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/(2026) 2146

Directive (EU) 2015/1535

Notification: 2026/0223/PL

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 06-11-2026.

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 06-11-2026. - Prolonge le délai de statu quo jusqu'au 06-11-2026.- Die Laufzeit des Status quo wird verlängert bis 06-11-2026.- Удължаване на крайния срок на статуквото до 06-11-2026. - Prodlužuje lhůtu současného stavu do 06-11-2026. - Fristen for status quo forlænges til 06-11-2026. - Παρατείνει την προθεσμία του status quo 06-11-2026. - Amplía el plazo de statu quo hasta 06-11-2026. - Praeguse olukorra tähtaega pikendatakse kuni 06-11-2026. - Jatkaa status quon määräaikaa 06-11-2026 asti. - Produžuje se vremensko ograničenje statusa quo do 06-11-2026. - Meghosszabbítja a korábbi állapot határidejét 06-11-2026-ig. - Proroga il termine dello status quo fino al 06-11-2026. - Status quo terminas pratęsiamas iki 06-11-2026. - Pagarina “status quo” laika periodu līdz 06-11-2026. - Jestendi t-terminu tal-istatus quo sa 06-11-2026. - De status-quoperiode wordt verlengd tot 06-11-2026. - Przedłużenie status quo do 06-11-2026. - Prolonga o prazo do statu quo até 06-11-2026. - Prelungește termenul status quo-ului până la 06-11-2026. - Predlžuje sa lehota súčasného stavu do 06-11-2026. - Podaljša rok nespremenjenega stanja do 06-11-2026. - Förlänger tiden för status quo fram till 06-11-2026.

The Commission received this detailed opinion on the 06-08-2026. - La Commission a reçu cet avis circonstancié le 06-08-2026. - Die Kommission hat diese ausführliche Stellungnahme am 06-08-2026 empfangen. - Комисията получи настоящото подробно становище относно 06-08-2026. - Komise obdržela toto podrobné stanovisko dne 06-08-2026. - Kommissionen modtog denne udførlige udtalelse den 06-08-2026. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 06-08-2026. - La Comisión recibió el dictamen circunstanciado el 06-08-2026. - Komisjon sai üksikasjaliku arvamuse 06-08-2026. - Komissio sai tämän yksityiskohtaisen lausunnon 06-08-2026. - Komisija je zaprimila ovo detaljno mišljenje dana 06-08-2026. - A Bizottság 06-08-2026-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 06-08-2026. - Komisija gavo šią išsamiai išdėstytą nuomonę 06-08-2026. - Komisija saņēma šo sīki izstrādāto atzinumu 06-08-2026. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-06-08-2026. - De Commissie heeft deze uitvoerig gemotiveerde mening op 06-08-2026 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 06-08-2026. - A Comissão recebeu o presente parecer circunstanciado em 06-08-2026. - Comisia a primit avizul detaliat privind 06-08-2026. - Komisia dostala toto podrobné stanovisko dňa 06-08-2026. - Komisija je to podrobno mnenje prejela dne 06-08-2026. - Kommissionen mottog detta detaljerade yttrande om 06-08-2026. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 06-08-2026.

MSG: 20262146.EN

1. MSG 115 IND 2026 0223 PL EN 06-11-2026 06-08-2026 IT DO 6.2(2) 06-11-2026

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. 2026/0223/PL - S00S - HEALTH, MEDICAL EQUIPMENT

