

Message 116

Communication from the Commission - TRIS/(2022) 03339
 Directive (EU) 2015/1535
 Translation of the message 115
 Notification: 2022/0417/B

Forwarding of a detailed opinion received by a Member State (Hungary) (article 6, paragraph 2, second indent of Directive (EU) 2015/1535). This detailed opinion extends the standstill period until 16-12-2022.

Comunicado detallado - Podrobné vyjádření - Udførlig udtalelse - Ausführlichen Stellungnahme - Üksikasjalik arvamus - Εμπειροπαιωμένη γνώμη - Detailed opinion - Avis circonstancié - Parere circostanziato - Detalizēts atzinums - Detali nuomonė - Részletes vélemény - Opinioni dettaljata - Uitvoerig gemotiveerde mening - Opinia szczegółowa - Parecer circunstanciado - Podrobný úsudok - Podrobno mnenje - Yksityiskohtainen lausunto - Detaljerat yttrande - Подробно становище - Aviz detaliat - Aviz detaliat.

Amplia el plazo del estatu quo hasta 16-12-2022. - Prodlužuje lhůtu pro stávající stav až do 16-12-2022. - Fristen for status quo forlænges til 16-12-2022. - Die Laufzeit des Status quo wird verlängert bis 16-12-2022. - Praeguse olukorra tähtaega pikendatakse kuni 16-12-2022. - Παρατείνει την προθεσμία του status quo μέχρι την 16-12-2022. - Extends the time limit of the status quo until 16-12-2022. - Prolonge le délai de statu quo jusqu'au 16-12-2022. - Proroga il termine dello status quo fino al 16-12-2022. - Pagarina "status quo" laika periodu līdz 16-12-2022. - Pratęsia status quo laiką limitą iki 16-12-2022. - Meghosszabbítja a korábbi állapot határidejét 16-12-2022-ig. - Jestendi t-terminu ta' l-istatus quo sa 16-12-2022. - De status-quo-periode wordt verlengd tot 16-12-2022. - Przedłużenie status quo do 16-12-2022. - Prolonga o prazo do statu quo ate 16-12-2022. - Časový limit momentálneho stavu sa predĺži až do 16-12-2022. - Podaljša rok nespremenjenega stanja do 16-12-2022. - Jatkaa status quo määräaika 16-12-2022 asti - Förlänger tiden för status quo fram till: 16-12-2022 - Удължаване на крайния срок на статуквото до 16-12-2022 - Prelungește termenul status quo-ului până la 16-12-2022.

Die Kommission hat diese ausführliche Stellungnahme am 16-09-2022 empfangen.
 The Commission received this detailed opinion on the 16-09-2022.
 La Commission a reçu cet avis circonstancié le 16-09-2022.

(MSG: 202203339.EN)

1. MSG 116 IND 2022 0417 B EN 16-12-2022 16-09-2022 COM 6.2(2) 16-12-2022

2. Magyarország

3A. Igazságügyi Minisztérium
 EU Jogi Megfelelésvizsgálati Főosztály - Műszaki Notifikációs Központ
 H-1055 Budapest, Nádor utca 22.
 E-mail: technicalnotification@im.gov.hu

3B. Külgazdasági és Külügyminisztérium
 Külgazdaság Fejlesztéséért Felelős Helyettes Államtitkárság
 H-1027 Budapest, Bem rakpart 47.

4. 2022/0417/B - X00M

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

6. 1. Background

Hungary supports the reduction of smoking and the control of the consumption of nicotine containing products for pleasure purposes. Accordingly, for a number of products, the Hungarian Government has adopted legislation stricter than that laid down in the Tobacco Products Directive (Directive 2014/40/EU of the European Parliament and of the Council 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), such as the introduction of uniform packaging for cigarettes and roll-your-own tobacco.

