EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2025/0110/FR (France)

Proposal for a Decree on the prohibition of products for oral use containing nicotine

Date received : 24/02/2025
End of Standstill : 26/05/2025 (25/08/2025)

Message

Message 001

Communication from the Commission - TRIS/(2025) 0538

Directive (EU) 2015/1535

Notification: 2025/0110/FR

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta' dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20250538.EN

1. MSG 001 IND 2025 0110 FR EN 24-02-2025 FR NOTIF

2. France

3A. Ministères économiques et financiers
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4. 2025/0110/FR - X00M - GOODS AND MISCELLANEOUS PRODUCTS

5. Proposal for a Decree on the prohibition of products for oral use containing nicotine

6. Products for oral use containing nicotine, particularly in the form of portioned sachets or porous sachets, paste, beads, liquids, chewing gum, lozenges, strips, or any combination of these forms.

7.

8. The draft decree defines products for oral use containing nicotine, intended for human consumption by ingestion or absorption, in particular in the form of portioned sachets or porous sachets, paste, candies, beads, liquids, chewing gum, lozenges, strips or any combination of these forms. It specifies that these products are subject to a prohibition throughout the national territory, insofar as they are intended for the French market in the relevant metropolitan and overseas territories, with regard to their production, manufacture, transport, import, export, possession, offering, transfer or acquisition, as well as their distribution and use.

The text also provides for derogations from this prohibition: for example, chewing tobacco, medicinal products and raw materials for pharmaceutical use, foodstuffs within the meaning of Regulation (EC) No 178/2002 of the European Parliament and of the Council containing naturally occurring nicotine or complying with Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin are not covered by the prohibition.

A specific derogation also applies to products used for research purposes.

Infringements of this prohibition will be investigated and established by competition, consumer and fraud enforcement officers, customs officers, and officials of the Directorate General for Public Finance, on the basis of Article L. 5414-3 of the Public Health Code. The penalties applicable in the event of failure to comply with this prohibition are those laid down in Chapter II of Title III of Book IV of Part Five of the Public Health Code.

9. The text aims to ensure a high level of public health protection by prohibiting the production, manufacture, transport, import, export, possession, offer, transfer, acquisition, distribution, and use of products for oral use containing nicotine on French territory, provided they are intended for the French market, whether in metropolitan or overseas territories.
The extent of the prohibition is justified by the desire to protect the population from any attempt to introduce these products, including in a roundabout manner, particularly through parallel or clandestine markets likely to establish themselves in the territory.
Due to its harmfulness to human health, nicotine was classified as a poisonous substance in French legislation as early as 1957 and can only be used or marketed under certain conditions, similar to already regulated products (tobacco products, vaping products, and medicinal products). Article L. 5132-8 of the French Public Health Code authorises the prohibition of any operation relating to poisonous substances by a decree of the Council of State.
The competences of the Union in the field of health are governed by Article 168 of TFEU. In particular, it provides for regulatory competence to ensure a high level of protection of human health, notably through high standards of quality and safety of medicinal products and devices for medical use. Furthermore, Article 168 recalls that the European Union must respect the responsibilities of the Member States for the definition of their health policy.

The provisions of this draft decree are justified, necessary, and proportionate to achieve the objective of protecting public health:

1. In the first place, the prohibition is justified by the need to ensure a high level of protection of public health, and in particular of young people. On this point, it should be recalled, on the one hand, that the health and life of individuals

rank first among the assets and interests protected by the TFEU and that, under Article 168, the European Union must respect the responsibilities of the Member States for the definition of their health policy. It is for the Member States to decide at what level they intend to ensure the protection of public health and how this level is to be achieved.
In addition to its addictive nature, new research shows that, beyond the inherent harmfulness of certain nicotine-containing products, such as tobacco products, nicotine itself is a health hazard, especially for young people up to 25 years of age. Nicotine consumption affects the brain and leads to problems with concentration and learning new skills, both of which are essential to young people's development. However, nicotine induces persistent changes in the developing brain of adolescents: it acts in several regions of the brain, including the nucleus accumbens, the internal prefrontal cortex, and the amygdala, all of which contribute to the regulation of emotions. Chronic nicotine use in adolescence also induces epigenetic changes that sensitise the brain to other drugs and increase the risk of psychoactive substance use.
In addition, nicotine can affect the mental well-being of young adolescents, causing depression, cognitive impairment, and making them prone to anxiety. Children and adolescents are more sensitive to the negative side effects of nicotine consumption and are also more prone to addiction than adults. However, products for oral use containing nicotine sometimes display very high doses of nicotine, as well as other ingredients and flavourings whose combined health effects and risks have not been studied.

It is important to note that products for oral use containing nicotine pose specific public health risks. Their ease of consumption, coupled with their attractive marketing, creates an environment conducive to overconsumption, especially for the youngest, which can lead to serious health hazards. The gradual spread of this type of product on French territory has led to a very significant increase in cases of intoxication reported to poison centres. Thus, in a report published on 30 November 2023, ANSES identified 131 cases of intoxication linked to products for oral use containing nicotine in 2022, compared to 19 in 2020, figures that are likely to be underestimated.
Nicotine is classified by the European CLP Regulation as having acute toxicity, requiring the following labelling for preparations containing more than 0.1% w/w (i.e. approximately 1 mg/ml): 'Fatal if in contact with skin', 'toxic if swallowed' and 'fatal if swallowed'.
The question of the lethal dose of nicotine by ingestion is currently not resolved by scientific data. In humans, this lethal dose varies significantly, depending on the route of administration, nicotine sensitivity, smoking or non-smoking status, rate of absorption and rate of elimination. In its opinion of 22 January 2015 (referral No 2014-SA-0130), ANSES highlights that 'human data shows that early signs of intoxication may occur from 0.3 mg/kg in adults and 0.2 mg/kg in children', considering that 'the possibility of effects at low doses cannot be ruled out, particularly in individuals who have not developed habituation.'
It should be recalled that even when products for oral use containing nicotine are not directly intended to be ingested (pouches), some of the nicotine can be dissolved in saliva, then swallowed, and reabsorbed in the gastrointestinal tract.

