

AGREEMENT
ON MUTUAL RECOGNITION
BETWEEN JAPAN
AND THE EUROPEAN COMMUNITY

JAPAN and THE EUROPEAN COMMUNITY (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 subparagraph (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 subparagraph (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 visit manufacturing facilities of the other Party on the condition that such other Party and the manufacturing facilities concerned consent to such visit and, if such other Party so requests, officials of the Competent Authority of such other Party join the visit, 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 subparagraph (b) of this paragraph takes place. Such visit 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 subparagraph (b) of this paragraph. The Party shall use the information obtained by its Competent Authority in connection with such visit only for the purpose above.
- (b) The definition of the emergency and the modalities of such visit referred to in subparagraph (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. (a) The provisions concerning the scope and coverage of paragraph 1 of Part A of each Sectoral Annex shall not be changed unless the Parties amend this Agreement in accordance with the first sentence of subparagraph (b) of this paragraph.

(b) This Agreement may be amended by agreement between the Parties. However, if the amendments relate only to changes of laws, regulations and administrative provisions, Designating Authorities or Competent Authorities specified in Part B of the Sectoral Annexes, the amendments may be made by exchange of diplomatic notes between the Government of Japan and the European Community, in conformity with their applicable domestic procedures.

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, Part B of the Sectoral Annex shall be amended 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 the second sentence of subparagraph (b) of paragraph 3 of this Article.

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 Brussels, this fourth day of April, 2001.

For Japan:

木村崇之

For the European Community:

Gunnar Lund
M. P. Carl