
Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, and amendments thereto, excluding equipment falling within the scope of the Sectoral Annex on Telecommunications Terminal Equipment and Radio Equipment With regard to the electromagnetic compatibility aspects of the above products, Council Directive 89/336/EEC of May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto	Electrical Appliance and Material Safety Law (Law No. 234, 1961) and amendments thereto Cabinet Order of the Electrical Appliance and Material Safety Law (Cabinet Order, No. 324, 1962) and amendments thereto

SECTION II: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE REQUIREMENTS AND THE CONFORMITY ASSESSMENT PROCEDURES	
European Community	**Japan**
Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, and amendments thereto Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, and amendments thereto, insofar as this Directive applies to equipment covered by this Sectoral Annex	Electrical Appliance and Material Safety Law (Law No. 234, 1961) and amendments thereto Ordinance of the Electrical Appliance and Material Safety Law (Ministerial Ordinance of the Ministry of International Trade and Industry, No. 84, 1962) and amendments thereto Ordinance concerning Technical Requirements for Electrical Appliances and Materials (Ministerial Ordinance of the Ministry of International Trade and Industry, No. 85, 1962) and amendments thereto Working Regulations for Ordinance concerning Technical Requirements for Electrical Appliances and Materials (Public Utilities Department, Agency of Natural Resources and Energy, Ministry of International Trade and Industry, No. 192, 1975) and amendments thereto, which implements the Ordinance concerning Technical Requirements for Electrical Appliances and Materials

SECTION III: DESIGNATING AUTHORITIES	
European Community	**Japan**
Designating Authorities of the European Community are the following authorities of the Member States of the European Community or authorities succeeding them **Belgium** Ministère des Affaires Economiques Ministerie van Economische Zaken **Denmark** Boligministeriet *For EMC aspects:* Telestyrelsen **Germany** Bundesministerium für Arbeit und Sozialordnung *For EMC aspects:* Bundesministerium für Wirtschaft und Technologie **Greece** Ministry of Development **Spain** Ministerio de Industria y Energia **France** Ministère de l'Economie, des finances et de l'industrie **Ireland** Department of Enterprise and Employment	Ministry of Economy Trade and Industry or an authority succeeding this ministry

Italy Ministero dell'Industria, del Commercio e dell'Artigianato **Luxembourg** Ministère des Transports **Netherlands** Staat der Nederlanden **Austria** Bundesministerium für wirtschaftliche Angelegenheiten **Portugal** *Under the authority of the Government of Portugal*: Instituto Português da Qualidade **Finland** Kauppa-ja teollisuusministeriö Handels-och industriministeriet **Sweden** *Under the authority of the Government of Sweden*: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) **United Kingdom** Department of Trade and Industry	

SECTION IV : THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE CRITERIA FOR DESIGNATION	
The criteria to be applied by Japan in designating Conformity Assessment Bodies to assess products against the European Community's requirements	**The criteria to be applied by the European Community in designating Conformity Assessment Bodies to assess products against Japan's requirements**
Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, and amendments thereto Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives and amendments thereto, to be taken into account	Electrical Appliance and Material Safety Law (Law No. 234, 1961) and amendments thereto Cabinet Order of the Electrical Appliance and Material Safety Law (Cabinet Order, No. 324, 1962) and amendments thereto Ordinance of the Electrical Appliance and Material Safety Law (Ministerial Ordinance of the Ministry of International Trade and Industry, No. 84, 1962) and amendments thereto

SECTORAL ANNEX

ON

GOOD LABORATORY PRACTICE

(GLP)

FOR CHEMICALS

PART A

1. This Sectoral Annex applies to:

(a) the confirmation of the compliance of test facilities with the principles of GLP for the testing of chemicals, being either substances or preparations, as set out in the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex; and,

(b) the acceptance of the data generated by confirmed test facilities.

2. (a) For the purpose of this Sectoral Annex:

(i) "criteria for confirmation" are the principles of GLP as stipulated in the laws, regulations and administrative provisions of each Party specified in Section III of Part B of this Sectoral Annex and that are consistent with Annex II of the OECD Council Decision of 12 May 1981 [C(81)30 (Final)] as amended by OECD Council Decision of 26 November 1997 [C(97) 186 (Final)]; and

(ii) "verification" means the monitoring of the compliance of a test facility with the principles of GLP by procedures such as study audits and inspections that are set out in the laws, regulations and administrative provisions of each Party specified in Section III of Part B of this Sectoral Annex and that are consistent with OECD Council Decision – Recommendation of 2 October 1989 [C(89) 87(Final)], and in particular its Annexes I and II, as amended by the OECD Council Decision of 9 March 1995 [C(95)8(Final)].