The definition of products for pleasure purposes that contain nicotine but no tobacco, including nicotine pouches, is provided in Section 1(y) of Act XLII of 1999 on the protection of non-smokers and certain regulations on the consumption and distribution of tobacco products, which stipulates that

"smoking-substitute nicotine-containing product shall mean a product, other than an electronic cigarette, refill container or cartridge, that contains nicotine, but no tobacco, that is not considered as a medicinal product and whose active substance enters the body orally (through the mucous membrane)".

For all products covered by the generic term 'smoking replacement products containing nicotine', it is necessary, from the point of view of public health, to regulate the ingredients — particularly the maximum allowed nicotine

content — as well as the packaging, access and retail sale, which is in the process of being developed in Hungary.

The Belgian Government seeks to prohibit the placing on the market of nicotine pouches, relying on the precautionary principle. A nicotine pouch is a product that does not contain tobacco and serves as an alternative to smokers instead of traditional cigarettes.

The 'Royal Decree prohibiting the manufacture and placing on the market of certain similar products' (hereinafter referred to as: Draft Decree) was notified by the Belgian government to the European Commission on 15 June 2022 through the TRIS notification system. Based on the explanatory memorandum to the Draft Decree, the main objective of the ban is to prevent any of the known and potentially harmful health effects of the use of nicotine pouches, to deter young people from using them and to avoid possible negative effects on anti-smoking efforts.

2. The Tobacco Products Directive

The implementation and effectiveness of the Tobacco Products Directive is still undergoing review by the Commission. According to the 2021 Report from the Commission on the application of the Tobacco Products Directive (Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of Directive 2014/40/EU to the manufacture, presentation and sale of tobacco and related products), the next revision should take into account changes in internationally agreed rules and standards as well as scientific and technical knowledge. Paragraph 7 of the report also explicitly states that the Tobacco Products Directive "does not fully capture certain new products not containing tobacco, such as oral nicotine pouches". The entry into force of the Belgian Draft Decree would also precede the conclusions of a properly conducted debate in the institutions of the European Union on the potential harm-reducing benefits of nicotine pouches, based on scientific research and data, and their inclusion in the EU legal act to be adopted.

In addition to the above, it is necessary to examine the practices of Member States regarding the marketing of nicotine pouches. The Czech Republic, Denmark and Sweden have recently introduced legislation on nicotine pouches to strike a balance between the availability of products for smokers looking for alternatives and the protection of non-smokers and young people. The entry into force of the Draft Decree would thus lead to more fragmented internal market rules, contrary to the Commission's objective of approximating Member States' rules on the manufacture and sale of tobacco and related products.

3. Strategy under the FCTC and proposed by the European Parliament

The WHO Framework Convention on Tobacco Control (hereinafter referred to as FCTC) recommends that governments adopt policies "that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke".

Nicotine pouches are likely to be less harmful than combustible cigarettes, given that they do not contain tobacco, they do not generate combustion, and accordingly, they do not release tobacco smoke. Making nicotine pouches available allows smokers to (1) reduce their tobacco consumption by switching to nicotine pouches and (2) to reduce their exposure to tobacco smoke. Currently 1.4 million EU citizens use nicotine pouches in Member States. The vast majority of these consumers have switched from smoking to nicotine pouches as they offer an alternative and possibly less risky way to consume nicotine. By banning the marketing of nicotine pouches, these users may return to the consumption of traditional cigarettes, which would frustrate the achievement of these two objectives and would clearly undermine the effectiveness of efforts to reduce the harm caused by smoking.

Furthermore, the ban proposed by the Draft Decree is not in line with the tobacco control strategy recently recognised by the European Parliament. In its reply to the Commission's 'Europe's Beating Cancer Plan. Communication from the Commission to the European Parliament and the Council', the Parliament called on the Commission to monitor scientific assessments of the health risks associated with electronic cigarettes, heated tobacco products and novel tobacco product categories, including an assessment of the risks associated with the use of these products compared to the consumption of other tobacco products. While the Parliament's report focused on e-cigarettes as a smoking cessation tool, nicotine pouches can play a similar role in helping to stop smoking.

