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COMMISSION STAFF WORKING DOCUMENT

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) 112 final/2}

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Glossary

Term or acronym	*Meaning or definition*
AVMSD	Audiovisual Media Services Directive 2010/13/EU
Cancer Plan	Europe's Beating Cancer Plan
COPD	Chronic obstructive pulmonary disease
DALYs	Disability-Adjusted Life Years
e-cigarette	Electronic cigarette
ENDS	Electronic Nicotine Delivery Systems
ENNDS	Electronic Non-Nicotine Delivery Systems
EU	European Union
EU-27	All current EU countries
FCTC	Framework Convention on Tobacco Control
FTE	Full-time equivalents
HTP	Heated tobacco product
JRC	Joint Research Centre
RYO	Roll-your-own-tobacco
TAD	Tobacco Advertising Directive 2003/33/EC
TAPS	Tobacco advertising, promotion, and sponsorship
TFEU	Treaty on the Functioning of the European Union
TNCO	Tar, Nicotine, and Carbon Monoxide
TTD	Tobacco Taxation Directive 2011/64/EU
TPD	Tobacco Products Directive 2014/40/EU
TPD 1	Directive 2001/37/EC
WHO	World Health Organization

1. INTRODUCTION

The Commission has been working on tobacco control since the 1980s, balancing the need for the smooth functioning of the internal tobacco and related products market[1] 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 addresses efforts to ensure that people in the EU are not exposed to second-hand smoke and aerosols from tobacco and related products[2].

Key legislative milestones include Directive 2001/37 (Tobacco Products Directive 1 (TPD1))[3] which was adopted in June 2001 and remained in force until May 2016, when it was repealed and replaced by Directive 2014/40/EU (the Tobacco Products Directive or the TPD)[4]. Additionally, Directive 2003/33/EC (the Tobacco Advertising Directive (TAD))[5] relating to the advertising and sponsorship of tobacco products was adopted on 26 May 2003.

An essential part of the Commission's work on tobacco control is to ensure that the relevant EU legislation stands the test of time, taking into account the latest market, digital, scientific and international developments[6]. Today, in addition to the risks of traditional tobacco products, people in many parts of the world, including the EU, face new health risks from novel products. These products include novel tobacco products like heated tobacco products (HTPs), nicotine products such as nicotine pouches, various types of electronic nicotine delivery systems (ENDS), including nicotine-containing electronic cigarettes (e-cigarettes), Electronic Non-Nicotine Delivery Systems (ENNDS), such as nicotine-free e-cigarettes and heated herbal products[7]. Young people and adolescents are exposed to an unprecedented array of flavoured, colourful and widely marketed nicotine products[8].

On a global scale, the World Health Organization's Framework Convention on Tobacco Control[9] (FCTC) aims to protect people from the harmful effects of tobacco products and is binding on the EU and its Member States. The Sustainable Development Goals urged countries, via Target 3a[10], to implement the WHO FCTC more robustly.

In 2021, Europe's Beating Cancer Plan[11] (the "Cancer Plan") emphasised the importance of tobacco control as a key component of disease prevention efforts, with 27% of all cancers in Europe

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1 Within the current tobacco control framework, the term related products refers to e-cigarettes and refill containers and to herbal products for smoking.

2 https://health.ec.europa.eu/publications/proposal-council-recommendation-smoke-and-aerosol-free-environments_en, Council Recommendation on smoke-and aerosol-free environments - European Commission

3 OJ L 194, 18.7.2001, p. 26.

4 OJ L 127, 29.4.2014, p. 1.

5 OJ L 152, 20.6.2003, p. 16.

6 See Article 114(3) of the Treaty on the Functioning of the European Union (TFEU).

7 https://www.who.int/news/item/25-01-2017-electronic-nicotine-delivery-systems-and-electronic-non-nicotine-delivery-systems-(ends-ennds). Unless the text expressly refers to nicotine-free e-cigarettes, the term "e-cigarettes" means nicotine-containing e-cigarettes.

8 https://www.who.int/europe/news-room/feature-stories/item/sweet-flavours-and-bright-colours-lure-youth-into-nicotine-addiction

9 https://www.who.int/news-room/questions-and-answers/item/tobacco-and-the-who-framework-convention-on-tobacco-control

10 Target 3a is to 'strengthen the implementation of the World Health Organization Framework Convention on Tobacco Control in all countries, as appropriate'.

11 https://health.ec.europa.eu/document/download/26fc415a-1f28-4f5b-9bfa-54ea8bc32a3a_en?filename=eu_cancer-plan_en_0.pdf. The information in this paragraph comes from the same source.

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 revision of the TPD.

In 2022, the Commission adopted Delegated Directive (EU) 2022/2100[12] on the withdrawal of certain exemptions in respect of Heated Tobacco Products (HTPs). The ban on characterising flavours was consequently extended to HTPs and EU Member States no longer have the possibility to exempt HTPs for smoking from stricter labelling requirements. The ban became applicable in 2023. The adoption of the Delegated Directive responded to a significant increase of sales of HTPs across the EU, as highlighted in a Commission report[13].

The Cancer Plan also announced that the Commission would propose an update to the Council Recommendation on Smoke-Free Environments by extending its coverage to emerging products, such as e-cigarettes and HTPs, and expanding smoke-free environments, including outdoor spaces. In December 2024, on the basis of the Commission's proposal, the Council adopted the Council Recommendation on smoke-and aerosol-free environments replacing Council Recommendation 2009/C 296/02[14]. Additionally, in May 2024, the EU tobacco traceability system was extended to include tobacco products other than cigarettes and roll-your-own (RYO) tobacco. Since then, the traceability system has been applicable to all tobacco products.

The harmful effects of traditional tobacco products, such as cigarettes and RYO tobacco, on health have been well documented since the 1950s, when the link between smoking and lung cancer was first established. The causal relationship between tobacco use and mortality and morbidity is well established[15]. The evidence on tobacco's damaging health impact has only grown stronger ever since[16].

Tobacco consumption is linked to a higher risk of various diseases. It is a leading cause of chronic obstructive pulmonary disease (COPD), cancer, and cardiovascular conditions, responsible for approximately 16% of mortality linked to ischemic heart disease. In 2022, smoking was responsible for approximately 20% of cancer cases in the EU, causing at least 16 different types of cancer and contributing to over 80% of all lung cancer deaths, accounting for over 250 000 deaths from trachea, bronchus and lung cancer[17]. Tobacco also plays a substantial role in increasing the burden of communicable diseases. In the context of COVID-19, for instance, smokers face an elevated risk of infection and are more likely to develop severe forms of the illness because their lung health is already compromised[18]. Based on reported mortality numbers, a decline by 8.6% in mortality due to tobacco use in the EU between 2012 and 2023 is assumed[19].

12 OJ L 283, 3.11.2022, p. 4.
13 EUR-Lex – 52022DC0279 – EN – EUR-Lex.
14 EUR-Lex – 32024H07425 – EN – EUR-Lex.
15 'The health consequences of smoking: 50 years of progress', A Report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention, 2014, FCTC/COP/11/6 Liability (Article 19 of the FCTC).
16 https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/tobacco-smoking_en, https://www.who.int/europe/news-room/fact-sheets/item/effects-of-tobacco-on-health
17 Perez-Cornago, A., Sarasa-Renedo, A., Jarach, C., Wollgast, J. and Maragkoudakis, P., Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches, Publications Office of the European Union, Luxembourg, 2026, https://data.europa.eu/doi/10.2760/0061469, JRC146139 ('JRC (2025a)').
18 Ibid.
19 Based on IHME Global Burden of Disease Results Tool, as accessed on 30 March 2026.

1.1 Purpose and scope of the evaluation

The TPD and the TAD both aim to ensure the smooth functioning of the internal market and a high level of public health protection, especially for young people. They also have the same Treaty bases for their adoption, namely Articles 53, 62, and 114 TFEU, so the two Directives are intrinsically connected from a regulatory point of view. This justifies an integrated assessment.