(b) For the purpose of this Sectoral Annex, any term, unless otherwise defined in this Agreement, has the meaning assigned to it in the "OECD Principles of Good Laboratory Practice" as contained in Annex II of the OECD Council Decision of 12 May 1981 [C (81) 30 (Final)], the "Guides for Compliance Monitoring Procedures for Good Laboratory Practice" as contained in Annex I of the OECD Council Decision – Recommendation of 2 October 1989 [C (89) 87 (Final)], the GLP Consensus Document "The Application of the GLP Principles to Field Studies" (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 6), and all amendments made thereto.

(c) It is understood that the term "amendment" referred to in Part B of this Sectoral Annex includes the following cases that:

(i) a Party entirely or partially changes its applicable laws, regulations and / or administrative provisions listed in Part B of this Sectoral Annex, whether those names are changed or not;

(ii) a Party terminates its applicable laws, regulations and /or administrative provisions listed in Part B of this Sectoiral Annex and adopts new laws, regulations and / or administrative provisions substituting the previous laws, regulations and / or administrative provisions, whether the previous names are changed or not; and

(iii) a Party incorporates the whole or relevant part of its applicable laws, regulations and / or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and / or administrative provisions.

(d) In making amendments to the laws, regulations and administrative provisions specified in Section III of this Sectoral Annex, the Parties should take account of the need to maintain consistency with the relevant decisions and recommendations of the OECD.

3. With respect to paragraph 2 of Article 2 of this Agreement, each Party shall, as a result of the acceptance of the confirmation of test facilities by the Competent Authorities of the other Party, accept the data for a test item generated by the confirmed test facilities as equivalent to the data generated by its own test facilities which are confirmed to be compliant with the principles of GLP, taking into account the equivalence of GLP compliance monitoring programme of both Parties, which are consistent with the OECD Council Decision-Recommendation of 2 October 1989 [C(89)87 (Final)] as amended by the OECD Council Decision of 9 March 1995 [C (95) 8 (Final)], provided:

(a) a certificate or an alternative document on the GLP compliance status of the test facility issued by the Competent Authority of that other Party, in accordance with the applicable laws, regulations and administrative provisions of that other Party specified in Section III of Part B of this Sectoral Annex, is attached to the data; and

(b) the testing for which the data is generated is covered by the principles of GLP in both Parties pursuant to the applicable laws, regulations and administrative provisions of each Party.

4. (a) The list of the confirmed facilities referred to in paragraph 3 and 6 of Article 8 of this Agreement shall be provided in an appropriate agreed format and include the following information:

(i) the name and address of the test facility;

(ii) the dates of verification or confirmation;

(iii) the GLP compliance status; and

(iv) the areas of expertise as listed in point 4 of the Appendix to Annex III of the OECD Council Decision-Recommendation of 2 October 1989 [C (89) 87 (Final)].

(b) Each Party shall, to the extent possible, provide the other Party with additional information on the confirmed facilities upon a reasoned request by that other Party.

(c) Each Party shall transmit to the other Party, without delay, information on any withdrawal of the certificate of a confirmed test facility if the facility has been found to be non-compliant with the principles of GLP.

5. (a) Each Party may request the other Party, by indicating in writing a reasoned doubt on whether a study was conducted in accordance with the principles of GLP, to conduct further inspections or study audits on a confirmed test facility, in accordance with the applicable laws, regulations and administrative provisions of that other Party.

(b) The requested Party shall inform the requesting Party of the results of the inspections or study audits, or provide an explanation why such an inspection or study audit has not been carried out.

(c) The requesting Party shall not be obliged to accept the data generated by the test facility concerned from the date on which the request is made, until the results of the further inspection or study audit conducted by the Competent Authority of the requested Party have re-confirmed the compliance of the test facility with the principles of GLP.

(d) If, in exceptional cases, doubts persist, and the requesting Party can justify a specific concern, that Party may contest the compliance of the test facility concerned in accordance with the provisions of Article 7 of this Agreement.

PART B

SECTION I

THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE COVERAGE OF CHEMICALS SUBJECT TO TESTING IN ACCORDANCE WITH THE PRINCIPLES OF GLP

EUROPEAN COMMUNITY	JAPAN
Medicinal Products: Council Directive 87/19/EEC of 22 December 1986 amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products and amendments thereto Commission Directive 91/507/EEC of 19 July 1991 modifying the Annex to Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of propietary medicinal products and amendments thereto Veterinary Medicinal Products: Council Directive 87/20/EEC of 22 December 1986 amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products and amendments thereto	<u>Pharmaceuticals:</u> Pharmaceutical Affairs Law (Law No. 145, 1960) and amendments thereto, which is implemented by: Ordinance of the Enforcement of the Pharmaceutical Affairs Law (Ministerial Ordinance of the Ministry of Health and Welfare, No. 1, 1961) and amendments thereto <u>Veterinary Drugs:</u> Pharmaceutical Affairs Law (Law No. 145, 1960) and amendments thereto, which is implemented by: Ordinance on the Control of Veterinary Drugs (Ministerial Ordinance of the Minister of Agriculture, Forestry, No. 3, 1961) and amendments thereto <u>Agricultural Chemicals:</u> Agricultural Chemicals Regulation Law (Law No. 82, 1948) and amendments thereto

