



Council of the  
European Union

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## PROPOSAL

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 11 June 2019

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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No. Cion doc.: COM(2019) 269 final

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Subject: Proposal for a 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) to the EEA Agreement

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Delegations will find attached document COM(2019) 269 final.

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Encl.: COM(2019) 269 final



Brussels, 11.6.2019  
COM(2019) 269 final

2019/0130 (NLE)

Proposal for a

**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) to the EEA Agreement**

(Text with EEA relevance)

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

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 in order to incorporate 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.

- **Consistency with existing policy provisions in the policy area**

The annexed draft Joint Committee Decision extends the already existing EU policy to the EEA EFTA States (Norway, Iceland and Liechtenstein).

- **Consistency with other Union policies**

The extension of the EU acquis to the EEA EFTA States, through their incorporation into the EEA Agreement is conducted in conformity with the objectives and principles of that Agreement, aiming at establishing a dynamic and homogeneous European Economic Area, based on common rules and equal conditions of competition.

### 2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The legislation to be incorporated into the EEA Agreement is based on Article 114 of the Treaty on the Functioning of the European Union in conjunction with Article 218(9) thereof.

Article 1(3) of Council Regulation (EC) No 2894/94<sup>1</sup> 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.

- **Subsidiarity (for non-exclusive competence)**

The proposal complies with the subsidiarity principle for the following reason.

The objective of this proposal, namely to ensure the homogeneity of the Internal Market, cannot be sufficiently achieved by the Member States and can therefore, by reason of the effects, be better achieved at Union level.

The process of incorporation of the EU acquis into the EEA Agreement is conducted in conformity with the Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area which confirms the approach taken.

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<sup>1</sup> OJ L 305, 30.11.1994, p. 6–8

- **Proportionality**

In accordance with the principle of proportionality, this proposal does not go beyond what is necessary in order to achieve its objective.

- **Choice of the instrument**

In conformity with Article 98 of the EEA Agreement, the chosen instrument is the EEA Joint Committee decision. The EEA Joint Committee shall ensure the effective implementation and operation of the EEA Agreement. To this end, it shall take decisions in the cases provided for in the EEA Agreement.

### **3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS**

- **Ex-post evaluations/fitness checks of existing legislation**

Not applicable.

### **4. BUDGETARY IMPLICATIONS**

There are no budgetary implications expected as a result of the incorporation of Directive 2014/40/EU into the EEA Agreement.

### **5. OTHER ELEMENTS**

#### **The main adaptations requested by the EFTA side**

*Adaptation (a):* It is important to ensure that the Commission has access to data and information, as provided for in Article 5(7). More precise adaptations, if necessary, will be included in the Joint Committee Decisions related to the implementing legislation of Directive 2014/40/EU.

*Adaptation (b):* Due to constitutional constraints in EEA EFTA States, it is not possible to have fees charged directly by the Commission. The solution proposed is in conformity with the two-pillar structure of the EEA Agreement.

*Adaptation (c):* Norway has had an exemption from the prohibition of tobacco for oral use since 1994. Considering that tobacco for oral use is an established product on the Norwegian market used by 14% of the population (Statistics Norway, 2017), this exemption is still justified. To address the specific national circumstances in Norway supported by statistics regarding the health risks related to the use of oral tobacco and its use patterns (explained below), Norway would like to add an alternative health warning for tobacco for oral use.

The use of tobacco for oral use has increased dramatically in Norway in the last 10-15 years, especially among young people. Little over a decade ago, few young men and hardly any women used it. Now, among 16–24 years old, 33% of boys and 18% of girls in Norway use it,

and there are no signs of this trend stopping. In Sweden, the other country where the sale of tobacco for oral use is permitted, the same increase among young women is not observed, so this is a national circumstance particular to Norway.

Furthermore, in Norway an estimated 20% of female users continue to use tobacco for oral use during pregnancy. There is convincing evidence that oral tobacco use during pregnancy may lead to reduced birth weight, increased risk of premature birth and stillbirth. There are also indications that it may contribute to pre-eclampsia and increase the risk of respiratory failure among new-borns and lip/palate malformations. With the rapidly increasing use among young women, the risk of more pregnant women using snus is likely to increase in the coming years. The consequences could be an increase in adverse pregnancy outcomes and developmental disorders in the foetus and infant.

Given the specific national circumstances in the country, Norway should be free to allow the alternative health warning for tobacco for oral use placed on the market in Norway.

*Adaptation (d)*: In Norway, the sale of tobacco for oral use is permitted due to this being a traditional tobacco product there. This exemption should remain in force.

Proposal for a

## 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) to the EEA Agreement**

(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 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>2</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>3</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 (Technical regulations, standards, testing and certification) to the EEA Agreement.
- (3) Directive 2014/40/EU of the European Parliament and of the Council<sup>4</sup> is to be incorporated into the EEA Agreement.
- (4) Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement should therefore be amended accordingly.
- (5) The position of the Union within the EEA Joint Committee should therefore be based on the attached draft decision,

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<sup>2</sup> OJ L 305, 30.11.1994, p. 6.

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

<sup>4</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.

HAS ADOPTED THIS DECISION:

*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*