The TPD and TAD are therefore evaluated as a single policy intervention. This evaluation covers the TPD, including the implementing and delegated acts adopted on its basis, and the TAD, which together form the tobacco control framework. For the purposes of this evaluation, the tobacco-control legal framework is understood to consist of these two Directives, including the implementing and delegated acts adopted on the basis of the TPD. An overview of these implementing and delegated acts is provided in Annex 1.

Article 28 of the TPD establishes an obligation for the Commission to submit a report on the application of this Directive to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions no later than five years from 20 May 2016, *and whenever necessary thereafter*. This Report should indicate *the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments*. Also according to Article 28 of the TPD, the Commission should pay special attention to several areas, including: *market developments concerning novel tobacco products* considering, inter alia, notifications received under Article 19; *market developments concerning electronic cigarettes and refill containers* considering, amongst others, information collected in accordance with Article 20, including on the initiation of consumption of such products by young people and non-smokers and the impact of such products on cessation efforts as well as measures taken by EU Member States regarding flavours. The report was published on 20 May 2021[20].

The evaluation period – the period of time covered by the evaluation – for the TPD and the TAD began in 2012, when the Commission's proposal for the TPD was adopted, and ends in 2025. The geographical scope of the evaluation covers the EU Member States. The evaluation takes into account -to the extent possible- that Croatia joined the EU in 2013, and the UK left the EU in 2020. This evaluation follows the Better Regulation guidelines and requirements. The tobacco control legal framework is assessed using the following evaluation criteria:

- **effectiveness**: assessing the extent to which the objectives of the tobacco control framework have been achieved or the progress made towards achieving them so far;
- **efficiency**: analysing the relationship between the costs and benefits of the tobacco control framework;
- **relevance**: examining whether the objective and the provisions of the tobacco control framework are still fit for purpose;
- **coherence**: focusing on how effectively the two Directives of the tobacco control framework operate together, and on how they interact with other EU legislation and policies, and assessing their internal consistency;
- **EU added value**: considering the extent to which the implementation of the tobacco control framework has resulted in additional benefits that EU Member States could not have brought about individually.

1.2 Engagement of stakeholders

The following consultation activities were undertaken:

[20] EUR-Lex – 52021DC0249 – EN – EUR-Lex.

- a call for evidence[21] that was open from 20 May 2022 to 17 June 2022 and resulted in 24 359 contributions, mostly from EU citizens (93%);
- a public consultation[22] that was open from 21 February to 16 May 2023 and resulted in more than 17 000[23] contributions. The majority of the responses (89%) came from EU and non-EU citizens;
- a targeted survey[24] of key stakeholders other than EU citizens (EU Member States' competent authorities, civil society organisations and economic operators in the tobacco industry or related industries) that was carried out in June-July 2023 and resulted in 64 responses.
- a second targeted survey[25] addressing the administrative efforts related to the implementation of the tobacco control framework, was carried out between October 2024 and February 2025. It was distributed to 29 European countries (the 27 EU Member States plus Iceland and Norway) through the Expert Group on Tobacco Policy and was analysed by the Commission's Joint Research Centre (JRC).
- targeted interviews[26] of key stakeholders other than EU citizens that were carried out in July 2023 and resulted in 26 completed interviews of 30 stakeholders (eight EU Member States, 10 economic operators and 12 civil society Organisations).

The consultation activities and their outcomes are presented in a synopsis report which can be found in Annex 5.

1.3 Methodology and limitations of the evaluation

This evaluation draws on a broad and diverse evidence base, including a supporting study conducted by an external contractor. The evaluation is also informed by the outcomes of the extensive stakeholder consultation activities that are described in the previous section. It also incorporates findings from expert studies, scientific reports, surveys and other documents addressing the following matters:

- The use and impact of digital promotion of tobacco and nicotine products, in particular the current marketing practices and behavioural effects related to the digital promotion of tobacco and nicotine products;
- The advertising of tobacco and related products, with particular focus on whether the current scope of EU tobacco-control legislation adequately covers all forms of digital advertising and promotion;
- 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 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 and second-hand smoking in the EU;
- The health outcomes associated with the use of e-cigarettes, HTPs and nicotine pouches;

[21] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control_en

[22] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation_en

[23] Initial number of submissions: 17 773.

[24] Annex 5: Synopsis report of the different consultation activities.

[25] Annex 5: Synopsis report of the different consultation activities.

[26] Annex 5: Synopsis report of the different consultation activities.

- The administrative efforts of the EU 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;
- The implementation, application and impact of the TPD and TAD;
- The attitudes of EU citizens towards tobacco and related products, in particular the prevalence of tobacco and nicotine products use in the EU;
- The sales value and volume of tobacco and related products;
- The characteristics of novel tobacco, nicotine products and ENNDS;
- The relationship between EU tobacco control legislation and other relevant areas of EU law.

The previous evaluation of the TPD took place in 2010. Prior to this, the TAD was adopted in 2003 without an accompanying impact assessment that could establish a comprehensive baseline of the situation at that time, including quantitative data to support evaluation criteria such as the public health impact or economic costs.

The TPD was introduced at a time when market trends, consumer behaviour and product availability were considerably different from today. Many tobacco and nicotine products that have since become widely available and particularly popular among young people, such as e-cigarettes, HTPs and nicotine pouches - either did not exist at all or were only emerging with limited market share and prevalence . The digital promotion of tobacco and nicotine products has also evolved rapidly in recent years, significantly influencing the prevalence and use of these products among young people[27]. This factor was not taken into account in the previous evaluation of the tobacco control framework.

The following table describes the limitations and corresponding mitigation measures.

Limitations	**Mitigation measures**
Lack of quantitative data on the costs incurred by certain EU Member States.	15 EU Member States were not able to provide a complete estimate of the administrative burden, in full-time equivalents (FTE), because the implementation of the tobacco-control framework is often spread across multiple ministries and departments. To get around this constraint, the comparative analysis draws on the quantitative input from the remaining 12 EU Member States that replied fully to the questionnaire, supplemented by qualitative information provided by all EU Member States. This input was obtained by means of the targeted surveys.
Lack of quantitative data on the costs incurred by economic operators in complying with the tobacco-control framework.	Extensive efforts were made to obtain quantitative data on the costs incurred by economic operators in implementing and applying the tobacco-control framework. However, the quantitative data were very limited, with only a small number of economic operators providing concrete estimates of the financial costs. The quality and reliability of the data

[27] Lazuras, L., Assessment of the use and impact of digital marketing of tobacco and nicotine products, 2025.