Commission Directive 92/18/EEC of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products and amendments thereto Plant Protection Products: Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market as last amended by Commission Directive 95/35/EC of 14 July 1995 and amendments thereto Biocides: Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market and amendments thereto Feed additives: Council Directive 87/153/EEC of 16.2.87 fixing guidelines for the assessment of additives in animal nutrition as amended by Commission Directive 94/40/EC of 22 July 1994, and amendments thereto New and Existing Chemicals: Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and amendments thereto	Feed additives: Laws concerning Safety Assurance and Quality Improvement of Feed (Law No. 35, 1953) and amendments thereto, which is implemented by: The Establishment of the Standards for Evaluation of Feed Additives (Livestock Industry Bureau and Fisheries Agency, Ministry of Agriculture, Forestry and Fisheries, 4-Chiku-A-201, 1992) and amendments thereto New Chemicals and Designated Chemicals: Law concerning the Examination and Regulation of Manufacture etc. of Chemical Substances (Law No. 117, 1973) and amendments thereto, which is implemented by: Ordinance Prescribing Test Items Relating to New Chemical Substances and Toxicity Research of Designated Chemical Substances (Ministerial Ordinance of the Prime Minister, the Minister of Health and Welfare and the Minister of International Trade and Industry, No. 1, 1974) and amendments thereto Chemicals generated in the workplace: Industrial Safety and Health Law (Law No. 57, 1972) and amendments thereto, which is implemented by: Ordinance on Industrial Safety and Health (Ministerial Ordinance of the Ministry of Labour, No. 32, 1972) and amendments thereto

Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations and amendments thereto Council Regulation (EEC) No. 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances and amendments thereto <u>Food additives:</u> Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs and amendments thereto Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs and amendments thereto <u>Cosmetics:</u> Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products and amendments thereto	

SECTION II

COMPETENT AUTHORITIES

EUROPEAN COMMUNITY	**JAPAN**
Competent Authorities of the European Community are the following authorities or authorities succeeding them **Austria** *For all:* Federal Ministry for Agriculture, Forestry, Environment and Water Management Belgium *For all:* Institut Scientifique de la Santé Publique Denmark *For industrial chemicals:* Danish Agency for Trade and Industry *For medicinal products:* Danish Medicines Agency Finland: For all: National Product Control Agency for Welfare and Health **France** For industrial chemicals, pesticides and other than medicinal products and cosmetics: Groupe Interministériel des Produits Chimiques For medicinal products (except veterinary medicinal products) and	Competent Authorities of Japan are the following authorities or authorities succeeding them *For Pharmaceuticals:* Ministry of Health, Labour and Welfare *For Veterinary Drugs:* Ministry of Agriculture, Forestry and Fisheries *For Agricultural Chemicals:* Ministry of Agriculture, Forestry and Fisheries *For Feed Additives:* Ministry of Agriculture, Forestry and Fisheries *For New Chemicals and Designated Chemicals:* Ministry of Health, Labour and Welfare Ministry of Economy Trade and Industry *For Chemicals generated in the work place:* Ministry of Health, Labour and Welfare

cosmetics: Agence Française de Sécurité Sanitaire des Produits de Santé For veterinary medicinal products: Agence Française de Sécurité Sanitaire des Aliments Agence nationale du médicament vétérinaire	

Germany *For all:* Federal Ministry for Environment, Nature Conservation and Nuclear Safety Greece *For all:* General Chemical State Laboratory Ireland *For all:* Irish Laboratory Accreditation Board (ILAB) Italy *For all:* Ministry of Health Netherlands For all: Ministry of Health, Welfare and Sports Inspectorate for Health Protection (GLP Department) **Portugal** For industrial chemicals and pesticides: Instituto Portugues da Qualidade IPQ Ministerio da Industria e Comercio For medicinal products and veterinary medicinal products: Instituto National de Farmacia e do Medicamento **Spain**	

For medicinal products: Agencia Española del Medicamento - Subdirección General de Seguridad de Medicamentos For pesticides: Ministerio de Agricultura, Pesca y Alimentación	

Sweden *For medicinal products, hygiene and cosmetics products:* Läkemedelsverket (Medical Products Agency) *For all other products:* Styrelsen för ackreditering och teknisk (Swedish Board for Accreditation and Conformity Assessment – SWEDAC) United Kingdom *For all:* Department of Health GLP Monitoring Authority	

