Message 201

Communication from the Commission - TRIS/(2025) 2239

Directive (EU) 2015/1535

Notification: 2025/0110/FR

Forwarding of the response of the Member State notifying a draft (France) to of Romania.

MSG: 20252239.EN

1. MSG 201 IND 2025 0110 FR EN 25-08-2025 21-08-2025 FR ANSWER 25-08-2025

2. France

3A. Ministères économiques et financiers
Direction générale des entreprises
SCIDE/SQUALPI - Pôle Normalisation et réglementation des produits
Bât. Sieyès -Teledoc 143
61, Bd Vincent Auriol
75703 PARIS Cedex 13

3B. Ministère du travail, de la santé, des solidarités et des familles
Direction général de la santé
Sous-direction santé des populations et prévention des maladies chroniques
Bureau de la prévention des addictions (SP3)
14, avenue Duquesne
75007 PARIS

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

5.

6. Under Directive (EU) 2015/1535, the French authorities provided notification of a draft decree on 24 February 2025 prohibiting the production, manufacture, transport, import, export, possession, supply, transfer, acquisition, distribution, and use of products containing nicotine for oral use within the national territory.

In the context of this notification, and pursuant to Article 6 (2) of Directive (EU) 2015/1535, the Italian authorities also issued a detailed opinion on 30 April 2025, extending the deadline for the standstill period until 25 August 2025.

Subsequent detailed opinions were also issued by:
- The Greek authorities on 8 May 2025;
- The Hungarian authorities on 16 May 2025;
- The Slovak authorities on 19 May 2025;
- The Swedish authorities on 22 May 2025;
- The Czech and Italian authorities on 26 May 2025.

These Member State opinions converge around three particular points:
- The alleged contradiction of the draft text with Article 114 TFEU;
- The assumption that the products covered by the text may be subject to a proposed act by the European Commission in

the coming months as part of the revision of Directive 2014/40/EU;
- The unjustified barrier to the free movement of goods, as guaranteed by Article 34 TFEU, which the banning of the concerned products represents.

The comments below made by the French authorities respond to the issues raised by the Romanian, Greek, Hungarian, Slovak, Swedish, Czech, and Italian authorities in opposition to the notified draft text.

1. Regarding the absence of any contradiction with Article 114 of the TFEU

The Romanian authorities indicated that, according to Article 114 of the TFEU, Member States cannot adopt national measures stricter than those stipulated in harmonized EU directives, especially in areas which have already been harmonized by law at the EU level.

Pursuant to the second sentence of Article 114 (1) of the TFEU, “The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.” ’

Under this Article, Member States may not, in principle, maintain or adopt national legislation that deviates from a harmonisation measure that has been accepted based on this article. The only exceptions are the strict conditions provided for under the procedure established in paragraphs 4 to 7 of the same article (notification by the Member State and approval by the Commission).

However, the Romanian authorities do not specify which Union harmonisation legislation would be affected by the measures envisaged by the French authorities.

The detailed opinions suggest, but do not show, how Directive 2014/40/EU on reconciling Member State laws, regulations, and administrative provisions for the manufacture, presentation, and sale of tobacco and related products may be the harmonising legislation covering oral products containing nicotine. However, the products covered by the draft notified text by France do not fall within the scope of Directive 2014/40/EU, which addresses smoking tobacco and vaping products producing aerosols or inhaled smoke. These smoking tobacco and vaping products are not covered by the French notified regulatory text.

In addition, the French draft regulation specifically endeavours to exclude other products already covered by European regulations which could fall within the scope of the notified text, such as chewing tobacco, medicinal products, medical devices, or foodstuffs naturally containing nicotine.

Consequently, Article 114 of the TFEU is not applicable if the products covered by the notified draft regulation do not fall within the scope of Directive 2014/40/EU or if the products concerned are covered by other European legislation.

2. Regarding the absence of any European Commission initiative on the subject

The Romanian, Greek, and Hungarian authorities claim that the Commission intends to regulate nicotine pouches as part of their revision of Directive 2014/40/EU on tobacco products. In this context, the notified proposal would disrupt this EU-level review process and create diverging legal regimes which would affect the functioning of the internal market. On this point, the Hungarian authorities argue that since the harmonised rules would not completely ban these products, it could result in them re-entering the French market and generating high costs.