	collected could not be verified, as there was no opportunity to validate the information provided. The views of economic operators and qualitative input on the costs were used in the analysis.
Quantification of the benefits resulting from the implementation of the tobacco control framework has proven challenging. This limits the ability to fully assess the framework's economic impact.	To assess the cost-effectiveness of the tobacco control framework, the analysis compares its estimated annual implementation costs with some likely quantitative benefits resulting of its implementation. In particular, the analysis takes into account reductions in direct healthcare expenditure related to tobacco-related illnesses and indirect costs, including productivity losses. In addition, a high-level estimate of total population health benefits due to smoking cessation is presented, including through valuating future life years saved. However, the analysis does not take into account other probable cost reductions linked to the implementation of the tobacco control framework, most notably: • benefits from lowered smoking initiation rates. • reductions in health burden or monetary losses attributable to second-hand smoke-related mortality and morbidity. It is difficult to quantify the cost reductions related to the decreased health burden due to the lack of comparable data since 2012. However, it is reasonable to assume that the observed decline in tobacco-related deaths over the past decade has contributed to a significant reduction in costs related to these broader categories. This is why, the analysis acknowledges that, despite the absence of precise figures, these wider impacts should be considered in the overall cost-benefit analysis of the framework. To further strengthen the analysis, stakeholder input was also incorporated.
Quantification of the economic burden of tobacco consumption in the EU has been difficult due to the many factors involved, and the fact that no study provides only a single figure.	To assess the economic costs of tobacco consumption in the EU, the analysis took into account the following estimated costs: direct healthcare expenditure on tobacco-related illnesses; indirect costs, including productivity losses and informal care; value of years of life lost to death from smoking; losses attributable to second-hand smoke-related mortality and morbidity.
Determining the quantitative contribution of individual measures of the tobacco control framework and the effects of other EU legislation and external factors on the reduction of smoking prevalence and smoking related mortality and morbidity, has proven very challenging. No data was available to clearly quantify the specific	In the absence of quantitative data, it was not possible to make a clear distinction between the specific contributions of the TPD and the TAD measures. The analysis therefore considers that both sets of measures have contributed to the observed benefits, without specifying the precise extent of each contribution. However, the conclusions indicate which measures appear to have had the greatest

impact of all these factors on the relevant outcomes.	impact based on qualitative input. The evaluation also explicitly recognises the contribution of other relevant legislation, such as the Tobacco Taxation Directive (TTD)[28], national fiscal measures, the Market Surveillance Regulation, and national tobacco control measures, where appropriate. Regarding external factors, while some may have influenced trends such as the reduction in smoking prevalence, this evaluation focuses on assessing the effects of the EU tobacco control measures rather than analysing all external factors that contribute to tobacco use.
The simplification and burden reduction aspect primarily reflect the perspectives of EU Member States and the Commission.	A core objective of the tobacco control framework is to ensure a high level of public health protection, particularly for young people. This can sometimes be incompatible with all simplification efforts aimed at economic operators, as easing regulatory requirements could undermine public health protection. For example, reducing or further simplifying industry reporting will limit monitoring capabilities in a rapidly evolving market, hindering the EU Member States' and Commission's timely responses to emerging health risks. This highlights the unique nature of tobacco control legislation, which prioritises protecting public health over easing conditions for the tobacco industry. For this reason, simplification was not included as a key aspect in the consultation activities.
The monitoring and evaluation framework data do not enable the quantitative attribution of observed consumption trends to the individual factors influencing them.	This evaluation takes into account that factors besides the tobacco control measures established by the TPD and the TAD, may have influenced consumer behaviour and contributed to the observed decline in smoking prevalence during the evaluation period. These additional factors are presented in Sections 2.1 and 4.1.2. Accordingly, the evaluation does not attribute the observed positive outcomes exclusively to the implementation of the EU tobacco control framework. While the data provided by monitoring and evaluating the tobacco control framework allow for an assessment of its effectiveness, efficiency, coherence and relevance, they do not permit a quantitative attribution of outcomes to individual policy measures or other factors impacting consumer behaviour. As a result, the evaluation focuses on assessing the performance of the TPD and the TAD within the limits of the available evidence.

[28] OJ L 176, 5.7.2011, p. 24.

Despite the limitations illustrated, the evidence gathered is reliable enough to support the evaluation of the tobacco control framework. The evaluation's conclusions are based on evidence from multiple sources, present consistent and well-supported findings. The full titles of the various sources used in this evaluation are given in Annex 3.

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTIONS?

2.1 Description of the policy intervention and its objectives

The objectives of the tobacco control framework are to facilitate the smooth functioning of the internal market, while ensuring a high level of human health protection, especially for young people and to fulfil the EU's obligations under the FCTC.

The framework balances the regulation of tobacco and related products and public health protection objectives. It places particular emphasis on protecting young people by aiming to reduce the appeal of tobacco products and deter them from taking up tobacco initiation. By providing consumers with clear information about the health risks of tobacco products and prohibiting misleading information, the framework seeks to reduce tobacco use. In addition to establishing uniform standards that streamline the internal market for tobacco and related products[29], the framework addresses health challenges posed by emerging products at the time of its adoption, namely e-cigarettes and refill containers as well as herbal products for smoking. The framework also supports stronger cooperation among EU Member States' competent authorities on tobacco control issues, helping them to achieve their public health objectives. Overall, it enables a coordinated response to challenges that threaten both the functioning of the internal market and public health protection.

To this end, the tobacco control framework approximates EU Member States' laws regarding: (a) tobacco products' ingredients, emissions, and related reporting obligations, including the maximum emission levels of tar, nicotine and carbon monoxide for cigarettes; (b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products; (c) the prohibition on the placing on the market of tobacco for oral use; (d) cross-border distance sales of tobacco products; (e) the obligation to submit a notification of novel tobacco products; (f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, as well as herbal products for smoking; (g) the advertising of tobacco products and their promotion in the press and other printed publications, radio broadcasting, information society services and through tobacco related sponsorship, including the free distribution of tobacco products.

The TPD repealed TPD 1adopted on 5 June 2001. The Commission presented its proposal for the current TPD in 2012[30], accompanied by an impact assessment[31]. While TPD 1 had already aimed to address some of these needs, significant differences in EU Member States' laws on the manufacture, presentation, and sale of tobacco products continued to hinder the smooth functioning of the internal market[32]. Matters have been made worse by market, international, and scientific

[29] Recital 6 of the TPD.

[30] https://health.ec.europa.eu/document/download/ac6fc422-00d6-4fa1-a9c8-70325639f5f8_en?filename=com_2012_788_en.pdf

[31] https://health.ec.europa.eu/document/download/4feef42c-f49f-49ac-864f-edae2a24c0c7_en?filename=com_2012_788_ia_en.pdf

[32] Recitals 4, 6, 15, 23, 36 and 49 of the TPD.

developments at the time TPD 1 was adopted, which underscored the need for a modernised TPD, as explained in the impact assessment[33].

The TPD updated TPD1 introducing a number of new rules to address emerging developments. These rules include the prohibition of placing on the market of certain tobacco products with a characterising flavour, more stringent reporting obligations for manufacturers and importers, mandatory combined health warnings consisting of a text warning, a corresponding colour photograph and smoking cessation information, traceability markings and security features, as well as specific requirements regarding the appearance and content of unit packets of cigarettes and RYO tobacco. The TPD also introduced rules on novel tobacco products, e-cigarettes and refill containers, and herbal products for smoking and cross-border distance sale of tobacco products, e-cigarettes and refill containers.

The TAD regulates tobacco advertising and sponsorship with cross-border implications in the media other than television. In particular, the Directive bans the advertising of tobacco products in radio broadcasting as well as in the press and other printed publications, and information society services with two exceptions: professionals in the tobacco trade and publications which are printed and published in non-EU countries, where those publications are not principally intended for the EU market. The TAD also bans the sponsorship of events or activities involving, or taking place in, several EU Member States or otherwise having cross-border effects, including the free or discounted distribution of tobacco products. The TPD complements and thus indirectly updates the TAD by introducing a ban on the advertising and sponsorship with respect to e-cigarettes and refill containers, in parallel to the ban on such activities in relation to traditional tobacco products in the TAD. In other words, the TPD identified and addressed an important need that was not there in 2003, namely the need to regulate the advertising and sponsorship of e-cigarettes and refill containers.

It should be clear that the TPD and the TAD do not harmonise all tobacco-control rules that may have an impact on the achievement of their public health protection objective. For example, rules concerning smoke-free environments, domestic sales arrangements (such as specific opening times for tobacco retailers, restrictions on the places of sale, strict licencing systems for tobacco retailers), domestic advertising, brand stretching, age limits for the sale of tobacco and related products, support services and programmes for smoking cessation, are not harmonised at EU level[34]. EU Member States remain free to regulate these matters within the remit of their own jurisdiction.

