



EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP
AND SMES

Single Market Policy, Regulation and Implementation
Prevention of Technical Barriers

Brussels, 19.12.2019

GROW.B.2 [REDACTED] (2019) 8798610



Subject: Your complaints CHAP (2019) 1109 of 12 April 2019 and CHAP (2019) 1715 of 19 June 2019 against Greece

Dear [REDACTED]

We refer to our letter of 27 September 2019 informing you of the results of the examination of your complaints in subject and of our intention to proceed with the closure of the file, and to the additional arguments that you sent on 25 October 2019 to support your complaints, in reply to our letter.

After analysis of your additional arguments, we confirm our conclusions and we do not intend to propose to the Commission to initiate an infringement procedure against Greece for failure to comply with EU law. The reasons underpinning this decision are the following.

Articles 34 and 36 TFEU

Certain electronic cigarettes which are intended to allow the consumption of nicotine-free vapour can also be used for the consumption of nicotine-containing vapour and should therefore comply with the applicable rules in Tobacco Products Directive 2014/40/EU¹.

Consequently, only provisions governing those electronic cigarettes that would not fall under the definition provided by Article 2(16) of the Tobacco Products Directive are to be assessed under Articles 34 and 36 TFEU. The question is whether the notification scheme and the packaging and labelling requirements at issue create an obstacle to free movement of goods as guaranteed by Article 34 TFEU.

The prior-notification requirement and the packaging and labelling requirements in terms of informing the consumers about the addictiveness and toxicity of the products, as well as attaching a warning label to the products concerned, do result into a double regulatory burden when the products are imported from Member States which do not have such

¹ 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 (OJ L 127, 29.4.2014, p.1).

restrictions in place. Therefore, they can be considered as measures having an equivalent effect to a quantitative restriction under Article 34 TFEU. However, in order to determine whether the requirements constitute a breach of the free movement rules, it must be examined whether they can be justified under Article 36 TFEU or on grounds of overriding requirements in the public interest.

The protection of the health and life of humans laid down in Article 36 TFEU constitutes a fundamental requirement recognised in Union law, and it is for the Member States, within the limits imposed by the Treaty, to decide the level of protection they wish to afford.² Use of nicotine-free electronic cigarettes does not come without health risks. While further research is necessary, their use has been associated with side effects such as mouth and throat irritation and inflammation. Furthermore, frequently found small particles increase the risk of heart disease, lung cancer and asthma attacks and metal particles have been associated with toxicity and carcinogenic properties³. The Greek government referred to a WHO report according to which flavour is one of the factors that influences willingness to try the products and certain flavours, such as candy-like aromas, appeal to children and those who have not smoked before. Consequently, the restrictions in place, which aim at efficient monitoring of these products, as well as increasing consumer awareness of their possible harmful effects, serve an authorised objective of protection of human health.

The notification scheme of the Tobacco Products Directive has been under scrutiny of the Court of Justice of the European Union (hereinafter the Court) in *Pillbox* 38⁴. The Court held that unlike tobacco products, electronic cigarettes are relatively new products, whose risks to human health still need to be clarified.⁵ The Court highlighted the importance of the precautionary principle, according to which where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.⁶ There is still scientific uncertainty with regard to the negative effects of non-refillable electronic cigarettes without nicotine, and different approaches to regulate these products are applied in different Member States.

In order to be justified, the measures must also be appropriate for attaining the legitimate objectives pursued and not exceed the limits of what is necessary in order to achieve those objectives. In accordance with the precautionary principle, and taking into consideration that both nicotine-free and nicotine-containing electronic cigarettes are relatively new products, whose risks to human health still need to be clarified, restrictive measures such as those at issue are appropriate to achieve the objective of protection of human health. Since the notification regime is significantly less onerous than the requirement of prior authorisation of products⁷, the measure does not go beyond what is necessary to achieve this objective. In addition, most of the information requested is relevant to electronic cigarettes not falling under the scope of the Tobacco Products

² Case C- 387/18, *Delfarma*, EU:C:2019:556, para. 29.