In addition, nicotine stimulates nicotinic acetylcholine receptors (nAChR) located in the central nervous system, at the interganglionic junctions of the autonomic nervous system and on target organs throughout the body, as part of the parasympathetic autonomic nervous system. Because of the overall expression of these receptors, their stimulation leads to vast physiological effects that impact the cardiovascular system, such as free radical production, inflammation, vascular wall adhesion, and atherosclerosis.
In addition, recent studies have found an association between the consumption of tobacco products for oral use containing nicotine (prohibited by EU legislation) and endothelial dysfunction (a marker of cardiovascular risk), as well as decreases in diastolic heart function and a high risk of fatal ischaemic heart disease and stroke. Increased heart rate and arterial stiffness have also been observed in recent studies on nicotine sachets.

Finally, changes in the oral mucosa have been observed in users of products for oral use containing nicotine. These changes appear in the form of lesions on the oral mucosa, which reveal significant changes in the cellulite, epithelium, and connective tissue. Among other effects, the researchers reported pain and gum blisters.

Among products for oral use containing nicotine, the case of nicotine sachets ('pouches' in English) is particular because these products have undeniable similarities with a tobacco product banned by all EU Member States, except Sweden: the 'snus'. The same appearance, the same method of use, the same mechanism for delivering nicotine, the possibility of

discreet and invisible use. The presence of inhalation-friendly flavourings, such as menthol, and attractive packaging also contributes to the attractiveness of products for oral use containing nicotine among young people.
The Court of Justice of the European Union (CJEU), by a judgment of 22 November 2018 in Case C-151/17 (ECLI:EU:C:2018:938) concerning the validity of Article 1(c) and Article 17 of Directive 2014/40/EU (tobacco products), concluded that those provisions which prohibit the placing on the market of tobacco products for oral use do not infringe the principles of non-discrimination, proportionality, subsidiarity, free movement of goods, etc., thus justifying the prohibition of snus on grounds of public health and the need to protect young people, while stating that the prohibition does not constitute a disproportionate restriction on the free movement of goods.
The risks that justified the prohibition on snus also concern products for oral use containing nicotine.
This should prevent nicotine sachets from continuing to gain popularity, especially among young people. In addition to the prohibition on tobacco for oral use (and therefore snus), it is necessary to impose a prohibition on products for oral use containing nicotine, even when they are not composed of tobacco. The prohibition covers the various forms of these products, because if the prohibition applied only to nicotine sachets, circumvention of this prohibition would be extremely easy, by developing and marketing these products in other packaging or in another form. The extension of the prohibition to all products for oral use containing nicotine enables to protect against the successive development of new nicotine-containing products that may sustain addiction.
For the French authorities, the development of such a market, based on nicotine, is contrary to the objective of a tobacco-free generation set in its national tobacco control programmes (PNLT) since 2016, and in the European Plan to Beat Cancer, with products that aim to maintain or initiate nicotine dependence.

2. In order to ensure the proportionality of the text, the decree limits the prohibition only to products for oral use containing nicotine, intended for human consumption by ingestion or absorption, which present specific health risks as mentioned above. This decree excludes products that, while containing nicotine, are subject to other regulations, in order to ensure the consistency of this text with all existing regulations.
The decree also establishes derogations enabling to improve this proportionality. Thus, products for oral use containing nicotine may be used for research purposes or marketed as medicinal products or pharmaceutical products, if these products can scientifically demonstrate therapeutic benefits in a tobacco cessation process.
For smokers wishing to quit smoking, it is worth recalling that nicotine replacement treatments already exist in France, with a marketing authorisation based on clinical evidence.

3. Finally, the prohibition of products for oral use containing nicotine constitutes a very minor barrier to trade, as many nicotine-containing products, duly notified and complying with legislative and regulatory obligations, remain authorised. This obstacle is justified by the risks to public health. The right to health protection is an objective shared by the European Union (Article 35 of the Charter of Fundamental Rights of the European Union) and France, where it has a constitutional value, recognised by paragraph 11 of the Preamble to the French Constitution of 1946. In addition, many international texts place this right as a fundamental right. Given the health challenges posed by the introduction and distribution of products for oral use containing nicotine (accessibility, attractiveness, availability, aggressive marketing), it is necessary, in order to ensure this objective of protecting public health, to introduce a prohibition on the marketing of these products, without waiting for the possible revision of the European directives.

In view of the attractiveness, harmfulness, dependence and method of use, the French authorities consider that the prohibition of the production, manufacture, transport, import, export, possession, offering, transfer, acquisition, distribution and use of products for oral use containing nicotine is justified in order to achieve the objective of preserving public health in view of the many associated risks. This prohibition will be accompanied by clear communication on the risks associated with the use of nicotine-containing products and special awareness-raising among young people and healthcare professionals.

10. References to reference texts:

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

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