**COUNCIL OF THE EUROPEAN UNION**

**Brussels, 12 March 2012**

**7554/12**

**Interinstitutional File: 2012/0044 (NLE)**

**EEE 22**
**AELE 18**
**AGRILEG 34**

**PROPOSAL**

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| from: | European Commission |
| dated: | 9 March 2012 |
| No Cion doc.: | COM(2012) 98 final |
| Subject: | Proposal for a Council Decision 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 |

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director, to Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union.

Encl.: COM(2012) 98 final

EUROPEAN COMMISSION

Brussels, 9.3.2012
COM(2012) 98 final

2012/0044 (NLE)

Proposal for a

# COUNCIL DECISION

**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.**

# EXPLANATORY MEMORANDUM

## 1. CONTEXT OF THE PROPOSAL

In order to ensure the requisite legal security and homogeneity of the Internal Market, the EEA Joint Committee is to integrate all the relevant Union legislation into the EEA Agreement as soon as possible after its adoption.

## 2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

The draft Decision of the EEA Joint Committee (annexed to the proposed Council Decision) aims to amend Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement by adding new Union acquis in this field. This concerns 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, which is to be incorporated into the Agreement. Regulation 470/2009 provides the possibility for the Commission and Member States to request opinions from European Medicines Agency. In the present draft EEA Joint Committee Decisions it is proposed that the EEA EFTA States may request such opinions, but that these requests shall first 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

## 3. LEGAL ELEMENTS OF THE PROPOSAL

Article 1(3) of Council Regulation (EC) No 2894/94 concerning arrangements for implementing the EEA Agreement provides that the Council establishes the position to be adopted on the Union's behalf on such Decisions, on a proposal from the Commission.

The Commission submits the Draft Decision of the EEA Joint Committee for adoption by the Council as the Union's position. The Commission would hope to be able to present it in the EEA Joint Committee at the earliest possible opportunity.

2012/0044 (NLE)

Proposal for a

# COUNCIL DECISION

## 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.

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 168(4)(b) and 218 (9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Annex II to the Agreement on the European Economic Area, ("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,[1] should be incorporated in the EEA Agreement. Regulation (EC) No 470/2009 repeals Council Regulation (EEC) No 2377/90 and amends 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. 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 by OJ L 293, 11.11.2010, p. 72, is to be incorporated into the Agreement,

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

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

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1 OJ L 152, 16.6.2009, p. 11

2 OJ L 15, 20.1.2010, p. 1.

HAS ADOPTED THIS DECISION:

*Article 1*

The position to be taken by the Union within the EEA Joint Committee on the proposed amendment to Annex II 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 Brussels, 9.3.2012

*For the Council*
*The President*

**ANNEX**

**Draft**

**DECISION OF THE EEA JOINT COMMITTEE**
**No**

**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, hereinafter referred to as 'the Agreement', and in particular Article 98 thereof,

Whereas:

(1) Annex II to the Agreement was amended by Decision of the EEA Joint Committee No ... of …[1].

(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, 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[2] is to be incorporated into the Agreement.

(3) 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[3], as corrected by OJ L 293, 11.11.2010, p. 72, is to be incorporated into the Agreement,

HAS ADOPTED THIS DECISION:

*Article 1*

Chapter XIII of Annex II to the Agreement shall be amended as follows:

1. The following text shall be inserted in point 12 (deleted):

'**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

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1 OJ L …
2 OJ L 152, 16.6.2009, p. 11.
3 OJ L 15, 20.1.2010, p. 1.

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. The following text shall be inserted in point 13 (deleted):

'**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 by OJ L 293, 11.11.2010, p. 72.'

3. The following indent shall be 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 Regulations (EC) No 470/2009 and 37/2010, as corrected by 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.

*Article 3*

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

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

*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 Brussels, .

*For the EEA Joint Committee*

*The President*

*The Secretaries*
*to the EEA Joint Committee*