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European Community and Japan

Agreement on mutual recognition between the European Community and Japan (with annexes and Final Act). Brussels, 4 April 2001

Entry into force: *1 January 2002 by notification, in accordance with article 14*

Authentic texts: *Danish, Dutch, English, Finnish, French, German, Greek, Italian, Japanese, Portuguese, Spanish and Swedish*

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Only the authentic English and French texts of the Agreement and the Final Act with joint declarations are published herein. The other authentic texts of the Agreement, the annexes and the exchanges of letters of the Final Act are not published herein, in accordance with article 12 (2) of the General Assembly Regulations to give effect to Article 102 of the Charter of the United Nations, as amended, and the publication practice of the Secretariat.

Communauté européenne et Japon

Accord de reconnaissance mutuelle entre la Communauté européenne et le Japon (avec annexes et acte final). Bruxelles, 4 avril 2001

Entrée en vigueur : *1^{er} janvier 2002 par notification, conformément à l'article 14*

Textes authentiques : *danois, néerlandais, anglais, finnois, français, allemand, grec, italien, japonais, portugais, espagnol et suédois*

Enregistrement auprès du Secrétariat des Nations Unies : *Conseil de l'Union européenne, 11 janvier 2011*

Seuls les textes authentiques anglais et français de l'Accord, de l'acte final et ses déclarations communes sont publiés ici. Les autres textes authentiques de l'Accord, de ses annexes et des échanges de lettres de l'acte final ne sont pas publiés ici, conformément au paragraphe 2 de l'article 12 du règlement de l'Assemblée générale destiné à mettre en application l'Article 102 de la Charte des Nations Unies, tel qu'amendé, et à la pratique dans le domaine des publications du Secrétariat.

AGREEMENT
ON MUTUAL RECOGNITION
BETWEEN THE EUROPEAN COMMUNITY
AND JAPAN

THE EUROPEAN COMMUNITY and JAPAN (hereinafter referred to as "the Parties");

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

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 the European Community and Japan 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.