SECTION III

THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE PRINCIPLES OF GLP, VERIFICATION AND CONFIRMATION

EUROPEAN COMMUNITY	JAPAN
Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances as last amended by Commission Directive 1999/11/EC of 8 March 1999 and amendments thereto Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of Good Laboratory Practice (GLP), as last amended by Commission Directive 1999/12/EC of 8 March 1999 and amendments thereto	<u>Pharmaceuticals:</u> Pharmaceutical Affairs Law (Law No. 145, 1960) and amendments thereto, which is implemented by: (a) Ordinance Prescribing Standards for the Conduct of Non-clinical Laboratory Studies on Safety of Drugs (Ministerial Ordinance of the Ministry of Health and Welfare, No. 21, 1997) and amendments thereto; (b) the Treatment of Materials Concerning Non-clinical Laboratory Studies on Safety of Drugs Which Should be Attached to the Application for the Product (import) Approval (Evaluation Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Yakushin No. 253; Safety Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Yakuan No. 29, 1997) and amendments thereto; and (c) The Establishment of the Guidelines for the Conduct of GLP On-site Inspection (Evaluation Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Yakushin No. 254; Safety Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Yakuan No. 30, 1997) and amendments thereto <u>Veterinary Drugs:</u> Pharmaceutical Affairs Law (Law No. 145, 1960) and amendments thereto, which is implemented by: (a)Ordinance prescribing Standards for the Conduct of Non-clinical Laboratoy Studies

	on Safety of Veterinary Drugs (Ministerial Ordinance of the Ministry of Agriculture, Forestry and Fisheries, No. 74, 1997) and amendments thereto; and (b) Management of Pharmaceutical Affairs Law (Livestock Industry Bureau, Ministry of Agriculture, Forestry and Fisheries, 12-Chiku-A-No. 729, 2000) and amendments thereto <u>Agricultural Chemicals:</u> Agricultural Chemicals Regulation Law (Law No. 82, 1948) and amendments thereto, which is implemented by: The Good Laboratory Practice for toxicological studies on agricultural chemicals (Agricultural Production Bureau, Ministry of Agriculture, Forestry, and Fisheries, 11-Nosan- No. 6283, 1999) and amendments thereto

	Feed additives: Laws concerning Safety Assurance and Quality Improvement of Feed (Law No. 35, 1953) and amendments thereto, which is implemented by: (a) The Good Laboratory Practice on feed additives (Livestock Industry Bureau and Fisheries Agency, Ministry of Agriculture, Forestry and Fisheries, 63-Chiku-A-No. 3039, 1988) and amendments thereto; and (b) The Establishment of the Guidelines for the Inspection based on the Good Laboratory Practice on Feed Additives (Livestock Industry Bureau and Fisheries Agency, Ministry of Agriculture, Forestry and Fisheries, 1-Chiku-A-No. 3441, 1990) and amendments thereto New Chemicals and Designated Chemicals: Law concerning the Examination and Regulation of Manufacture etc. of Chemical Substances (Law No. 117, 1973) and amendments thereto, which is implemented by: (a) Standard Concerning Testing Facility Provided in Article 4 of the Ordinance Prescribing Test Items Relating to New Chemical Substances and Toxicity Research of Designated Chemical Substances (Planning and Coordination Bureau, Environmental Agency, Kanpogyou No. 39; Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Yakuhatsu No. 229; Basic Industries Bureau, Ministry of International Trade and Industry, 59 Kikyoku No. 85, 1984) and amendments thereto; and

	(b) Test Results Used as Criteria for Determination at the Examination etc. of New Chemical Substances (Environmental Health Bureau, Ministry of Health and Welfare, Eisei No. 39; Basic Industries Bureau, Ministry of International Trade and Industry, 63 Kikyoku No. 822, 1988) and amendments thereto <u>Chemicals generated in the workplace:</u> Industrial Safety and Health Law (Law No. 57, 1972) and amendments thereto, which is implemented by: (a) Public Notification of the Standard to be Satisfied by the Test Facility etc. under the Provision of Article 34-3 (2) of the Ordinance on Industrial Safety and Health (Notification of the Ministry of Labour, No. 76, 1988) and amendments thereto; (b) The Enforcement of the Ordinance to amend a Part of the Ordinance on Industrial Safety and Health, Ordinance to Amend a Part of the Ordinance on Safety of Boiler and High Pressure Container, and the Ordinance to Amend a Part of the Ordinance on Preventing Organic Solvents Hazard, etc. (Labour Standards Bureau, Ministry of Labour, Kihatsu No. 602, 1988) and amendments thereto; and (c) Establishment of the Guideline of Certification of Compliance with GLP under the Industrial Safety and Health Law Regarding Test Facility, etc. (Labour Standards Bureau, Ministry of Labour, Kihatsu No. 123, 1989) and amendments thereto

SECTORAL ANNEX

ON

GOOD MANUFACTURING PRACTICE

(GMP)

FOR MEDICINAL PRODUCTS

PART A

1. This Sectoral Annex applies to:

(a) the confirmation of the compliance with GMP requirements of manufacturing facilities for medicinal products to which the GMP requirements of both Parties are applied in accordance with the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex; and

(b) the acceptance of the data generated by confirmed manufacturing facilities (the certificate issued by confirmed manufacturing facilities in accordance with the provisions of Part A of this Sectoral Annex).

