

Brussels, 27.2.2020 C(2020) 1066 final

COMMISSION IMPLEMENTING DECISION

of 27.2.2020

concerning national provisions notified by Greece prohibiting the placing on the market of chewing and nasal tobacco

(Only the Greek text is 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) By e-mail of 4 March 2019, Greece informed the Commission of draft national provisions to amend Law 4419/2016. The amendment to Law 4419/2016 provides for a prohibition on the placing on the market of chewing and nasal tobacco.
- (2) By e-mail of 4 April 2019, the Commission sent a request for further information in which the Greek authorities were asked to confirm that the information submitted is to be considered a notification in accordance with Article 24(3) of Directive 2014/40/EU and asked for additional justification concerning the grounds for the introduction of the measure in question. The Greek authorities provided that information by e-mail, received on 23 April 2019. Following a further request for clarifications sent by the Commission on 25 July 2019, the Greek authorities supplied additional information about the notified measure by e-mail received on 4 September 2019.
 - 1.1 Notification procedure under Article 24(3) of Directive 2014/40/EU
- (3) Pursuant to Article 24(3) of Directive 2014/40/EU, a Member State may prohibit a certain category of tobacco or related products once 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 Commission of the relevant national provisions and the grounds for their introduction.
- (4) Article 24(3) of Directive 2014/40/EU further provides that, within a period of six months of the date of receiving the notification, accompanied by the required justification, 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

OJ L 127, 29.04.2014, p. 1.

disguised restriction on trade between Member States. As the notification, within the meaning of Article 24(3) of Directive 2014/40/EU was completed following the submission of additional information by the Greek authorities on 4 September 2019, the six month time limit commences from that date.

1.2 Union legislation

- (5) 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.
- (6) Article 17 of Directive 2014/40/EU provides for the prohibition on the placing on the market of tobacco for oral use. This prohibition does not include chewing or nasal tobacco products as defined in Article 2(6) and (7) of the Directive. The prohibition on oral tobacco was initially 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 Council⁴.
- (7) Article 151 of the Act of Accession of Austria, Finland and Sweden⁵ grants Sweden a derogation from the prohibition on 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

(8) According to the notification, it is proposed to insert the following provision in Law 4419/2016: "Chewing tobacco, nasal tobacco [...] are not allowed to be placed on the market."

II. ASSESSMENT

2.1 The position of Greece

- (9) In their notification, the Greek authorities claim that the prohibition on the placing on the market of chewing and nasal tobacco is based on public health grounds. The Greek authorities recall that chewing and nasal tobacco contain nicotine, often in high concentration, which is an addictive substance. Besides the obvious nicotine dependence, the Greek authorities also list significant health risks associated with the consumption of such smokeless tobacco products, including different forms of cancer, cardiovascular diseases, dental and gum diseases. In this context, the authorities refer to numerous scientific studies, including studies prepared by the International Agency for Research on Cancer (IARC), the report of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and reports of the Secretariat of the Conference of the Parties to the Framework Convention on Tobacco Control.
- (10) Greek authorities submit that the grounds underlying the proposed measure relate to the specific situation in that Member State.

⁵ OJ C 241, 29.8.1994.

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).

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).

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).

- (11) Whilst acknowledging that measures taken to combat tobacco use have resulted in a significant decline in tobacco use among young people, in particular over the past few years, the Greek authorities, however, submit that, when compared with other European countries, the consumption of tobacco products in general remains high in Greece. The Greek authorities further submit that there is evidence of a significant rise in the consumption of smokeless tobacco products since 2016, including products marketed as chewing and nasal tobacco, which have not been traditionally consumed in Greece. In that context, the Greek authorities refer to increasing number of notifications of such products via the EU Common Entry Gate (EU-CEG)⁶ and their corresponding sales volume.
- (12) The Greek authorities consider that the evident increase in smokeless tobacco products sales strongly suggests that there is a possibility of future market development, within the meaning of recital 54 of Directive 2014/40/EU, which may possibly lead to important public health risks, hindering tobacco cessation efforts aimed at the population in Greece.
- (13) In addition, the Greek authorities explain that the proposed prohibition is of great importance to the political goal of reducing the number of smokers by up to 50 % in the next 5 years, as recently declared by the Greek government. In this regard, the Greek authorities recall the SCENIHR report on "Health Effects of Smokeless Tobacco Products" (2008), in which it is clearly observed that smokeless tobacco may lead to high levels of addiction causing withdrawal symptoms during cessation, similar to those of smoking and increases the likelihood of commencing or resuming smoking. Furthermore, there is a lack of scientific evidence to support the contribution of those products as an aid to smoking cessation.
- (14) The Greek authorities find that since consumption of conventional tobacco products, although having declined significantly in past years, mostly in the 15-24 age group, is still high in Greece compared to other European countries, this raises major public health concerns, especially given the increase in smoking-related cancers and respiratory and cardiovascular diseases, while being one of the most common preventable causes of death. The Greek authorities fear that the clearly observed withdrawal symptoms during cessation from smokeless tobacco products could result in more people taking up smoking or resuming it after successful cessation.
- (15) Furthermore, the Greek authorities refer to the overt marketing of products in the domestic market under the guise of chewing and nasal tobacco, which demonstrate attributes and use patterns identical to oral tobacco.
- (16) In this regard, the Greek authorities highlight the difficulties in ensuring the enforcement of the prohibition of oral tobacco, which is often difficult to differentiate from chewing and nasal tobacco. The Greek authorities note that they have observed the appearance on the Greek market, in particular online, of products wrongfully presented as chewing tobacco, which, based on their characteristics and mode of use, should be considered as oral tobacco. The ways in which these products are presented may result in a circumvention of the ban on oral tobacco and, as a consequence, the presence of illegal products on the Greek market.

