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) 1147

Directive (EU) 2015/1535

Notification: 2025/0044/ES

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 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: 20251147.EN

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

2. Italy

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

Direzione Generale Consumatori e Mercato
Divisione II - Normativa tecnica - Sicurezza e conformità dei prodotti, qualità prodotti e servizi
00187 Roma - Via Molise, 2

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. 2025/0044/ES - X60M - Tobacco

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

6. The Spanish Ministry of Health notified, on 24 January 2025, through the TRIS system, a draft Royal Decree introducing measures that could create technical barriers to trade within the EU single market.
Certain restrictions provided for in the draft Spanish Decree could contradict the principle of free movement of goods and the harmonisation objective established by the EU tobacco regulatory framework, particularly Directive 2014/40/EU itself.
The specific problems identified in the draft mentioned above are set out below.

PROBLEM AREAS

1. De facto prohibition of nicotine pouches and violation of the principle of free movement of goods
Paragraph 15 of the draft Royal Decree (amending Article 52) provides that "it shall be prohibited to place on the market, sell, distribute or offer free of charge nicotine bags containing a) more than 0.99 mg nicotine per bag". Therefore, it undertakes to set a maximum limit of 0.99 mg nicotine per pouch, providing for a de facto ban on the product since no product on the market has such low concentration levels. This provision conflicts with Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), as it would restrict the free movement of goods in the single market.
Article 34 TFEU establishes a rule that "quantitative restrictions on imports and measures having equivalent effect are prohibited between EU Member States". The concentration limit set by the draft Spanish Royal Decree, therefore, constitutes a measure having an effect equivalent to quantitative restrictions, as defined under Article 34 TFEU. This limit would effectively exclude all nicotine pouches from the market, thus introducing a general and absolute ban.
If the Spanish measure were adopted, products (nicotine pouches) lawfully manufactured and marketed in other Member States following their national legislation could not be introduced and marketed in Spain.
Concerning the limit of 0.99 mg nicotine, it would be appropriate to indicate to what scientific publications the reference is made to justify this limit.
Italy shows – at present – that the prevailing literature is attributable to the in-depth studies carried out by the Bundesinstitut für Risikobewertung (BfR) – the Institute for Risk Assessment of Federal Germany – an Independent Public Authority of Germany.
The BfR identified 16.6 mg per pouch as the maximum nicotine concentration threshold for those products.
In conclusion, in the light of the above considerations, the Spanish measure appears to be contrary to the principle of the free movement of goods in breach of Article 34 TFEU.

2. Rules on labelling and presentation of products with impacts on legal certainty
The Royal Decree introduces restrictions on the labelling and presentation of products (electronic cigarettes with and without nicotine, nicotine pouches and heated herbal products) by providing that packaging must not include colours and elements that "may attract the attention or special interest of consumers [...]" (paragraph 9(3) for electronic cigarettes; paragraph 16 Chapter I, amending Article 53(3) for nicotine pouches; paragraph 16 Chapter II, amending Article 56(3) for heated herbal products).
This provision has an ambiguous scope. Therefore, we ask for further clarification to avoid individual and arbitrary interpretations, undermining legal certainty on the subject with interpretative doubts about the actual scope.
It should be noted that the proposed Royal Decree aims to introduce a specific provision on areas expressly regulated – and therefore subject to harmonised regulation – by Directive 2014/40/EU, namely the labelling and packaging of electronic cigarettes (with nicotine).

Article 20(4) of the Tobacco Products Directive 2014/40/EU (TPD) requires EU manufacturers to include information on nicotine content for electronic cigarettes and does not prohibit the inclusion of other elements (e.g. concerning product characteristics, flavourings, ...) on the packaging, including through elements or images.
Therefore, Spain is asked how the notified measure aligns with the EU-level harmonised standard.

3. Prior notification obligation for non-harmonised product categories
Article 20(2) of the TPD requires manufacturers and importers of electronic cigarettes and refill cartridges to submit a notification six months before placing them on the market. This notification is made on EU-CEG, in line with the Commission Implementing Decision (EU) 2015/2183 format.
The draft Royal Decree stipulates the following: “Manufacturers or importers wishing to introduce on the market electronic cigarettes, nicotine-free electronic cigarettes or refill cartridges with or without nicotine shall apply to the Directorate-General for Public Health and Health Equity via the EU-CEG portal and following the format laid down in the Implementing Decision (EU) 2015/2183 of the Commission. The communications referred to in Paragraphs 1 and 2 shall be made: [...], six months before their placing on the market.”
It therefore extends the obligation to nicotine-free electronic cigarettes, as well as nicotine pouches and herbal heated products, which the TPD does not cover.
These products do not fall within any of the product categories defined by Directive 2014/40/EU; consequently, there is currently no category in the EU-CEG system within which they can adequately be registered. Therefore, you are requested to clarify how this registration should occur due to technical and legal impossibility.

