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) 0389

Directive (EU) 2015/1535

Notification: 2024/0610/AT

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 08-05-2025.

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 08-05-2025. - Prolonge le délai de statu quo jusqu'au 08-05-2025.- Die Laufzeit des Status quo wird verlängert bis 08-05-2025.- Удължаване на крайния срок на статуквото до 08-05-2025. - Prodlužuje lhůtu současného stavu do 08-05-2025. - Fristen for status quo forlænges til 08-05-2025. - Παρατείνει την προθεσμία του status quo 08-05-2025. - Amplía el plazo de statu quo hasta 08-05-2025. - Praeguse olukorra tähtaega pikendatakse kuni 08-05-2025. - Jatkaa status quon määräaikaa 08-05-2025 asti. - Produžuje se vremensko ograničenje statusa quo do 08-05-2025. - Meghosszabbítja a korábbi állapot határidejét 08-05-2025-ig. - Proroga il termine dello status quo fino al 08-05-2025. - Status quo terminas pratęsiamas iki 08-05-2025. - Pagarina “status quo” laika periodu līdz 08-05-2025. - Jestendi t-terminu tal-istatus quo sa 08-05-2025. - De status-quoperiode wordt verlengd tot 08-05-2025. - Przedłużenie status quo do 08-05-2025. - Prolonga o prazo do statu quo até 08-05-2025. - Prelungește termenul status quo-ului până la 08-05-2025. - Predlžuje sa lehota súčasného stavu do 08-05-2025. - Podaljša rok nespremenjenega stanja do 08-05-2025. - Förlänger tiden för status quo fram till 08-05-2025.

The Commission received this detailed opinion on the 10-02-2025. - La Commission a reçu cet avis circonstancié le 10-02-2025. - Die Kommission hat diese ausführliche Stellungnahme am 10-02-2025 empfangen. - Комисията получи настоящото подробно становище относно 10-02-2025. - Komise obdržela toto podrobné stanovisko dne 10-02-2025. - Kommissionen modtog denne udførlige udtalelse den 10-02-2025. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 10-02-2025. - La Comisión recibió el dictamen circunstanciado el 10-02-2025. - Komisjon sai üksikasjaliku arvamuse 10-02-2025. - Komissio sai tämän yksityiskohtaisen lausunnon 10-02-2025. - Komisija je zaprimila ovo detaljno mišljenje dana 10-02-2025. - A Bizottság 10-02-2025-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 10-02-2025. - Komisija gavo šią išsamiai išdėstytą nuomonę 10-02-2025. - Komisija saņēma šo sīki izstrādāto atzinumu 10-02-2025. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-10-02-2025. - De Commissie heeft deze uitvoerig gemotiveerde mening op 10-02-2025 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 10-02-2025. - A Comissão recebeu o presente parecer circunstanciado em 10-02-2025. - Comisia a primit avizul detaliat privind 10-02-2025. - Komisia dostala toto podrobné stanovisko dňa 10-02-2025. - Komisija je to podrobno mnenje prejela dne 10-02-2025. - Kommissionen mottog detta detaljerade yttrande om 10-02-2025. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 10-02-2025.

MSG: 20250389.EN

1. MSG 115 IND 2024 0610 AT EN 08-05-2025 10-02-2025 IT DO 6.2(2) 08-05-2025

2. Italy

3A. MINISTERO DELLE IMPRESE E DEL MADE IN ITALY
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Div. XIII – Agroindustria, industrie culturali e creative, industria del turismo

4. 2024/0610/AT - X60M - Tobacco

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

6. Following the examination of the draft Order banning certain substances in tobacco products and liquids for electronic cigarettes (2024/0610/AT), carried out by the competent administrations, Italy issues the following detailed opinion.
Background
On 7 November, as part of the TRIS notification procedure, Austria sent to the Commission notification 2024/0610/AT of the draft "National Ordinance containing a national list of substances banned in tobacco products and electronic cigarettes". This list aims to ban certain substances in tobacco products and e-cigarettes, raising significant concerns in terms of compatibility with EU law, particularly regarding the violation of the free movement of goods and the principle of proportionality, for the following reasons.
Severability
1. Most of the elements on the list of banned substances are indispensable in e-cigarette liquids and essential additives in tobacco products. Their ban would therefore make product reformulation technically impossible, effectively banning all tobacco and vaping products. This constitutes a quantitative restriction on imports within the meaning of Article 34 TFEU, involving a total or partial ban on importing or transiting goods. The ban imposed by Austria through the list creates an obstacle to cross-border trade by preventing the sale of compliant products which have been lawfully placed on the market in other Member States. Such measures are therefore contrary to the objectives of the internal market, which are to ensure the free movement of goods and equal access to the market.

