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) 1058

Directive (EU) 2015/1535

Notification: 2025/0044/ES

Forwarding of a detailed opinion received by a Member State (Romania) (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 10-04-2025. - La Commission a reçu cet avis circonstancié le 10-04-2025. - Die Kommission hat diese ausführliche Stellungnahme am 10-04-2025 empfangen. - Комисията получи настоящото подробно становище относно 10-04-2025. - Komise obdržela toto podrobné stanovisko dne 10-04-2025. - Kommissionen modtog denne udførlige udtalelse den 10-04-2025. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 10-04-2025. - La Comisión recibió el dictamen circunstanciado el 10-04-2025. - Komisjon sai üksikasjaliku arvamuse 10-04-2025. - Komissio sai tämän yksityiskohtaisen lausunnon 10-04-2025. - Komisija je zaprimila ovo detaljno mišljenje dana 10-04-2025. - A Bizottság 10-04-2025-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 10-04-2025. - Komisija gavo šią išsamiai išdėstytą nuomonę 10-04-2025. - Komisija saņēma šo sīki izstrādāto atzinumu 10-04-2025. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-10-04-2025. - De Commissie heeft deze uitvoerig gemotiveerde mening op 10-04-2025 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 10-04-2025. - A Comissão recebeu o presente parecer circunstanciado em 10-04-2025. - Comisia a primit avizul detaliat privind 10-04-2025. - Komisia dostala toto podrobné stanovisko dňa 10-04-2025. - Komisija je to podrobno mnenje prejela dne 10-04-2025. - Kommissionen mottog detta detaljerade yttrande om 10-04-2025. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 10-04-2025.

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1. MSG 115 IND 2025 0044 ES EN 28-07-2025 10-04-2025 RO DO 6.2(2) 28-07-2025

2. Romania

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4. 2025/0044/ES - X60M - Tobacco

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

6. Article 52 of the notified draft provides for limiting the maximum nicotine content to 0.99 mg per nicotine pouch. This limitation constitutes a de facto ban, as setting such an extremely low limit for the nicotine content in pouches represents an indirect prohibition of these products and violates the principle of the free movement of goods provided for in Article 34 of the TFEU, given that such products are already regulated and freely circulate in other Member States. These types of products have been regulated in several Member States, including Romania, with a maximum limit of 20 mg/pouch. The threshold established by Spain, of 0.99 mg/pouch, creates significant barriers to trade, breaching the principle of mutual recognition of goods lawfully marketed in another Member State, in accordance with Regulation (EU) No. 2019/515 (Member States where these products have been regulated include, in addition to Romania, Sweden, the Czech Republic, Denmark, Hungary, Germany, Finland, Austria, and Slovakia). Moreover, Spain does not provide any justification to support the restriction of circulation of these products as required under Article 36 of the TFEU.

We consider that Spain is thus imposing an unjustified restriction, which is not supported by clear evidence of a significant risk to public health. Furthermore, as revealed in the Impact Assessment accompanying the draft, Spain did not evaluate less restrictive options, such as banning the sale of these products to minors, a measure already implemented by Romania in 2024, which would have been proportionate to the intended objective.

The ban on flavours other than tobacco does not meet the justification criteria imposed by EU legislation and is incompatible with Articles 34 and 36 of the TFEU, as it limits market access for products that are lawfully marketed in the majority of Member States (principle of mutual recognition). The ban of flavours in electronic cigarettes, except for tobacco flavour, exceeds the discretionary powers granted to Member States under the Tobacco Products Directive (TPD).

According to Recital 47 of the TPD, Member States are free to allow or prohibit the use of certain flavours in electronic cigarettes. However, they do not have the authority to regulate ingredients in a manner that goes beyond the limits established by the TPD, as proposed by Spain.

As regards the regulation of ingredients, Member States "must be able to clearly justify and provide adequate evidence that the additives listed and any additional additives to be prohibited fall under one or more of the categories mentioned in Articles 7(6) and 20(3) of the TPD."

The draft notified by Spain provides for a ban on flavours not only for conventional tobacco products but also for all categories of electronic cigarettes, including nicotine-free ones. This measure stands out for its level of strictness, as current European legislation does not impose such restrictions outside of traditional tobacco products.

The proposed measure should meet two fundamental criteria: i) it must be suitable for achieving the intended objective; and ii) it must not go beyond what is strictly necessary to achieve that objective. From the analysis of the draft, Spain does not fulfil these conditions. Restricting flavours exclusively to tobacco contradicts the stated goal of the draft, to prevent smoking, and may even encourage the use of combustible tobacco products over less harmful, smoke-free

alternatives.

The draft notified by Spain introduces several provisions regarding the labelling of tobacco and related products that clearly exceed the framework established by the Tobacco Products Directive (TPD). While the TPD Directive explicitly regulates requirements for tobacco products and nicotine-containing e-cigarettes, the Spanish draft extends these regulations to product categories that are not currently covered by harmonized EU legislation. The disproportionate imposition of labelling and presentation rules on novel tobacco products and related products affects legitimate EU businesses. The restriction on colours and design elements that "may attract attention" imposes a disproportionate limitation on trade, equivalent to a de facto ban on trademarks and logos in Spain. The measure is ambiguous, lacks legal clarity, and is open to arbitrary interpretation.

Thus, the draft explicitly includes in its scope products such as nicotine-free e-cigarettes, nicotine-free refill containers, nicotine pouches, and heated herbal products. These products, although not covered by the TPD, would be subject to detailed labelling and packaging obligations, including the display of a full list of ingredients, nicotine content where applicable, and health warnings. For example, nicotine-free e-cigarettes would be required to display the warning: "Smoking this product is harmful to health", wording that is not provided for in the TPD.

This violates the principle of mutual recognition, as such products circulate legally in other Member States. Banning distinctive elements will promote illicit trade in tobacco and related products and facilitate the entry of illegal products into the internal market, harming legitimate EU businesses, reducing tax revenues, and undermining public health protection.

Another issue is the introduction of an extensive reporting system applicable to all targeted products, requiring the collection of information on sales volumes, consumer preferences (especially among young people and non-smokers), as well as market studies and other relevant data. An additional requirement includes a mandatory informational leaflet, containing usage instructions, contraindications, potential risks, and the manufacturer’s contact information, a requirement not found in the TPD.

Conclusion:

The draft notified by Spain infringes both Articles 34 to 36 TFEU (free movement of goods) and 20(4) of the TPD Directive (right to indicate nicotine and flavours on packaging), as well as Articles 16 and 17 of the Charter of Fundamental Rights (freedom to conduct a business and right to property), and the WTO TRIPS Agreement, which prohibits restrictions on trademarks without a solid justification.

In addition to the above, another aspect contrary to EU case law (in particular the “supplementary single provision”) concerns the short transition period. The draft does not provide any transition period for nicotine pouches and heated herbal products, meaning the new requirements could take effect immediately. Only a 10-month compliance period is foreseen for electronic cigarettes and refill containers, regardless of nicotine content, with mandatory market withdrawal in the 12th month. Implementing these provisions requires significant time for adaptation, as companies need to reformulate products, modify production lines, and change labelling and packaging. According to the case law of the Court of Justice of the EU (C-309/02, Radlberger), the lack of an adequate transition period constitutes a restriction on the free movement of goods.

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