



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) 1234

Directive (EU) 2015/1535

Notification: 2025/0110/FR

Forwarding of a detailed opinion received by a Member State (Greece) (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 - Opinioni dettaljata - Uitvoerig gemotiveerde mening - Opinia szczegółowa - Parecer circunstanciado - Avis 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. - Prodłużuje 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 määraaika 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 08-05-2025. - La Commission a reçu cet avis circonstancié le 08-05-2025. - Die Kommission hat diese ausführliche Stellungnahme am 08-05-2025 empfangen. - Комисията получи настоящото подробно становище относно 08-05-2025. - Komise obdržela toto podrobné stanovisko dne 08-05-2025. - Kommissionen modtog denne udførlige udtalelse den 08-05-2025. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 08-05-2025. - La Comisión recibió el dictamen circunstanciado el 08-05-2025. - Komisjon sai üksikasjaliku arvamuse 08-05-2025. - Komissio sai tämän yksityiskohtaisen lausunnon 08-05-2025. - Komisija je zaprimila ovo detaljno mišljenje dana 08-05-2025. - A Bizottság 08-05-2025-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 08-05-2025. - Komisija gavo šią išsamiai išdėstytą nuomonę 08-05-2025. - Komisija saņēma šo sīki izstrādāto atzinumu 08-05-2025. - Il-Kummissjoni rċeviet din l-opinioni dettaljata dwar il-08-05-2025. - De Commissie heeft deze uitvoerig gemotiveerde mening op 08-05-2025 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 08-05-2025. - A Comissão recebeu o presente parecer circunstanciado em 08-05-2025. - Comisia a primit avizul detaliat privind 08-05-2025. - Komisia dostala toto podrobné stanovisko dňa 08-05-2025. - Komisija je to podrobno mnenje prejela dne 08-05-2025. - Kommissionen mottog detta detaljerade yttrande om 08-05-2025. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 08-05-2025.

MSG: 20251234.EN

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

2. Greece

3Α. ΕΛΟΤ, ΚΕΝΤΡΟ ΠΛΗΡΟΦΟΡΗΣΗΣ ΟΔΗΓΙΑΣ 98/34/Ε.Ε, ΚΗΦΙΣΟΥ 50, 121 33 ΠΕΡΙΣΤΕΡΙ, ΑΘΗΝΑ, Τ/Φ: + 30210- 2120104, Τ/Ο: + 30210- 2120131



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3B. ΓΕΝΙΚΗ ΓΡΑΜΜΑΤΕΙΑ ΒΙΟΜΗΧΑΝΙΑΣ, ΓΕΝ. Δ/ΝΣΗ ΒΙΟΜΗΧΑΝΙΚΩΝ ΥΠΟΔΟΜΩΝ ΚΑΙ ΕΠΙΧΕΙΡΗΜΑΤΙΚΟΥ ΠΕΡΙΒΑΛΛΟΝΤΟΣ, Δ/ΝΣΗ ΑΣΦΑΛΕΙΑΣ ΚΑΙ ΣΥΜΜΟΡΦΩΣΗΣ ΒΙΟΜΗΧΑΝΙΚΩΝ ΠΡΟΪΟΝΤΩΝ, ΤΜΗΜΑ Δ΄ ΓΕΝΙΚΗΣ ΑΣΦΑΛΕΙΑΣ ΠΡΟΪΟΝΤΩΝ Τηλ.: 210 3893695, αρμ.: Χ. Νικόλσκι, e-mail: nikolsky@mindev.gov

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

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

6. We hereby request you to submit a reasoned opinion immediately to the European Commission on the draft Regulatory Decree submitted by France “on the prohibition of products for oral use containing nicotine”.

The draft French Regulatory Decree was posted on the TRIS database of the European Union on 24.02.2025, with notification number 2025/0110/FR under the public consultation procedure of Directive 1535/2015/EE, in order to inform the Member States of the European Union. According to the draft Regulatory Decree, a total ban is imposed on the manufacture, import, possession, sale and distribution and use of products for oral use containing nicotine, including nicotine pouches, with the exception of authorised medicinal products or other products used for research.

In particular:

a) France’s legislative provision as mentioned above is regarded as creating obstacles to the free movement of goods (Article 34 of the Treaty on the Functioning of the European Union, TFEU) which is based on the principles of proportionality and subsidiarity. The total ban is not adequately justified; it does take into account the negative effects of nicotine on human health, but it does not take into account the proportionality of the measure in relation to the basic parameters of the free market. Obstacles are therefore created to the placing of these products on the French market, whereas these products are freely marketed in other Member States. Under EU law (Article 36 TFEU), restrictions on trade are only permitted by way of exception, such as in this case, on the grounds of protection of public health. However, this provision has not taken into account and does not include any references to specific documented sources; in addition, similar products are marketed in all countries but with clear restrictions on nicotine content.

b) This French draft is being introduced at a time when the European Commission has announced the start of the process for the revision of the Tobacco Products Directive (TPD). At the revision stage, an evaluation of the specific products is expected to take place and, thus, all Member States will be able to adapt their legislation unaffected by this legislative initiative of France.

By way of example, we mention Finland’s and Poland’s legislative proposals, whose anti-smoking legislation respectively proposes the selling of such products with exceptions on the basis of the principle of proportionality, as follows:

1. Finland

- Maximum nicotine content: 16.6 mg/g
- Retail licence and supervisory control
- Mandatory labelling of packaging with warnings on addiction and indication of ingredients
- Prohibition of use in assembly areas for minors
- Prohibition of possession and purchase for persons under the age of 18



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2. Poland

- Maximum nicotine content: 20 mg/g
- Prohibition of sale to adults by means of vending machines
- Prohibition of cross-border distance sales, advertising and promotion
- Obligation on producers/importers to indicate ingredients
- Mandatory warning for addiction on the packaging

The examples indicated above demonstrate the possibility of Member States imposing legal regulations which are strict but also respect the requirements of the free market as a basic parameter of the European Union.

Greece, as a country which is very interested in protecting the health of its own citizens, especially minors, as well as ensuring the application of competition rules and healthy entrepreneurship, has already submitted reasoned opinions on other drafts notified by other Member

States. We believe that at the present stage, where the revision of the Tobacco Products Directive is currently under way, total bans are not in line with the basic component of the European Union, which is the free movement of goods.

For the reasons set out above, we consider that the submission of a reasoned opinion is necessary. In view of the foregoing, we request that the above individual regulations proposed by France, which do not take into account the basic principles of the economic and monetary union, in particular the principle of proportionality and free competition as a basic horizontal policy of the European Union, are amended in order to meet the above parameters, with a view to protecting the interests and the Greek economy.

The Secretary-General for Industry
Eleftherios Kritikos

European Commission
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