Council of the European Union

Brussels, 6 December 2024
(OR. en)

15957/24
ADD 1

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:	Draft DECISION OF THE EEA JOINT COMMITTEE amending 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

DRAFT

DECISION OF THE EEA JOINT COMMITTEE No …

of …

amending 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

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area ('the EEA Agreement'), and in particular Article 98 thereof,

Whereas:

(1) 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[1] is to be incorporated into the EEA Agreement.

(2) Annexes II and X and Protocol 37 to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

[1] OJ L 458, 22.12.2021, p. 1.

Article 1

Annex II to the EEA Agreement shall be amended as follows:

1. The following is inserted after the seventeenth paragraph of the introductory part of Chapter XIII:

‘The EFTA States shall be fully associated with the work of the Member State Coordination Group on Health Technology Assessment, including its subgroups, as established by Article 3 of Regulation (EU) 2021/2282 of the European Parliament and of the Council and shall have the same rights and obligations within it as the EU Member States.

By way of derogation from the previous paragraph, the members designated by the EFTA States shall not be entitled to participate in votes. However, where voting takes place, positions of the members designated by the EFTA States shall be recorded separately upon their request.

Pursuant to Article 12(2) of Regulation (EU) 2021/2282, where consensus cannot be reached, divergent scientific opinions by the EFTA States, including the scientific grounds on which those opinions are based, shall be incorporated in the reports.’

2. The following is inserted after point 22k (Commission Implementing Regulation (EU) 2022/1255) of Chapter XIII:

‘23. **32021 R 2282**: 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).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

Paragraph 4(a) of Protocol 1 to this Agreement shall not apply to Article 3.’

3. The following is inserted in the introductory part of Chapter XXX:

‘The EFTA States shall be fully associated with the work of the Member State Coordination Group on Health Technology Assessment, including its subgroups, as established by Article 3 of Regulation (EU) 2021/2282 of the European Parliament and of the Council and shall have the same rights and obligations within it as the EU Member States.

By way of derogation from the previous paragraph, the members designated by the EFTA States shall not be entitled to participate in votes. However, where voting takes place, the positions of the members designated by the EFTA States shall be recorded separately upon their request.

Pursuant to Article 12(2) of Regulation (EU) 2021/2282, where a consensus cannot be reached, divergent scientific opinions by the EFTA States, including the scientific grounds on which those opinions are based, shall be incorporated in the reports.'

4. The following point is inserted after point 15 (Commission Implementing Regulation (EU) 2020/1207) of Chapter XXX:

'16. **32021 R 2282**: 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).

The provisions of the Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

Paragraph 4(a) of Protocol 1 to this Agreement shall not apply to Article 3.'

Article 2

The following is added in point 2 (Directive 2011/24/EU of the European Parliament and of the Council) of Annex X to the EEA Agreement:

', as amended by:

– **32021 R 2282**: Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 (OJ L 458, 22.12.2021, p. 1).'

Article 3

The following point is inserted in Protocol 37 to the EEA Agreement:

‘50. Member State Coordination Group on Health Technology Assessment (Regulation (EU) 2021/2282 of the European Parliament and of the Council).’

Article 4

The text of Regulation (EU) 2021/2282 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 5

This Decision shall enter into force on …, provided that all the notifications under Article 103(1) of the EEA Agreement have been made*.

* [No constitutional requirements indicated.] [Constitutional requirements indicated.]

Article 6

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, …

For the EEA Joint Committee
The President

The Secretaries
To the EEA Joint Committee