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COMMISSION IMPLEMENTING DECISION

of 26.7.2016

concerning national provisions notified by Finland prohibiting the placing on the market of certain categories of smokeless tobacco products

(Only the Finnish and Swedish texts are authentic)

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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 Article 24(3) thereof,

Whereas:

I. FACTS

- (1) On 19 February 2016, Finland notified the Commission under Article 24(3) of Directive 2014/40/EU of a draft law regulating the sale and import of smokeless tobacco products. The draft law provides for a prohibition on the placing on the market of smokeless tobacco products, including, the following product categories: tobacco for oral use, chewing tobacco and nasal tobacco. The notification was accompanied by explanations and data justifying the proposed measure.

1.1 Notification procedure under Article 24(3) of Directive 2014/40/EU

- (2) Pursuant to Article 24(3) of Directive 2014/40/EU a Member State may prohibit a certain category of tobacco or related products where the conditions laid down in that Article are fulfilled. In particular, any such prohibition is to be based on grounds relating to the specific situation in the Member State concerned and must be justified by the need to protect public health, taking into account the high level of protection of human health achieved through that Directive. Any Member State wishing to introduce such a prohibition is required to notify the relevant national provisions to the Commission.
- (3) Article 24(3) further provides that, within a period of six months of the date of receiving the notification, the Commission is to either approve or reject the draft national provisions in question after having verified whether or not they are justified, necessary and proportionate and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States.

¹ OJ L 127, 29.4.2014, p. 1.

1.2 Union legislation

- (4) Directive 2014/40/EU regulates the manufacture, presentation and sale of tobacco and related products placed on, or intended to be placed on the Union market.
- (5) Article 17 of Directive 2014/40/EU provides for the prohibition on the placing on the market of tobacco for oral use. Such a prohibition had initially been established in 1992 following an amendment introduced by Council Directive 92/41/EEC² to Council Directive 89/622/EEC³. The prohibition was subsequently re-enacted in Directive 2001/37/EC of the European Parliament and of the Council.⁴
- (6) Article 151 of the Act of Accession of Austria, Finland and Sweden⁵ grants Sweden a derogation from the prohibition of placing oral tobacco on the market, making it the only Member State in which the placing on the market of tobacco for oral use is permitted.

1.3 National Provisions Notified

- (7) According to the notification, it is proposed to insert the following provision into the Finnish Tobacco Act: "*Smokeless tobacco products may not be sold or otherwise supplied.*"
- (8) Pursuant to the notification, "smokeless tobacco products" comprise the following product categories: tobacco for oral use, chewing tobacco, nasal tobacco. The term may also be regarded as encompassing any other non-combustible tobacco products (however, such other products are neither defined nor otherwise referred to in the notification). The notification also confirms that the prohibition is to apply to the online sale of smokeless tobacco products as provided for in Article 18 of Directive 2014/40/EU⁶.
- (9) The proposed prohibition on the placing on the market of smokeless tobacco products is accompanied by measures aimed at restricting the import of such products. These measures include derogations with respect to the importation of limited quantities of such products by private individuals for personal use.
- (10) In addition, the Finnish authorities propose inserting a transitional period which would permit smokeless tobacco products, other than tobacco for oral use, to be sold and otherwise supplied until 20 May 2017. It is envisaged that such a transitional period would apply to products which are already on the Finnish market when the Tobacco Act enters into force.

² Council Directive 92/41/EEC of 15 May 1992 amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products (OJ L 158, 11.6.1992, p. 30).

³ Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products (OJ L 359, 8.12.1989, p. 1).

⁴ Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, p. 26).

⁵ OL C 241, 29.8.1994.

⁶ The text of the draft Finnish Tobacco Act was submitted to the Commission by the Finnish authorities on 27 April 2016.