2. For the purpose of this Sectoral Annex:

(a) The term "medicinal products" means drugs which are industrially manufactured for human use as defined in the laws, regulations and administrative provisions of Japan specified in Section I of Part B of this Sectoral Annex, and medicinal products and intermediate products which are industrially manufactured for human use as defined in the laws, regulations and administrative provisions of the European Community in Section I of Part B of this Sectoral Annex.

The definition of medicinal products above may include medicinal products intended for clinical trials, active ingredients, chemical and biological pharmaceuticals, immunologicals, radiopharmaceuticals, stable medicinal products derived from human blood or human plasma and, where appropriate, vitamins, minerals and herbal medicines.

(b) The term “criteria for confirmation” means the GMP requirements.

(c)The term "Good Manufacturing Practice (GMP)" means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications.

(d) The term "inspection" means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP requirements including the requirements of the applicable marketing authorisation or product specifications. Such inspection is conducted in accordance with laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex carried out by a Competent Authority listed in Section II of Part B of this Sectoral Annex, and may include pre-marketing and post-marketing inspection.

(e) It is understood that the term "amendment" referred to in Part B of this Sectoral Annex includes the following cases that:

(i) a Party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether those names are changed or not;

(ii) a Party terminates its applicable laws, regulations and /or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and / or administrative

provisions substituting the previous laws, regulations and / or administrative provisions, whether the previous names are changed or not; and

(iii) a Party incorporates the whole or relevant part of its applicable laws, regulations and / or administrative provisions listed in Part B of this Sectoral Annex into another laws, regulations and/or administrative provisions.

3. This Agreement does not cover mutual recognition of batch release (Kentei) referred to in Article 43 of the Pharmaceutical Affairs Law (Law No. 145, 1960) of Japan and batch release referred to in Article 4 of Directive 89/342/EEC of 3 May 1989 and in Article 4 of Directive 89/381/EEC of 14 June 1989 of the European Community.

4. With respect to paragraph 2 of Article 2 of this Agreement, each Party shall, as a result of the acceptance of confirmation of manufacturing facilities carried out by the Competent Authorities of the other Party, accept, regarding the medicinal products for which its marketing authorization has been issued or for which product specifications are applicable, the certificate issued by the confirmed manufacturing facilities of the conformity of each batch to the marketing authorization or product specifications and exempt the importers from the testing of each batch, in accordance with the laws, regulations and administrative provisions of each Party specified in the Section I of Part B of this Sectoral Annex, taking into account the equivalence of GMP requirements of both Parties, provided that:

(a) such certificate is issued by the confirmed manufacturing facilities on the results of a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks;

(b) the certificate contains a statement that the product has been manufactured in conformity with GMP requirements; and

(c) both Parties apply the equivalent GMP requirements to the products of which the certificate is issued.

5. In the certificate issued by the confirmed manufacturing facilities and related to each batch to be exported, as referred to in paragraph 4 above, it will be certified, through the testing which is required for the manufacturing of medicinal products in accordance with the laws, regulations and administrative provisions of each Party specified in Section II of Part B of this Sectoral Annex, that each batch of medicinal products is manufactured as required by the applicable marketing authorisation or product specifications of the importing Party.

6. A sub-committee of the Joint Committee will be established in particular to monitor the progress of the preparatory work set out in paragraph 9 of this Sectoral Annex and the operation of this Sectoral Annex. It will report to the Joint Committee.

7. (a) The Parties will exchange information on, in particular:

(i) GMP for specific products or classes of products;

(ii) new technical guidance or inspection procedures;

(iii) quality defect, batch recalls, counterfeiting and other problems concerning quality; and

(iv) any suspension or withdrawal of a manufacturing authorisation.

(b) The Parties will agree detailed alert procedures through the sub-committee of the Joint Committee to fulfil specific objectives of this Sectoral Annex.

(c) Equivalence of GMP for specific products or classes of products will be coordinated according to a procedure established by the sub-committee of the Joint Committee.

(d) Notwithstanding paragraph 6 of Article 8 of this Agreement, each Party shall provide the other Party and the Joint Committee with a list of the confirmed manufacturing facilities at the frequency to be decided by the Joint Committee.

