COUNCIL DECISION

of 24 April 2012

on the position to be taken by the European Union in the EEA Joint Committee concerning an amendment to Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

(2012/229/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43, Article 168(4)(b) and 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 [1], and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Annex II to the Agreement on the European Economic Area [2] ('the EEA Agreement') contains specific provisions and arrangements concerning technical regulations, standards, testing and certification.

(2) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin [3] should be incorporated into the EEA Agreement. Regulation (EC) No 470/2009 repealed Council Regulation (EEC) No 2377/90 [4] and amended Directive 2001/82/EC of the European Parliament and of the Council [5] and Regulation (EC) No 726/2004 of the European Parliament and of the Council [6]. Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin [7], as corrected in OJ L 293, 11.11.2010, p. 72, should also be incorporated into the EEA Agreement.

(3) Annex II to the EEA Agreement should therefore be amended accordingly.

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

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken by the European Union in the EEA Joint Committee on the proposed amendment to Annex II (Technical regulations, standards, testing and certification) 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 day of its adoption.

Done at Luxembourg, 24 April 2012.

For the Council
The President
N. WAMMEN

[1] OJ L 305, 30.11.1994, p. 6.
[2] OJ L 1, 3.1.1994, p. 3.
[3] OJ L 152, 16.6.2009, p. 11.
[4] Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1).
[5] Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).
[6] Regulation (EC) No 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
[7] OJ L 15, 20.1.2010, p. 1.

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DECISION No .../2012 OF THE EEA JOINT COMMITTEE

of

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

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

Whereas:

(1) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council [1] is to be incorporated into the EEA Agreement.

(2) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin [2], as corrected in OJ L 293, 11.11.2010, p. 72, is to be incorporated into the EEA Agreement.

(3) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Chapter XIII of Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement shall be amended as follows:

(1) point 12 is replaced by the following:

'12. **32009 R 0470**: Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

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

(a) References to other acts in the Regulation shall be considered relevant to the extent and in the form that those acts are incorporated into the Agreement.

(b) An EFTA State may request the Agency to issue an opinion according to Article 9(1), first paragraph of Article 11, Article 15(1) and Article 27(2). Such a request shall, in the first place, be addressed to the Commission which shall, where it considers that the request is of common interest, forward it to the Agency for further processing.';

(2) point 13 is replaced by the following:

'13. **32010 R 0037**: Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1), as corrected in OJ L 293, 11.11.2010, p. 72.';

(3) the text of point 14 (Council Regulation (EEC) No 2377/90) is deleted;

(4) the following indent is added in points 15p (Directive 2001/82/EC of the European Parliament and of the Council) and 15zb (Regulation (EC) No 726/2004 of the European Parliament and of the Council):

'— **32009 R 0470**: Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 (OJ L 152, 16.6.2009, p. 11).'.

Article 2

The texts of Regulation (EC) No 470/2009 and of Regulation (EU) No 37/2010, as corrected in OJ L 293, 11.11.2010, p. 72, in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

[1] OJ L 152, 16.6.2009, p. 11.
[2] OJ L 15, 20.1.2010, p. 1.

Article 3

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

Article 4

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 …, …

For the EEA Joint Committee

The President *The Secretaries to the EEA Joint Committee*

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