Ref. Ares(2020)769575 - 06/02/2020
Ref. Ares(2019)7825542 - 19/12/2019

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) 8794800

[redacted]

Subject: **Your complaints CHAP (2019) 1954, CHAP (2019) 1955, CHAP (2019) 1956, CHAP (2019) 1957 and CHAP (2019) 1958 of 8 July 2019 against Greece**

Dear [redacted]

I refer to your complaints of 8 July 2019, registered on 10 July under numbers CHAP (2019) 1954, CHAP (2019) 1955, CHAP (2019) 1956, CHAP (2019) 1957 and CHAP (2019) 1958, and to your correspondence dated 8 August 2019.

Your complaints relate to the *Greek Law 4600/2019, government gazette 43/A/9-3-2019, articles 96 and 97*, notified by Greece pursuant to Directive (EU) 2015/1535[1] (notifications 2019/80/GR and 2019/94/GR).

In your complaints, you claim that Greece infringed Article 25 of the CLP Regulation[2], Article 14(1) of the Services Directive[3], Article 12 of the General Product Safety Directive[4], Articles 26(2), 34, 36, 54 and 61 of the Treaty on the Functioning of the European Union (TFEU), Article 16 of the Charter of Fundamental Rights, and Articles 5 and 6 of Directive (EU) 2015/1535.

The Commission services have completed their examination of your complaints. On the basis of the information you supplied, we are not planning to propose that the Commission initiates infringement procedures for failure to comply with Union law by Greece. The reasons underpinning this decision are the followings.

Articles 34 and 36 TFEU

[1] Directive (EU) 2015/153f of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).
[3] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ L 376, 27.12.2006, p. 36).
[4] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

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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/EU[5].

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 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.[6] 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 properties[7]. 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 38*[8]. The Court held that unlike tobacco products, electronic cigarettes are relatively new products, whose risks to human health still need to be clarified.[9] 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

[5] 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).

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

[7] https://www.who.int/tobacco/industry/product_regulation/BackgroundPapersENDS3_4November-.pdf

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

[9] Ibid. par. 41.

should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.[10] 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 products[11], 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 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

[10] Ibid. par. 55.
[11] Ibid. par. 70.

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 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 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.

Directive (EU) 2015/1535

You also invoke that Greece has failed to fulfil its obligations under Directive (EU) 2015/1535 by (1) adopting the challenged provisions before the end of the 3 months standstill period provided for by Article 6(1) of the Directive, (2) not communicating the texts of the laws amended by the draft notified under 2019/80/GR and 2019/94/GR, as required by Article 5(1), 2nd indent, of the Directive, (3) adopting Law 3730/2008 without prior notification.

In this respect, we would like to recall that the aim of the procedure set up by Directive (EU) 2015/1535 is to prevent upfront unjustified barriers to trade of goods and to the free movement of information society services.

After completion of a detailed analysis of the arguments presented in your complaints by the Commission services, no breach of the relevant provisions of EU law could be identified. In the absence of substantive issues in that respect, the Commission services

do not intend to proceed further with the aspects of your complaint relating to the notification procedure.

However, in accordance with the case law of the Court of Justice of the EU, individuals could challenge the legality of technical regulations adopted in breach of the procedural requirements of Directive (EU) 2015/1535 before a national court. According to established jurisprudence of the Court, individuals may rely on Articles 5 and 6 of Directive (EU) 2015/1535 before the national court, which must decline to apply a national technical regulation which has not been notified in accordance with the Directive (judgement of 30 April 1996 in Case C-194/94 *CIA Security International SA*, EU:C:1996:172, see also judgment of 10 July 2014, in Case C-307/13 *Ivansson and Others*, EU:C:2014:2058), or which, though notified, was adopted and implemented before the end of the three month standstill period (judgment of 16 July 2015, *UNIC and Uni.co.pel*, Case C-95/14, EU:C:2015:492, paragraphs 29-30).

Conclusion

I therefore wish to inform you that we intend to close your complaints. However, should you have any new information that might be relevant for the re-assessment of the case, I invite you to contact us within four weeks of this letter, after which date the complaints might be closed.

Yours sincerely,

[redacted]
Head of Unit

[redacted] Electronically signed on 19/12/2019 12:15 (UTC+01) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563