



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/(2024) 2987

Directive (EU) 2015/1535

Notification: 2024/0444/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 06-02-2025.

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 - Opinioni dettaljata - Uitvoerig gemotiveerde mening - Opinia szczegółowa - Parecer circunstanciado - Avis detaliat - Podrobné stanovisko - Podrobno mnenje - Detaljerat yttrande

Extends the time limit of the status quo until 06-02-2025. - Prolonge le délai de statu quo jusqu'au 06-02-2025. - Die Laufzeit des Status quo wird verlängert bis 06-02-2025. - Удължаване на крайния срок на статуквото до 06-02-2025. - Prodłużuje lhůtu současného stavu do 06-02-2025. - Fristen for status quo forlænges til 06-02-2025. - Παρατείνει την προθεσμία του status quo 06-02-2025. - Amplía el plazo de statu quo hasta 06-02-2025. - Praeguse olukorra tähtaega pikendatakse kuni 06-02-2025. - Jatkaa status quon määraaika 06-02-2025 asti. - Produžuje se vremensko ograničenje statusa quo do 06-02-2025. - Meghosszabbítja a korábbi állapot határidejét 06-02-2025-ig. - Proroga il termine dello status quo fino al 06-02-2025. - Status quo terminas pratęsiamas iki 06-02-2025. - Pagarina "status quo" laika periodu līdz 06-02-2025. - Jestendi t-terminu tal-istatus quo sa 06-02-2025. - De status-quoperiode wordt verlengd tot 06-02-2025. - Przedłużenie status quo do 06-02-2025. - Prolonga o prazo do statu quo até 06-02-2025. - Prelungește termenul status quo-ului până la 06-02-2025. - Predlžuje sa lehota súčasného stavu do 06-02-2025. - Podaljša rok nespremenjenega stanja do 06-02-2025. - Förlänger tiden för status quo fram till 06-02-2025.

The Commission received this detailed opinion on the 06-11-2024. - La Commission a reçu cet avis circonstancié le 06-11-2024. - Die Kommission hat diese ausführliche Stellungnahme am 06-11-2024 empfangen. - Комисията получи настоящото подробно становище относно 06-11-2024. - Komise obdržela toto podrobné stanovisko dne 06-11-2024. - Kommissionen modtog denne udførlige udtalelse den 06-11-2024. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 06-11-2024. - La Comisión recibió el dictamen circunstanciado el 06-11-2024. - Komisjon sai üksikasjaliku arvamuse 06-11-2024. - Komissio sai tämän yksityiskohtaisen lausunnon 06-11-2024. - Komisija je zaprimila ovo detaljno mišljenje dana 06-11-2024. - A Bizottság 06-11-2024-án/én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 06-11-2024. - Komisija gavo šią išsamiai išdėstytą nuomonę 06-11-2024. - Komisija saņēma šo sīki izstrādāto atzinumu 06-11-2024. - Il-Kummissjoni rċeviet din l-opinioni dettaljata dwar il-06-11-2024. - De Commissie heeft deze uitvoerig gemotiveerde mening op 06-11-2024 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 06-11-2024. - A Comissão recebeu o presente parecer circunstanciado em 06-11-2024. - Comisia a primit avizul detaliat privind 06-11-2024. - Komisia dostala toto podrobné stanovisko dňa 06-11-2024. - Komisija je to podrobno mnenje prejela dne 06-11-2024. - Kommissionen mottog detta detaljerade yttrande om 06-11-2024. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 06-11-2024.