4. Violation of the prohibition of discrimination

The ban in the Draft Decree treats nicotine pouches less favourably than products with a possibly worse risk profile available on the market (e.g. conventional cigarettes). The use of nicotine pouches is likely to pose a lower health risk than the consumption of conventional tobacco products (see above). By prohibiting products that are likely to be less harmful, the Draft Decree therefore unduly restricts the freedom of trade guaranteed by Article 36 TFEU.

5. Breach of the principle of proportionality

It is for the regulator to prove that the proportionality test is met and that the objectives of the Draft Decree could not have been met by less restrictive measures. The Belgian Government has not been able to sufficiently demonstrate those criteria by relying on the precautionary principle in its arguments. However, according to the

case law of the Court of Justice of the European Union (e.g. the judgement of the Court of Justice of 19 November 2020 in Case C-663/18, Kanavape), this is not sufficient to fulfil the proportionality test, given that the available scientific evidence shows that nicotine pouches (1) are likely to be less harmful than products containing tobacco; (2) do not cause increased smoking among young people; and (3) health effects can be beneficial due to the likely reduction of risk when used by smokers instead of conventional cigarettes. In addition to the ban, at the expert-level meetings of Member States on the subject of the regulation of nicotine pouches, several participants advocated the development of appropriate EU-level regulations regarding the maximum permitted nicotine content, as well as packaging, access and retail marketing. This also shows that the Belgian Government's concerns could be addressed by other less restrictive measures which are lighter than the total prohibition and which comply with the principle of proportionality.

6. Impact on illegal trade

As we have seen in the case of electronic cigarettes, the prohibition can cause the emergence and spread of products of unknown origin and composition in illegal circulation. This phenomenon is indirectly mentioned in the text of notification 2022/417/B: "Nicotine pouches serve as a substitute for conventional tobacco-based products and can give rise to similar health risks and social consequences. More specifically, they have a very similar presentation and effect to those of snus, a tobacco-based product that is already banned. There is therefore a real possibility for a nicotine pouch user to switch to snus."

The possibility of switching to a banned product is possible because consumers can access it illegally. Therefore, when prohibiting or authorising a category of products, it is appropriate to consider the known characteristics and potential effects compared to the characteristics and effects of all product categories on the market. For the above reasons, it can be assumed that a Member State banning an entire category of products under national competence will lead to an increase in illegal intra-EU trade. In order to avoid this, it would be more effective to regulate nicotine pouches at EU level.

7. Infringement of the principle of the free movement of goods

In our view, the Belgian Government cannot invoke the precautionary principle in order to justify the prohibition under EU law, given that the explanatory memorandum to the Draft Decree, while relying on studies listing the possibly adverse effects of nicotine pouches, does not take due account of the fact that they may have a beneficial effect on the health of those who switch from traditional cigarettes to nicotine pouches. The prohibition therefore unduly restricts the free movement of goods.

According to the provisions of Article 24(3) of the Tobacco Products Directive, a "Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive." At the same time, a ban on nicotine pouches would significantly restrict free trade between Member States without the prohibition likely to achieve the desired objective, due to the expected resumption of illegal trade.

8. The nicotine pouch and the snus

Contrary to what is stated in the Draft Decree, nicotine pouches should not be treated as a product such as snus, as there is a fundamental difference in that nicotine pouches do not contain tobacco and that they are legally sold as general consumer goods in the vast majority of EU Member States. Compared to snus, nicotine pouches are likely to have even fewer health risks and thus higher public health benefits.

9. Summary

In the light of the above, the adoption of the Draft Decree (1) would constitute an interference with the harmonisation of EU law; (2) would impede the implementation of the principles set out in the founding treaties; (3) would have a market distorting effect; and (4) lead to inappropriate distinctions between product categories and (5) cause harmful effects on public health.

The Belgian authorities are invited to consider the detailed Hungarian opinion and it is suggested that the text of the Draft Decree be amended.

European Commission

Contact point Directive (EU) 2015/1535

Fax: +32 229 98043

email: grow-dir2015-1535-central@ec.europa.eu