In accordance with Article 6 (3) of Directive (EU) 2015/1535, Member States postpone adopting a draft technical regulation for twelve months after its notification date if, within three months following that date, the Commission indicates the draft relates to an issue already covered by another directive, regulation, or decision submitted to the European Parliament and the Council.

The claim that the Commission would consider regulating nicotine-containing products for oral use appears unfounded.

Firstly, the European Commission had a three-month period to avail itself of the provisions of Article 6 (3) of Directive 2015/1535, however, it did not do so. Therefore, this type of complaint is unfounded. Moreover, Member States are not in a position to challenge another Member State.

In any event, while Directive 2014/40/EU is currently being evaluated, the Commissioner for Health did not provide any details on the revision timetable at the EPSCO Council on 20 June 2025. He committed only to doing so before his term ends (by 2029). He clarified at that time for the Member State Health Ministers present, and again at the subsequent press conference, that the Commission continues to work on the evaluation report and this needs to be followed up by publishing an impact assessment (Employment, Social Policy, Health and Consumer Affairs [Health] Council - Consilium)

Thus, as far as the French authorities are aware, no Commission initiative currently exists for regulating nicotine-containing products. Moreover, no revision of the legislation on tobacco or its related products is planned in the upcoming months.

3. Regarding the absence of any incompatibility between the measure and European Union law on the free movement of goods

The Romanian authorities consider the notified draft as infringing on the principle of the free movement of goods as set out in Article 34 of the TFEU, as well as the principles of mutual recognition and equal treatment. They argue that the draft constitutes an unjustified restriction of the free movement of goods and creates discrimination against nicotine pouches. According to the Romanian authorities, the French measure would not call forth any legitimate interest protection pursuant to Article 36 TFEU or CJEU case law, and the measure would be disproportionate as well.

The Greek, Hungarian, Slovak, Swedish, Czech, and Italian authorities agree with this analysis. They also consider the notified draft as contrary to Article 34 of the TFEU and insufficiently justified. This is particularly the case since nicotine-containing products for oral use would be treated less favourably than other nicotine-containing tobacco-free products, such as e-cigarettes, which may continue to be lawfully marketed. Although some of the opposing authorities recognise the adverse health effects of nicotine, they consider the French measure as disproportionate.

It should be noted that Article 34 of the TFEU prohibits quantitative restrictions on the importation of goods between Member States as well as any measures having similar effects. Pursuant to CJEU case law, this Article “reflects the obligation to comply with the principles of non-discrimination and of mutual recognition of products lawfully manufactured and marketed in other Member States, as well as the principle of ensuring free access of EU products to national markets.” (CJEU, 2 December 2010, C-108/09, Ker-Optika, para. 48).

However, in accordance with Article 36 TFEU and CJEU settled case-law, a barrier to the free movement of goods may be justified for the reasons of being in the general interest listed in Article 36 or due to imperative needs. This is the case provided such measures are proportionate (CJEU, 2 December 2010, C-108/09, Ker-Optika, paragraph 57) and do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States (CJEU, 12 November 2015, C-198/14, Visnapuu, paragraph 116). Therefore, if a measure is justified under Article 36 of the TFEU, it would not be considered contrary to Article 34 or the principles of non-discrimination and mutual recognition.

In this regard, the French authorities nevertheless consider the barrier envisaged under the notified draft as justified. This is the case even if it might be classified as restricting the free movement of goods by hindering the access of products originating in and legally marketed in other Member States to the French market.

On one hand, the French authorities invoke the objective of being in the general interest to justify the draft measure in opposition to the claims made by the Romanian authorities. As such, the notified draft is viewed as justified in terms of the goal of protecting public health and human life, since the measure aims to guarantee these in accordance with Article 36 of the TFEU and CJEU case law (CJEU, 8 October 2020, C-602/19, kohlpharma GmbH, point 40).