MSG: 20242987.EN

1. MSG 115 IND 2024 0444 LU EN 06-02-2025 06-11-2024 GR DO 6.2(2) 06-02-2025

2. Greece

ЗА. ΥΠΟΥΡΓΕΙΟ ΑΝΑΠΤΥΞΗΣ ΓΕΝΙΚΗ ΓΡΑΜΜΑΤΕΙΑ ΒΙΟΜΗΧΑΝΙΑΣ
ΓΕΝ. Δ/ΝΣΗ ΒΙΟΜΗΧΑΝΙΚΩΝ ΥΠΟΔΟΜΩΝ



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ΚΑΙ ΕΠΙΧΕΙΡΗΜΑΤΙΚΟΥ ΠΕΡΙΒΑΛΛΟΝΤΟΣ
Δ/ΝΣΗ ΑΣΦΑΛΕΙΑΣ ΚΑΙ ΣΥΜΜΟΡΦΩΣΗΣ ΒΙΟΜΗΧΑΝΙΚΩΝ ΠΡΟΪΟΝΤΩΝ
ΤΜΗΜΑ Δ΄ ΓΕΝΙΚΗΣ ΑΣΦΑΛΕΙΑΣ ΠΡΟΪΟΝΤΩΝ

3B. ΥΠΟΥΡΓΕΙΟ ΑΝΑΠΤΥΞΗΣ ΓΕΝΙΚΗ ΓΡΑΜΜΑΤΕΙΑ ΒΙΟΜΗΧΑΝΙΑΣ
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4. 2024/0444/LU - X60M - Tobacco

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

6. SUBJECT: “Submission of a Reasoned Opinion in relation to Luxembourg Notification 2024/0444/LU for the transposition of Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products”

We hereby request that you immediately submit a reasoned opinion to the European Commission, as set out in Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products, with regard to the proposed draft law by the Government of Luxembourg.

The legislative proposal, draft law 8333 of Luxembourg, was posted on the TRIS database of the European Commission on 5.8.2024 under notification number 2024/0444/LU in the context of the public consultation procedure of Directive 1535/2015/EU, to inform the Member States and the EU.

With this notification, Luxembourg aims to transpose the Delegated Directive as well as to regulate new nicotine products and nicotine pouches. In particular, the draft law of Luxembourg extends the obligation for heated tobacco products to carry combined health warnings to all other novel tobacco products and nicotine pouches. In addition, it imposes very low maximum nicotine content levels for nicotine pouches.

The proposed Luxembourg rules deviate significantly from those of the Delegated Directive and impose an additional barrier to the circulation of new nicotine products and nicotine pouches.

More specifically:

Restrictions are imposed on the labelling of novel tobacco products in breach of Directive 2014/40/EU (TPD) and Delegated Directive (EU) 2022/2100.

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 carry health warnings in accordance with Article 12 of the TPD, while the latter must comply with Articles 9-11 of the TPD.

Article 4(1) of the draft law provides that “Any packet and any outer packaging of cigarettes, roll-your-own tobacco, water pipe tobacco, nicotine sachets and novel tobacco 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 carry combined health warnings, a general warning and an information message, in breach of the mandatory provisions of the TPD and the Delegated Directive on labelling.

The draft law therefore 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



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heated tobacco products for smoking but to all novel smokeless tobacco products and nicotine pouches.

The draft law impedes the functioning of the internal market enshrined in Article 114 of the Treaty on the Functioning of the EU.

According to Article 114 of the Treaty, Member States are not allowed to adopt more stringent measures going beyond the provisions of EU directives. Recital 53 of Directive 2014/40/EU (TPD) indicates that 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 TPD 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 imposes disproportionate labelling restrictions on nicotine pouches and creates barriers to intra-EU trade in breach of Article 34 TFEU.

The TPD 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 effects.

Article 4(1) of the draft law imposes combined health warnings on packaging for nicotine pouches, as follows: "Any packet and any outer packaging of cigarettes, roll-your-own tobacco, water pipe tobacco, nicotine sachets and novel tobacco products must have a general warning, an information message and combined health warnings." By applying these warnings to nicotine pouches, the draft law distorts consumers' perception of the relative risks of different products and deprives consumers of their right to accurate information. Moreover, the draft law 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, such as the warnings required for e-cigarettes, tailored to the real risks of tobacco-free nicotine consumption, would achieve the same public health objectives without unduly hindering trade within the internal market.

The draft law sets disproportionate maximum levels of nicotine for nicotine pouches, 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 of 0.048 mg 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 an obstacle 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 regulations on behalf of Luxembourg be amended, so that they are in line with both the objectives of public health protection and the fundamental principles of free movement of goods and free competition, within the framework of Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products.



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