(e) Each Party will, upon reasoned request by the other Party, provide a copy of the most recent inspection report on a confirmed facility within 30 days from the date of the request. If the requested Party conducts an additional inspection, that Party will provide a copy of the report of such additional inspection to the requesting Party within 60 days from the date of the request. If after the exchange of inspection reports there remains serious cause for concern on whether a manufacturing facility in the other Party complies with GMP requirements, each Party may request the other Party to conduct further inspections on that facility.

(f) The Competent Authority of a Party will, upon request by an exporter, importer or the Competent Authority of the other Party, confirm that a manufacturing facility in its territory:

(i) is appropriately authorised to manufacture medicinal products in accordance with its laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex;

(ii) is regularly inspected by the Competent Authorities; and

(iii) complies with its GMP requirements that are recognised by both Parties as equivalent.

8. With regard to paragraph 2 of Article 5, the exporting Party shall, in accordance with its applicable laws, regulation and administrative provisions, inspect periodically the manufacturing facilities in order to ensure that the facilities fulfil its GMP requirements set out in the laws, regulations and administrative provisions of that Party specified in Section I of Part B of this Sectoral Annex.

9. (a) Articles 2, 4, 5, 7 and sub-paragraph (a) of paragraph 2 of Article 10 relating to this Sectoral Annex and the provisions of this Sectoral Annex other than paragraph 6 and sub-paragraph (b) of paragraph 7 and this paragraph shall not be applied before the thirtieth day after the date of exchange of diplomatic notes confirming each other that the preparatory work is completed. Such exchange of diplomatic notes is expected to take place within 18 months after the entry into force of this Agreement.

(b) Through the preparatory work, the Parties shall reconfirm the equivalence of GMP requirements and their implementation through the Joint Committee. The Joint Committee will decide the detailed procedures for implementing this Sectoral Annex.

PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING MEDICINAL PRODUCTS, GMP REQUIREMENTS FOR MEDICINAL PRODUCTS, VERIFICATION AND CONFIRMATION	
European Community	**Japan**
Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and amendments thereto Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and amendments thereto 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 and amendments thereto Council Regulation (EEC) No 2309/93 of 22 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 and amendments thereto The latest version of the 'Guide to Good Manufacturing Practice', Volume 4 of The rules governing medicinal products in the European Union and amendments thereto.	Pharmaceutical Affairs Law (Law No.145, 1960) and amendments thereto Enforcement Order of the Pharmaceutical Affairs Law (Cabinet Order No. 11, 1961) and amendments thereto Medicinal Products Stipulated in Article 1-2, Paragraph 1, Item 7 and 8 of Enforcement Order of the Pharmaceutical Affairs Law and Designated by the Minister for Health and Welfare Hereby (Public Notification of the Ministry of Health and Welfare, No.17, 1994) and amendments thereto Ordinance for Buildings and Facilities for Pharmacies, etc.(Ministerial Ordinance of the Ministry of Health and Welfare, No.2, 1961) and amendments thereto Ordinance for Manufacturing Control and Quality Control for Drugs and Quasi Drugs (Ministerial Ordinance of the Ministry of Health and Welfare, No.16, 1999) and amendments thereto Ordinance for Imported Drugs and Quasi Drugs Management and Quality Control (Ministerial Ordinance of the Ministry of Health and Welfare, No.62, 1999) and amendments thereto

SECTION II: COMPETENT AUTHORITIES

European Community	Japan
Competent Authorities of the European Community are the following authorities of the Member States of the European Community or authorities succeeding them Belgium Inspection Générale de la Pharmacie Algemene Farmaceutische Inspectie Denmark Lagemiddelstyrelsen Germany Bundesgesundheitsministerium Paul-Ehrlich Institut (biologicals only) Greece Ministry of Health and Welfare National Drug Organisation (E.O.F.) Spain Ministerio de Sanidad y Consumo Subdirección General de Control Farmacéutico France Agence du Médicament Ireland Irish Medicines Board Italy	Ministry of Health, Labour and Welfare or an authority succeeding this ministry

Ministero della Sanita Dipartimento Farmaci e Farmacovigilanza Luxembourg Division de la Pharmacie et des Médicaments Netherlands De Minister van Volksgezondheid, Welzijn, en Sport Inspectie voor de Gezondheidszorg Austria Bundesministerium für Arbeit, Gesundheit und Soziales Portugal Instituto da Farmácia e do Medicamento - INFARMED Finland Lääkelaitos/Läkemedelsverket (National Agency for Medicines) Sweden Läkemedelsverket (Medical Products Agency) United Kingdom Medicines Control Agency European Community European Agency for the Evaluation of Medicinal Products	

FINAL ACT

The undersigned:

The representative of

The EUROPEAN COMMUNITY, hereinafter referred to as “the Community”,

of the one part, and

the representative of Japan,

of the other part,

meeting for the signature of the Agreement on Mutual Recognition between the European Community and Japan, hereinafter referred to as the “Agreement”, have signed the following texts:

the Agreement including its Sectoral Annexes relating to:

