



Council of the  
European Union

Brussels, 26 May 2015  
(OR. en)

8203/15

---

**Interinstitutional File:**  
**2015/0086 (NLE)**

---

AELE 18  
EEE 6  
DENLEG 60  
MI 255  
AGRI 209

## **LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

---

Subject: COUNCIL DECISION on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning an amendment to Annex II (Technical regulations, standards, testing and certification) of the EEA Agreement (Novel foods)

---

**COUNCIL DECISION (EU) 2015/...**

**of ...**

**on the position to be adopted, on behalf of the European Union,  
within the EEA Joint Committee  
concerning an amendment to Annex II  
(Technical regulations, standards, testing and certification)  
of the EEA Agreement  
(Novel foods)**

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<sup>1</sup>, and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

---

<sup>1</sup> OJ L 305, 30.11.1994, p. 6.

Whereas:

- (1) The Agreement on the European Economic Area<sup>1</sup> ('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 258/97 of the European Parliament and of the Council<sup>2</sup> is to be incorporated into the EEA Agreement.
- (5) Commission Regulation (EC) No 1852/2001<sup>3</sup> is to be incorporated into the EEA Agreement.

---

<sup>1</sup> OJ L 1, 3.1.1994, p. 3.

<sup>2</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

<sup>3</sup> Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17).

- (6) Commission Recommendation 97/618/EC<sup>1</sup> is to be incorporated into the EEA Agreement.
- (7) Article 38 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council<sup>2</sup> amends Regulation (EC) No 258/97 and is to be incorporated into the EEA Agreement.
- (8) Annex II to the EEA Agreement should therefore be amended accordingly.
- (9) The position of the Union within the EEA Joint Committee should therefore be based on the attached draft Decision,

HAS ADOPTED THIS DECISION:

---

<sup>1</sup> Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 253, 16.9.1997, p. 1).

<sup>2</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

*Article 1*

The position to be adopted, on behalf of the 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*

---

Draft

**DECISION OF THE EEA JOINT COMMITTEE No .../2015**

**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 (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients<sup>1</sup> is to be incorporated into the EEA Agreement.
- (2) Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97<sup>2</sup> is to be incorporated into the EEA Agreement.
- (3) Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council<sup>3</sup> is to be incorporated into the EEA Agreement.

---

<sup>1</sup> OJ L 43, 14.2.1997, p. 1.

<sup>2</sup> OJ L 253, 21.9.2001, p. 17.

<sup>3</sup> OJ L 253, 16.9.1997, p. 1.

- (4) Article 38 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>1</sup> amends Regulation (EC) No 258/97 and is to be incorporated into the EEA Agreement.
- (5) This Decision concerns legislation regarding foodstuffs. Legislation regarding foodstuffs shall not apply to Liechtenstein as long as the application of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products is extended to Liechtenstein, as specified in the introduction to Chapter XII of Annex II to the EEA Agreement. This Decision is therefore not to apply to Liechtenstein.
- (6) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

---

<sup>1</sup> OJ L 268, 18.10.2003, p. 1.



## *Article 1*

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

1. The following is added after point 97 (Regulation (EU) No 1169/2011 of the European Parliament and of the Council):

‘98. **31997 R 0258**: Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1), as amended by:

- **32003 R 1829**: Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 (OJ L 268, 18.10.2003, p. 1),
- **32008 R 1332**: Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 (OJ L 354, 31.12.2008, p. 7).

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

The following shall be added to Article 7:

“When the Commission takes authorization decisions, the EFTA States will simultaneously and within 30 days of the Community Decision, 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.

Should any disagreement between the contracting parties arise to the administration of these provisions, Part VII of the Agreement shall apply *mutatis mutandis*.”

99. **32001 R 1852**: Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17).’.

2. Under the heading ‘*ACTS OF WHICH THE EFTA STATES AND THE EFTA SURVEILLANCE AUTHORITY SHALL TAKE DUE ACCOUNT*’ the following point is added after point 16 (Commission Recommendation 2013/647/EU):

- ‘17. **31997 H 0618**: Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 253, 16.9.1997, p. 1).’.

## *Article 2*

The texts of Regulations (EC) No 258/97, (EC) No 1852/2001 and (EC) No 1829/2003 and Recommendation 97/618/EC, 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\*.

*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*

...

---

---

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