4. The transitional period, contrary to Union case law
The draft Spanish Royal Decree establishes (under the "Single Transitional Provision”) a transitional period of only 10 months for the manufacture and introduction for consumption of electronic cigarettes and refill cartridges, whether or not containing nicotine, with an obligation to cease the sale of non-compliant products no later than the 12th month after the entry into force of the Royal Decree.
At the same time, nicotine pouches and herbal heated products do not have a transitional period, which means that the requirements can be applied when the measure enters into force.
Without prejudice to the general problems of the measure set out above, compliance with the provisions mentioned above will, in any case, require substantial adaptation time if they are confirmed. EU companies will be forced to change product recipes, revise production lines and implement changes to product labelling, packaging and presentation. Those adjustments cannot reasonably be completed within 10 months or, in the case of nicotine pouches and heated herbal products, from the date the Spanish measure entered into force.
The EU Court of Justice has ruled that not providing a reasonable transition period restricts the free movement of goods (C-309/02, Radlberger).

5. Non-proportionate restrictions on heated herbal products
Paragraph "Sixteen", Chapter II, introduces a regulatory framework for "heated herbal products" including reporting requirements, quality and safety requirements, and labelling and packaging requirements.
In this context, it should be noted that Italy has already introduced a comprehensive regulatory framework laying down specific national provisions for “smokeless inhalation products consisting of solid substances other than tobacco, whether or not containing nicotine” (Article 62-quater.2 of Legislative Decree No 504/1995 and specific administrative provisions of the Customs and Monopolies Agency).
Certain measures introduced by the draft Spanish Royal Decree appear to be particularly disproportionate and would de facto render Italian products - legally manufactured following the national regulatory framework in force - unable to be produced and exported to the Spanish market. Those provisions would therefore be inconsistent with the fundamental general principle of proportionality. Indeed, Member States are required to ensure that any restrictive measure is proportionate, irrespective of its justification. In order to be considered valid, a justification must demonstrate a clear link between the proposed measure and the intended objective, as well as evidence to support its effectiveness and evidence of the consideration of less restrictive alternative measures aimed at regulating these categories of products comprehensively and proportionately.
Restrictions must therefore be appropriate to the achievement of their objectives, limited to what is necessary and proportionate in the strict sense.

In principle, concerning such products, which are not subject to harmonised regulation, the measures proposed by Spain appear to be in breach of Articles 34 and 36 of the TFEU, as they restrict the placing on the market of products lawfully manufactured in other Member States.
Since Italy is one of the leading producers of these products and considering that the proposed Spanish measure lacks proportionality, this approach risks creating serious negative impacts on Italian exports and production.

6. Prohibition of flavourings contrary to the principle of proportionality
The Spanish Royal Decree introduces a ban on products containing flavours other than tobacco (applicable for e-cigarettes and nicotine-free e-cigarettes and refill cartridges with or without nicotine, nicotine pouches and heated herbal products).
This general prohibition appears to be extremely broad and disproportionate in that it covers all the types of products mentioned above, as well as all flavourings other than tobacco. In this context, it should also be pointed out that the TPD Directive does not prohibit the characterisation of flavours for tobacco-free products, particularly electronic cigarettes.
The measures introduced by the draft Spanish Royal Decree, therefore, appear to be inconsistent with the fundamental general principle of proportionality. It does not appear that less restrictive regulatory alternatives have been assessed to ensure a comprehensive and proportionate regulatory framework. Indeed, Member States are required to ensure that any restrictive measure is proportionate, irrespective of its justification. Restrictions must be appropriate to the achievement of their objectives, limited to what is necessary and proportionate in the strict sense.
Since Italy is one of the leading producers of these products and considering that the proposed Spanish measure lacks proportionality, this approach risks creating serious negative impacts on Italian exports and production.

CONCLUSIONS
In conclusion, the provisions of the Spanish legislation in question are significantly inconsistent with respect to the fundamental principle of the free movement of goods in the European single market and with regard to certain Union regulatory provisions in force in the sector. 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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