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signed by Mr Jordi AYET PUIGARNAU, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
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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 and administrative provisions of the
Member States concerning the manufacture, presentation and sale of
tobacco and related products**

Delegations will find attached document COM(2018) 579 final.

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

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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/EC¹ ('the Tobacco Products Directive') is to approximate 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 the Tobacco Products 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;

in order 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 obligations of the Union under the WHO Framework Convention for Tobacco Control (FCTC).

Article 27 of the Tobacco Products Directive confers powers on the Commission to adopt delegated acts in certain cases referred to therein and subject to the conditions laid down in that Article. The Commission is empowered to adopt delegated acts with regard to:

- the reduction of the maximum emission levels laid down in Article 3(1), where this is necessary based on internationally agreed standards (**Article 3(2)**);

¹ OJ L 127, 29.4.2014, p. 1.

- the integration of standards agreed by parties to the FCTC or by the WHO relating to maximum emission levels for emissions from cigarettes other than the emissions referred to in Article 3(1) and for emissions from tobacco products other than cigarettes into Union law (**Article 3(4)**);
- the adaptation of the methods of measurement of the tar, nicotine and carbon monoxide emissions, where this is necessary, based on scientific and technical developments or internationally agreed standards (**Article 4(3)**);
- the integration of standards agreed by the parties to the FCTC or by the WHO for measurement methods into Union law (**Article 4(5)**);
- the determination of maximum content levels for additives or combination of additives that result in a characterising flavour, where the content level or concentration of these additives or the combination thereof has resulted in prohibitions pursuant to Article 7(1) in at least three Member States (**Article 7(5)**);
- the setting of maximum content levels for additives, where an additive or a certain quantity thereof has been shown to amplify the toxic or addictive effect of a tobacco product, and where this has resulted in prohibitions pursuant to Article 7(9) in at least three Member States (**Article 7(11)**);
- the withdrawal of exemptions for tobacco products 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 (**Article 7(12)**);
- the adaptation of the wording of the information message laid down in Article 9(2) to scientific and market developments (**Article 9(5)**);
- the adaptation of the text warnings listed in Annex I taking into account scientific and market developments (**Article 10(3)(a)**);
- the establishment and adaptation of the picture library referred to in Article 10(1)(a) taking into account scientific and market developments (**Article 10(3) (b)**);
- the withdrawal of the 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 11(6)**);
- the adaptation of the wording of the health warning laid down in Article 12(1) to scientific developments (**Article 12(3)**);
- the definition of the key elements of the data storage contracts referred to in Article 15(8), such as duration, renewability, expertise required or confidentiality, including the regular monitoring and evaluation of those contracts (**Article 15(12)**);
- the extension of a prohibition by at least three Member States of placing on the market specific electronic cigarettes or refill containers or a type thereof, to all Member States, if such an extension is justified and proportionate (**Article 20(11)**);

- the adaptation of the wording of the health warning in Article 20(4)(b) (**Article 20(12)**).

2. LEGAL BASIS

This report is required under Article 27(2) of the Tobacco Products Directive. Pursuant to that Article, the power to adopt delegated acts is conferred on the Commission for a period of five years from 19 May 2014 and the Commission is required to draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. EXERCISE OF THE DELEGATION

3.1 Procedural Aspects

In the reporting period the Commission adopted two delegated acts based on Articles 10(3)(b) and 15(12) of the Tobacco Products Directive.

Prior to their adoption, the two draft delegated acts were submitted to the Expert Group on Tobacco Policy², established *inter alia* to ensure appropriate expert consultation for the preparation of delegated acts. The European Parliament has been systematically invited to the meetings of this Expert Group. The documents relevant to these consultations were transmitted 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 Acts³. After adoption, the delegated acts were notified to the European Parliament and to the Council. No objection to either of the delegated acts adopted by the Commission under the Tobacco Products Directive was raised by the European Parliament or the Council within the 2 month period provided for in Article 27(5) of the Directive. In the case of the delegated act adopted pursuant to Article 15(12) of the Directive the European Parliament requested an extension of the deadline by 2 months.

3.2 Delegated acts adopted under the Tobacco Products Directive

3.2.1. Article 10(3)(b)

Article 10(3)(b) empowers the Commission to adopt delegated acts to establish and adapt a picture library. The pictures contained in that library are an integral part of the combined health warning which is required to appear on each unit packet and outside packaging of tobacco products for smoking placed on the EU market. Accordingly, the

² Commission Decision C(2014) 3509 final of 4.6.2014 setting up the group of experts on tobacco policy.

³ 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).

Commission adopted 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 products⁴. In line with the delegated powers conferred upon it, the Commission may make use of this delegated power in the future to adapt the picture library.

3.2.2. Article 15(12)

In accordance with Article 15(1) and (5), Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier, in order to enable their movements to be recorded by all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet. Article 15(8) requires Member States to ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant traceability data recorded in this context. Article 15(12) empowers the Commission to adopt delegated acts to define the key elements of the data storage contracts, such as duration, renewability, expertise required or confidentiality, including the regular monitoring and evaluation of those contracts. To ensure the effective functioning of the traceability system in general and the interoperability of the data storage system in particular, the Commission adopted Delegated Regulation (EU) 2018/573 of 15 December 2017 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products⁵.

