EUROPEAN
COMMISSION

Brussels, 29.10.2013
COM(2013) 738 final

2013/0354 (NLE)

Proposal for a

# COUNCIL DECISION

**on the position to be adopted, on behalf of the European Union, in the EEA Joint Committee amending 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 EU legislation into the EEA Agreement as soon as possible after its adoption.

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

The EEA EFTA Member States welcome Regulation (EU) No 528/2012 on Biocides. The EEA EFTA Member States would like to be associated as closely as possible with the work of the European Chemicals Agency in this regard and the EEA EFTA Member States will not only comply with the Regulation, but would also like to contribute actively to the work foreseen under Regulation 528/2012. The draft EEA Joint Committee Decision (annexed to the proposed Council Decision) has been drafted with this in mind.

The Commission wishes to stress certain features of the draft EEA Joint Committee Decision.

The entry into force of this Joint Committee Decision in Liechtenstein will come later than the date of entry into force in the other EFTA states.

Liechtenstein has an agreement with Switzerland on biocidal products. Based on this Agreement, Switzerland processes the Liechtenstein applications and Liechtenstein authorises (or prohibits) the biocidal product in question.

Switzerland will align in the near future its legislation in this field to the new developments in the EU (Regulation 528/2012) and in the light of this, the Agreement between Liechtenstein and Switzerland laying down the cooperation in the field of authorisation procedures for biocidal products will be updated.

This solution ensures a high level of protection of both human and animal health and the environment, while guaranteeing the proper functioning of the internal market, explicitly mentioned as one of the objectives of the Regulation.

In this context, it has to be emphasised that the suggested solution does not prohibit the placing on the market of biocidal products and does not infringe any of the freedoms guaranteed by the EEA Agreement, in particular not the free movement of goods. This also does not result in any distortion of competition within the EEA.

Moreover, the EFTA side proposes adaptations in particular in relation to the participation of the EFTA states in the work of the coordination group under Article 35 of Regulation 528/2012 and the process of granting Union authorisations and corresponding decisions in the EFTA states.

## 3. LEGAL ELEMENTS OF THE PROPOSAL

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products is to be incorporated into the EEA Agreement.

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

2013/0354 (NLE)

Proposal for a

# COUNCIL DECISION

## on the position to be adopted, on behalf of the European Union, in the EEA Joint Committee amending 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 Article 114 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[1], 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[2] ("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 thereto.

(3) Annex II to the EEA Agreement contains specific provisions on technical regulations, standards, testing and certification.

(4) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products is to be incorporated into the EEA Agreement.

(5) Regulation (EU) No 528/2012 repeals, with effect from 1 September 2013, Directive 98/8/EC of the European Parliament and of the Council[3] which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement with effect from 1 September 2013.

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

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

[1] OJ L 305, 30.11.1994, p. 6.
[2] OJ L 1, 3.1.1994, p. 3.
[3] OJ L 123, 24.4.1998, p. 1.

HAS ADOPTED THIS DECISION:

*Article 1*

The position to be adopted, on behalf of the European Union, in 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,

*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 ("the EEA Agreement"), and in particular Article 98 thereof,

Whereas:

(1) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[4] is to be incorporated into the EEA Agreement.

(2) Regulation (EU) No 528/2012 repeals, with effect from 1 September 2013, Directive 98/8/EC of the European Parliament and of the Council[5] which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement with effect from 1 September 2013.

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

HAS ADOPTED THIS DECISION:

*Article 1*

The text of point 12n (Directive 98/8/EC of the European Parliament and of the Council) of Chapter XV of Annex II shall be replaced by the following with effect from 1 September 2013:

'**32012 R 0528**: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

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

(a) The EFTA States shall participate in the work of the European Chemicals Agency, hereinafter referred to as 'the Agency', as set up by European Parliament and Council Regulation (EC) No 1907/2006.

(b) Notwithstanding the provisions of Protocol 1 to the Agreement, the term 'Member State(s)' contained in the Regulation shall be understood to include, in addition to its meaning in the Regulation, the EFTA States.

(c) As regards the EFTA States, the Agency shall, as and when appropriate, assist the EFTA Surveillance Authority or the Standing Committee, as the case may be, in the performance of their respective tasks.

(d) The following paragraph shall be added in Article 35:

[4] OJ L 167, 27.6.2012, p. 1.
[5] OJ L 123, 24.4.1998, p. 1.

"4. The EFTA States shall be entitled to participate fully in the work of the coordination group and shall within it have the same rights and obligations as EU Member States, except the right to vote. The rules of procedures of the coordination Group shall give full effect to the EFTA States' participation."

(e) The following subparagraph shall be added in Article 44(5):

"When the Commission grants a Union authorisation or decides that a Union authorisation has not been granted, the EFTA States will simultaneously and within 30 days of the Commission act take corresponding decisions. The EEA Joint Committee shall be informed and shall periodically publish lists of such decisions in the EEA Supplement to the Official Journal."

(f) The following paragraph shall be added in Article 48:

"4. If the Commission cancels or amends a Union authorisation, the EFTA States shall cancel or amend the corresponding decision."

(g) The following subparagraph shall be added in Article 49:

"If the Commission cancels a Union authorisation, the EFTA States shall cancel the corresponding decision."

(h) The following paragraph shall be added in Article 50:

"4. If the Commission amends a Union authorisation, the EFTA states shall amend the corresponding decision."

(i) The following paragraph shall be added in Article 75:

"5. The EFTA States shall be entitled to participate fully in the work of the Biocidal Products Committee and shall within it have the same rights and obligations as EU Member States, except the right to vote."

(j) The following paragraph shall be added in Article 78:

"3. The EFTA States shall, as from the entry into force of this Decision participate in the financing of the Agency. For this purpose the procedures laid down in Article 82(1)(a) and Protocol 32 of the Agreement shall apply *mutatis mutandis*."

(k) Should any disagreement between the Contracting Parties arise as to the administration of these provisions, Part VII of the Agreement shall apply *mutatis mutandis*.'

*Article 2*

The texts of Regulation (EU) No 528/2012 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 EEA Agreement have been made[*].

For Liechtenstein, this Decision shall enter into force on the same day or on the day of entry into force of the Agreement between Liechtenstein and Switzerland laying down the

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

cooperation in the field of authorisation procedures for biocidal products according to Regulation (EU) No 528/2012, whichever is the later.

*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