1. Telecommunications Terminal Equipment and Radio Equipment

2. Electrical Products

3. Good Laboratory Practice (GLP) for Chemicals

4. Good Manufacturing Practice (GMP) for Medicinal Products

The representative of the Community and the representative of Japan have made the Joint Declarations and exchanges of letters listed below and annexed to this Final Act:

– Joint Declaration on future negotiations on the Mutual Recognition Agreement between Japan and the European Community

– Joint Declaration on international guides or recommendations concerning the technical competence of conformity assessment bodies (CABs)

– Joint Declaration on facilitating market access

– Exchange of letters concerning completeness of the Sectoral Annexes

– Exchange of letters on the preparatory work for the Sectoral Annex on GMP for Medicinal Products and information exchange

– Exchange of letters on the use of languages

JOINT DECLARATIONS
CONCERNING THE AGREEMENT ON MUTUAL RECOGNITION BETWEEN JAPAN AND THE EUROPEAN COMMUNITY

Upon the signing of the Agreement on Mutual Recognition between Japan and the European Community the Government of Japan (GOJ) and the European Community (EC) state the following with regard to the Agreement.

1. On future negotiations on the Mutual Recognition Agreement between Japan and the EC

   To build on this Agreement, the GOJ and the EC will commence the negotiations on the further extension of the sectoral coverage of the Agreement two years from the date that the Agreement enters into force. In particular, the GOJ and the EC express their intention to commence negotiations on Medical Devices and on Pressure Equipment within that period.

2. On international guides or recommendations concerning the technical competence of Conformity Assessment Bodies (CABs)

   The GOJ and the EC express their intention to consider the relevant guides or recommendations issued by international standardisation bodies as an indication of adequate technical competence of CABs with regard to the implementation of the applicable requirements of both Parties under the Agreement.

3. On facilitating market access

   The GOJ and the EC recognise that the significance of the Agreement lies in promoting trade and facilitating effective market access between Japan and the EC with regard to conformity assessment of products and confirmation of facilities covered under the agreement.

EXCHANGE OF LETTERS

CONCERNING COMPLETENESS OF THE SECTORAL ANNEXES

The [European Commission][Government of Japan] confirms that the Sectoral Annexes of the Agreement on Mutual Recognition between the European Community and Japan contain all existing third party conformity assessment or compliance procedures relating to requirements, products or data covered by those Sectoral Annexes.

EXCHANGE OF LETTERS ON THE PREPARATORY WORK FOR THE SECTORAL ANNEX ON GMP FOR MEDICINAL PRODUCTS AND INFORMATION EXCHANGE

The [European Community][GOJ] underlines its commitment to a thorough and speedy implementation of the preparatory work required by paragraph 9 of the Sectoral Annex on GMP for Medicinal Products. It will be guided in its task by the needs to set out the phases of preparatory work, and the components of a GMP compliance and two-way alert programmes against which reconfirmation of equivalence will take place taking into account the previous experiences.

The [EC][GOJ] will organise an exchange of information, including at least one seminar which would, inter alia, cover the criteria for designation and the criteria for confirmation in the coming months.

EXCHANGE OF LETTERS ON THE USE OF LANGUAGES

The [European Community][GOJ] will in exchanging information, including, for example, GMP inspection reports, under the Agreement use their own languages with a summary in English unless otherwise agreed. It is appropriate that the Joint Committee looks into this matter at an early opportunity.

RECORD OF DISCUSSION

In connection with the negotiations on the Agreement on Mutual Recognition between Japan and the European Community, signed at []today (hereinafter referred to as the "Agreement"), the undersigned hereby wish to record the following:

1. It is confirmed that the term "administrative provisions" referred to in the Agreement means measures taken by the relevant administrative authority(ies) to implement any relevant laws and regulations.

2. It is confirmed by the European Community that international agreements which it has concluded are directly applicable by it in its territory and binding upon its institutions and Member States.

For Japan: For the European Community:

FINANCIAL Statement 2001-2005

External trade relations – Mutual Recognition Agreement

1. TITLE

External Trade Relations-

Mutual Recognition Agreements with Japan.

2. BUDGETARY HEADINGS: B7-8500

A-7010

3. LEGAL BASIS

- Article 133 of the Treaty of Rome

- Proposal for Council decisions N° .... on the implementation by the European Community of a mutual recognition agreement with Japan.

4. DESCRIPTION OF OPERATION :

4.1 General objective:

The purpose of this agreement is to establish mutual recognition of certification of conformity of products with technical regulations or standards of the partner 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 Agreement 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 will be awarded according to the Commission's "Vademecum on Grant Management". Grants may 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 will be awarded according to the rules of the "Vademecum on Grant Management".

