Message 115

Communication from the Commission - TRIS/(2025) 1146

Directive (EU) 2015/1535

Notification: 2025/0044/ES

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 28-07-2025.

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 28-07-2025. - Prolonge le délai de statu quo jusqu'au 28-07-2025.- Die Laufzeit des Status quo wird verlängert bis 28-07-2025.- Удължаване на крайния срок на статуквото до 28-07-2025. - Prodlužuje lhůtu současného stavu do 28-07-2025. - Fristen for status quo forlænges til 28-07-2025. - Παρατείνει την προθεσμία του status quo 28-07-2025. - Amplía el plazo de statu quo hasta 28-07-2025. - Praeguse olukorra tähtaega pikendatakse kuni 28-07-2025. - Jatkaa status quon määräaikaa 28-07-2025 asti. - Produžuje se vremensko ograničenje statusa quo do 28-07-2025. - Meghosszabbítja a korábbi állapot határidejét 28-07-2025-ig. - Proroga il termine dello status quo fino al 28-07-2025. - Status quo terminas pratęsiamas iki 28-07-2025. - Pagarina “status quo” laika periodu līdz 28-07-2025. - Jestendi t-terminu tal-istatus quo sa 28-07-2025. - De status-quoperiode wordt verlengd tot 28-07-2025. - Przedłużenie status quo do 28-07-2025. - Prolonga o prazo do statu quo até 28-07-2025. - Prelungește termenul status quo-ului până la 28-07-2025. - Predlžuje sa lehota súčasného stavu do 28-07-2025. - Podaljša rok nespremenjenega stanja do 28-07-2025. - Förlänger tiden för status quo fram till 28-07-2025.

The Commission received this detailed opinion on the 28-04-2025. - La Commission a reçu cet avis circonstancié le 28-04-2025. - Die Kommission hat diese ausführliche Stellungnahme am 28-04-2025 empfangen. - Комисията получи настоящото подробно становище относно 28-04-2025. - Komise obdržela toto podrobné stanovisko dne 28-04-2025. - Kommissionen modtog denne udførlige udtalelse den 28-04-2025. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 28-04-2025. - La Comisión recibió el dictamen circunstanciado el 28-04-2025. - Komisjon sai üksikasjaliku arvamuse 28-04-2025. - Komissio sai tämän yksityiskohtaisen lausunnon 28-04-2025. - Komisija je zaprimila ovo detaljno mišljenje dana 28-04-2025. - A Bizottság 28-04-2025-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 28-04-2025. - Komisija gavo šią išsamiai išdėstytą nuomonę 28-04-2025. - Komisija saņēma šo sīki izstrādāto atzinumu 28-04-2025. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-28-04-2025. - De Commissie heeft deze uitvoerig gemotiveerde mening op 28-04-2025 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 28-04-2025. - A Comissão recebeu o presente parecer circunstanciado em 28-04-2025. - Comisia a primit avizul detaliat privind 28-04-2025. - Komisia dostala toto podrobné stanovisko dňa 28-04-2025. - Komisija je to podrobno mnenje prejela dne 28-04-2025. - Kommissionen mottog detta detaljerade yttrande om 28-04-2025. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 28-04-2025.

MSG: 20251146.EN

1. MSG 115 IND 2025 0044 ES EN 28-07-2025 28-04-2025 GR DO 6.2(2) 28-07-2025

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 3893695, αρμ.: Χ. Νικόλσκυ, e

4. 2025/0044/ES - 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 regarding the submitted draft Royal Decree of Spain on “the manufacture, presentation and marketing of tobacco and related products” of 9 June 2017.

The Spanish draft Royal Decree was posted on the European Commission’s TRIS database on 24.01.2025 under notification number 2025/0004/ES in the context of the public consultation procedure of Directive (EU) 2015/1535, to inform the Member States of the European Union.
According to the draft Royal Decree, a maximum permitted nicotine content of 0.99 mg per pouch is imposed on nicotine pouches, introducing disproportionate nicotine levels for nicotine pouches and adversely affecting the principle of free movement of goods, as enshrined in Article 34 of the Treaty on the Functioning of the European Union (TFEU).

In particular:

A) Restrictions are imposed that contradict the provisions of Directive 2014/40/EU and Delegated Directive (EU) 2022/2100 on 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.
The draft Royal Decree introduces a nicotine content limit of 0.99 mg per nicotine pouch and imposes disproportionate restrictions which effectively lead to a restriction of the product's circulation. It should be noted that these products are also legally marketed in other European Union countries such as the Czech Republic, Denmark, Slovakia, Hungary with a maximum nicotine content of 12 mg per pouch. The German Federal Institute proposes a limit of 16.6 mg per pouch.

The draft Royal Decree imposes disproportionate labelling restrictions on nicotine pouches and novel nicotine products and creates barriers to intra-EU trade in breach of Article 34 TFEU.
In addition, the nicotine limit of 0.99 mg per nicotine pouch effectively leads to a ban on their marketing in violation of Article 36 of the Treaty on the Functioning of the European Union which provides that: “restrictions on the free movement of goods may be justified on grounds of public interest”, which is not mentioned in the Spanish draft Royal Decree.

B) The Spanish draft Royal Decree creates obstacles to the functioning of the EU internal market, in breach of Article 114 TFEU and in particular: 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 Spanish draft Royal Decree 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 the above, Spain cannot introduce requirements for health warnings on tobacco products that are different from the requirements laid down in Directive 2014/40/EU, which already set high levels of human health protection. The issue of nicotine content as defined in Article 20(3)(b) of Directive 2014/40 is considered compatible and harmonised within the EU. In application of the principle of proportionality, deviation from the provisions of the Directive is considered to create additional burden for manufacturers and barriers to trade in general.

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 Spain in order to ensure compliance not only with the objectives of public health protection but also with the fundamental principles of 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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European Commission
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