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Proposal for a

COUNCIL DECISION

**on the position to be adopted, on behalf of the European Union,
in the EEA Joint Committee concerning an amendment to Annex II of 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 draft Decision of the EEA Joint Committee (annexed to the proposed Council Decision) aims to amend Annex II to the EEA Agreement in order to incorporate the following in the EEA Agreement.

More concretely, Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances as well as Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products.

Regulation (EC) No 1107/2009 repeals Directive 91/414/EEC. However, a list of active substances approved according to the provisions of Directive 91/414/EEC shall be deemed to have been approved under Regulation (EC) No 1107/2009. Provisions of Directive also apply to the approval of active substances listed in part B of the Annex to Regulation (EU) No 540/2011 which have been approved in accordance with transitional measures.

The EFTA States consider the need to continue the right to limit the access to the their markets of plant protection products containing active substances approved in accordance with Council Directive 91/414/EEC or the Transitional measures in Article 80 of Regulation (EC) No 1107/2009

Consequently, adaptation texts to Regulation (EC) No 1107/2009 and Regulation (EU) No 540/2011 are necessary.

The EFTA States, with the exception of Liechtenstein, may be ‘rapporteur Member State’ and ‘co-rapporteur’.

Liechtenstein is exempted from the obligation to become a potential rapporteur Member State on basis of its geographical size and the administrative and laboratory capacities necessary to perform the examination and evaluation tasks versus the expected demand and benefit. It shall also be noted that Article 49 shall not apply to Liechtenstein.

Article 18 (f) of Regulation (EC) No 1107/2009 related to the Work Programme.

The allocation of the evaluation of active substances, mentioned in the above-mentioned Article, is to be subject to consent from the concerned EFTA State. Therefore the draft JCD amends Article 18 clarifying such position.

On Articles 37(4), 42(2) and 47(3) of Regulation (EC) No 1107/2009 related to period for examination, procedure and the specific case of low-risk plant protection products, an adaptation in terms of time limits is necessary.

The given period of 120 days for MS to make national decisions on acceptance a plant protection product after receiving the examining MS's assessment shall, for the EFTA States, at the earliest, run from the date when the Act of approval of the active substances contained in the plant protection product/ low-risk plant protection product is incorporated into the present Agreement.

Due to the delays in the EEA Agreement's decision-making procedure, there are cases where the active substance has not been yet approved in the EFTA States. Therefore the time should start running once the substance is incorporated in the EEA Agreement.

Article 48 of Regulation (EC) No 1107/2009 on placing on the market and use of plant protection products containing a genetically modified organism shall contain an additional provision.

When a plant protection product containing a genetically modified organism has been properly authorised under this Regulation, an EFTA State may not prohibit, restrict or impede the placing on the market of this plant protection product. This is without prejudice to the safeguard procedure provided in case of risk to human health or the environment in Directive 2001/18/EC.

A transitional period for plant protection products that are approved according to national provisions in the EFTA States is necessary.

Annex I – Definition of zones for the authorisation of plant protection products as referred to in Article 3(17).

Iceland, Norway and Liechtenstein should be included as part of the respective zones. Therefore the Annex I shall be amended adding Iceland and Norway as a part of Zone A – North. Liechtenstein as a part of Zone B – Centre.

It is also necessary to add standard phrases in Norwegian and Icelandic to the lists in the corresponding annexes to Regulation (EU) 547/2011.

Annex II to the EEA agreement should therefore be amended accordingly.

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.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43(2), 114(1) and 168(4)(b) 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 Area¹, and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement on the European Economic Area² ('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 to the EEA Agreement.
- (3) Annex II to the EEA Agreement contains specific provisions and arrangements concerning technical regulations, standards, testing and certification.
- (4) Regulation (EC) No 1107/2009 of the European Parliament and of the Council³ is to be incorporated into the EEA Agreement.
- (5) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁴ is to be incorporated into the EEA Agreement.
- (6) Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁵ is to be incorporated into the EEA Agreement.

¹ OJ L 305, 30.11.1994, p. 6.

² OJ L 1, 3.1.1994, p. 3.

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OJ L 309, 24.11.2009, p. 1.

⁴ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (Text with EEA relevance), OJ L 153, 11.6.2011, p.1.

⁵ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European

- (7) Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁶ is to be incorporated into the EEA Agreement.
- (8) Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁷ is to be incorporated into the EEA Agreement.
- (9) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁸ is to be incorporated into the EEA Agreement.
- (10) Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁹ is to be incorporated into the EEA Agreement.
- (11) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹⁰ is to be incorporated into the EEA Agreement.
- (12) Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹¹ is to be incorporated into the EEA Agreement.
- (13) Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹² is to be incorporated into the EEA Agreement.

Parliament and of the Council as regards the list of approved active substances Text with EEA relevance (OJ L 153, 11.6.2011, p. 187).

⁶ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances (OJ L 155, 11.6.2011, p. 1).

⁷ Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products (OJ L 155, 11.6.2011, p. 67.)

⁸ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127).

⁹ Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products (OJ L 155, 11.6.2011, p. 176).

¹⁰ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

¹¹ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1).

¹² Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and

- (14) Regulation (EC) No 1107/2009 repeals Council Directives 79/117/EEC¹³ and 91/414/EEC¹⁴, which are incorporated into the EEA Agreement and which are consequently to be repealed under the EEA Agreement.
- (15) Regulation (EU) No 283/2013 repeals Regulation (EU) No 544/2011, which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement.
- (16) Regulation (EU) No 284/2013 repeals Regulation (EU) No 545/2011, which is incorporated into the EEA Agreement and which is consequently to be repealed under the EEA Agreement.
- (17) Annex II to the EEA Agreement should therefore be amended accordingly.
- (18) The position of the Union within EEA Joint Committee should therefore be based on the attached draft Decision.

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted, on behalf of the European Union, within 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 date of its adoption.

Done at Brussels,

*For the Council
The President*

of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85).

¹³ Council Directive of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (79/117/EEC) (OJ L 33, 8.2.1979, p. 36.)

¹⁴ Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC) (OJ L 230, 19.8.1991, p. 1.)