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Commission Implementing Decision 2015/2186/EU of 25 November 2015 on establishing a format for the submission and making available of information on tobacco products (OJ L 312, 27.11.2015, p. 5-18).

https://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

(17) The Greek authorities emphasise that their efforts in the field of tobacco control arise in a context where Greece suffers from a particularly high-level of smokers, including amongst young users of tobacco products. The Greek authorities explain that given the tendency of younger people, especially adolescents, to experience and taste new products, the link between the rise in the consumption of chewing and nasal tobacco and the decrease in smoking rates in the age group 15-24 cannot be excluded. This, along with the wide and false perception regarding the role of such products in smoking cessation efforts, in which the products are often marketed as alternative tobacco products, is indicative of a significant risk of a new consumer trend, which should be prevented.

2.2 Evaluation

- (18) It should be recalled that in Case C-547/14 *Philip Morris brands and others*, the Court of Justice held that Directive 2014/40/EU is not intended to interfere with the policies of 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 Directive⁸. 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"⁹.
- (19) In accordance with this case law, the notified measure that provides for the prohibition on the placing on the market of chewing and nasal tobacco concerns an aspect not harmonised by Directive 2014/40/EU.
- (20) Nevertheless, pursuant to Article 24(3) of Directive 2014/40/EU, the Commission is required to verify whether 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 Member States.
- (21) In this regard, the Commission observes that it is apparent from the notification that the proposed measure is to be adopted on public health grounds. In its notification, the Greek authorities detail the health risks associated with the consumption of chewing and nasal tobacco. The Greek authorities further emphasise that the proposed measure is intended to strengthen tobacco control legislation and to ensure a high level of health protection by means of tobacco control in Greece.
- (22) It is also apparent from the notification that the national provisions are based on grounds that relate to the specific situation in Greece. Information submitted by the Greek authorities in support of the notified measure reveal an increase and potential future increase in the consumption of chewing and nasal tobacco in that Member State. Such increase suggests that there is a possibility of future market development, within the meaning of recital 54 of Directive 2014/40/EU, which may possibly lead to important public health risks, hindering tobacco cessation efforts aimed at the population in Greece. Furthermore, information received from the Greek authorities points to products being placed on the Greek market that aim at circumventing the ban on oral tobacco by marketing products under the guise of chewing and nasal tobacco.

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

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

- (23) 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 Greece and to prevent chewing and nasal tobacco products, that are less well established in Greece, from taking root in that Member State. The prohibition would limit access to those products, thereby reducing the risk of formation of addiction and dependence.
- In addition, the proposed measure prohibiting the placing on the market of chewing and nasal tobacco may be considered necessary as regards the objective pursued and could not have been attained by a less restrictive alternative measure. In this context, the Commission notes that as regards the objective to prevent the formation of addiction and dependence on chewing and nasal tobacco which are products not traditionally consumed by the Greek population, 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 need and entitlement of Member States to take timely preventive action, particularly in a context where there is a potential risk for future widespread use and dependence.
- (25) The Commission considers that, based on the considerations set out above 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.
- (26) Moreover, based on the information supplied by the Greek authorities, given that the scope of the ban would apply to domestic and imported products alike, the Commission considers that there is no reason to conclude that the prohibition of chewing and nasal tobacco would constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

III. CONCLUSION

- On the basis of the considerations set out above, having regard to the information and data submitted by the Greek authorities, 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.
- (28) It is therefore appropriate for national measures prohibiting the placing on the market of chewing and nasal tobacco to be approved,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions prohibiting the placing on the market of chewing and nasal tobacco notified by the Hellenic Republic in accordance with Article 24(3) of Directive 2014/40/EU are approved.

Article 2

This Decision is addressed to the Hellenic Republic.

Done at Brussels, 27.2.2020

For the Commission Stella KYRIAKIDES Member of the Commission

> CERTIFIED COPY For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION