



Council of the  
European Union

Brussels, 24 November 2021  
(OR. en)

14301/21

---

---

**Interinstitutional File:  
2021/0370(NLE)**

---

---

**AELE 111  
EEE 93  
N 141  
ISL 86  
FL 88  
MI 882  
ECO 131**

**PROPOSAL**

---

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	22 November 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2021) 712 final
Subject:	Proposal for a COUNCIL DECISION on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee, concerning the amendment to Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement (Tobacco Product Directive)

---

Delegations will find attached document COM(2021) 712 final.

---

Encl.: COM(2021) 712 final



Brussels, 22.11.2021  
COM(2021) 712 final

2021/0370 (NLE)

Proposal for a

**COUNCIL DECISION**

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

**(Tobacco Product Directive)**

(Text with EEA relevance)

## EXPLANATORY MEMORANDUM

### **1. SUBJECT MATTER OF THE PROPOSAL**

This proposal concerns the decision establishing the position to be adopted on the Union's behalf in the EEA Joint Committee in connection with the envisaged adoption of the Joint Committee Decision concerning an amendment of Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

### **2. CONTEXT OF THE PROPOSAL**

#### **2.1. The EEA Agreement**

The Agreement on the European Economic Area ('the EEA Agreement') guarantees equal rights and obligations within the Internal Market for citizens and economic operators in the EEA. It provides for the inclusion of EU legislation covering the four freedoms throughout the 30 EEA States comprising of EU Member States, Norway, Iceland and Liechtenstein. In addition, the EEA Agreement covers cooperation in other important areas such as research and development, education, social policy, the environment, consumer protection, tourism and culture, collectively known as "flanking and horizontal" policies. The Agreement entered into force on 1 January 1994. The European Union together with its Member States is a party to the Agreement.

#### **2.2. The EEA Joint Committee**

The EEA Joint Committee is responsible for the management of the EEA Agreement. It is a forum for exchanging views linked to functioning of the EEA Agreement. Its decisions are taken by consensus. In accordance with the Treaty of Lisbon, responsibility for coordinating EEA matters on the EU side is with the European External Action Service.

#### **2.3. The envisaged act of the EEA Joint Committee**

The EEA Joint Committee is expected to adopt the EEA Joint Committee Decision ('the envisaged act') regarding the amendment of Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement.

The purpose of the envisaged act is to incorporate the Tobacco Product Directive<sup>1</sup> including its amending Commission Delegated Directive<sup>2</sup> into the EEA Agreement and to repeal under the EEA Agreement Directive 2001/37/EC<sup>3</sup>.

The envisaged act will become binding on the parties in accordance with Articles 103 and 104 of the EEA Agreement.

---

<sup>1</sup> OJ L 127, 29.4.2014, p. 1.

<sup>2</sup> OJ L 360, 17.12.2014, p. 22.

<sup>3</sup> OJ L 194, 18.7.2001, p. 26.

### 3. POSITION TO BE TAKEN ON THE UNION'S BEHALF

The Commission submits the draft Decision of the EEA Joint Committee for adoption by the Council as the Union's position. The position, once adopted, should be presented in the EEA Joint Committee at the earliest possible opportunity.

The content and nature of the draft of the annexed Decision of the EEA Joint Committee go beyond what can be considered mere technical adaptations in the sense of the Council Regulation No 2894/94. The Union position shall therefore be established by the Council.

The annexed Decision of the EEA Joint Committee contains *inter-alia* the following adaptations.

1. Due to constitutional constraints in the EEA EFTA States, it is not possible to have fees from entities established in the EEA EFTA States charged directly by the European Commission. Such responsibility falls within the remit of the EFTA Surveillance Authority. The following subparagraph shall therefore be added to Articles 6(4) and 7(13):

“In cases concerning manufacturers and importers in the EFTA States, the EFTA Surveillance Authority shall collect any fees charged by the Commission.”

2. With regard to Norway, the following subparagraph shall be added to Article 12(1):  
“Taking into account the specific national circumstances supported by statistics regarding the health risks related to the use and use patterns of oral tobacco, tobacco for oral use placed on the market in Norway may carry the following alternative health warning:

‘This tobacco product increases the risk of harm to the foetus and stillbirth’

3. In Norway, similarly to Sweden, the sale of tobacco for oral use is permitted due to this being a traditional tobacco product there. This exemption should remain in force.