II. ASSESSMENT

2.1 On the scope of the assessment

- (11) At the outset, it is recalled that in Case C-547/14 *Philip Morris brands and others*, the Court of Justice has held that Directive 2014/40/EU is not intended to interfere with the policies of the Member States concerning the lawfulness of tobacco products as such. The Court clarified that Article 24(3) of Directive 2014/40/EU concerns an aspect of tobacco regulation that is not covered by the harmonisation measures in the directive⁷. The Court ruled that Article 24(3) "seeks to delineate the scope of the directive by clarifying that tobacco and related products which comply with the requirements laid down by the directive may move freely on the internal market, provided that those products belong to a category of tobacco products or related products which is, as such, lawful in the Member State in which they are marketed"⁸.
- (12) In accordance with this case-law, the notified measure proposing to ban the placing on the market of smokeless tobacco products, concerns an aspect not harmonised by Directive 2014/40/EU.
- (13) The Commission observes that while the draft legislation refers to "smokeless tobacco products" in general, the explanations and justifications advanced by the Finnish authorities in support of the draft measure concern – and are limited to – three specific product categories, namely, tobacco for oral use, chewing tobacco and nasal tobacco. Given that the placing on the market of tobacco for oral use is already the subject of a Union law prohibition, the scope of this assessment is therefore limited to chewing tobacco and nasal tobacco. Insofar as the Finnish authorities are proposing to extend the prohibition to any additional category of tobacco or related product, a further notification would be required to be submitted under Article 24(3) of Directive 2014/40/EU in respect of such additional category (accompanied by the necessary explanations and justifications provided for in that Article).
- (14) The Commission further observes that while the Finnish authorities have notified a number of provisions regulating smokeless tobacco products, it is only those measures which concern proposed restrictions on the placing on the market of such products which are of direct relevance to the assessment to be carried out under Article 24(3) of Directive 2014/40/EU. Indeed, it is clear from Article 24(1) of Directive 2014/40/EU that the provisions contained in this section concern the "placing on the market of tobacco or related products". Pursuant to the definition provided by Article 2(40) of Directive 2014/40/EU, "placing on the market" means "to make products, irrespective of their place of manufacture, available to consumers placed in the Union".

2.2 The position of Finland

- (15) By its notification, Finland claims that the proposed national provisions providing for the prohibition of the placing on the market of smokeless tobacco products are based on public health grounds that are specific to that Member State.
- (16) The Finnish authorities recall that smokeless tobacco products contain nicotine which is addictive. In addition, Finland observes that the International Agency for Research

⁷ Judgement in *Philip Morris Brands and others*, C-547/14, ECLI:EU:C:2016:325, paragraph 90.

⁸ Judgement in *Philip Morris Brands and others*, C-547/14, ECLI:EU:C:2016:325, paragraph 91.

on Cancer (IARC) has classified smokeless tobacco products as carcinogenic. It is asserted that the cancer risk of smokeless tobacco users is higher than that of non-tobacco users and that evidence suggests an increased risk of fatal myocardial infarction and pregnancy complications among smokeless tobacco users. Finland states that it seeks to promote the reduction and ultimately the cessation of tobacco consumption in Finland.

