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Addition of the RSB opinion SEC(2026) 111 final and update of the cover page with cross references.
The text remain unchanged.

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE EVALUATION

of the Tobacco Products Directive (2014/40/EU), the Tobacco Advertising Directive (2003/33/EC) and other related tobacco control policies across the EU

{SEC(2026) 111 final} - {SWD(2026) 111 final/2}

EVALUATION CONTEXT

The Commission has been working on tobacco control since the 1980s, balancing the need for the smooth functioning of the internal market of tobacco and related products with the need for a high level of health protection, especially for young people. This work includes regulating several aspects of the manufacture, presentation, sale, advertising and sponsorship of tobacco and related products. It also includes ensuring that people in the EU are not exposed to second-hand smoke and aerosols from tobacco and related products.

Key legislative milestones include Directive 2001/37 (TPD1)[3] which was adopted in June 2001 and remained in force until May 2016, when it was repealed and replaced by Directive 2014/40/EU (the Tobacco Products Directive or the TPD) concerning the manufacture, presentation and sale of tobacco and related products. Additionally, Directive 2003/33/EC (the Tobacco Advertising Directive or the TAD) relating to the advertising and sponsorship of tobacco products was adopted on 26 May 2003.

In 2021, Europe's Beating Cancer Plan (the "Cancer Plan") emphasised the importance of tobacco control as a key component of disease prevention efforts, with 27% of all cancers in Europe attributed to tobacco use. By eliminating tobacco use, nine out of every ten cases of lung cancer could be avoided. The Cancer Plan called for the strengthening of EU-level regulatory instruments to support such efforts, including a review of the TPD. The purpose of this evaluation is to assess the rules of the EU tobacco control framework, namely the TPD, including the implementing and delegated acts adopted on its basis, and the TAD, in terms of the following criteria: effectiveness, efficiency, coherence, relevance, and EU added value. Each criterion was assessed by combining quantitative, qualitative, legal, and scientific evidence. This structure enabled the integration of diverse inputs, including stakeholder consultations, legal mappings, and prevalence surveys. The evaluation examines the two Directives as a single policy intervention.

This evaluation draws on a broad and diverse evidence base, including a supporting study conducted by an external contractor. It is also informed by the results of extensive stakeholder consultation activities, such as a call for evidence (open from 20 May 2022 to 17 June 2022 which resulted in more than 24 000 contributions), a public consultation (open from 21 February to 16 May 2023 which resulted in more than 17 000 contributions), as well as targeted surveys and interviews with key stakeholders other than EU citizens (conducted from June 2023 to February 2025). In addition, the evaluation incorporates findings from expert studies, scientific reports, surveys, and other documents addressing matters related to tobacco control, such as: the use and impact of digital promotion of tobacco and nicotine products; the causes, drivers and level of cross-border distance sales in the EU; the EU tobacco traceability system and the illicit trade in tobacco products in the EU; the implementation of the WHO Framework Convention on Tobacco Control (FCTC), with particular focus on its implementation by EU Member States and the EU; the regulatory approaches of EU Member States to novel tobacco and nicotine products, particularly in areas and for products not covered by the EU tobacco-control framework; the health-related costs attributable to tobacco use in the EU; the administrative efforts of the Member States in implementing the TPD and TAD, in particular the human and financial resources allocated to the implementation of these two Directives; trends and patterns of use of tobacco and nicotine products in the EU by comparing them with the use of traditional tobacco products[1]; the relationship between EU tobacco control legislation and other relevant areas of EU law.

[1] This includes cigarettes, Roll-Your-Own tobacco, cigarillos, cigars, pipe tobacco and chewing tobacco.

The situation concerning tobacco and related products in the EU has changed dramatically since 2012. Between 2012 and 2023, the sales value and volume of traditional tobacco products, particularly cigarettes, as well as the smoking prevalence, especially among young people, and the share of daily smokers, have decreased in the EU. At the same time, since 2012, there has been a clear shift among young people from traditional tobacco products to novel tobacco and nicotine products. The sales and reported use of e-cigarettes and heated tobacco products (HTPs) have increased sharply. The market has become increasingly diverse, with the emergence of new nicotine products, such as nicotine pouches, whose sales value also grew rapidly between 2018 and 2023, and electronic non-nicotine delivery systems (ENNDS).