On the other hand, the French authorities also consider the notified draft as proportionate to the pursued objective. As such, it does not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. In accordance with settled CJEU case-law, for a measure to be proportionate, it must be shown that it is: firstly, necessary to attaining the pursued objective; secondly, appropriate for assuring this attainment; and, thirdly, that the measure does not go beyond what is necessary in attaining the objective. In other words, the objective could not be otherwise achieved with less restrictive measures (CJEU, 7 November 2024, C-503/23, Centro di Assistenza Doganale Mellano, paragraph 83).

• Regarding the necessary nature of the measure

The Romanian, Greek, Hungarian, and Slovakian authorities point out that the proposed measure lacks any scientific basis and that the French authorities have not provided solid evidence demonstrating that nicotine pouches present a significant risk to public health, and specifically a high health risk compared to other legally marketed products containing nicotine. In their view, no scientific studies to date have demonstrated that nicotine pouches promote dependence or the use of illicit substances. On the contrary, according to the Hungarian authorities, the available scientific evidence shows that nicotine pouches do not pose a higher risk than other tobacco products currently on the market.

In opposition to these arguments, it should be pointed out that there is ample scientific evidence to confirm that these products pose a risk to human health and that no benefits in marketing them having been shown.

The French authorities would first like to note certain points previously submitted under the notification which justify the need for the measure.

The available scientific literature shows that nicotine presents a proven health risk, particularly for young people. It affects the brain and leads to problems in concentration and learning new skills, two aspects essential to the development of the human brain up to age 25 (Nicotine on the developing brain E. Castro and all. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10392865/ It is also been established that nicotine consumption during adolescence can affect the mental well-being of young adolescents, causing depression, cognitive impairment, and a predisposition to anxiety.
Chronic nicotine use in adolescence may also increase the risk of psychoactive substance use (Yuan M, Cross SJ, Loughlin SE, Leslie FM. Nicotine and the adolescent brain. J Physiol. 2015 Aug 15;593(16):3397-412. doi: 10.1113/JP270492. Epub 2015 June 23. PMID: 26018031; PMCID: PMC4560573).

In addition, it is pointed out that nicotine is considered acutely toxic under Regulation (EC) 1272/2008 on the classification, labelling and packaging of substances and mixtures (the so-called CLP Regulation), which mandates the following labelling for preparations containing more than 0.1% m/m (i.e. approximately 1 mg/ml): “fatal in contact with skin”, “toxic if swallowed” and “fatal if swallowed”.

The question of what constitutes a lethal dose of nicotine taken by swallowing has not yet been determined based on scientific data. In humans, the lethal dose varies significantly, depending on the route of administration, sensitivity to nicotine, smoking or non-smoking status, and absorption and elimination rates.

Additional elements exist to equally allow justifying the necessary nature of the measures envisaged under the notified draft text.

A study carried out in 2023 (M. Jackson, J., Weke, A. & Holliday, R. Nicotine pouches: a review for the dental team. Br Dent J 235, 643-646 (2023)) concluded that prolonged regular use of oral products containing nicotine, such as pouches, may increase the risk of oral problems such as mouth pain, ulcers, or gingival recession.

A health risk assessment of nicotine pouches carried out by the German Federal Institute for Risk Assessment (Health risk assessment of nicotine pouches Updated BfR Opinion no. 023/2022, 7 October 2022

https://www.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf) also concluded that the main risk associated with the use of nicotine pouches lies in the high levels of nicotine involved, which have significant effects on the cardiovascular system. Pouches also pose high risks to children or pregnant and breastfeeding women, as well as to people with cardiovascular diseases.

In addition to their direct effects on health, the indirect effects of the environmental pollution generated by these pouches are also beginning to be documented. Nicotine pouches are manufactured in an envelope comprised of plastic. As with cigarette butts, this plastic may end up in the environment in the form of micro or nano plastics. Microplastics may cause inflammation and oxidative stress in animals and humans and these biological responses can lead to cell damage. The pouches may also act as vectors for other toxic substances, thereby increasing their harmful potential.

