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 (Text with EEA relevance)

TITLE IV

FINAL PROVISIONS

Article 23

Cooperation and enforcement

1 Member States shall ensure that manufacturers and importers of tobacco and related products provide the Commission and the competent authorities of the Member States with complete and correct information requested pursuant to this Directive and within the time limits set out herein. The obligation to provide the requested information shall lie primarily with the manufacturer, if the manufacturer is established in the Union. The obligation to provide the requested information shall lie primarily with the importer, if the manufacturer is established outside the Union and the importer is established inside the Union. The obligation to provide the requested information shall lie jointly with the manufacturer and the importer if both are established outside the Union.

2 Member States shall ensure that tobacco and related products which do not comply with this Directive, including the implementing and delegated acts provided for therein, are not placed on the market. Member States shall ensure that tobacco and related products are not placed on the market if the reporting obligations set out in this Directive are not complied with.

3 Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures that are necessary to ensure that these penalties are enforced. The penalties provided for shall be effective, proportionate and dissuasive. Any financial administrative penalty that may be imposed as a result of an intentional infringement may be such as to offset the economic advantage sought through the infringement.

4 The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the correct application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive in a uniform manner.

Article 24

Free movement

1 Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.

2 This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the

standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.

3 A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection of human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within the period of six months, the national provisions shall be deemed to be approved.

Article 25

Committee procedure

1 The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3 Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

4 Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 26

Competent authorities

Member States shall designate the competent authorities that shall be responsible for the implementation and enforcement of the obligations provided for in this Directive within three months of 20 May 2016. Member States shall inform the Commission about the identity of the designated authorities without delay. The Commission shall publish that information in the *Official Journal of the European Union*.

Article 27

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Articles 3(2) and (4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) shall be conferred on the Commission for a period of five years from 19 May 2014. The Commission shall 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 The delegation of powers referred to in Articles 3(2) and(4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5 A delegated act adopted pursuant to Articles 3(2) and (4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 28

Report

1 No later than five years from 20 May 2016, and whenever necessary thereafter, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.

When drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information at its disposal.

2 In the report, the Commission shall indicate, in particular, the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco and related products. The Commission shall pay special attention to:

a the experience gained with respect to the design of package surfaces not governed by this Directive taking into account national, international, legal, economic and scientific developments;

b market developments concerning novel tobacco products considering, inter alia, notifications received under Article 19;

c market developments which constitute a substantial change of circumstances;

d the feasibility, benefits and possible impact of a European system for the regulation of the ingredients used in tobacco products, including the establishment, at Union level, of a list of ingredients that may be used or present in, or added to tobacco products, taking into account, inter alia, the information collected in accordance with Articles 5 and 6;

e market developments concerning cigarettes with a diameter of less than 7,5 mm, and consumer perception of their harmfulness as well as the misleading character of such cigarettes;

f the feasibility, benefits and possible impact of a Union database containing information on ingredients and emissions from tobacco products collected in accordance with Articles 5 and 6;

g market developments concerning electronic cigarettes and refill containers considering, amongst others, information collected in accordance with Article 20, including on the initiation of consumption such products by young people and non-smokers and the impact of such products on cessation efforts as well as measures taken by Member States regarding flavours;

h market developments and consumer preferences as regards waterpipe tobacco, with a particular focus on its flavours.

The Member States shall assist the Commission and provide all available information for carrying out the assessment and preparing the report.

3 The report shall be followed-up by proposals for amending this Directive, which the Commission deem necessary to adapt it - to the extent necessary for the smooth functioning of the internal market - to developments in the field of tobacco and related products, and to take into account new developments based on scientific facts and developments concerning internationally agreed standards for tobacco and related products.

Article 29

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 May 2016. They shall forthwith communicate to the Commission the text of those provisions.

The Member States shall apply those measures from 20 May 2016, without prejudice to Articles 7(14), 10(1)(e), 15(13) and 16(3).

2 When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. The Member States shall determine how such reference is to be made and how that statement is to be formulated.

3 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 30

Transitional provision

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until 20 May 2017:

(a) tobacco products manufactured or released for free circulation and labelled in accordance with Directive 2001/37/EC before 20 May 2016;

(b) electronic cigarettes or refill containers manufactured or released for free circulation before 20 November 2016;

(c) herbal products for smoking manufactured or released for free circulation before 20 May 2016.

Article 31

Repeal

Directive 2001/37/EC is repealed with effect from 20 May 2016, without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law of that Directive.

References to the repealed Directive shall be construed as references to this Directive and read in accordance with the correlation table in Annex III to this Directive.

Article 32

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 33

Addressees

This Directive is addressed to the Member States.