The landscape of digital promotion for tobacco and nicotine products, particularly novel ones, has evolved significantly in recent years, contributing to their rising popularity and use, especially among young people. The evaluation also indicates the increasing evidence of health risks associated with the use of novel products.

KEY FINDINGS

Overall, the evaluation concludes that the implementation of the EU tobacco control framework measures, particularly those related to advertising and sponsorship, ingredients' regulation, and labelling and packaging, has: limited the advertising and promotion of tobacco products and e-cigarettes across traditional media channels; increased public awareness of the harmful effects of tobacco use; reduced the appeal and uptake of traditional tobacco products; influenced young people's attitudes towards smoking; and supported cessation efforts.

Together with other EU legislation, such as the Tobacco Taxation Directive (TTD), the Audiovisual Media Services Directive (AVMSD), the Classification, Labelling and Packaging (CLP) Regulation, and national fiscal measures and tobacco control policies and legislation (in areas not harmonised by the EU framework),The tobacco control framework has contributed to the reduction of smoking prevalence in the EU, particularly among young people, as well as to a decline in the sales value and volume of traditional tobacco products, especially cigarettes, between 2012 and 2023.

These measures have therefore contributed to the reduction of tobacco-related deaths and the health-related costs associated with smoking across the EU. The framework has also enabled the EU to meet its obligations under the FCTC and its Protocol to Eliminate Illicit Trade in Tobacco Products.

Despite significant progress, the evaluation indicates that smoking prevalence in the EU remains high, particularly among young people, and the tobacco use continues to impose a substantial burden on public healthcare systems. The emergence and rapid increase in the use of novel tobacco and nicotine products, such as heated tobacco products, e-cigarettes, and nicotine pouches, pose new challenges to public health. Beyond their direct health risks, these products may act as a gateway to nicotine addiction and traditional tobacco use/smoking, the harmful effects of which have been well established since the 1950s. While the sales of traditional tobacco products declined between 2012 and 2023, the overall sales value of all tobacco and related products increased during the same period.

New marketing practices exacerbate this problem. Novel tobacco and nicotine products are increasingly promoted through digital channels, especially social media, often via influencers. Such targeted online promotion has been shown to increase uptake, particularly among young people, complicating public health protection efforts.

Given the rapid growth in consumption and sales of novel products, their aggressive digital marketing, and emerging evidence of health risks associated with the use of these products, the evaluation underlines that the current framework - originally designed to reduce smoking prevalence - no longer adequately protects public health, especially that of young people.

While the measures introduced under the tobacco control framework facilitated the smooth functioning of the internal market of tobacco and related products within the EU by harmonising several aspects of their manufacture, presentation, sale and advertising, inconsistencies in national regulations continue to pose challenges. Divergent rules on the regulation of flavours in e-cigarettes, plain packaging requirements, disposable e-cigarettes, tobacco heating devices as well as nicotine products other than e-cigarettes, and Electronic Non-Nicotine Delivery Systems (ENNDS) are creating barriers and disrupting the internal market.

Other shortcomings identified in the evaluation include:

- The limited scope of the framework, which covers only e-cigarettes among the nicotine products. ENNDS and new types of herbal products are also not covered.
- Uncertainty about whether tobacco heating devices fall within the framework when sold separately from heated tobacco products.
- Lack of explicit coverage for non-tobacco consumption-related items under the TPD definition of '*tobacco products*'.
- Absence of rules on the regulation of flavours in e-cigarettes and a complex, inefficient and ineffective procedure for determining and prohibiting characterising flavours in tobacco products.
- Technical limitations of the EU Common Entry Gate (EU-CEG) IT tool.
- Differing labelling requirements for HTPs depending on their classification as smokeless or tobacco products for smoking, compounded by the absence of a definition of combustion in the TPD.
- The availability of snus products in EU Member States other than Sweden, that undermines the effectiveness of Article 17 of the TPD.
- The limited scope of TAD and TPD advertising rules that do not cover new nicotine products, such as nicotine pouches, as well as certain promotional activities that influence the consumers' behaviour.
- The difficulty of meeting the conditions of the "substantial change of circumstances" clause of the TPD as well as the absence of an equivalent mechanism for e-cigarettes.
- The possible inadequacy of the uniform nicotine limit of the TPD in addressing new nicotine forms with faster or stronger addictive potential.
- The resource-intensiveness of certain provisions of the tobacco control framework, namely the procedure on the determination of characterising flavours in tobacco products, the EU tobacco traceability system, the notification procedure of Article 24(3) TPD concerning EU Member States' prohibition of certain categories of tobacco or related products and the EU Common Entry Gate (EU-CEG) system.

