EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 115

Communication from the Commission - TRIS/(2025) 0664

Directive (EU) 2015/1535

Notification: 2024/0660/LU

Forwarding of a detailed opinion received by a Member State (Greece) (article 6, paragraph 2, second indent of Directive (EU) 2015/1535). This detailed opinion extends the standstill period until 10-06-2025.

Detailed opinion - Avis circonstancié - Ausführliche Stellungnahme - Подробно становище - Podrobné stanovisko - Udførlig udtalelse - Εμπεριστατωμένη γνώμη - Dictamen circunstanciado - Üksikasjalik arvamus - Yksityiskohtainen lausunto - Detaljno mišljenje - Részletes vélemény - Parere circostanziato - Išsamiai išdėstyta nuomonė - Sīki izstrādāts atzinums - Opinjoni dettaljata - Uitvoerig gemotiveerde mening - Opinia szczegółowa - Parecer circunstanciado - Aviz detaliat - Podrobné stanovisko - Podrobno mnenje - Detaljerat yttrande

Extends the time limit of the status quo until 10-06-2025. - Prolonge le délai de statu quo jusqu'au 10-06-2025.- Die Laufzeit des Status quo wird verlängert bis 10-06-2025.- Удължаване на крайния срок на статуквото до 10-06-2025. - Prodlužuje lhůtu současného stavu do 10-06-2025. - Fristen for status quo forlænges til 10-06-2025. - Παρατείνει την προθεσμία του status quo 10-06-2025. - Amplía el plazo de statu quo hasta 10-06-2025. - Praeguse olukorra tähtaega pikendatakse kuni 10-06-2025. - Jatkaa status quon määräaikaa 10-06-2025 asti. - Produžuje se vremensko ograničenje statusa quo do 10-06-2025. - Meghosszabbítja a korábbi állapot határidejét 10-06-2025-ig. - Proroga il termine dello status quo fino al 10-06-2025. - Status quo terminas pratęsiamas iki 10-06-2025. - Pagarina “status quo” laika periodu līdz 10-06-2025. - Jestendi t-terminu tal-istatus quo sa 10-06-2025. - De status-quoperiode wordt verlengd tot 10-06-2025. - Przedłużenie status quo do 10-06-2025. - Prolonga o prazo do statu quo até 10-06-2025. - Prelungește termenul status quo-ului până la 10-06-2025. - Predlžuje sa lehota súčasného stavu do 10-06-2025. - Podaljša rok nespremenjenega stanja do 10-06-2025. - Förlänger tiden för status quo fram till 10-06-2025.

The Commission received this detailed opinion on the 11-03-2025. - La Commission a reçu cet avis circonstancié le 11-03-2025. - Die Kommission hat diese ausführliche Stellungnahme am 11-03-2025 empfangen. - Комисията получи настоящото подробно становище относно 11-03-2025. - Komise obdržela toto podrobné stanovisko dne 11-03-2025. - Kommissionen modtog denne udførlige udtalelse den 11-03-2025. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 11-03-2025. - La Comisión recibió el dictamen circunstanciado el 11-03-2025. - Komisjon sai üksikasjaliku arvamuse 11-03-2025. - Komissio sai tämän yksityiskohtaisen lausunnon 11-03-2025. - Komisija je zaprimila ovo detaljno mišljenje dana 11-03-2025. - A Bizottság 11-03-2025-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 11-03-2025. - Komisija gavo šią išsamiai išdėstytą nuomonę 11-03-2025. - Komisija saņēma šo sīki izstrādāto atzinumu 11-03-2025. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-11-03-2025. - De Commissie heeft deze uitvoerig gemotiveerde mening op 11-03-2025 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 11-03-2025. - A Comissão recebeu o presente parecer circunstanciado em 11-03-2025. - Comisia a primit avizul detaliat privind 11-03-2025. - Komisia dostala toto podrobné stanovisko dňa 11-03-2025. - Komisija je to podrobno mnenje prejela dne 11-03-2025. - Kommissionen mottog detta detaljerade yttrande om 11-03-2025. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 11-03-2025.

MSG: 20250664.EN

1. MSG 115 IND 2024 0660 LU EN 10-06-2025 11-03-2025 GR DO 6.2(2) 10-06-2025

2. Greece

3A. ΕΛΟΤ, ΚΕΝΤΡΟ ΠΛΗΡΟΦΟΡΗΣΗΣ ΟΔΗΓΙΑΣ 98/34/Ε.Ε, ΚΗΦΙΣΟΥ 50, 121 33 ΠΕΡΙΣΤΕΡΙ, ΑΘΗΝΑ, Τ/Φ: + 30210- 2120104, Τ/Ο: + 30210- 2120131

3Β. ΓΕΝΙΚΗ ΓΡΑΜΜΑΤΕΙΑ ΒΙΟΜΗΧΑΝΙΑΣ,ΓΕΝ. Δ/ΝΣΗ ΒΙΟΜΗΧΑΝΙΚΩΝ ΥΠΟΔΟΜΩΝ ΚΑΙ ΕΠΙΧΕΙΡΗΜΑΤΙΚΟΥ ΠΕΡΙΒΑΛΛΟΝΤΟΣ, Δ/ΝΣΗ ΑΣΦΑΛΕΙΑΣ ΚΑΙ ΣΥΜΜΟΡΦΩΣΗΣ ΒΙΟΜΗΧΑΝΙΚΩΝ ΠΡΟΪΟΝΤΩΝ,ΤΜΗΜΑ Δ΄ ΓΕΝΙΚΗΣ ΑΣΦΑΛΕΙΑΣ ΠΡΟΪΟΝΤΩΝ,Πλ. Κάνιγγος, Αθήνα 10181 Τηλ.: 210 3893942, αρμ.: Σταματία Χρόνη

4. 2024/0660/LU - X60M - Tobacco

5. article 6, paragraph 2, second indent of Directive (EU) 2015/1535

6. We hereby request that you immediately submit a reasoned opinion to the European Commission on the draft law “amending the amended Law of 11 August 2006 on tobacco control” submitted by Luxembourg.