In addition, these products pose a growing risk of poisoning. In a study published in July 2025 (Bulletin Vigil Anses No. 26,https://vigilanses.anses.fr/sites/default/files/VigilAnsesN26_Sachetsnicoine_Juillet2025.pdf), the French National Agency for Food, Environmental and Occupational Health, and Safety (l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail française-ANSES) again raised an alert about the risks associated with the use of nicotine pouches, having first reported on this in September 2023 (Anses toxicovigilance report on tobacco products, related products and flavourings - Assessment of cases reported to poison control centres from 1 January 2017 to 31 December 2022,https://www.anses.fr/fr/system/files/Toxicovigilance2023AUTO0121Ra.pdf). In the period from 2017 to 2022, approximately ten adolescents between ages 12 and 17 manifested a severe nicotine intoxication syndrome comprised of prolonged vomiting and hypotension as well as convulsions and consciousness disorders requiring medical attention (Anses Vigil Bulletin No. 21, https://vigilanses.anses.fr/sites/default/files/VigilAnses_N21_article_tabac.pdf). The 2023 and 2024 figures from the ANSES study noted above, which were published in 2025, confirm this trend. According to that study, poison centres received 90 calls due to adverse reactions related to the use of nicotine pouches and in one out of two cases (54 %), those calls involved a person between ages 12 and 17. These adolescents had mainly used nicotine pouches in groups and at school (65 %). Eleven adolescents presented with severe nicotine intoxication syndrome which required treatment in an emergency department. There are probably many other cases treated in other care facilities which do not come in contact with poison centres. ANSES has thus reiterated their alert on the risks of short-term intoxication as well as longer-term nicotine dependence in adolescents. Particular attention should also be paid to the emergence on the market of pouches advertised as not having nicotine, but which in reality contain nicotine analogues (e.g. 6-methylnicotine or metanate) for which toxicological data remains insufficient.

Regarding the appropriate nature of the measure

In this regard, the Romanian authorities consider that the French have not demonstrated how the proposed ban would have a beneficial impact on public health, given that other nicotine-based products (rolling tobacco, traditional cigarettes, and electronic cigarettes) will continue to be available on the French market. Moreover, they assert that nicotine pouches represent a lower-risk alternative to traditional cigarettes and can contribute to a reduction in smoking.

Additionally, the Swedish authorities even consider that the envisaged measure could have negative consequences for public health since, in their view, cigarettes and smoking tobacco pose a higher health risk than smokeless tobacco and nicotine-based products, such as moist tobacco that is sucked on. Based on OECD data, the Swedish authorities thus consider the consumption of nicotine-containing products for oral use as a positive development in public health since they replace cigarette consumption.

Despite the assertions of the Swedish authorities, there is currently no scientific research, apart from those financed by the tobacco industry, demonstrating the benefits of nicotine products in reducing tobacco consumption.

On the contrary, scientific evidence shows an increasing risk of addiction to nicotine-containing products in young non-tobacco users. For example, American researchers (Robichaud MO, Seidenberg AB, Byron MJ, Tobacco companies introduce 'tobacco-free' nicotine pouches, Tobacco Control 2020;29:e145-e146.) have identified the risk posed by nicotine pouches particularly in terms of attracting non-smokers and young people. This is because some products come in a range of fruit flavours and are more discreet than e-cigarettes.

The World Health Organisation points out in a report published in 2024 [Hooking the next generation: how the tobacco industry captures young customers]. Geneva, World Health Organisation, 2024), that the tobacco industry is striving to attract children and young people with innovative tobacco-free products in order to replace consumers who quit tobacco use or die. The range of items used by the industry to appeal to young people has expanded considerably, with the addition of products such as electronic cigarettes, heated tobacco products, and nicotine pouches. In the WHO European Region, for example, the popularity of electronic cigarettes among young people surpasses that of traditional cigarettes, with 32 % of 15-year-olds surveyed saying they had used an electronic cigarette at some point and 20 % in the last 30 days. The ingredients in these products, including flavoured substances and additives, their modern design, and their use of illustrations and packaging tailored to children are all ways used to make these addictive products particularly attractive to young people. The methods employed by the tobacco industry include positioning many nicotine-based products as “safer” than cigarettes. This may mislead policymakers and consumers, making them forget that nicotine itself is an addictive substance and harmful to health, in particular to the brains of children and young people.

