



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) 1161

Directive (EU) 2015/1535

Notification: 2025/0110/FR

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 25-08-2025.

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 25-08-2025. - Prolonge le délai de statu quo jusqu'au 25-08-2025. - Die Laufzeit des Status quo wird verlängert bis 25-08-2025. - Удължаване на крайния срок на статуквото до 25-08-2025. - Prodłużuje lhůtu současného stavu do 25-08-2025. - Fristen for status quo forlænges til 25-08-2025. - Παρατείνει την προθεσμία του status quo 25-08-2025. - Amplía el plazo de statu quo hasta 25-08-2025. - Praeguse olukorra tähtaega pikendatakse kuni 25-08-2025. - Jatkaa status quon määräaika 25-08-2025 asti. - Produžuje se vremensko ograničenje statusa quo do 25-08-2025. - Meghosszabbítja a korábbi állapot határidejét 25-08-2025-ig. - Proroga il termine dello status quo fino al 25-08-2025. - Status quo terminas pratęsiamas iki 25-08-2025. - Pagarina "status quo" laika periodu līdz 25-08-2025. - Jestendi t-terminu tal-istatus quo sa 25-08-2025. - De status-quoperiode wordt verlengd tot 25-08-2025. - Przedłużenie status quo do 25-08-2025. - Prolonga o prazo do statu quo até 25-08-2025. - Prelungește termenul status quo-ului până la 25-08-2025. - Predlžuje sa lehota súčasného stavu do 25-08-2025. - Podaljša rok nespremenjenega stanja do 25-08-2025. - Förlänger tiden för status quo fram till 25-08-2025.

The Commission received this detailed opinion on the 30-04-2025. - La Commission a reçu cet avis circonstancié le 30-04-2025. - Die Kommission hat diese ausführliche Stellungnahme am 30-04-2025 empfangen. - Комисията получи настоящото подробно становище относно 30-04-2025. - Komise obdržela toto podrobné stanovisko dne 30-04-2025. - Kommissionen modtog denne udførlige udtalelse den 30-04-2025. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 30-04-2025. - La Comisión recibió el dictamen circunstanciado el 30-04-2025. - Komisjon sai üksikasjaliku arvamuse 30-04-2025. - Komissio sai tämän yksityiskohtaisen lausunnon 30-04-2025. - Komisija je zaprimila ovo detaljno mišljenje dana 30-04-2025. - A Bizottság 30-04-2025-án/én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 30-04-2025. - Komisija gavo šią išsamiai išdėstytą nuomonę 30-04-2025. - Komisija saņēma šo sīki izstrādāto atzinumu 30-04-2025. - Il-Kummissjoni rċeviet din l-opinioni dettaljata dwar il-30-04-2025. - De Commissie heeft deze uitvoerig gemotiveerde mening op 30-04-2025 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 30-04-2025. - A Comissão recebeu o presente parecer circunstanciado em 30-04-2025. - Comisia a primit avizul detaliat privind 30-04-2025. - Komisia dostala toto podrobné stanovisko dňa 30-04-2025. - Komisija je to podrobno mnenje prejela dne 30-04-2025. - Kommissionen mottog detta detaljerade yttrande om 30-04-2025. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 30-04-2025.

MSG: 20251161.EN

1. MSG 115 IND 2025 0110 FR EN 25-08-2025 30-04-2025 RO DO 6.2(2) 25-08-2025

2. Romania

3A. Ministerul Economiei, Digitalizării, Antreprenoriatului și Turismului
Direcția Afaceri Europene și Relații Internaționale



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4. 2025/0110/FR - X00M - GOODS AND MISCELLANEOUS PRODUCTS

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

6. The draft notified by France prohibits the production, manufacture, transport, import, export, possession, offering, transfer, purchase, distribution, and use of oral nicotine products on its territory. This draft infringes the principle of the free movement of goods laid down in Article 34 of the TFEU. The ban on the marketing of nicotine pouches in France creates trade barriers and fragments the market, violating the principle of mutual recognition governed by Regulation (EU) 2019/515, since these products are legally marketed in other Member States, including Romania. Furthermore, France does not provide justifications based on overriding reasons of public interest as defined by the case-law of the CJEU, as required under Article 36 of the TFEU. The measure proposed by France does not meet the exemption conditions set out in Article 36 of the TFEU, namely: that it must be appropriate for achieving the intended objective and must not go beyond what is necessary to attain that objective.

Prohibiting the marketing of regulated products in other Member States fragments the market and creates barriers to trade in the Single Market. France has not demonstrated that the restriction is justified in accordance with Article 36 of the TFEU. The adopted measure lacks a scientific basis and could therefore lead to serious distortions of competition and negatively impact economic operators legally operating in this sector, including those from Romania.

The public health impact of such a ban is questionable, especially given that other nicotine products, particularly combustible tobacco, remain available on the French market. The draft discriminates against nicotine pouches compared to other nicotine products that remain legal in France (e.g., traditional cigarettes or e-cigarettes), without providing an objective justification. This differentiation between comparable products contravenes the principle of equal treatment, as established by the case-law of the Court of Justice of the European Union.

The French authorities do not provide solid evidence that nicotine pouches pose a significant risk to public health. So far, no scientific studies have been presented demonstrating that nicotine pouches promote addiction or the use of illicit substances.

Moreover, nicotine pouches represent a lower-risk alternative to traditional cigarettes and can contribute to smoking reduction.

According to Article 114 of the TFEU, Member States cannot adopt national measures stricter than those stipulated in harmonized EU directives, especially in areas where legislation has already been harmonized at the EU level. A measure can only be justified if it is proportionate to the pursued objective.

If the objective is the protection of minors and the prevention of addiction, France could propose alternative, balanced, and proportionate measures in relation to that objective, which would ensure a high level of human health protection without creating barriers to trade.

Thus, an alternative measure could be the prohibition of sales to minors, which Romania implemented in 2024, and/or the imposition of a maximum nicotine level of 20 mg/pouch.

Regulating nicotine pouches, instead of imposing a total ban, would have a far lesser impact on trade between EU Member States while still meeting public health objectives.

The measure imposed by France through the notified draft prevents the regulation of nicotine pouches at EU level, which the European Commission intends to undertake during the review of the TPD. Adopting a unilateral ban would disrupt this EU-level review process and create divergent legal regimes that affect the functioning of the internal market.

According to Article 6(3) of the Single Market Transparency Directive (SMTD), Member States should postpone the adoption of national regulations if there is a European Commission initiative on the same subject.



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France violates the fundamental principles of the internal market, creates unjustified technical trade barriers, and disproportionately restricts the competitiveness of products already regulated and allowed in other Member States. These negative effects occur despite the existence of viable alternative regulatory solutions that can ensure public health protection without undermining the functioning of the single market.

European Commission

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