

# DIRECTIVES

## COMMISSION DELEGATED DIRECTIVE (EU) 2022/2100

of 29 June 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)

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/EC <sup>(1)</sup>, 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 products <sup>(2)</sup> 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.

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

<sup>(2)</sup> 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:

'12. 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:

*'Article 11*

**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 23 July 2023 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 23 October 2023.

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 June 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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