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) 1371

Directive (EU) 2015/1535

Notification: 2025/0110/FR

Forwarding of a detailed opinion received by a Member State (Italy) (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 - 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 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. - Prodlužuje 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 määräaikaa 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 26-05-2025. - La Commission a reçu cet avis circonstancié le 26-05-2025. - Die Kommission hat diese ausführliche Stellungnahme am 26-05-2025 empfangen. - Комисията получи настоящото подробно становище относно 26-05-2025. - Komise obdržela toto podrobné stanovisko dne 26-05-2025. - Kommissionen modtog denne udførlige udtalelse den 26-05-2025. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 26-05-2025. - La Comisión recibió el dictamen circunstanciado el 26-05-2025. - Komisjon sai üksikasjaliku arvamuse 26-05-2025. - Komissio sai tämän yksityiskohtaisen lausunnon 26-05-2025. - Komisija je zaprimila ovo detaljno mišljenje dana 26-05-2025. - A Bizottság 26-05-2025-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 26-05-2025. - Komisija gavo šią išsamiai išdėstytą nuomonę 26-05-2025. - Komisija saņēma šo sīki izstrādāto atzinumu 26-05-2025. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-26-05-2025. - De Commissie heeft deze uitvoerig gemotiveerde mening op 26-05-2025 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 26-05-2025. - A Comissão recebeu o presente parecer circunstanciado em 26-05-2025. - Comisia a primit avizul detaliat privind 26-05-2025. - Komisia dostala toto podrobné stanovisko dňa 26-05-2025. - Komisija je to podrobno mnenje prejela dne 26-05-2025. - Kommissionen mottog detta detaljerade yttrande om 26-05-2025. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 26-05-2025.

MSG: 20251371.EN

1. MSG 115 IND 2025 0110 FR EN 25-08-2025 26-05-2025 IT DO 6.2(2) 25-08-2025

2. Italy

3A. Ministero delle Imprese e del Made in Italy
Dipartimento Mercato e Tutela

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3B. Ministero delle Imprese e del Made in Italy
Direzione generale per la politica industriale, la riconversione e la crisi industriale, l'innovazione, le PMI e il made in Italy
Div. XIII – Agroindustria, industrie culturali e creative, industria del turismo

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

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

6. France notified, on 24 February 2025, via the TRIS system, a draft decree aimed at prohibiting the production, manufacture, transport, import, export, possession, offer, transfer, purchase, distribution, and use of oral products containing nicotine on French territory. The measure has raised considerable criticism regarding its compatibility with the principles of the free movement of goods and the principle of proportionality.
The specific problems identified in the draft mentioned above are set out below.

PROBLEM AREAS

1. Absolute ban in violation of the principle of free movement of goods
The draft decree defines products for oral use containing nicotine, intended for human consumption by ingestion or absorption, in particular in the form of portioned sachets, porous sachets, toothpaste, candies, beads, liquids, chewing gum, lozenges, strips, or any combination of these forms. It specifies that these products are subject to a prohibition throughout the national territory, insofar as they are intended for the French market in the metropolitan and overseas territories concerned, about their production, manufacture, transport, import, export, possession, offer, transfer or acquisition, as well as distribution and use.
The abovementioned total ban on oral products containing nicotine, such as nicotine sachets or nicotine pouches, contravenes the principle of the free movement of goods enshrined in Articles 34 to 36 of the Treaty on the Functioning of the European Union (TFEU). The prohibition constitutes a measure of equivalent effect to quantitative restrictions within the scope of Articles 34 and 35 TFEU. Article 34 TFEU states that 'quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States'.
Similarly, Article 35 TFEU prohibits national measures that result in a quantitative restriction or a restriction having an equivalent effect, which affects exports. It should be noted that the Court of Justice of the European Union (CJEU) ruled in the renowned Cassis de Dyon judgment (CJEU, Case C-120/78) that a Member State may not prohibit or restrict the sale of a product that is lawfully manufactured and sold in another Member State, and that has not been harmonised at EU level. This ruling is at the origin of the principle of mutual recognition. The adoption of the French draft decree would prevent the placing and sale in France of products that are legally manufactured and marketed in other Member States, following their applicable national legislation, as they are not subject to harmonised legislation.
To this end, it should be recalled that Italy has already equipped itself with an articulated regulatory framework, as a result of a structured and long-lasting institutional activity that has also taken into account assessments of the riskiness of use of the products, establishing specific national provisions for nicotine sachets (Article 62-quater.1, Legislative Decree No. 504/1995 and specific administrative clauses defined by the Customs and Monopolies Agency).
All this being said, the draft decree would violate the principle of mutual recognition and create an obstacle to the free movement of goods within the European single market.
Therefore, France is asked how the notified measure accords with the EU-wide regulations.

2. Violation of the principle of proportionality
Member States, when restricting fundamental freedoms defined at the EU level (including the free movement of goods), must ensure, even where permitted by the TFEU, that any restrictive measures are, in any case, proportionate, regardless of their justification. Restrictions must be appropriate to achieve their objectives, limited to what is necessary and proportionate in a strict sense, demonstrating that the positive effects of the measure outweigh its negative impacts.

The burden of proof regarding the justification of the restriction lies with the Member State proposing the measure. According to the CJEU, "the reasons put forward by a Member State as justification must therefore be accompanied by an analysis of the appropriateness and proportionality of the measure adopted by that State (...)" (CJEU, Case C-456/10). Therefore, the French authorities would be required to provide comprehensive reasons to demonstrate that the proposed product ban is the only effective means to protect the declared interests. However, no alternative policy option to an outright ban appears to have been evaluated to pursue the same objective. Indeed, the French authorities have not provided an assessment of the ineffectiveness of less restrictive alternatives, such as prohibiting sales to minors and regulating the category of nicotine pouches through specific provisions, rather than imposing an outright ban. To this end, it is suggested that several regulatory alternatives exist that are less restrictive than an outright ban, ensuring the quality and safety of the products while preventing their sale to young people. Similar regulatory solutions have been proposed and adopted in several Member States, including Italy. In this context, it is also worth noting that in other countries, such as the United States, the Food and Drug Administration has recently approved the marketing of sachets. In light of the above reasoning, the French draft decree appears to be at odds with the principle of proportionality, as several less restrictive measures with less impact on trade between EU Member States could be considered.

3. Arbitrary discrimination
The introduction of an absolute ban on oral products containing nicotine would seem to constitute a 'means of arbitrary discrimination' within the scope of Art. 36 TFUE. Such an absolute ban would apply to a particular category of products, which, by definition and characteristics, are products which are not for smoking; all smoking products are permitted on the French market.
In this context, the French draft decree acknowledges the undeniable similarities between oral products containing nicotine and snus, a tobacco product banned by all EU Member States except Sweden. It states that 'the risks that justified the ban on Snus also apply to oral products containing nicotine'. In this regard, it is emphasised that, although both Snus and oral products containing nicotine are types of products characterised by the same mode of consumption (oral use), they are nevertheless two substantially different products, given their specific intrinsic characteristics. Consequently, the supposed total equivalence between Snus and oral products containing nicotine is lacking.
In light of the above considerations, the French prohibition would constitute a means of arbitrary discrimination within the scope of Article 36 TFEU.

CONCLUSIONS
In conclusion, there is a significant inconsistency in the provisions of the French legislation in question regarding the fundamental principle of the free movement of goods in the European single market, as well as the principle of proportionality. The measure would consequently lead to the introduction of a trade barrier in the internal market, which would negatively impact the key harmonisation objectives set by European law.

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European Commission
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