Other EU legislation may also contribute to the achievement of the objectives of the TPD and the TAD. This includes Council Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco (the TTD) which has similar objectives, the Audiovisual Media Services Directive 2010/13/EU[35], which prohibits all forms of audiovisual commercial communications for tobacco products, e-cigarettes and refill containers, Regulation (EU) 2019/1020 on market surveillance and compliance of products[36] and the Classification, Labelling and Packaging (CLP) Regulation (Regulation (EC) No 1272/2008) on the classification, labelling and packaging of substances and mixtures[37].

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33 https://health.ec.europa.eu/document/download/4feef42c-f49f-49ac-864f-edae2a24c0c7_en?filename=com_2012_788_ia_en.pdf

34 Recitals 47, 48 and 55 of the TPD.

35 OJ L 95, 15.4.2010, p. 1.

36 OJ L 169, 25.6.2019, p. 1.

37 OJ L 353, 31.12.2008, p. 1.

In particular policy measures linked to smoke-free environments and taxation are reported[38] to be impactful, contributing to the achievement of public health objectives, in addition to the TPD and the TAD. However, there is considerable variation across EU Member States in both smoke-free environment rules and tobacco taxation. As illustrated in the figures below, while some EU Member States have adopted comprehensive smoking bans covering a wide range of indoor places, others have less strict arrangements in place, with exemptions for certain venues.

Figure 1: Number of EU countries with comprehensive bans on smoking and with designated smoking rooms, by venue, 2024[39]



Figure 2: Additional indoor and outdoor smoke-free venues in the EU, 2024[40]



Similar divergences are also evident in the taxation of tobacco products. As the evaluation of the TTD[41] and the impact assessment accompanying the Commission proposal for a revised TTD[42]

38 Hoffman, S.J., Tan, C. (2015).

39 Source: WHO, *Two decades of the implementation of the WHO Framework Convention on Tobacco Control in the European Union: progress, challenges and the road ahead*, 2025, https://www.who.int/europe/publications/i/item/WHO-EURO-2025-12743-52517-81148

40 Ibid.

41 https://taxation-customs.ec.europa.eu/system/files/2020-02/10-02-2020-tobacco-taxation-report.pdf

42 https://taxation-customs.ec.europa.eu/taxation/excise-duties/excise-duties-tobacco/revision-tobacco-taxation-directive-proposal_en

point out, significant price differences between EU Member States exist, largely reflecting different national choices in setting rates above the minimum rates established in the TTD and disparities in the tax treatment of novel products.

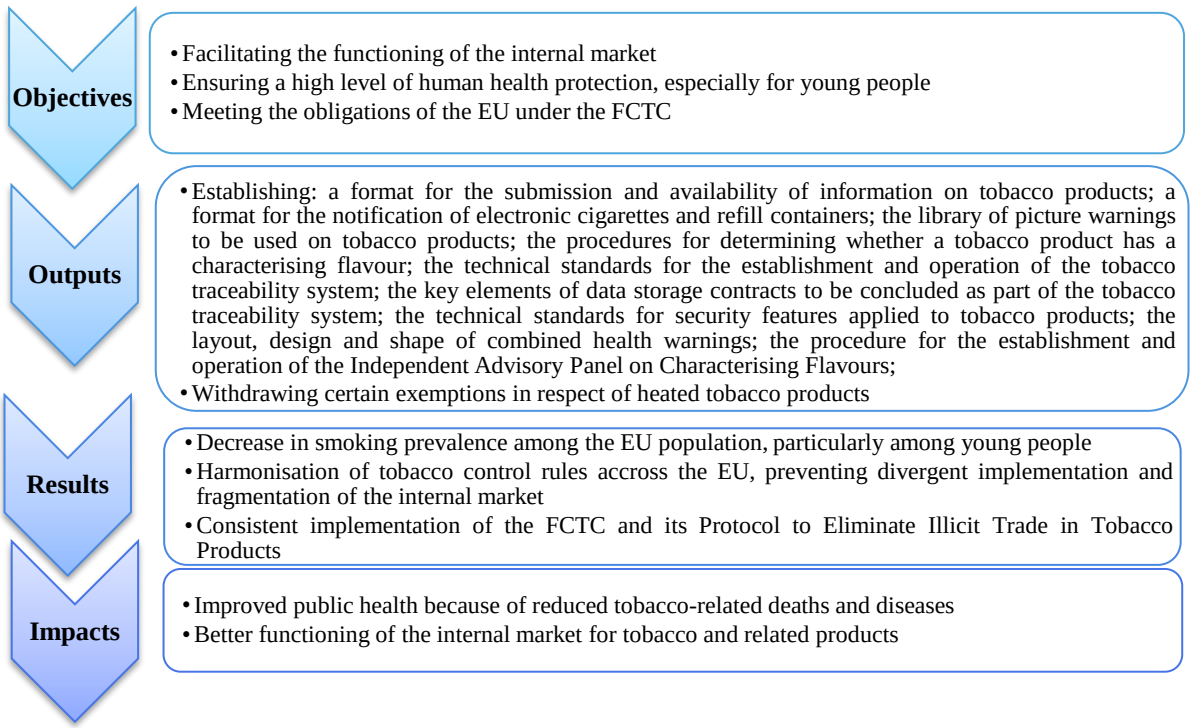
Besides national and EU legislation, other factors also contribute to the achievement of the objectives of the TPD and TAD, in particular the objective of ensuring a high level of human health protection, especially for young people. These factors are described in Section 4.1.2 ("*Other factors affecting consumer behaviour*") and reflected in the broader context of tobacco control in the intervention logic diagram.

Products that fall within and outside the scope of the TPD and the TAD are described in the table below.

	Tobacco Products Directive 2014/40/EU	**Tobacco Advertising Directive 2003/33/EC**
Products in the scope of the TPD and the TAD	All tobacco products (cigarettes, cigars, cigarillos, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, tobacco for oral use, nasal tobacco, chewing tobacco, novel tobacco products), electronic cigarettes and refill containers, herbal products for smoking	All tobacco products (cigarettes, cigars, cigarillos, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, tobacco for oral use, nasal tobacco, chewing tobacco, novel tobacco products)
Out-of-scope products	Nicotine products other than e-cigarettes and refill containers (nicotine pouches, nicotine gums, nicotine nasal sprays and other nicotine products that exist or may emerge in the future), herbal products other than herbal products for smoking (heated herbal products and other herbal products that may emerge in the future), ENNDS	Nicotine products (e-cigarettes and refill containers, nicotine pouches, nicotine gums, nicotine nasal sprays and other nicotine products that exist or may emerge in the future), herbal products (herbal products for smoking, heated herbal products and other herbal products that may emerge in the future), ENNDS

The intervention logic of the tobacco control framework is described below[43]:

[43] Figure 21 presents the interplay of key measures of the TPD and TAD in relation to taking up smoking and quitting smoking.



2.2 Points of comparison

This evaluation assesses the changes the EU policy intervention has brought over time. The situation before the policy intervention became functional, was defined as a point of comparison. Even though the TPD and the TAD were adopted on different dates, a single point of comparison was used for both, since the TPD indirectly updated the TAD. The situation in 2012, when the Commission's proposal for the TPD was adopted, served as the baseline. This evaluation therefore assesses changes from 2012 to the present.

In 2012, the UK was still an EU Member State, while Croatia had not yet joined the EU[44]. This difference has a minor impact on comparing the 2012 situation with the present, particularly in terms of data on the prevalence of traditional tobacco products and e-cigarettes. While this impact is difficult to quantify precisely, it does not affect the arguments and conclusions of this evaluation because the analysis focuses on overall trends and developments within the EU, which remain consistent despite EU membership changes.