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

6. 1. Foreword
The Italian Government has examined the draft law notified by the Republic of Poland under the procedure laid down in Directive (EU) 2015/1535, concerning the introduction of new technical requirements applicable to certain categories of nicotine-containing products, including single-use electronic cigarettes, nicotine pouches and other nicotine-containing products.
While recognising that the protection of public health, and in particular the prevention of the consumption of nicotine-containing products by minors and young people, constitutes an objective of general interest which the Member States are entitled to pursue in the exercise of the powers conferred on them by EU law, considers that national measures liable to affect the free movement of goods must comply with the principles of necessity and proportionality enshrined in the Treaty on the Functioning of the European Union, as well as with the existing harmonised regulatory framework and the procedural obligations laid down in Directive (EU) 2015/1535. In the light of the examination of the notified draft, the Italian Government therefore considers it appropriate to make the following observations.
2. Observations of the Italian Government
2.1 Coordination with the process of harmonisation of Union law
The notified draft concerns an area currently undergoing a review of European Union legislation. In this context, the introduction of new national technical requirements requires a particular assessment of their impact on the harmonisation process and the functioning of the internal market.
The European Commission has, in fact, included the revision of Directive 2014/40/EU (Tobacco Products Directive – TPD) and Directive 2011/64/EU (Tobacco Excise Directive – TED) in its Work Programme for 2026. As part of this initiative, a Call for Evidence relating to the review of the regulations governing tobacco products and nicotine-containing products was published on 18 May 2026, followed by the launch of a public consultation in accordance with the principles of the Better Regulation programme. These activities are designed to assess the adequacy of the current regulatory framework and whether the level of harmonisation within the Union should be updated in the light of market developments and the emergence of new product categories.
In light of this context, the documentation provided does not make it possible to ascertain whether the proposed measures have also been assessed in relation to the ongoing review process, nor what their impact might be on the future harmonised framework and on the risk of further fragmentation of the internal market.
This circumstance is of particular significance for the purposes of the procedure laid down in Directive (EU) 2015/1535, given that the notified draft concerns a sector in which the European Commission has already launched initiatives aimed at reviewing the harmonised rules, as well as, more generally, compliance with the principle of sincere cooperation enshrined in Article 4(3) TEU and the objectives of Article 114 TFEU.
In this context, there is strong evidence to support the application of Article 6(3) of Directive (EU) 2015/1535, which provides that Member States must suspend the adoption of a draft technical regulation for a period of 12 months if, within three months of notification, the Commission communicates its intention to propose or adopt a Union legislative act on the matter, or confirms that the national draft acts in an area already covered by a legislative proposal.
2.2 The need for a more detailed justification of the proposed measures
The notified draft introduces a ban on the marketing of single-use electronic cigarettes, nicotine pouches containing flavourings other than tobacco, and other nicotine-containing products.
With regard to electronic cigarettes, it should be noted that Article 24(3) of Directive 2014/40/EU allows Member States to adopt additional national requirements for specific categories of products, provided that such measures are justified on

grounds of public health protection, are proportionate to the objective pursued, and are based on the specific circumstances of the Member State concerned.
The notified documentation identifies as the main purpose of the measures the reduction of the attractiveness of nicotine-containing products to minors and young people. However, the information provided does not make it possible to verify fully the extent to which the specific restrictions proposed are necessary in the light of the objectives pursued, or to ascertain whether those objectives can be achieved by less restrictive measures.
In particular, the Regulatory Impact Assessment annexed to the notification does not develop a comparative analysis of possible regulatory alternatives and, with regard to certain categories of products, itself highlights the limited availability of data capable of assessing their economic and health effects. This circumstance complicates the verification of the necessity and proportionality of the proposed measures.
In the light of the foregoing, the documentation provided does not appear to contain sufficiently detailed information to allow for a full assessment of the measures' compliance with the requirements set out in Article 24(3) of Directive 2014/40/EU and with the principles of necessity and proportionality as established by the case-law of the Court of Justice of the European Union.
2.3 Necessity and proportionality of the proposes measures
The notified draft introduces restrictions affecting the marketing of different categories of nicotine-containing products by establishing:
• the ban on the placing on the market of 'other nicotine-containing products' other than tobacco or related products regulated by the Tobacco Products Directive (2014/40/EU) (TPD) and by national legislation;
• the prohibition of flavourings other than tobacco in nicotine bags;
• a ban on the placing on the market of single-use electronic cigarettes, whether containing nicotine or not.
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The Italian Government recognises that the Member States have a wide margin of discretion in determining the level of protection of public health that they intend to ensure. However, this discretion must be exercised in compliance with the principle of proportionality and the fundamental freedoms guaranteed by the Treaty on the Functioning of the European Union.
According to the established case-law of the Court of Justice, it is for the Member State to demonstrate, on the basis of objective and verifiable evidence, that the restrictions introduced are suitable for achieving the objective pursued and do not go beyond what is necessary to achieve it, taking into account the possible existence of less restrictive measures that are equally effective (see the judgement of the Court of Justice of 23 December 2015, Scotch Whisky Association, C-333/14, as well as Vanderborght (C-339/15) and Commission v Poland (C-200/24)).
In this respect, the notified draft and the accompanying documents do not make it possible to fully verify the reasons why the introduction of generalised bans is the most appropriate measure to achieve the objectives pursued, nor do they explain the reasons that led to the exclusion of the use of other potentially suitable regulatory instruments.
The documentation provided does not, therefore, appear to contain sufficient information to allow for a full assessment of whether the proposed measures comply with the principle of proportionality.
Similarly, although the draft legislation does not formally ban nicotine pouches, the ban on all flavours other than tobacco appears to be a particularly restrictive measure, having an effect equivalent to quantitative restrictions, which is not in line with the aforementioned Articles 34 and 36 TFEU, nor with the established case law of the Court of Justice referred to above.
In the present case, Poland has already recently introduced a number of measures specifically targeting nicotine bags, including restrictions on sales, access for minors and additional regulatory requirements (minimum age for purchase, restrictions on sales channels and nicotine limits). However, the documentation notified does not contain any assessment of the practical effectiveness of those measures, nor does it state the reasons why they are insufficient to achieve the objectives pursued.
The proposal also raises questions of consistency and proportionality, as it would subject nicotine bags to a more restrictive regime than that provided for in Directive 2014/40/EU for electronic cigarettes. In the absence of a specific demonstration of the reasons justifying such a stricter treatment, the prohibition of flavourings appears difficult to reconcile with the principle of proportionality and the overall coherence of the European regulatory framework for nicotine-containing products.
It is also relevant to note that other Member States have chosen to regulate nicotine bags through specific regulatory regimes rather than through generalised prohibitions. In particular, Italy has developed one of the most advanced

