

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 27 September 2001

concerning the conclusion of the Agreement on Mutual Recognition between the European Community and Japan

(2001/747/EC)

THE COUNCIL OF THE EUROPEAN UNION,

The texts referred to in the first paragraph are attached to this Decision.

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

Article 2

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

Having regard to the proposal of the Commission,

Whereas:

Article 3

(1) The Agreement on Mutual Recognition between the European Community and Japan was signed, on behalf of the European Community, on 4 April 2001, subject to its possible conclusion at a later date, and should be approved.

1. The Commission, assisted by the special committee appointed by the Council (hereinafter 'special committee') shall represent the Community in the Joint Committee established under Article 8 of the Agreement and in any subcommittees established in accordance with paragraph 2 of the same Article. The Commission shall proceed, after consultation with the special committee, to notifications, requests and exchange of information and to the proposals for:

(2) The appropriate internal procedures should be established to ensure the proper functioning of the Agreement. It is therefore necessary to delegate to the Commission the power to proceed to amendments of part B of the Sectoral Annexes to the Agreement and to take certain decisions for its implementation,

(a) registration of conformity assessment bodies,

(b) provision of lists of facilities,

(c) termination, suspension, or withdrawal of conformity assessment bodies,

(d) non-acceptance of confirmation and of data generated by facilities,

(e) non-acceptance of certificates emanating from suspended conformity assessment bodies,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement on Mutual Recognition between the European Community and Japan, including its Annexes, together with the joint declarations and the Exchanges of Letters annexed to the Final Act, are hereby approved on behalf of the European Community.

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

- (f) appointments of experts,
(g) actions taken in the context of verifications, visits or contestations,

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 adopted by the Community in the Joint Committee or if appropriate in any subcommittees shall be determined by the Commission following consultation of the special committee, with regard to:

- (a) adoption of the rules of procedure, in accordance with Article 8(2) of the Agreement;
(b) establishment of subcommittees in accordance with Article 8(2) of the Agreement;
(c) adoption of the modalities of exchange of information in accordance with Article 8(3)(c) of the Agreement;
(d) registration of conformity assessment bodies, their verification and related decisions in accordance with Articles 5, 7, 8(3)(a), 8(3)(d) and 9 of the Agreement;
(e) establishment and publication of the lists of registered conformity assessment bodies and confirmed facilities in accordance with Article 8(3)(b) of the Agreement;
(f) verification, visit and contestation of confirmed facilities and related decisions, in accordance with Articles 5, 7 and 10 of the Agreement;

- (g) definition of emergencies and modalities for visits of facilities in accordance with Article 10(2)(b) of the Agreement;

- (h) establishment of procedures for implementing the Sectoral Annex on good manufacturing practice (GMP) in accordance with points 7(b), 7(c) and 9(b) of this Sectoral Annex.

3. The Commission, following consultation of the special committee, shall manage and approve the transitional arrangements associated with implementation of the Sectoral Annex on GMP, and shall send the other party, on behalf of the European Community, the diplomatic note confirming that the preparatory work is completed (in accordance with point 9(a) of the Sectoral Annex on GMP).

4. The Commission shall approve all modifications of part B of the Sectoral Annexes, in consultation with the special committee and shall send the other party, on behalf of the European Community, the diplomatic note referred to in Article 15(3)(b) of the Agreement.

5. In all other cases the position to be adopted by the Community in the Joint Committee or a subcommittee shall be determined by the Council, acting by a qualified majority on a proposal from the Commission.

Done at Brussels, 27 September 2001.

For the Council
The President
M. VERWILGHEN