Experts in marketing, advertising, and youth note that nicotine pouches are positioned as fashionable lifestyle brands, as evident in their promotional material as well as content on social media or at music festivals. This echoes some of the methods already used in the past by the tobacco industry to promote addiction to tobacco and nicotine.

The French authorities therefore conclude the proposed banning measure is appropriate to the objective of protecting public health.

Regarding the proportionality of the measure

The group of national authorities issuing detailed opinions maintain that other measures could be envisioned which are less restrictive and would guarantee a high level of protection of public health without creating trade restrictions. The authorities concerned therefore propose banning the sale of products concerning minors, imposing a maximum nicotine content level (e.g. 20 mg/pouch), and undertaking labelling measures and additionally health warnings. They indicate that regulating nicotine pouches, rather than a totally banning them, would have a lower impact on trade between Member States, while respecting public health protection objectives.

The authorities that issued detailed opinions have thus argued that similar products are marketed in other Member States (Finland, Poland, Italy) according to less stringent regulations. These include, for example: setting a maximum nicotine content limit, banning their sale to minors or use in places where minors are allowed to gather, mandatory labelling of packaging with warnings on addiction and an indication of ingredients, and banning distance selling, cross-border advertising and promotion, etc.

In the light of these factors, the French authorities may not be able to demonstrate how the envisaged ban may be the only means to effectively protect human health.

Firstly, the French authorities maintain that the points put forward above support the necessary nature of the measure by demonstrating that the proposed ban does not go beyond what is necessary to achieve the objective of protecting public health.
In order to ensure the proportionality of the measure, the notified text limits the ban to products containing nicotine for oral use, which are intended for human consumption by ingestion or absorption, and which present the specific health risks mentioned above. This text also creates exceptions to ensure proportionality. Thus, products containing nicotine for oral use may be used for research purposes or marketed in the form of medicines or pharmaceutical products. This is based on the assumption that such use can be scientifically demonstrated as having therapeutic benefits while quitting smoking.

In the second place, countering to the claim made by some Member States issuing detailed opinions, several Member States have also adopted provisions banning nicotine-containing products for oral use on public health grounds. Belgium and the Netherlands have thus banned nicotine pouches since 2023. Lithuania, Portugal, and Cyprus also additionally prohibit the sale of nicotine pouches

(https://taxation-customs.ec.europa.eu/document/download/415b9aff-9b71-4e3a-b0b4 0f49bea3fad7_en?filename=SWD_2025_560_1_EN_impact_assessment_part1_v4.pdf Annex 14, page 169.) according to the Commission's Impact Report for the revision of Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco.

For smokers wishing to stop, it is worth pointing out that nicotine replacement treatments already exist in France and have a marketing authorisation based on clinical evidence.

• Regarding the absence of arbitrary discrimination and the disguised restriction of trade between Member States

According to the detailed opinions issued, the notified draft would treat nicotine-containing products for oral use less favourably than other nicotine products which may continue to be lawfully marketed in France. In this sense, the draft text would constitute a means of arbitrary discrimination or a disguised restriction of trade between Member States.

In accordance with Article 36 of the TFEU, restrictions on the free movement of goods may be permitted under certain conditions, provided that such prohibitions or restrictions do not constitute a means of arbitrary discrimination or a disguised restriction of trade between Member States.

In accordance with settled case-law, a measure is regarded as arbitrary discrimination or a disguised restriction on trade between Member States if it discriminates against goods originating in other Member States, indirectly protects certain national products, and cannot be justified on health protection grounds (CJEU, 12 November 2015, C-198/14, Visnapuu, paragraphs 123 and 124).

The French authorities assert that the notified measure does not infringe on the principle of the free movement of goods as laid down in the TFEU if one takes into account, on one hand, the aforementioned high health risks associated with the use of nicotine oral products and public health and consumer protection objectives on the other. They further assert, firstly, the measure does not discriminate against goods originating in other Member States. Secondly, the measure does not have the effect of indirectly protecting national production (especially since the main production locations for these products are outside French territory).

In any event, even if the measure could be deemed as restricting the free movement of goods, it seems justified according to Court case-law. This is based on grounds relating to protecting consumer and public health and the proportionate nature of the measure in the light of this objective.

****

European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu