



Council of the
European Union

Brussels, 6 December 2024
(OR. en)

15957/24

Interinstitutional File:
2024/0298(NLE)

AELE 103
N 100
FL 53
ISL 61
MI 955
SAN 664
RELEX 1486

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: COUNCIL DECISION on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning the amendment of Annex II (Technical regulations, standards, testing and certification), Annex X (Services in general) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement (Health Technology Assessment)

COUNCIL DECISION (EU) .../...

**on the position to be adopted, on behalf of the European Union,
within the EEA Joint Committee concerning the amendment
of Annex II (Technical regulations, standards, testing and certification),
Annex X (Services in general)
and Protocol 37 (containing the list provided for in Article 101)
to the EEA Agreement
(Health Technology Assessment)**

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168 in conjunction with Article 218(9) thereof,

Having regard to Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area¹, and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

¹ OJ L 305, 30.11.1994, p. 6.

Whereas:

- (1) The Agreement on the European Economic Area² (the ‘EEA Agreement’) entered into force on 1 January 1994.
- (2) Pursuant to Article 98 of the EEA Agreement, the EEA Joint Committee may decide to amend, inter alia, Annex II (Technical regulations, standards, testing and certification), Annex X (Services in general) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement.
- (3) Regulation (EU) 2021/2282 of the European Parliament and of the Council³ should be incorporated into the EEA Agreement.
- (4) Annex II (Technical regulations, standards, testing and certification), Annex X (Services in general) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement should therefore be amended accordingly.
- (5) The position of the Union within the EEA Joint Committee should therefore be based on the attached draft decision,

HAS ADOPTED THIS DECISION:

² OJ L 1, 3.1.1994, p. 3.

³ Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1).

Article 1

The position to be adopted on behalf of the Union within the EEA Joint Committee on the proposed amendment of Annex II (Technical regulations, standards, testing and certification), Annex X (Services in general) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement, shall be based on the draft decision of the EEA Joint Committee attached to this Decision.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at ..., ...

For the Council

The President