### 4. LEGAL BASIS

#### 4.1. Procedural legal basis

##### 4.1.1. Principles

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for decisions establishing ‘*the positions to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement.*’

The concept of ‘*acts having legal effects*’ includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are ‘*capable of decisively influencing the content of the legislation adopted by the EU legislature*’<sup>4</sup>.

---

<sup>4</sup> Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraphs 61 to 64.

#### *4.1.2. Application to the present case*

The EEA Joint Committee is a body set up by an agreement, namely the EEA Agreement. The act, which the EEA Joint Committee is called upon to adopt, constitutes an act having legal effects. The envisaged act will be binding under international law in accordance with Articles 103 and 104 of the EEA Agreement.

The envisaged act does not supplement or amend the institutional framework of the Agreement. Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU in conjunction with Article 1(3) of Council Regulation No 2894/94 concerning arrangements for implementing the Agreement on the European Economic Area.

### **4.2. Substantive legal basis**

#### *4.2.1. Principles*

The substantive legal basis for a decision under Article 218(9) TFEU in conjunction with Article 1(3) of Council Regulation No 2894/94 depends primarily on the substantive legal basis of the EU legal act to be incorporated into the EEA Agreement.

If the envisaged act pursues two aims or has two components and if one of those aims or components is identifiable as the main one, whereas the other is merely incidental, the decision under Article 218(9) TFEU must be founded on a single substantive legal basis, namely that required by the main or predominant aim or component. Exceptionally, if it is established, however, that the act simultaneously pursues a number of objectives, or has several components, which are inextricably linked without one being incidental to the other, such that various provisions of the Treaty are applicable, such a measure will have to be founded on the various legal bases corresponding to those components<sup>5</sup>.

#### *4.2.2. Application to the present case*

The envisaged act pursues objectives and has components in the area of facilitation of the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health. These elements of the envisaged act are inseparably linked without one being incidental to the other.

Therefore, the substantive legal basis of the proposed decision comprises the following provisions: Articles 53(1), 62 and 114 of the Treaty on the Functioning of the European Union.

### **4.3. Conclusion**

The legal basis of the proposed decision should be Articles 53(1), 62 and 114, in conjunction with Article 218(9) TFEU and Article 1(3) of Council Regulation No 2894/94 concerning arrangements for implementing the Agreement on the European Economic Area.

---

<sup>5</sup> Judgment of the Court of Justice of 4 September 2018, *Commission v Council*, C-244/17, ECLI:EU:C:2018:662, paragraph 37.

## **5. PUBLICATION OF THE ENVISAGED ACT**

As the act of the EEA Joint Committee will amend Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement, it is appropriate to publish it in the *Official Journal of the European Union* after its adoption.

Proposal for a

**COUNCIL DECISION**

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

**(Tobacco Product Directive)**

(Text with EEA relevance)

**THE COUNCIL OF THE EUROPEAN UNION,**

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 53(1), 62 and 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>6</sup>, 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<sup>7</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, which contains provisions on technical regulations, standards, testing and certification.
- (3) Directive 2014/40/EU of the European Parliament and of the Council<sup>8</sup> is to be incorporated into the EEA Agreement.
- (4) Commission Delegated Directive 2014/109/EU<sup>9</sup> is to be incorporated into the EEA Agreement.

---

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

<sup>7</sup> OJ L 1, 3.1.1994, p. 3.

<sup>8</sup> Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, as corrected by OJ L 150, 17.6.2015, p. 24.

- (5) Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement should therefore be amended accordingly.
- (6) The position of the Union in the EEA Joint Committee should therefore be based on the draft EEA Joint Committee Decision set out in the Annex to this Decision,

HAS ADOPTED THIS DECISION:

*Article 1*

The position to be adopted on the Union's behalf within the EEA Joint Committee on the proposed amendment of 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*

---

<sup>9</sup> Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products, OJ L 360, 17.12.2014, p. 22.