2. Furthermore, Article 36 TFEU provides that a restriction may be justified only by an objective of general interest and, as specified by the case-law of the CJEU, must be accompanied by appropriate evidence or by an analysis of the appropriateness and proportionality of the restrictive measure adopted. This has not been demonstrated, nor have less restrictive alternatives been considered.
The order claims to take into account the same ingredient requirements as those laid down in the Tobacco Products Directive 2014/40/EU (TPD) and to provide legal certainty by clarifying which substances fall within the categories of ingredients banned by the TPD. However, many of the components of the proposed list are widely used in the production of tobacco products and e-cigarettes and are additives permitted by the Directive. By banning glycerol, which is included among others in the list of ingredients, Austria is unlawfully introducing divergent requirements, which run counter precisely to the harmonised framework of the TPD, undermining legal certainty.
Glycerol is not classified as a CMR substance under CLP Regulation No 1272/2008; therefore, the ban lacks a scientific and legal basis. As reported by the OECD and the European Chemicals Agency (ECHA), scientific evidence indicates that glycerol is of low toxicity when ingested, inhaled or in contact with the skin.
Section 5.4 of the proposed list refers to substances from the "MAK/BAT list of values" published by the German Research Foundation Deutsche Forschungsgemeinschaft (DFG). This list was created to inform about the protection of workers in industrial environments from certain hazards and was not designed or intended for the regulation of consumer products. For this reason, these values are not consistent with methods and classifications established by EU legislation, and applying these lists to tobacco products and e-cigarettes by analogy is inappropriate and scientifically incorrect, as the exposure contexts and regulatory purposes are fundamentally different.
Regulatory considerations
The objective of Directive 2014/40/EU on tobacco products is to approximate the laws, regulations and administrative provisions of the Member States concerning, inter alia, ingredients and emissions of tobacco products and related reporting requirements with a view to facilitating the smooth functioning of the internal market for tobacco products

(Article 1).
The Austrian draft measure would introduce differentiated rules (through the introduction of a unilateral ban by a single Member State) contrary to the main objectives identified by Directive 2014/40/EU and the common provisions defined by it, undermining legal certainty regarding the regulation of ingredients in the EU regulatory framework, de facto banning the production and marketing of products that fully comply with the harmonised regulations in force. It should be recalled that Recital 15 of the Tobacco Products Directive itself highlights the problems arising from the lack of a harmonised approach to the regulation of ingredients in tobacco products which affects "the smooth functioning of the internal market and has a negative impact on the free movement of goods across the Union".
In the light of the above, the following is noted:
1. The Tobacco Products Directive 2014/40/EU, transposed into Italian law by Legislative Decree 6/2016, does not classify glycerol among the banned substances in any way, but limits itself to providing enhanced reporting obligations for this substance, as well as for other additives, in accordance with Article 6 of the Directive, through Implementing Decision (EU) 2016/7871.
2. Although glycerol is not banned under Article 7 of the Tobacco Products Directive, the Commission is empowered to adopt implementing acts to ban a tobacco product containing additives (including glycerol) in quantities that increase its CMR properties at the time of consumption. Ten years after the entry into force of the Directive, there is no evidence that the Commission has adopted any implementing act banning tobacco products containing glycerol or amending to that effect the list of permitted substances set out in Implementing Decision (EU) 2016/787.
3. It is the TPD itself that identifies any additional relevant reference sources at Union level for the application of product ingredient legislation. Under Article 5.2 of the Directive, manufacturers and importers are required to report ingredients used in tobacco products, including whether they have been registered under the REACH Regulation (Regulation (EC) No 1907/2006) and their classification under the CLP Regulation (Regulation (EC) No 1272/2008).
4. The CLP Regulation, recently revised and updated in December 2024, sets out a harmonised and binding approach for the assessment of chemicals in the EU. It should be noted that the same Regulation does not include glycerol among the substances with CMR properties.
The draft Austrian order therefore appears inconsistent and in conflict with the harmonised provisions of the Tobacco Products Directive 2014/40/EU, with the provisions of Implementing Decision (EU) 2016/787 and with the provisions of the REACH and CLP Regulations.

Conclusions
In conclusion, there is a significant inconsistency in the provisions of the Austrian legislation in question with the EU legislation in force, both in terms of the specific legislation applicable to the products in question and with respect to the more general common legislation on chemicals.
It should be noted that the rules in question proposed by Austria give rise to a ban on the release for consumption in the EU (and therefore de facto related manufacturing and distribution) of products subject to harmonised Community legislation that do not appear to have characteristics such as to be banned under the applicable EU legislation on ingredients and additives of the products in question. The Austrian measure would consequently lead to the introduction of a trade barrier in the internal market with negative impacts on the key harmonisation objectives set by European law and the Tobacco Products Directive itself.

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