Situation in 2012:

- Tobacco use caused approximately 700 000 deaths (or around 580 000 deaths when adjusted to the current EU-27 make-up)[45];
- 28% of EU-27 citizens were smokers[46] (of boxed or hand-rolled cigarettes, cigars or a pipe). The prevalence of smoking was 29% among young people aged 15-24 and 17% among those aged 55 and older. Boxed cigarettes were by far the most commonly consumed tobacco product across all EU Member States;

44 https://www.europarl.europa.eu/factsheets/en/sheet/167/the-enlargement-of-theunion

45 European Commission (2012). *Report on the public consultation on the revision of the Tobacco Products Directive* and IHME Global Burden of Disease Results Tool.

46 https://europa.eu/eurobarometer/surveys/detail/1060. The information in the next bullet points sourced from the same reference.

- The regular use of e-cigarettes was rare, with only 7% of EU citizens having tried them. Additionally, 23% did not know what an e-cigarette was, and 31% had not heard of the product;
- The economic burden of smoking on EU Member States, including direct healthcare costs and productivity losses due to disability, was cautiously estimated to be around EUR 130 billion[47];
- The lack of a harmonised approach to regulating tobacco products and e-cigarettes had a negative impact on the free movement of these products across the EU, and imposed significant administrative burden on EU Member States and other stakeholders[48];
- The total value of the EU tobacco and related products' market was EUR 155 billion, with cigarettes making up 87.2% of the market[49];
- The total value of the EU market for traditional tobacco products[50] was EUR 154 billion;
- The market value of cigarettes was EUR 135 billion;
- The market value of e-cigarettes was EUR 909 million[49];
- Products such as HTPs, nicotine pouches and ENNDS were generally not yet present in the EU market[51];
- FCTC implementation varied widely across EU Member States[52].

3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

The situation concerning tobacco and related products in the EU has changed dramatically since 2012. Over the past decade, the sale and reported use of e-cigarettes and HTPs, particularly among young people, have risen sharply. At the same time, the market has become increasingly diverse, with the emergence of new nicotine-free and nicotine-containing products, such as nicotine pouches which appeared for the first time in the market of some EU Member States in 2018, and ENNDS[53]. Driven by new forms of digital promotion, these novel products have become widely available with their market share significantly increasing. Diversification is often evident within the same type products. E-cigarettes, for example, now come in a wide range of forms and types[54].

47 Based on Goodchild M, et al. Tob Control 2018, Global economic cost of smoking-attributable diseases, notably presented cost estimates for 2012 as share of GDP, covering direct healthcare costs and labour market productivity losses due to smoking-related disability.

48 https://health.ec.europa.eu/document/download/4feef42c-f49f-49ac-864f-edae2a24c0c7_en?filename=com_2012_788_ia_en.pdf. See also recitals 4, 6, 15, 23, 36 and 49 of the TPD.

49 Euromonitor International Ltd, Tobacco, 2025 industry edition © All rights reserved. This document includes source material that is the exclusive property of Euromonitor International Ltd and its licensors and is provided without any warranties or representations about accuracy or completeness. Further sharing, disclosure, publication or making available of all or part of the material contained in this document (or any data or other material derived from it) will require Euromonitor's prior written consent. Euromonitor International Ltd cannot be held liable for analysis or findings within this report and cannot be held liable for any reliance on such materials in any capacity and any reliance is done at the users risk. The information in the next four bullet points is taken from the same source.

50 This includes cigarettes, roll-your-own tobacco, cigarillos, cigars, pipe tobacco and chewing tobacco.

51 Evidence indicates that a nicotine pouch product was first registered in 2008. Source: https://frepouch.com/blogs/behind-the-tin/the-evolution-of-nicotine-delivery-from-chew-to-fresh-pouches

52 https://health.ec.europa.eu/document/download/4feef42c-f49f-49ac-864f-edae2a24c0c7_en?filename=com_2012_788_ia_en.pdf.

53 It is important to distinguish between electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS). E-cigarettes are the most common type of ENDS. ENDS contain nicotine, while ENNDS are nicotine-free.

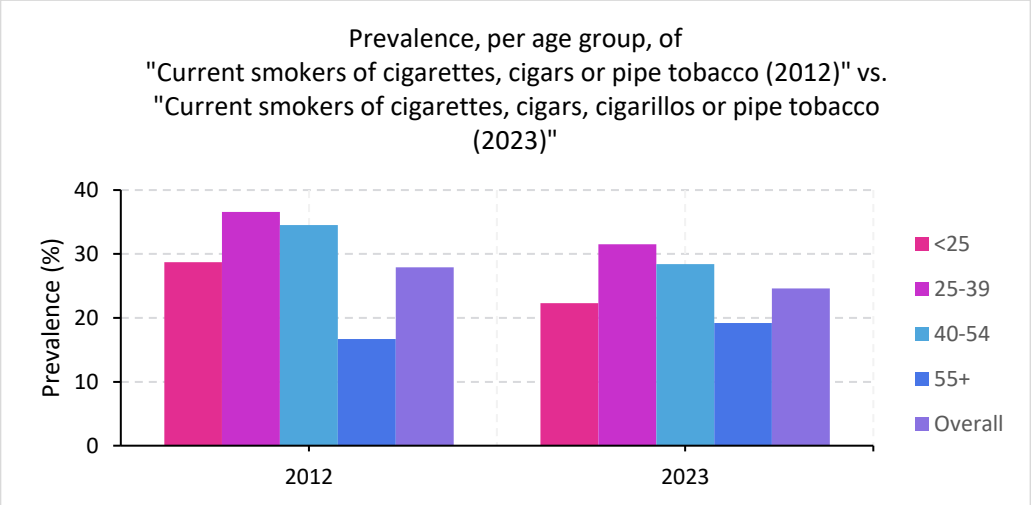
54 https://www.who.int/news-room/questions-and-answers/item/tobacco-e-cigarettes

In response, EU Member States have adopted various regulatory approaches to addressing these novel products in areas not covered by the tobacco control framework. For example, an increasing number of EU Member States are introducing rules on products such as e-cigarettes with flavours, nicotine pouches and ENNDS. Despite these national efforts, the continued market diversification has led to a change of prevalence patterns in the EU. These patterns are illustrated below.

Prevalence of smoking

The prevalence of traditional tobacco product use[55] has decreased from 28% of EU citizens in 2012, including 29% of young people aged 15-24[56], to 24% of EU citizens in 2023, with 22% of young people [57]. The noted increase in smoking in the 55+ group from 16.7% to 19.2% between 2012 and 2023 could be explained through a cohort effect[58]. A more detailed analysis would require more granular data in the age categories and this granularity is not available. In general, significant differences remain between EU Member States, with rates ranging from 8% to 37%. Boxed cigarettes continued to be the most commonly used category in 2023.

Figure 3: Prevalence of smoking in the EU (2012-2023)[59]



Around 21% of respondents to the 2023 Eurobarometer survey reported smoking traditional tobacco products every day in 2023[60]. The percentage of daily or occasional smokers was similar among people aged 25 to 59 years old ranging from 27% to 30%. Among people aged 20 to 24, 24% reported smoking at least occasionally, while this figure was 15% for both the 15 to 19 age group and people over 60. Notably, in every age group, most of smokers smoked 6 or more units per day, indicating intensive use.

