



Council of the
European Union

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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) and Protocol 37 containing the list provided for in Article 101 to the EEA Agreement (Reinforced role for EMA in crisis preparedness and management for medicinal products and medical devices)

COUNCIL DECISION (EU) 2024/...

of ...

**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)
and Protocol 37 containing the list provided for in Article 101 to the EEA Agreement
(Reinforced role for EMA in crisis preparedness
and management for medicinal products and medical devices)**

(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 Article 114 and Article 168(4), point (c) 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 II') and Protocol 37 containing the list provided for in Article 101 ('Protocol 37') to the EEA Agreement.
- (3) Regulation (EU) 2022/123 of the European Parliament and of the Council³ should be incorporated into the EEA Agreement.
- (4) Annex II and Protocol 37 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) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, 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) 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