regulatory frameworks in the European Union for this sector. These products are subject to a specific regime provided for in Article 62-quater.1 of the Consolidated Text on Excise Duties (Legislative Decree No 504/1995), which regulates their manufacture, import, distribution and sales methods. The system provides for authorisation obligations for economic operators, controls by the Customs and Monopolies Agency, specific tax liability, traceability requirements and a dedicated supervisory regime. In 2026, the Italian legislature further strengthened these regulations by introducing specific regulatory requirements (packaging and maximum nicotine limits), a ban on sales to minors and on distance sales, including cross-border sales, as well as a comprehensive system of penalties to ensure the effective enforcement of the rules applicable to the sector.

The existence of an advanced regulatory model already in place in a Member State demonstrates that the objectives of public health protection can be pursued through regulatory, control and supervisory measures without recourse to further restrictions on product characteristics. The Italian experience may therefore constitute a regulatory best practice relevant for the assessment of the necessity of the notified measure and confirms the existence of less restrictive approaches compatible with the objectives of the internal market and with the principle of proportionality enshrined in Union law.

2.4 Impact on the internal market and legal certainty

The measures provided for in the notified draft are likely to affect the marketing in Poland of products lawfully manufactured and marketed in other Member States.

Of particular significance are the provisions concerning ‘other nicotine-containing products’, the definition of which – formulated in residual and broad terms – could encompass categories of products not expressly covered by current EU legislation.

The wording of the provision could give rise to uncertainty as to its scope of application, thereby affecting the predictability of the rules and legal certainty for economic operators and the authorities responsible for enforcing the legislation.

In this regard, the Court of Justice has repeatedly held, in its judgements in Commission v France (C 24/00) and Commission v Denmark (C 192/01), that systematic or generalized prohibitions cannot be justified unless the Member State demonstrates, on a case-by-case basis and on the basis of the latest available scientific evidence, that there is a genuine risk to public health.

Furthermore, the notified documentation does not contain a sufficiently detailed assessment of the impact that these measures might have on the functioning of the internal market, with particular regard to the marketing of products lawfully placed on the market in other Member States. In light of these factors, the notified draft requires further examination with regard to the compatibility of the proposed measures with Articles 34 and 36 of the Treaty on the Functioning of the European Union.

2.5 Adequacy of the impact assessment

The Regulatory Impact Assessment attached to the notification constitutes an essential element for the assessment of the conformity of the notified draft with the principles of necessity and proportionality.

However, examination of the documentation shows that, with regard to some of the proposed measures, the impact assessment itself highlights the limited availability of data suitable to estimate their economic, health and commercial effects.

Furthermore, no specific comparative analyses have been carried out regarding the effectiveness of any alternative, less restrictive measures, nor has there been a detailed assessment of the effects that the proposed bans might have on the internal market.

These elements do not allow a fully comprehensive verification of the necessity of the proposed measures and their proportionality with regard to the objectives pursued.

3. Conclusion

In the light of the above considerations, the notified draft and its accompanying documentation do not allow a full assessment of the compliance of the proposed measures with the principles of necessity and proportionality, with Articles 34 and 36 of the Treaty on the Functioning of the European Union and, with regard to electronic cigarettes, with the preconditions laid down in Article 24(3) of Directive 2014/40/EU.

For these reasons, the Italian Government, pursuant to Article 6(2) of Directive (EU) 2015/1535, issues this detailed opinion and invites the Polish authorities to inform the European Commission of the measures they intend to take in response to this opinion, in accordance with the provisions of said Article.

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