55 The term 'use' refers to 'reporting currently smoking'.

56 https://europa.eu/eurobarometer/surveys/detail/1060

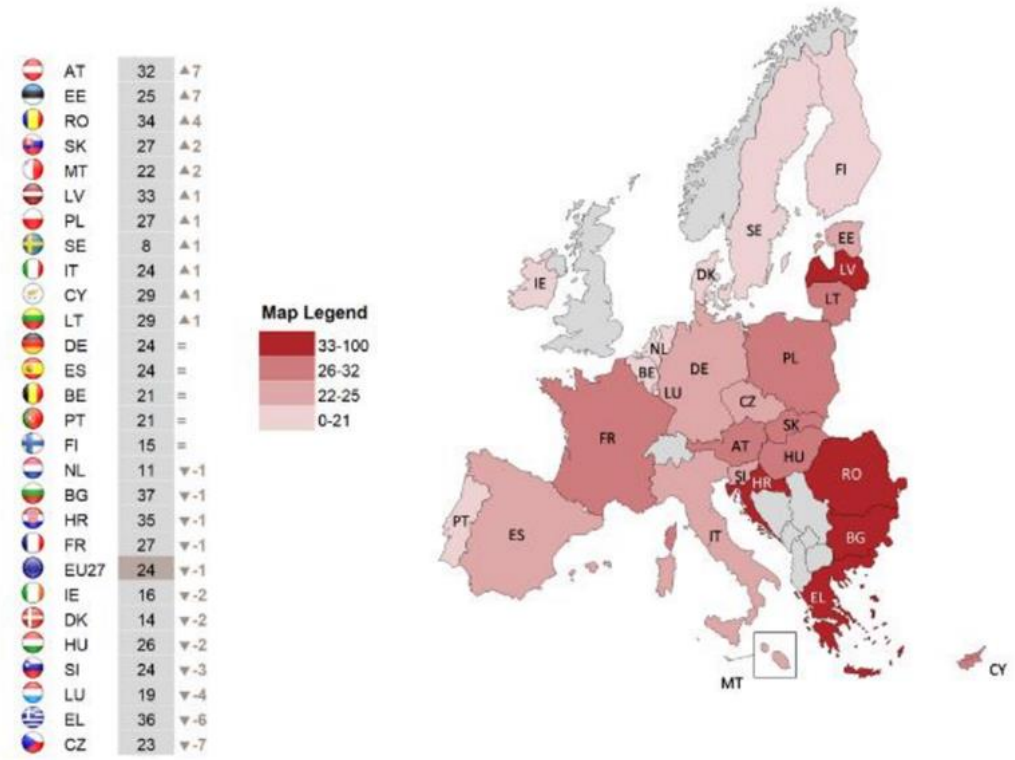
57 https://europa.eu/eurobarometer/surveys/detail/2995. The remaining information in this paragraph comes from the same source.

58 In 2012 there were an estimated 24 million smokers in the EU aged 44-54. In 2023 this group would have joined the 55+ group, in part possibly explaining the noted prevalence rate increase (which concerns an increase by 7.6 million smokers aged 55+ in the EU between 2012 and 2023).

59 https://europa.eu/eurobarometer/surveys/detail/1060, https://europa.eu/eurobarometer/surveys/detail/2995. The table uses decimal values as reported in the microdata of the relevant Eurobarometer editions.

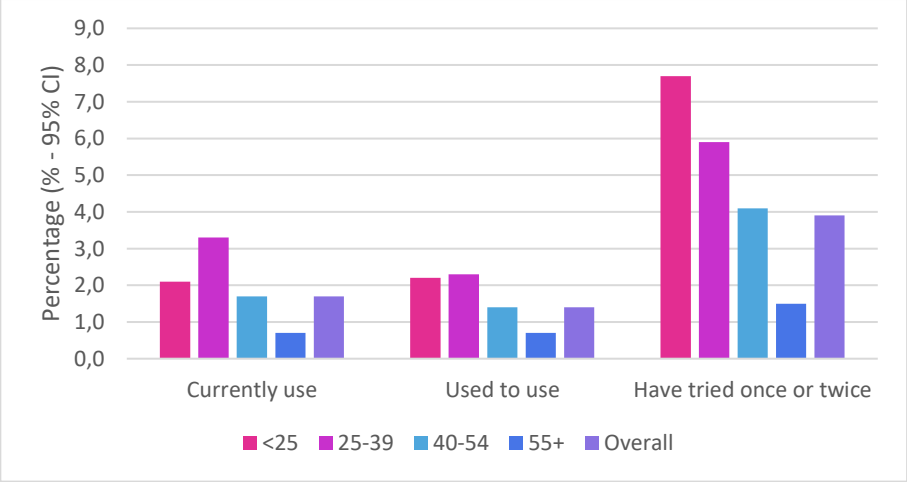
60 Berlingieri, F., Casabianca, E. and Vlachos, S., Trends and patterns of use of tobacco and nicotine products in the EU, Publications Office of the European Union, Luxembourg, 2026, https://data.europa.eu/doi/10.2760/3233096, JRC143862. ('JRC (2025b)'). The information in this paragraph is taken from the same report.

Figure 4: Prevalence of smoking by EU Member State (2023)[61]



Prevalence of HTPs use

Figure 5: Prevalence of heated tobacco products use in the EU (2023)[62]



From 2020 to 2023, the share of HTP users in the EU increased, both in the general population and among younger age groups. Daily users of HTPs are the large majority of consumers of this product type, with the highest share of consumers found among the 30 to 44-year-olds (2.6%) and smaller shares among the overall population (1.4%)[63].

61 https://europa.eu/eurobarometer/surveys/detail/2995
62 https://europa.eu/eurobarometer/surveys/detail/2995
63 JRC (2025b).

Figure 6: Prevalence of heated tobacco products use in the EU (2020-2023)[64]

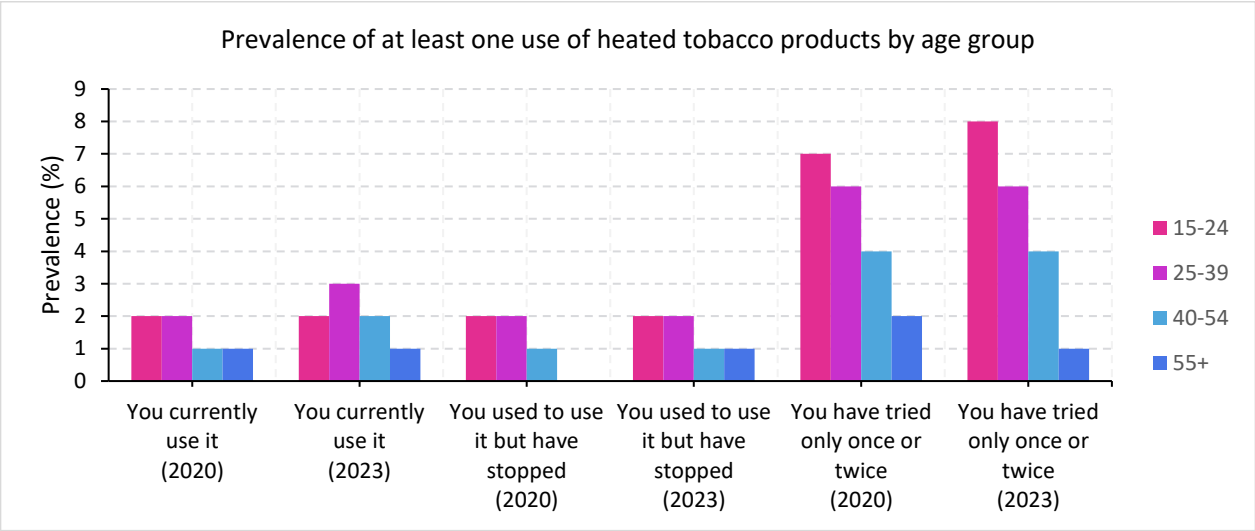
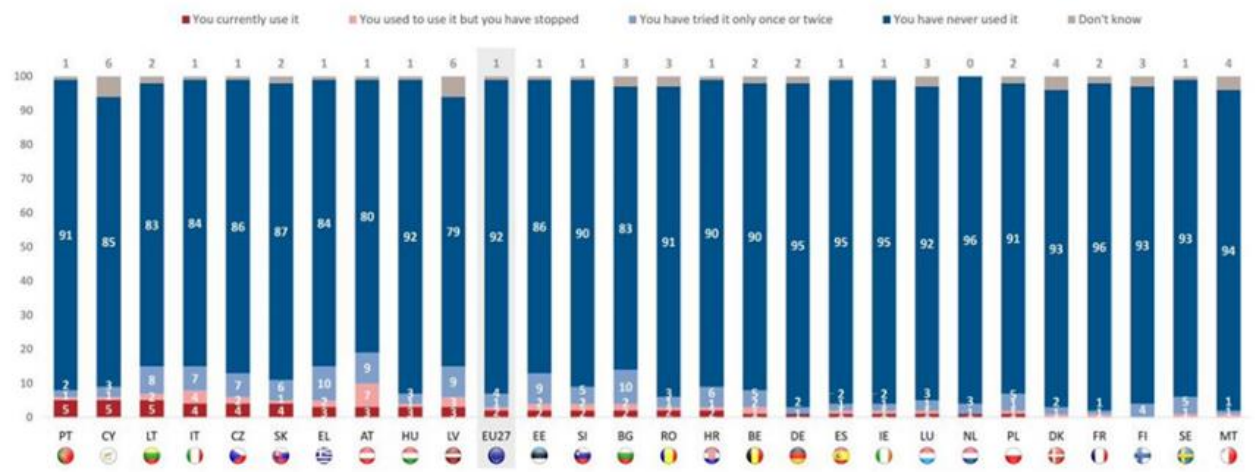


