EUROPEAN
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2024/0136 (NLE)

Proposal for a

COUNCIL DECISION

on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning an amendment to 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)

EXPLANATORY MEMORANDUM

1. SUBJECT MATTER OF THE PROPOSAL

This proposal concerns the decision establishing the position to be adopted on the Union's behalf in the EEA Joint Committee in connection with the envisaged adoption of the Joint Committee Decision concerning an 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

2. CONTEXT OF THE PROPOSAL

1.1. The EEA Agreement

The Agreement on the European Economic Area ('*the EEA Agreement*') guarantees equal rights and obligations within the Internal Market for citizens and economic operators in the EEA. It provides for the inclusion of EU legislation covering the four freedoms throughout the 30 EEA States comprising of EU Member States, Norway, Iceland and Liechtenstein. In addition, the EEA Agreement covers cooperation in other important areas such as research and development, education, social policy, the environment, consumer protection, tourism and culture, collectively known as "*flanking and horizontal*" policies. The EEA Agreement entered into force on 1 January 1994. The Union together with its Member States is a party to the EEA Agreement.

1.2. The EEA Joint Committee

The EEA Joint Committee is responsible for the management of the EEA Agreement. It is a forum for exchanging views linked to the functioning of the EEA Agreement. Its decisions are taken by consensus and are binding on the Parties. The responsibility for coordinating EEA matters on the EU side is with the Secretariat General of the European Commission.

1.3. The envisaged act of the EEA Joint Committee

The EEA Joint Committee is expected to adopt the EEA Joint Committee Decision ('*the envisaged act*') regarding 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.

The purpose of the envisaged act is to incorporate into the EEA Agreement Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices[1].

The envisaged act will become binding on the parties in accordance with Articles 103 and 104 of the EEA Agreement.

3. POSITION TO BE TAKEN ON THE UNION'S BEHALF

The Commission submits the annexed draft Decision of the EEA Joint Committee for adoption by the Council as the Union's position. The position, once adopted, should be presented in the EEA Joint Committee at the earliest possible opportunity.

[1] 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, as corrected by OJ L 71, 9.3.2023, p. 37 (OJ L 20, 31.1.2022, p. 1).

The annexed draft Decision of the EEA Joint Committee introduces participation rights for the EEA EFTA States in the Executive Steering Group on Shortages and Safety of Medicinal Products, and Emergency Task Force and Executive Steering Group on Shortages of Medical Devices, which goes beyond what can be considered mere technical adaptations in the sense of Council Regulation (EC) No 2894/94[2]. The Union position shall therefore be established by the Council.

4. LEGAL BASIS

1.4. Procedural legal basis

1.4.1. Principles

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for decisions establishing '*the positions to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement*.'

The concept of '*acts having legal effects*' includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are '*capable of decisively influencing the content of the legislation adopted by the EU legislature*'[3].

1.4.2. Application to the present case

The EEA Joint Committee is a body set up by an agreement, namely the EEA Agreement. The act, which the EEA Joint Committee is called upon to adopt, constitutes an act having legal effects. The envisaged act will be binding under international law in accordance with Articles 103 and 104 of the EEA Agreement.

The envisaged act does not supplement or amend the institutional framework of the Agreement. Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU in conjunction with Article 1(3) of Council Regulation (EC) No 2894/94.

1.5. Substantive legal basis

1.5.1. Principles

The substantive legal basis for a decision under Article 218(9) TFEU in conjunction with Article 1(3) of Council Regulation (EC) No 2894/94 depends primarily on the substantive legal basis of the EU legal act to be incorporated into the EEA Agreement.

If the envisaged act pursues two aims or has two components and if one of those aims or components is identifiable as the main one, whereas the other is merely incidental, the decision under Article 218(9) TFEU must be founded on a single substantive legal basis, namely that required by the main or predominant aim or component.

1.5.2. Application to the present case

Since the Joint Committee Decision incorporates into the EEA Agreement Regulation (EU) 2022/123, it is appropriate to base this Council decision on the same substantive legal base as the act that is incorporated. Therefore, the substantive legal basis of the proposed decision is Article 114 and Article 168(4), point (c) of the TFEU.

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[2] Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area, OJ L 305, 30.11.1994, p. 6.

[3] Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraphs 61 to 64.

1.6. Conclusion

The legal basis of the proposed decision should be Article 114 and Article 168(4), point (c) TFEU, in conjunction with Article 218(9) TFEU and Article 1(3) of Council Regulation (EC) No 2894/94.

5. PUBLICATION OF THE ENVISAGED ACT

As the act of the EEA Joint Committee will amend Annex II (Technical Regulations, standards, testing and certification) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement, it is appropriate to publish it in the *Official Journal of the European Union* after its adoption.

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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 Area[4], and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Agreement on the European Economic Area[5] ('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) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement.

(3) Regulation (EU) 2022/123 of the European Parliament and of the Council[6] should be incorporated into the EEA Agreement.

(4) Annex II (Technical Regulations, standards, testing and certification) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement should therefore be amended accordingly.

4 OJ L 305, 30.11.1994, p. 6.

5 OJ L 1, 3.1.1994, p. 3.

6 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, as corrected by OJ L 71, 9.3.2023, p. 37 (OJ L 20, 31.1.2022, p. 1).

(5) The position of the Union within the EEA Joint Committee should therefore be based on the attached draft Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted, on behalf of the Union, within the EEA Joint Committee on the proposed amendment to 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 Brussels,

For the Council
The President