



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) 0352

Directive (EU) 2015/1535

Notification: 2024/0610/AT

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 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 - Opinioni 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. - Prodłużuje 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 määraaika 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 pratęsimas 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-quo periode 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 06-02-2025. - La Commission a reçu cet avis circonstancié le 06-02-2025. - Die Kommission hat diese ausführliche Stellungnahme am 06-02-2025 empfangen. - Комисията получи настоящото подробно становище относно 06-02-2025. - Komise obdržela toto podrobné stanovisko dne 06-02-2025. - Kommissionen modtog denne udførlige udtalelse den 06-02-2025. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 06-02-2025. - La Comisión recibió el dictamen circunstanciado el 06-02-2025. - Komisjon sai üksikasjaliku arvamuse 06-02-2025. - Komissio sai tämän yksityiskohtaisen lausunnon 06-02-2025. - Komisija je zaprimila ovo detaljno mišljenje dana 06-02-2025. - A Bizottság 06-02-2025-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 06-02-2025. - Komisija gavo šią išsamiai išdėstytą nuomonę 06-02-2025. - Komisija saņēma šo sīki izstrādāto atzinumu 06-02-2025. - Il-Kummissjoni rċeviet din l-opinioni dettaljata dwar il-06-02-2025. - De Commissie heeft deze uitvoerig gemotiveerde mening op 06-02-2025 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 06-02-2025. - A Comissão recebeu o presente parecer circunstanciado em 06-02-2025. - Comisia a primit avizul detaliat privind 06-02-2025. - Komisia dostala toto podrobné stanovisko dňa 06-02-2025. - Komisija je to podrobno mnenje prejela dne 06-02-2025. - Kommissionen mottog detta detaljerade yttrande om 06-02-2025. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 06-02-2025.

MSG: 20250352.EN

1. MSG 115 IND 2024 0610 AT EN 08-05-2025 06-02-2025 RO DO 6.2(2) 08-05-2025

2. Romania

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



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4. 2024/0610/AT - X60M - Tobacco

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

6. The provisions contained in the draft notified by Austria introduce regulations going beyond Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (TPD Directive), which fragment the market and create trade barriers to the free movement of goods.

The draft indirectly prohibits the substance glycerol in points 1.4 and 5.4: 'Substances which, according to the MAK and BAT values list (published by the Deutsche Forschungsgemeinschaft (DFG)), have been classified by the MAK Commission as having carcinogenic effects in categories 1, 2, 4, or 5, as teratogenic effects in categories A, B, or C, and as germ cell mutagenic effects in categories 1, 2, 3A, or 3B.'

Article 5(2) of the TPD, which requires manufacturers to declare the classification of ingredients used in tobacco products, including any classification as CMR substances under Regulation (EC) No 1272/2008 (CLP), imposes the requirement to rely solely on CLP classifications when determining CMR properties. The MAK and BAT lists referred to include substances that may have harmful effects on health in the context of occupational exposure, having nothing to do with the exposure of users of conventional cigarettes, heated tobacco products or e-cigarettes. Austria's use of the MAK and BAT lists is therefore legally and scientifically unfounded. These lists do not correspond to the methods and classifications established under EU legislation, including the CLP and REACH Regulations.

The European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) concluded that there is insufficient evidence to classify glycerol as a teratogenic substance.

Glycerol is a food additive approved in the European Union in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, where it is listed as allowed for use quantum satis (no maximum limit specified).

Glycerol is an essential element in liquids for electronic cigarettes, and its prohibition makes it practically impossible to manufacture these products, amounting to a de facto ban on all vaping products and heated tobacco, which constitutes a restriction equivalent to a trade barrier within the meaning of Article 34 of the Treaty on the Functioning of the European Union, hindering the free movement of products lawfully marketed in another Member State.

Austria has not demonstrated that the restriction is justified under the provisions of Article 36 TFEU, and the measure adopted lacks a scientific basis, as a result of which it could lead to a serious distortion of competition and affect economic operators legally active in the sector.

In view of the above, Romania formulates its detailed opinion and calls on the Austrian authorities to align the draft with the harmonised legislative framework of the TPD and to remove unjustified restrictions affecting producers and cross-border trade.



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