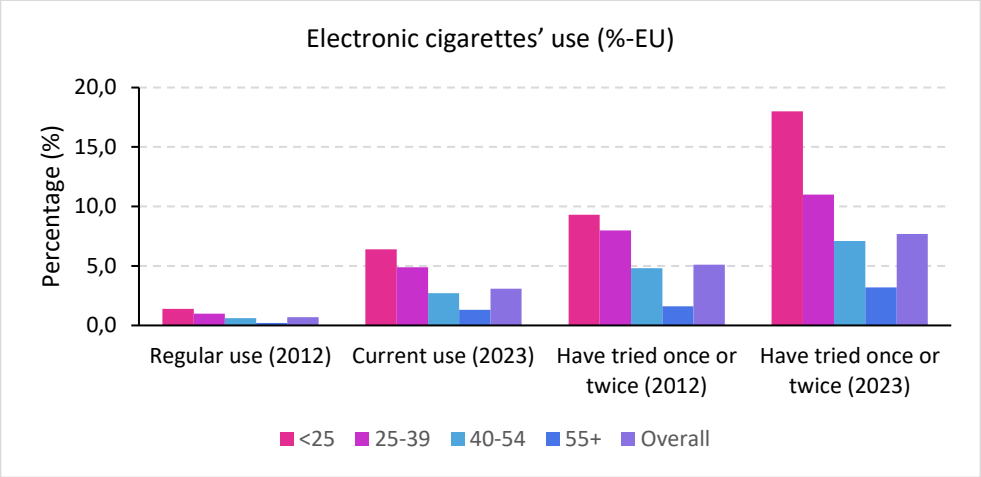
Figure 7: Prevalence of heated tobacco products use by EU Member State (2023)[65]



Prevalence of e-cigarette use

64 https://europa.eu/eurobarometer/surveys/detail/2240,https://europa.eu/eurobarometer/surveys/detail/2995.
65 https://europa.eu/eurobarometer/surveys/detail/2995

Figure 8: Prevalence of electronic cigarettes use in the EU (2012-2023)[66]



Approximately one in five consumers of tobacco and nicotine products aged 15 to 19 years and more than one in ten consumers aged 20 to 24 years started first by regularly using e-cigarettes[67] At the same time, there has been a steady decline in the occasional use of cigarettes among 15-year-olds of both sexes between 2014 and 2022[68].

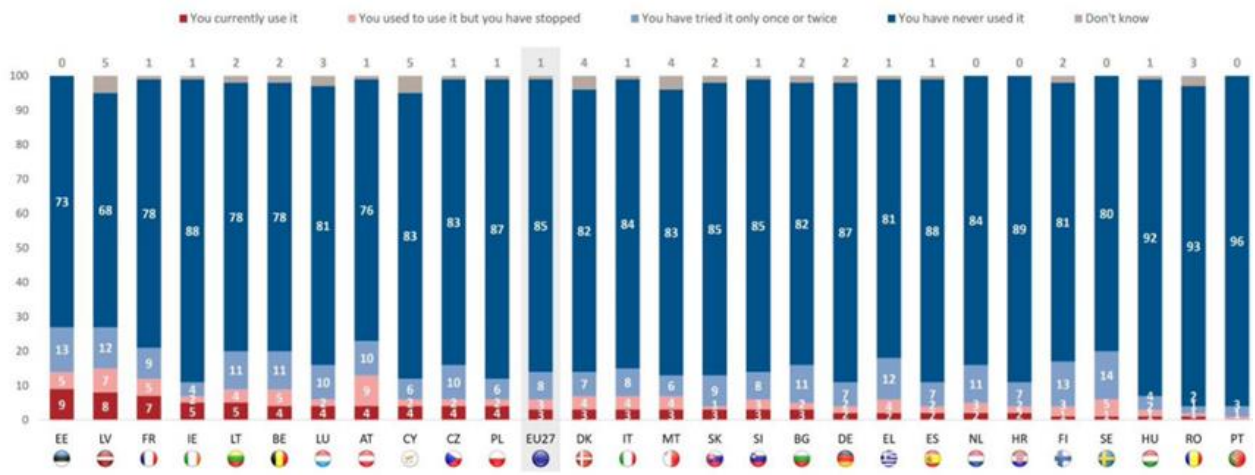
Daily e-cigarette use has also increased in recent years, rising from 1% in 2020 to 1.7% in 2023. This upward trend is especially pronounced among people under 30, among whom usage increased from 1.4% to 3%.

In 2022, 21% of 15-year-old adolescents in the EU used e-cigarettes monthly. In the same year, the share of 15-year-olds occasionally using e-cigarettes was higher than the share using traditional cigarettes in most EU Member States. In most countries, the share of adolescents aged 11 and 13 remain at or below 10%. However, higher rates were observed among 13-year-old girls in Bulgaria and Lithuania, where usage reached or exceeded 20%.

It is also important to note that among the current and former young users of traditional or novel products in 2023, e-cigarettes have become the first novel product used by young people. Flavours play a significant role in this trend, as illustrated in figure 12.

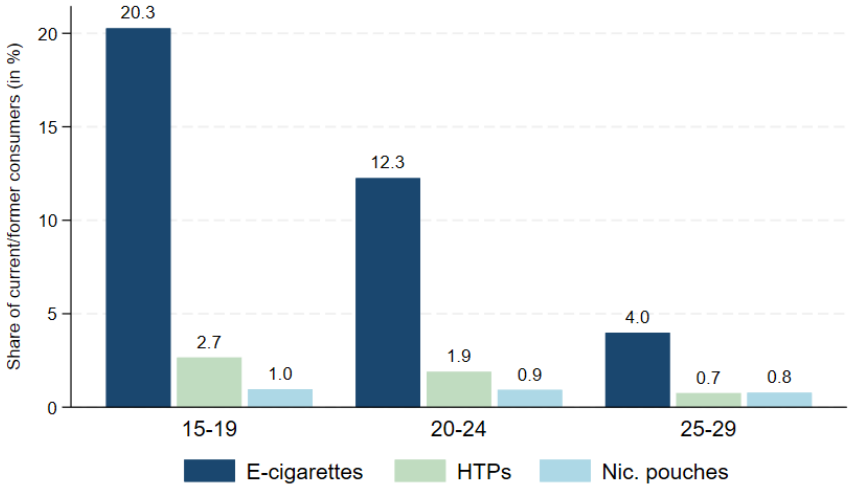
Figure 9: Prevalence of e-cigarette use by EU Member State (2023)[69]

66 https://europa.eu/eurobarometer/surveys/detail/1060, https://europa.eu/eurobarometer/surveys/detail/2995
67 JRC (2025b).
68 The information in the next three paragraphs comes from the JRC (2025b) report.
69 https://europa.eu/eurobarometer/surveys/detail/2995



The highest share of daily e-cigarette use in 2023 was observed in France (5% of daily e-cigarette users)[70].