³ https://www.who.int/tobacco/industry/product_regulation/BackgroundPapersENDS3_4November-.pdf

⁴ Case C-477/14, *Pillbox* 38, ECLI:EU:C:2016:324.

⁵ *Ibid.* par. 41.

⁶ *Ibid.* par. 55.

⁷ *Ibid.* par. 70.

Directive as well, such as the name and contact details of the manufacturer, a list of all ingredients contained in the product, and toxicological data regarding the product's ingredients. Hence, the measures are justified and proportionate to attain the objectives of protection of human health in accordance with Article 36 TFEU.

Services Directive

Your complaints also argue that there is an infringement of Article 14(1) of the Services Directive because Article 18b(1) of the Greek Law 4600/2019 renders mandatory the prohibition of electronic (i.e. internet) promotion of nicotine-free liquids, and this would particularly affect Greek companies given that non-Greek distributors might anyway trade the products in question through the internet, unlike Greek traders.

However, the Commission services do not consider that the Services Directive applies to the Greek legislation.

First, the Greek legislation aims at regulating the trade of goods i.e. certain nicotine-free liquids used for vaping, rather than services. Your argument that the Services Directive is also applicable because there could be potential effects of the legislation on service markets through internet is not supported by evidence, and cannot limit the legal analysis from the perspective of the EU rules applicable to the free movement of goods, which already includes the effects of the Greek legislation on EU trade.

Second, Article 2(f) of the Services Directive concerns health services.

Third, the conditions under Article 14(1) of the Services Directive would not be met. The circumstances explained in the complaints show an alleged reverse discrimination against Greek providers' interests. However, such a differentiated treatment against the Greek operators in Greece, if confirmed, does not fall under the scope of Article 14(1) of the Services Directive which concerns the freedom of establishment of providers from other EU Member States.

General Product Safety Directive

According to Article 6 of Directive 2001/95/EC on general product safety (GPSD), Member States have to ensure that producers and distributors comply with their obligations under GPSD in such way that products placed on the market are safe.

According to Article 12 of the GPSD when a Member State adopts or decides to adopt measures or action to prevent, restrict or impose specific conditions on the possible marketing or use of specific products because of a serious risk, it shall immediately notify the Commission through the RAPEX notification system.

Article 12 GPSD refers to "measure" or "action" which have to be notified in RAPEX and not to technical rules. Even if it is likely that adoption of technical rules and adoption of concrete measures and/or actions goes together, these constitute two different procedures. The notification of a measure/action in RAPEX concerns concrete and well identified products on the market which have to be verified and possibly tested to examine, on a case by case, whether they present the serious risk which is a precondition to the notification in RAPEX. The existence of a technical rule does not necessarily make all the products falling within in a certain category dangerous per se. We will contact the

Greek Authorities in that respect but the notification of the technical rules and the notification in RAPEX are to be kept separate.

The CLP Regulation

You mention under point 8 of your complementary document to the complaint that a health warning such as "This product could damage your health" for containers refillable with nicotine-free liquid as introduced by Article 18a d) of the notified Greek draft is contradictory to the CLP Regulation.

The CLP Regulation also applies to containers refillable with nicotine-free liquid, which are mixtures in a container, if the conditions of being a substance/mixture classified as hazardous are fulfilled.

According to the available information, there is insufficient evidence to prove that the alleged infringement is running counter to the free movement clause (Article 51) and that the alleged violation would prohibit, restrict or impede the placing on the market of substances and mixtures.

Conclusion

In the light of the above, we conclude that your additional arguments of 25 October 2019 did not provide any new element leading us to reconsider our previous position. I therefore confirm that your complaints were closed on 19 December 2019.

Yours sincerely,

A black rectangular box redacting the signature of the Head of Unit.

Head of Unit