3.3 Delegated powers conferred by the following provisions of the Tobacco Products Directive that have not been exercised

3.3.1. Article 3(2)

Regarding the delegated power foreseen under Article 3(2) to decrease the maximum emission levels for tar, nicotine and carbon monoxide based on internationally agreed standards, no such new standard has emerged. The Commission has therefore not yet made use of this delegated power.

3.3.2. Article 3(4)

Regarding the delegated power foreseen under Article 3(4) to integrate into Union law standards agreed by the parties to the FCTC or by the WHO relating to maximum emission levels for emissions from cigarettes other than the emissions referred to in Article 3(1) and for emissions from tobacco products other than cigarettes, no such new standard has emerged. The Commission has therefore not yet made use of this delegated power.

3.3.3. Article 4(3)

Regarding the delegated power foreseen under Article 4(3) to adapt the methods of measurement of tar, nicotine and carbon monoxide emissions to scientific and technical developments or internationally agreed standards, no developments or standards have

⁴ OJ L 360, 17.12.2014, p. 22.

⁵ OJ L 96, 16.4.2018, p. 1.

emerged that would justify an adjustment for the purpose of the Tobacco Products Directive. The Commission has therefore not yet made use of this delegated power.

3.3.4 Article 4(5)

Regarding the delegated power foreseen under Article 4(5) to integrate into Union law standards for measurement methods agreed by the parties to the FCTC or by the WHO, no such standards have emerged. The Commission has therefore not yet made use of this delegated power.

3.3.5. Article 7(5)

Regarding the delegated power foreseen under Article 7(5) to set maximum content levels for certain additives or combinations of additives that result in a characterising flavour, the necessary conditions (prohibitions pursuant to Article 7(1) in at least three Member States) have not been met. The Commission has therefore not yet made use of this delegated power.

3.3.6. Article 7(11)

Regarding the delegated power foreseen under Article 7(11) to set maximum content levels for additives that have been shown to amplify the toxic or addictive effects of a tobacco product, the necessary conditions (prohibitions pursuant to Article 7(9) in at least three Member States) have not been met. The Commission has therefore not yet made use of this delegated power.

3.3.7 Article 7(12)

Regarding the delegated power foreseen under Article 7(12) to withdraw exemptions for certain product categories from the prohibitions provided for under Article 7(1) and (7), the necessary condition (a substantial change of circumstances as established in a Commission report) has not been met. The Commission has therefore not yet made use of this delegated power.

3.3.8 Article 9(5)

Regarding the delegated power foreseen under Article 9(5) to adapt the general warnings and information messages on tobacco products for smoking to scientific and market developments, the Commission considers it premature to adapt the wording of the information message at this point as it considers the current messages appropriate and effective. The Commission has therefore not yet made use of this delegated power.

3.3.9 Article 10(3)(a)

Regarding the delegated power foreseen under Article 10(3)(a) to adapt the text warnings listed in Annex I taking into account scientific and market developments, the Commission considers it premature to adapt the text warnings at this point as it considers the current messages appropriate and effective. The Commission has therefore not yet made use of this delegated power.

3.3.10 Article 11(6)

Regarding the delegated power foreseen under Article 11(6) to withdraw from Member States the possibility of granting exemptions for particular categories of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco, the necessary condition (a substantial change of circumstances as established in a Commission report) has not been met. The Commission has therefore not yet made use of this delegated power.

3.3.11 Article 12(3)

Regarding the delegated power foreseen under Article 12(3) to adapt the wording of the health warnings on smokeless tobacco products to scientific developments, the Commission considers it premature to adapt the wording of the health warning as it considers the current message appropriate and effective. The Commission has therefore not yet made use of this delegated power.

3.3.12 Article 20(11)

Regarding the delegated power foreseen under Article 20(11) to prohibit specific electronic cigarettes or refill containers, or types thereof, the necessary conditions (prohibitions of these products on duly justified grounds pursuant to Article 20(11) in at least three Member States) have not been met. The Commission has therefore not yet made use of this delegated power.

3.3.13 Article 20(12)

Regarding the delegated power foreseen under Article 20(12) to adapt the health warnings on electronic cigarettes and refill containers, the Commission considers it premature to adapt the wording of the health warning of Article 20(4)(b) as it considers the current message appropriate and effective. The Commission has therefore not yet made use of this delegated power.

4. CONCLUSION

The Commission has exercised the delegated powers conferred on it by Article 10(3)(b) and Article 15(12) of the Tobacco Products Directive [2014/40/EU](#) in compliance with the objective, scope and content of the delegation.

As regards the other delegated powers conferred, the preconditions for their exercise have not yet been met. The delegation of powers should nevertheless be extended, as provided in Article 27(2) of the Tobacco Products Directive. The rationale for the delegation has not changed and the powers granted are essential for achieving the objective of the Tobacco Products Directive, 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.