- (17) Finland submits that the grounds underlying the proposed measure relate to the specific situation in that Member State. In the first instance, Finland makes reference to its geographical proximity to Sweden, the only Member State in which the sale of tobacco for oral use is permitted, as well as to Russia. Secondly, the Finnish authorities refer to the widespread and increasing consumption of tobacco for oral use among its population.
- (18) Concerning geographical proximity, the Finnish authorities explain that as a result of its extensive shared border with Sweden, Finland has been subject to sustained attempts to import tobacco for oral use into its territory. The Finnish authorities state that many shops have been established along the border with the specific aim of attracting Finnish consumers to buy tobacco for oral use. In addition, heavy passenger ferry traffic exists between the two countries and importation by sea is widespread. The Finnish authorities also report that tobacco for oral use bought in Sweden or in Russia often ends up on the black market in Finland, sold under the counter in kiosks or advertised on social networking sites.
- (19) The Finnish authorities claim that in the absence of a general ban on smokeless tobacco products, manufacturers and importers would be in a position to circumvent the prohibition on the placing on the market of tobacco for oral use by selling that product under the label of other smokeless tobacco products. The Finnish authorities explain that such circumvention is facilitated by the fact that in Union law, it is the intended use of a product and not its composition or preparation that distinguishes tobacco for oral use from other smokeless tobacco products. Documents annexed to the notification explain that some products marketed as chewing tobacco are not consumed like chewing gum, but are placed under the lip, along the upper or lower jaw or squeezed between teeth. As a consequence, it is very difficult for the authorities in Finland to determine, for example, whether a tobacco product is genuinely chewing tobacco or whether it is in fact tobacco for oral use packaged as chewing tobacco. In this context, reference is made to a number of seizures of products commercially imported or planned to be imported into Finland as chewing tobacco but subsequently determined to be tobacco for oral use.
- (20) The Finnish authorities detail and illustrate the enforcement measures implemented to date to combat the illicit market for tobacco for oral use and the practices outlined above, including a maximum prison sentence of six months for sale or commercial supply of this product and the cancellation of retail licenses in the case of the sale or storage of this product on retail premises. However, Finland considers that those measures are insufficient to prevent the illicit market for tobacco for oral use. On the contrary, it claims that consumption of smokeless tobacco products more generally is increasing.
- (21) The Finnish authorities consider that Finland's particular geographic vulnerability to attempts at importation of tobacco for oral use is exacerbated by the particular predisposition of its population to the consumption of that product. Operators seeking to import tobacco for oral use find a ready demand for it in Finland. In this context, the

Finnish authorities refer to the 2014 Eurobarometer survey which found that 14% of the Finnish population regularly use tobacco for oral use, compared to a 1% average in the Union as a whole. The Finnish authorities further present studies showing a dramatic increase in the use of tobacco for oral use, in particular amongst young people. They point to statistics illustrating an almost 500% increase, between 2013 and 2015, in the number of sixteen year-old boys consuming tobacco for oral use on a daily basis.

- (22) The Finnish authorities express concern that the predisposition of the population to the consumption of tobacco for oral use leaves it particularly vulnerable to other forms of smokeless tobacco products, such as chewing or nasal tobacco, becoming newly embedded within its society, and in particular, among young persons. Given the current high prevalence of tobacco for oral use amongst the Finnish population compared to the Union average and its geographical location, Finland considers that there is a risk of greater predisposition to other types of smokeless tobacco amongst its population.
- (23) The Finnish authorities consider that the actual and potential increase in the consumption of smokeless tobacco products undermines the positive developments that have taken place in reducing smoking in Finland and enters into direct conflict with its stated health policy objectives.

2.3 Evaluation

- (24) Pursuant to Article 24(3) of Directive 2014/40/EU, the Commission is required to verify whether or not the proposed national measures 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.
- (25) At the outset, the Commission observes that it is apparent from the notification submitted by Finland that the proposed national provisions are intended to support public health policy objectives in the field of tobacco control. Moreover, they are based on grounds that relate to the specific situation of Finland.
- (26) In this regard, the Commission observes that in justifying its national provisions, the Finnish authorities have made particular reference to Finland's specific geographical position, namely, its shared border with Sweden and Russia, from where illicit tobacco for oral use has been found to originate. The Finnish authorities have moreover identified and recorded repeated attempts at circumventing the ban on tobacco for oral use and produced statistics demonstrating the particular prevalence of tobacco for oral use in that Member State compared with other Member States of the Union. The Finnish authorities have further submitted data disclosing marked increases in the rate at which tobacco for oral use is being consumed in Finland.
- (27) The Finnish authorities express their concern that in the light of those factors, and in particular, the established predisposition of a considerable proportion of its population to tobacco for oral use, there is a particularly acute risk that the prohibition on the sale of tobacco for oral use may be circumvented and that forms of smokeless tobacco that are new to the Finnish market, such as nasal and chewing tobacco, will take root within its population and particularly among young people.
- (28) On the basis of the information and data supplied by Finland, the Commission considers that Finland's geographical proximity to Sweden, and the resulting access to a supply of tobacco for oral use, on the one hand, combined with the predisposition of its population to the consumption of such tobacco, and the corresponding demand for

such products on the other, leaves Finland particularly vulnerable with respect to the consumption of chewing tobacco and nasal tobacco within its territory.

