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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2014/40/EU 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

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Delegations will find attached document COM(2023) 491 final.

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Encl.: COM(2023) 491 final



Brussels, 17.8.2023  
COM(2023) 491 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND  
THE COUNCIL**

**on the exercise of the power to adopt delegated acts conferred on the Commission  
pursuant to Directive 2014/40/EU 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**

## 1. INTRODUCTION

The objective of 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> ('the Tobacco Products Directive') is to approximate the laws, regulations and administrative provisions of the Member States concerning:

- (a) the ingredients and emissions of tobacco products and related reporting obligations, including the maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;
- (b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products to ensure their compliance with that Directive;
- (c) the prohibition on the placing on the market of tobacco for oral use;
- (d) cross-border distance sales of tobacco products;
- (e) the obligation to submit a notification of novel tobacco products;
- (f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, and herbal products for smoking.

The Directive aims to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the European Union's obligations under the World Health Organisation (WHO) Framework Convention for Tobacco Control (FCTC) to which the European Union acceded on 30 June 2005.

Article 27 of the Tobacco Products Directive empowers the Commission, subject to certain conditions, to adopt delegated acts referred to in Article 3(2), Article 3(4), Article 4(3), Article 4(5), Article 7(5), Article 7(11), Article 7(12), Article 9(5), Article 10(3)(a), Article 10(3)(b), Article 11(6), Article 12(3), Article 15(12), Article 20(11) and Article 20(12).

## 2. LEGAL BASIS

This report is required under Article 27(2) of the Tobacco Products Directive, which confers the power on the Commission to adopt delegated acts for a period of 5 years from 19 May 2014. The Commission is required to draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power is tacitly extended for periods of an identical duration unless the

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

European Parliament or the Council opposes such an extension not later than 3 months before the end of each period.

### **3. EXERCISE OF THE DELEGATION IN THE CURRENT PERIOD**

The Commission adopted the first report on the exercise of the delegation of powers under the Tobacco Products Directive on 8 August 2018<sup>2</sup>.

During the current 5-year period as per the tacit extension of the delegation of powers, the Commission adopted one delegated act under Articles 7(12) and 11(6) of the Tobacco Products Directive.

Article 7(12) empowers the Commission to adopt delegated acts to withdraw the exemption for a particular tobacco product category, other than cigarettes and roll-your own tobacco, from the prohibitions laid down in Article 7(1) and (7) if there is a substantial change of circumstances as established in a Commission report. Similarly, Article 11(6) empowers the Commission to withdraw the possibility for Member States to grant labelling exemptions for particular categories of tobacco products for smoking, other than cigarettes, roll-your-own tobacco and waterpipe tobacco, if there is a substantial change of circumstances as established in a Commission report for the product category concerned.

On 15 June 2022, the Commission adopted a report<sup>3</sup> that established a substantial change of circumstances<sup>4</sup> regarding heated tobacco products. The report provides information and statistics on market developments. It showed 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 EU level.

Consequently, because of that substantial change of circumstances regarding heated tobacco products, the Commission adopted 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<sup>5</sup> ('the Delegated Directive'). This Delegated Directive extended 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, already applying to cigarettes and roll-your-own tobacco, to heated tobacco products. On the same grounds, it withdrew the possibility for Member States to grant exemptions for heated tobacco products, insofar as

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<sup>2</sup> Report from the Commission to the European Parliament and the Council on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2014/40/EU on the approximation of the laws and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (COM/2018/579 final).

<sup>3</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).

<sup>4</sup> Within the meaning of Article 2(28) of the Tobacco Products Directive.

<sup>5</sup> OJ L 283, 3.11.2022, p. 4.

they are tobacco products for smoking, from certain labelling obligations, namely the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10 of the Tobacco Products Directive.

Before its adoption, the draft Delegated Directive was submitted to the Expert Group on Tobacco Policy<sup>6</sup>, which was set up to ensure appropriate expert consultation for the preparation of delegated acts among other things. The European Parliament and the Council have been systematically invited to this expert group's meetings. The documents relevant to these consultations were sent simultaneously to the European Parliament and to the Council, as provided for in the Common Understanding between the European Parliament, the Council and the Commission on Delegated Acts<sup>7</sup>. After adoption, the Delegated Directive was notified to the European Parliament and to the Council with the latter requesting an extension of the deadline by 2 months. Neither the European Parliament nor the Council objected to the Delegated Directive adopted by the Commission under the Tobacco Products Directive within the extended period provided for in Article 27(5) of that Directive.

#### **4. CONCLUSION**

During the current 5-year period, the Commission adopted one delegated act based on Articles 7(12) and 11(6) of the Tobacco Products Directive. In this respect, the Commission has exercised the delegated powers conferred on by those articles in compliance with the objective, scope and content of the delegation.

As regards the other delegated powers conferred in the Tobacco Products Directive<sup>8</sup>, the preconditions to exercise them have not been met in the current 5-year period.

The delegation of powers conferred on the Commission pursuant to the Tobacco Products Directive should be extended in time, as set out in Article 27(2) of that Directive, and taking into account that following the first Commission report neither the European Parliament nor the Council opposed such an extension. The rationale for the delegation has not changed, and the powers granted are essential to achieve the Tobacco Products Directive's objective, namely facilitating the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of human health protection.

The Commission invites the European Parliament and the Council to take note of this report.

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<sup>6</sup> Commission Decision C(2014) 3509 final of 4.6.2014 setting up the group of experts on tobacco policy.

<sup>7</sup> Annex to the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

<sup>8</sup> The first report on the exercise of the delegation of powers under the Tobacco Products Directive provided information on the delegated acts adopted under Article 10(3)(b) and Article 15(12).