The draft law was posted on TRIS database of the European Commission on 09.12.2024 under notification number 2024/0660/LU in the context of the public consultation procedure of Directive (EU) 2015/1535, to inform the Member States and the EU.

The purpose of the amendments to this draft law is to regulate the manufacturing and marketing of nicotine pouches and novel nicotine products, extend the obligation for tobacco products to have combined health warnings to all other novel tobacco products and to nicotine sachets and sachets of novel nicotine products, and impose very low levels of maximum nicotine content for nicotine sachets and sachets of novel nicotine products.

The proposed Luxembourg rules deviate significantly from those of the European legislation and impose an additional barrier to the circulation of novel nicotine products and nicotine sachets.

In particular:

Restrictions are imposed on the labelling of novel tobacco products in breach of Directive 2014/40/EU on tobacco products and Delegated Directive (EU) 2022/2100 amending Directive 2014/40/EU as regards the withdrawal of certain exemptions in respect of heated tobacco products.

The Delegated Directive requires national legislation to distinguish the labelling rules between heated tobacco products not intended for smoking and those classified as tobacco products for smoking. The former must have health warnings in accordance with Article 12 of Directive 2014/40/EU, while the latter must comply with Articles 9-11 of the Tobacco Products Directive.

Article 4(1) of the draft law provides that “Each unit packet and any outer packaging of cigarettes, roll-your-own tobacco and, water pipe tobacco, nicotine sachets, novel tobacco products and novel nicotine products must have a general warning, an information message and combined health warnings”. This provision requires all novel tobacco products, including heated tobacco products, regardless of whether, considering their characteristics, they are smokeless tobacco products or tobacco products for smoking, to have combined health warnings, a general warning and an information message, in breach of the mandatory provisions of Directive 2014/40/EU and the Delegated Directive.

Therefore, the draft law goes beyond the requirements established under Article 1 of the Delegated Directive by extending the obligation to carry combined health warnings, a general warning and information message, not only to heated tobacco products for smoking but to all novel smokeless tobacco products and other products (nicotine sachets, novel nicotine products).

The draft law imposes disproportionate labelling restrictions on nicotine sachets and novel nicotine products and creates barriers to intra-EU trade in breach of Article 34 TFEU.

Directive 2014/40/EU distinguishes between health warnings for smokeless tobacco products and those for tobacco products for smoking, as part of the basic right of consumers to receive accurate information about the characteristics of a product. While health warnings for smokeless tobacco products focus on nicotine as a substance for which consumers

should be warned, all corresponding warnings imposed on tobacco products for smoking focus on the inhalation of smoke and related health impact.

The draft law, provisions of Article 4(1), is not in line with the principle of proportionality, which requires that any restriction on the free movement of goods must be appropriate, necessary, and the least restrictive means to achieve the public health objective pursued. This provision is neither necessary nor the least restrictive means of informing consumers about the risks associated with those products. Less restrictive alternatives, tailored to the real risks of smokeless nicotine consumption, would achieve the same public health objectives without unduly hindering trade within the internal market.

The draft law hinders the functioning of the internal market (Articles 4(2)(f) a), 26, 27, 114 and 115) of the Treaty on the Functioning of the EU.
Under Article 114 of the Treaty, Member States are not allowed to adopt more stringent measures, going beyond the provisions of EU Directives. According to recital 53 of Directive 2014/40/EU, the Tobacco Products Directive fully harmonises all product labelling requirements for all tobacco products and does not allow Member States to derogate from them. The draft law of Luxembourg introduces restrictions that are incompatible with the harmonisation measures of the Tobacco Products Directive and cannot be justified on health protection grounds, as they do not fall under the exceptions of Article 114(5) of the Treaty concerning fundamental requirements that would justify stricter national rules. In view of this, Luxembourg cannot introduce requirements for health warnings for tobacco products other than those laid down in Directive 2014/40/EU.

The draft law sets disproportionate maximum nicotine levels for nicotine pouches and novel nicotine products, in conflict with the principle of free movement of goods enshrined in Article 34 TFEU.

Article 34 of the Treaty on the Functioning of the EU guarantees the free movement of goods within the Member States. The draft law of Luxembourg introduces a nicotine limit on nicotine pouches and nicotine products of 0.048 mg of nicotine per nicotine pouch. These products are lawfully marketed in other Member States that have specific regulations in place, such as the Czech Republic, Slovakia, Denmark, and Hungary. In these countries they are marketed with a nicotine limit of at least 12 mg per pouch, following the recommendations of the German Federal Institute for risk assessment, which proposes a limit of 16.6 mg per pouch. If the draft law of Luxembourg is adopted, products lawfully marketed in other Member States in accordance with the respective legislations could not be sold in Luxembourg, thus creating a barrier to the free movement of goods in the EU and breaching Article 34 of the Treaty.

For the above reasons, we consider that the submission of a Reasoned Opinion is necessary. In view of the above, we request that the above provisions be amended by Luxembourg in order to comply with the objectives of public health protection and the fundamental principles of the free movement of goods and free competition, within the framework of Directive 2014/40/EU on tobacco products and Delegated Directive (EU) 2022/2100 amending Directive 2014/40/EU.

The Secretary-General for Industry

Eleftherios Kritikos

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