The evaluation also demonstrates that the tobacco control framework is a highly cost-effective tool in mitigating the public health and economic burden of tobacco consumption across the EU. In addition, the evaluation addresses aspects related to simplification and burden reduction, in particular in relation to the implementation of Article 7 of the TPD and Commission Implementing Regulation (EU) 2016/779 concerning the procedure for determining whether a tobacco product has a characterising flavour, as well as the reporting process through the EU Common Entry Gate (EU-CEG).

In terms of coherence, the evaluation concludes that the tobacco control framework's key components work cohesively and complement each other. The framework also aligns well with the TTD. While the framework is mostly coherent with the AVMSD, inconsistencies in addressing brand depictions and corporate promotions create a misalignment between the two instruments. The implementation of the EU tobacco control framework supports both the EU's and Member States' compliance with the WHO FCTC. However, there is still scope to further strengthen the implementation of the FCTC provisions concerning the tobacco industry interference and liability. In addition, the parallel application of the CLP Regulation and the TPD has created challenges for national enforcement authorities, highlighting the need for a clearer allocation of regulatory roles between the two instruments to support more effective enforcement.

The EU tobacco control framework has delivered significant added value by harmonising rules across Member States, ensuring the smooth functioning of the internal market while maintaining a high level of public health protection. Without harmonised EU legislation, divergent national rules would likely lead to market fragmentation, legal uncertainty, and barriers to trade. The framework has contributed to implement robust tobacco control measures despite industry opposition. It has created a uniform regulatory environment benefiting consumers Member States' competent authorities and public health systems, economic operators and the Commission.

The tobacco control framework remains as relevant as ever today given the rapid market evolution of tobacco and nicotine products. Its provisions ensure that e-cigarettes and novel tobacco products, such as HTPs, will continue to fall within its scope. The emergence of new tobacco and nicotine products as well as the rise of aggressive digital marketing targeting in particular young people further underscores the need for a strong and adaptive EU framework. Without it the market would be vulnerable to widespread exposure to new tobacco and nicotine products, threatening to reverse the progress achieved in reducing smoking prevalence and tobacco-related harm.

CONCLUSIONS AND LESSONS LEARNT

The evaluation concludes that the tobacco control framework introduced several effective measures that have contributed to the smooth functioning of the internal market, significantly strengthened public health protection, and supported the EU's compliance with its international obligations under the FCTC and its Protocol to Eliminate Illicit Trade in Tobacco Products.

Despite the positive aspects, the evaluation reveals that the smoking prevalence in the EU remains high, particularly among young people, and that the current framework is not aligned with market developments, consumption trends and digital marketing practices as certain provisions of the existing framework have been outpaced by the following developments: a) the emergence and widespread popularity of novel tobacco and nicotine products, namely e-cigarettes, HTPs, and nicotine pouches, especially among young people; b) the rapid evolution of digital marketing for tobacco and nicotine products, which significantly influences their use, in particular among youth.

Specific provisions of the TPD and TAD contain gaps or shortcomings that challenge the framework's overall effectiveness, particularly in addressing the emergence, rising use and aggressive online promotion of novel tobacco and nicotine products. As a result, the framework falls short of fully achieving its objectives regarding these products.

The main lesson learnt is that while the EU tobacco control framework has contributed to a high level of public health protection, particularly for young people, and has facilitated the smooth functioning of the internal market for the products it was designed to regulate, recent developments highlighted clear limitations in its ability to achieve its objectives with respect to novel products, in particular in terms of new public health challenges.

As the market continues to evolve and diversify rapidly, an increasing number of new products will emerge and fall outside the current scope of the framework. The continued effectiveness of the EU tobacco control framework in supporting the smooth functioning of the internal market and ensuring a high level of public health protection, particularly among young people, will depend on its capacity to address the rising use and associated public health challenges with the novel products by adapting to the evolving market developments, consumption patterns, and digital promotion practices.