A. Attendance at Joint Committee

These will be attended by Commission officials and some experts from the Member States. Travel and per diem expenses should be foreseen within the normal range of such expenses. The travel expenditure for officials will be covered by the "Mission budget" (A-7010). The reimbursement of travel and related expenses for experts will be made on line B7-8500.

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 experts from the Member States. Travel and per diem expenses should be foreseen within the normal range of such expenses. The travel expenditure for officials will be covered by the "Mission budget" (A-7010). The reimbursement of travel and related expenses for experts will be made on line B7-8500.

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 Euro 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 (4 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 Euro.

7.2 Breakdown by elements of the operation

"Trade Agreements with important Trading Partners"

For 2001, this involves the following calculation:

Budget Heading	Amounts (Euro)	Method of calculation	
		No. of missions	Standard Unit cost
Joint Committee[3] B7-8500	8 660	Bxl 1 Japan 2	Japan: Travel: 3 000 Euro; per diem: 260 Euro
Joint Sub-Committee[3] B7-8500	37 896	London 8 Japan 8	London: Travel: 360 Euro; per diem: 199 Euro
Seminars B7-8500	19 520	Japan 4 Bxl 4	Brussels: Travel: 800 Euro; per diem: 150 Euro
Verifications B7-8500	18 900	Japan 5	
Information B7-8500	10 000		
B7-8500: Total	94 976	32	

In Euro

(current prices)

Breakdown	Year 2001	Year 2002	2003	2004	2005	Total 2001-2005

[3] These will be attended by Commission officials and some experts from the Member States.

A. Joint Committee	8.660	8 660	8 660	1 250	7 560	34 790
B. Joint Sub-Committee	37 896	37 896	9 474	9 474	9 474	104 214
C. Seminars	19 520	19 520				39 040
D. Verifications	18 900	18 900	8 600	8 600	8 600	63 600
E. Information	10 000	10 000	10 000			30 000
Total	94 976	94 976	36 734	19 324	25 634	271 644

7.3 Indication of the timetable for commitment and payment appropriations

1000 Euro

	Year 2001	2002	2003	2004	2005	2006 and following years	Total
Schedule of Commitment	95	95	37	19	25		271
Payment appropriations							
2001	95						95
2002		95					95
2003			37				37
2004				19			19
2005					25		25
2006							
Total	95	95	37	19	25		271

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 133 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 133 Committee. The Commission will be responsible for implementation and management of the agreement.

- 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 a Joint Sub-Committee) have been set out in the Agreement and constitutes a minimum necessary for the proper functioning of the Agreement. The use of seminars in the initial phases to ensure familiarity with other systems will also be a necessary part of the confidence building.

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 agreement. Confidence and its maintenance are keys to the successful operation of the agreement.

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 70 millions Euro for EU exporters to Japan).

- 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, the Joint Committee established under the Agreement and by the economic operators concerned.

- Details and frequency of the planned evaluation

The evaluation of the effectiveness and usefulness of the agreements will be regularly monitored by the Commission and by the Joint Committee established under the agreement at annual meetings.

10. ADMINISTRATIVE EXPENSES

Human resources and administrative means are to be covered by the credits already allocated to the managing service. 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 Euro per staff member per year = 483 750 Euro).

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, the Joint Sub-Committee, 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 2001 this involves the following calculation:

Budget heading	Amounts (Euro)	Method of calculation	
		No. of missions	Standard Unit cost

Joint Committee A-7010	7 560	Japan 2	Japan: Travel: 3 000 Euro; per diem: 260 Euro
Joint Sub-Committee A-7010	7 560	Japan 2	
Seminars A-7010	15 120	Japan 4	
Verifications A-7010	11 340	Japan 3	
A-7010: Total	41 580	11	

In Euro

	Year 2001	Year 2002	2003	2004	2005	Total 2001-2005
A. Joint Committee	7 560	7 560	7 560	7 560	7 560	37 800
B Joint Sub-Committee	7 560	7 560	7 560	7 560	7 560	37 800
C. Seminars	15 120	15 120				30 240
D. Verifications	11 340	11 340	11 340	11 340	11 340	56 700
TOTAL	41 580	41 580	26 460	26 460	26 460	162 540

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES(SMEs)

Title of proposal

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

Reference number

The proposal

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

The impact on business

The business sectors affected are telecommunications terminal equipment, electrical equipment, medicinal products, and industrial chemicals.

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

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

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

Businesses will have to comply with Japanese 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 Japan.

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

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

Consultation

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

EU TRADE WITH JAPAN (M Euro)

EXPORTS		IMPORTS	
Products		Products	
Industrial Chemicals	2 066	Industrial Chemicals	1 958
Pharmaceuticals	2 030	Pharmaceuticals	784
Electrical Equipment	1 956	Electrical Equipment	10 042
Telecommunications Terminal Equipment	1 022	Telecommunications Terminal Equipment	1 500