- (29) Indeed, this conclusion is supported by the findings contained in a report submitted in 2010 to the Council on the implementation by the Kingdom of Sweden of the measures necessary to ensure that oral tobacco is not placed on the market in other Member States.⁹ The report found that, apart from Sweden, Finland was the only Member State in which prevalence of tobacco for oral use was significant and increasing. In addition, it found that Finland was the only Member State to have taken additional preventative measures to address the illicit flow of tobacco for oral use into its territory.
- (30) The Commission further considers that, having regard to those circumstances and taking into account the high level of protection of human health that Directive 2014/40/EU is intended to achieve, the proposed prohibition on the placing on the market of chewing and nasal tobacco may be regarded as justified and proportionate.
- (31) In this regard, it is considered that such a prohibition is apt to support the objective of combatting the unlawful sale of tobacco for oral use in Finland and to prevent chewing or nasal tobacco products, that are less well-established in Finland, from taking root in that Member State. Moreover, that prohibition would limit access to those products, thereby reducing the risk of the formation of addiction and dependence.
- (32) In addition, the proposed measure prohibiting the placing on the market of chewing and nasal tobacco may be considered necessary and the aim of this measure could not be attained by a less restrictive alternative measure. In this context, the Commission notes that according to the Finnish authorities, the imposition of criminal sanctions and the adoption of enforcement measures have not proven sufficient to prevent widespread attempts at selling tobacco for oral use packaged as other forms of smokeless tobacco products. Moreover, as regards the objective to prevent the formation of addiction and dependence on products that are novel to the Finnish market, it is recalled that nicotine is a particularly addictive toxic substance. Any measure that is less than a preventive measure, such as the proposed prohibition which operates at a stage before dependence on such products is established, would be less effective since it is manifestly much more difficult to diminish or cease addiction after dependence has been formed. The addictive nature of tobacco products underscores the entitlement to take timely preventive action in a context where, having regard to the particular predisposition of the population to particular categories of tobacco products, the risk for future widespread use and dependence is particularly acute.
- (33) The Commission notes that the notified measure is proposed as part of a public health initiative aimed at reducing tobacco consumption in Finland. Consistent with this objective, the measures at issue would apply both to imported goods as it would to products that may be produced in Finland. The Commission therefore considers that the notified provision may not be qualified as a means of arbitrary discrimination or a disguised restriction on trade between the Member States.

III. CONCLUSION

⁹ COM(2010)399 final

- (34) On the basis of the considerations set out above, having regard to the information and data submitted by Finland, and taking account of the objective of ensuring a high level of public health that Directive 2014/40/EU is intended to achieve, the national prohibition on the placing on the market of chewing- and nasal tobacco may be regarded as complying with the requirements laid down in Article 24(3) of the Directive.
- (35) This conclusion does not, however, extend to any other categories of smokeless tobacco product that have not been identified by the Finnish authorities and in respect of which a notification would be required under Article 24(3) of Directive 2014/40/EU.
- (36) It is therefore appropriate for national measures prohibiting the placing on the market of chewing tobacco and nasal tobacco to be approved,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions prohibiting the placing on the market of chewing tobacco and nasal tobacco proposed to be adopted by the Republic of Finland and notified on 19 February 2016 in accordance with Article 24(3) of Directive 2014/40/EU, are approved.

Article 2

This Decision is addressed to the Republic of Finland.

Done at Brussels, 26.7.2016

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission