

DECISION OF THE EEA JOINT COMMITTEE

No 288/2019

of 13 December 2019

amending Annex I (Veterinary and Phytosanitary Matters) and Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2020/306]

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) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ⁽¹⁾, as corrected by OJ L 117, 3.5.2019, p. 9, is to be incorporated into the EEA Agreement.
- (2) Regulation (EU) 2017/745 repeals, with effect from 26 May 2020, Council Directives 90/385/EEC ⁽²⁾ and 93/42/EEC ⁽³⁾ which are incorporated into the EEA Agreement and are therefore to be repealed under the Agreement with effect from 26 May 2020.
- (3) Annexes I and II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following indent is added in point 13 (Regulation (EC) No 178/2002 of the European Parliament and of the Council) in Part 7.1 of Chapter I and in point 41 (Regulation (EC) No 178/2002 of the European Parliament and of the Council) of Chapter II of Annex I to the EEA Agreement:

‘— **32017 R 0745**: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (OJ L 117, 5.5.2017, p. 1), as corrected by OJ L 117, 3.5.2019, p. 9.’

Article 2

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

- (1) The following indent is added in point 54zzzc (Regulation (EC) No 178/2002 of the European Parliament and of the Council) of Chapter XII, in point 15q (Directive 2001/83/EC of the European Parliament and of the Council) of Chapter XIII and in point 1a (Regulation (EC) No 1223/2009 of the European Parliament and of the Council) of Chapter XVI:

‘— **32017 R 0745**: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (OJ L 117, 5.5.2017, p. 1), as corrected by OJ L 117, 3.5.2019, p. 9.’

- (2) The following is inserted after point 10 (Commission Implementing Regulation (EU) No 920/2013) of Chapter XXX:

‘11. **32017 R 0745**: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1), as corrected by OJ L 117, 3.5.2019, p. 9.

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

- (a) The EFTA States shall participate fully in the Medical Device Coordination Group ('MDCG') established under Article 103, but shall not have the right to vote.

⁽¹⁾ OJ L 117, 5.5.2017, p. 1.

⁽²⁾ OJ L 189, 20.7.1990, p. 17.

⁽³⁾ OJ L 169, 12.7.1993, p. 1.

(b) The EFTA States shall participate in the European database on medical devices (Eudamed) set up by the Commission as referred to in Article 33.'

3. The texts of point 1 (Council Directive 93/42/EEC) and point 7 (Council Directive 90/385/EEC) of Chapter XXX shall be deleted with effect from 26 May 2020.

Article 3

The text of Regulation (EU) 2017/745, as corrected by OJ L 117, 3.5.2019, p. 9, 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 4

This Decision shall enter into force on 14 December 2019, or on the day following the last notification to the EEA Joint Committee under Article 103(1) of the EEA Agreement have been made (*), whichever is the later.

Article 5

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, 13 December 2019.

For the EEA Joint Committee
The President
Gunnar PÁLSSON

(*) Constitutional requirements indicated.