



Brussels, 29.6.2022
C(2022) 4367 final

COMMISSION DELEGATED DIRECTIVE (EU) .../...

of 29.6.2022

amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Directive 2014/40/EU¹ aims at facilitating the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of health protection, especially for young people. Under Article 7(12) of Directive 2014/40/EU, all tobacco products other than cigarettes and roll-your-own tobacco are exempted from the prohibitions of placing on the market of tobacco products with a characterising flavour or containing flavourings in any of their components or having certain technical features. On the basis of a substantial change of circumstances as defined in Article 2(28) of Directive 2014/40/EU, consisting in a substantial increase of the sales volumes of heated tobacco products, this Delegated Directive removes that exemption for heated tobacco products. On the same grounds, the Delegated Directive removes the Member States' possibility of granting exemptions for heated tobacco products from the labelling requirements referred to in Article 9(2) and Article 10 of Directive 2014/40/EU.

This Delegated Directive responds to the Commission's obligations under Article 7(12) and Article 11(6) of Directive 2014/40/EU to extend the prohibition of the placing on the market of tobacco products with a characterising flavour or containing flavourings in any of their components or having certain technical features (which already exists for cigarettes and roll-your-own tobacco) to heated tobacco products and to remove the Member States' possibility to grant exemptions for these products from the labelling requirements laid down in Article 9(2) and Article 10 of Directive 2014/40/EU.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

A wide range of data sources have been used to establish that the thresholds referred to in Article 2(28) of Directive 2014/40/EU have been reached. Those data sources are summarised in the Report on the establishment of a substantial change of circumstances for heated tobacco products². Article 7(12) and Article 11(6) of Directive 2014/40/EU do not confer discretion on the Commission but leave it with the technical task of establishing whether there has been a substantial change of circumstances for a particular product category, which is to result in the prohibition on the placing on the market of tobacco products with characterising flavours or containing flavourings in any of their components or having certain technical features, extending to that particular product category and in the removal of the Member States' possibility to grant exemptions from certain labelling requirements for that product category. The policy choice to prohibit the placing on the market of tobacco products with characterising flavours, with a view to achieving a high level of health protection, for young people in particular, has already been made by the Union legislature in Directive 2014/40/EU itself (see also recitals 19 and 26 of that

¹ 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 (OJ L 127, 29.4.2014, p. 1).

² Report from the Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU, COM/2022/279 final.

Directive). The ‘Group of experts on tobacco policy’ was consulted and provided its advice on this Delegated Directive.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 7(1) and (7) of Directive 2014/40/EU prohibit the placing on the market of tobacco products with a characterising flavour or that contain flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of their smell or taste or their smoke intensity. According to Article 7(12) of Directive 2014/40/EU, tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from these prohibitions. That paragraph requires the Commission to adopt delegated acts withdrawing that exemption for a particular product category, if there is a substantial change of circumstances as established in a Commission report.

Article 11(1) of Directive 2014/40/EU allows the Member States to exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10. Article 11(6) of Directive 2014/40/EU requires the Commission to adopt delegated acts withdrawing that possibility of granting exemptions for any of the particular product categories referred to in Article 11(1) if there is a substantial change of circumstances as established in a Commission report for the product category concerned.

Article 2(28) of Directive 2014/40/EU defines a ‘substantial change of circumstances’ as an increase of the sales volumes by product category by at least 10 % in at least five Member States based on sales data transmitted in accordance with Article 5(6) or an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies. According to that provision, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2,5 % of total sales of tobacco products at Union level.

The Report on the establishment of a substantial change of circumstances for heated tobacco products establishes that these thresholds have been met for heated tobacco products and that there has therefore been a substantial change of circumstances concerning that particular product category. Pursuant to Article 7(12) and Article 11(6) of Directive 2014/40/EU, the Commission is therefore to adopt a delegated act removing the exemption from the prohibitions of Article 7(1) and (7) of Directive 2014/40/EU regarding heated tobacco products, and the Member States’ possibility of granting exemptions for heated tobacco products from the labelling requirements laid down in Article 9(2) and Article 10 of Directive 2014/40/EU.

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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/EC¹, and in particular Articles 7(12) and 11(6) thereof,

Whereas:

- (1) Article 7(1) and (7) of Directive 2014/40/EU prohibits the placing on the market of tobacco products with a characterising flavour and tobacco products containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity.
- (2) Pursuant to Article 7(12) of Directive 2014/40/EU tobacco products other than cigarettes and roll-your-own tobacco are exempted from the prohibitions laid down in paragraphs 1 and 7.
- (3) Article 11(1) of Directive 2014/40/EU allows Member States to exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10.
- (4) A heated tobacco product is a novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s) and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking.
- (5) The Commission established in the Report on the establishment of a substantial change of circumstances for heated tobacco products² a substantial change of circumstances regarding heated tobacco products. The Report provides information and statistics on market developments which show that there was an increase of the sales volumes of heated tobacco products by at least 10 % in at least five Member States and that the sales volume of heated tobacco products at retail level exceeded 2,5 % of total sales of tobacco products at Union level.

¹ OJ L 127, 29.4.2014, p. 1.

² Report from the Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU, COM/2022/279 final.

- (6) In view of that substantial change of circumstances regarding heated tobacco products, Article 7(12) of Directive 2014/40/EU should be amended in order to extend the prohibition of the placing on the market of tobacco products with a characterising flavour or containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity, that already exists for cigarettes and roll-your-own tobacco, to heated tobacco products.
- (7) On the same grounds, Article 11(1) of Directive 2014/40/EU should be amended in order to withdraw the possibility for Member States to grant exemptions for heated tobacco products, in so far as they are tobacco products for smoking, from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10.
- (8) Directive 2014/40/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2014/40/EU

Directive 2014/40/EU is amended as follows:

- (1) Article 7(12) is replaced by the following:

‘Tobacco products other than cigarettes, roll-your-own tobacco and heated tobacco products shall be exempted from the prohibitions laid down in paragraphs 1 and 7. The Commission shall adopt delegated acts in accordance with Article 27 to withdraw that exemption for a particular product category, if there is a substantial change of circumstances as established in a Commission report.

For the purposes of the first subparagraph, ‘heated tobacco product’ means a novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s), and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking.’
- (2) Article 11 is amended as follows:
 - (a) the heading is replaced by the following:

‘Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products’;
 - (b) in paragraph 1, the first subparagraph is replaced by the following:

‘Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products as defined in Article 7(12), second subparagraph, from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10. In that event, and in addition to the general warning provided for Article 9(1), each unit packet and any outside packaging of such products shall carry one of the text warnings listed in Annex I. The general warning specified in Article 9(1) shall include a reference to the cessation services referred to in Article 10(1), point (b).’

Article 2

Transposition

1. Member States shall adopt and publish, by ... [*8 months after entry into force*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from ... [*11 months after entry into force*].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 29.6.2022

For the Commission
The President
Ursula VON DER LEYEN