Figure 10: First novel product used by current or former young users of traditional or novel products (2023)[71]



Note: Answers to the question: Which of the following products did you use or try first? Shares of sub-sample of respondents using or having used tobacco, nicotine products or e-cigarettes without nicotine.
Source: authors' calculation based on Special Eurobarometer 539. N=13,218 respondents.

70 JRC (2025b).
71 JRC (2025b).

Figure 11: How often do you use e-cigarettes with and without nicotine (among those who use e-cigarettes) (2023)[72]

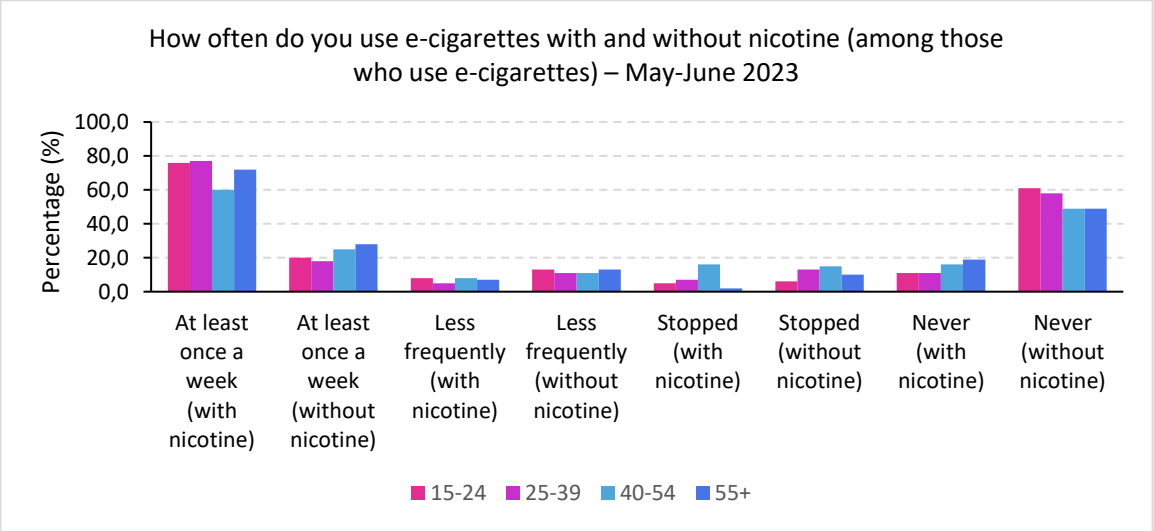
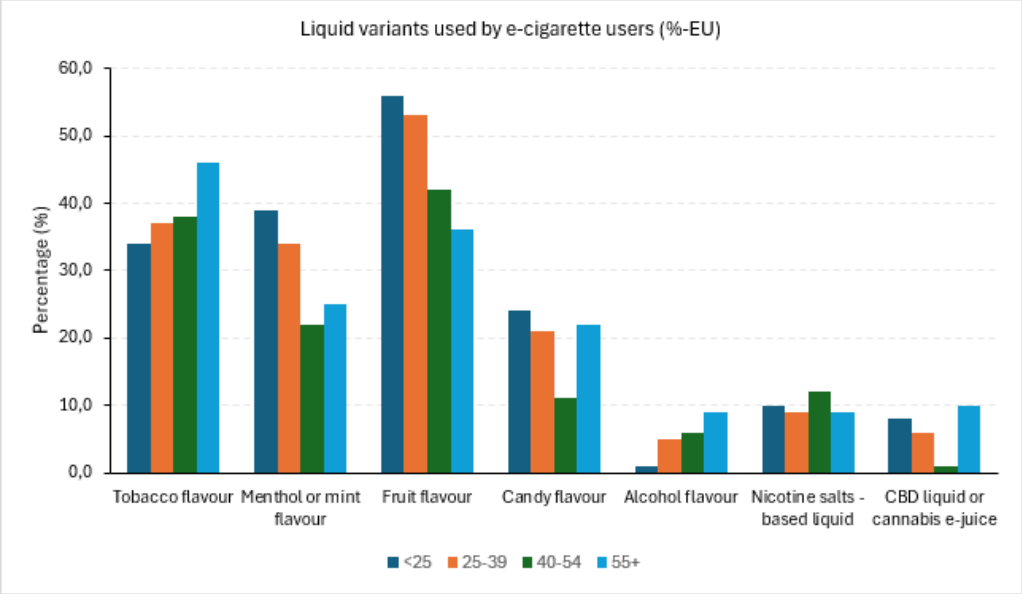


Figure 12: Liquid variants used by e-cigarette users (2023)[73]



Prevalence of nicotine pouch use

These products were largely absent from the market in 2012 but have become popular in recent years. Their prevalence was close to zero when the TPD entered into force in 2014, but nicotine pouches saw a marked increase in use by 2023, particularly among young people. These products come in a variety of flavours and packages attractive for young people, and in some cases, they contain high nicotine content[74]. As this chapter says later on, the market for nicotine pouches is

72 https://europa.eu/eurobarometer/surveys/detail/2995
73 https://europa.eu/eurobarometer/surveys/detail/2995
74 Salokannel M., Ollila, E. (2021), https://www.who.int/europe/news-room/fact-sheets/item/effects-of-tobacco-on-health.

growing rapidly. In 2023, Sweden, Denmark accounted for two thirds of total sales, followed by Austria and Czechia[75].

In 2023 4% of EU citizens had used nicotine pouches, with certain EU Member States showing even higher levels of use[76]. The highest shares of users among young people are in Sweden where 24% of respondents aged 15-24 and 13% of respondents aged 25-39 currently use nicotine pouches[77]. In 2023, individuals in their twenties reported the highest daily use of e-cigarettes and nicotine pouches among all age groups. According to national-level Eurobarometer data, consumption shares are particularly high in some EU Member States; for example, in 2024, almost 13% of 16-29-year-olds in Sweden used nicotine pouches daily[78]. Also in Sweden, the occasional use of nicotine pouches in 2023 was higher among adolescents than among the overall population[79].

Figure 13: Prevalence of nicotine pouch use in the EU (2023)[80]

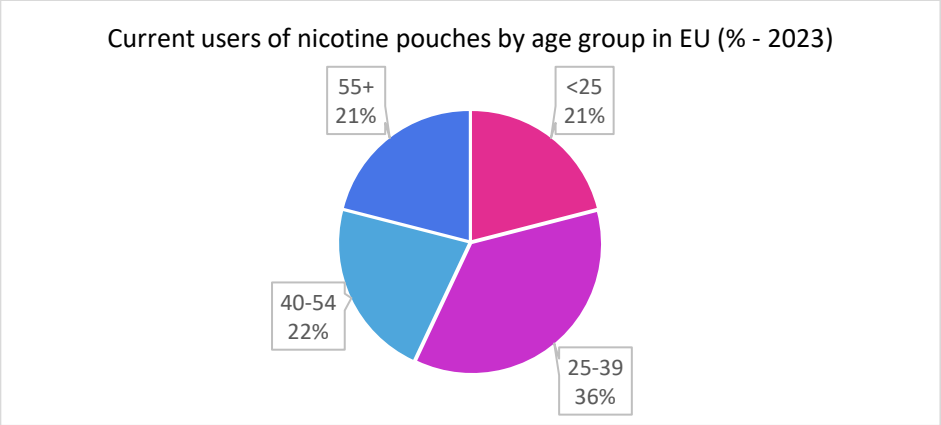
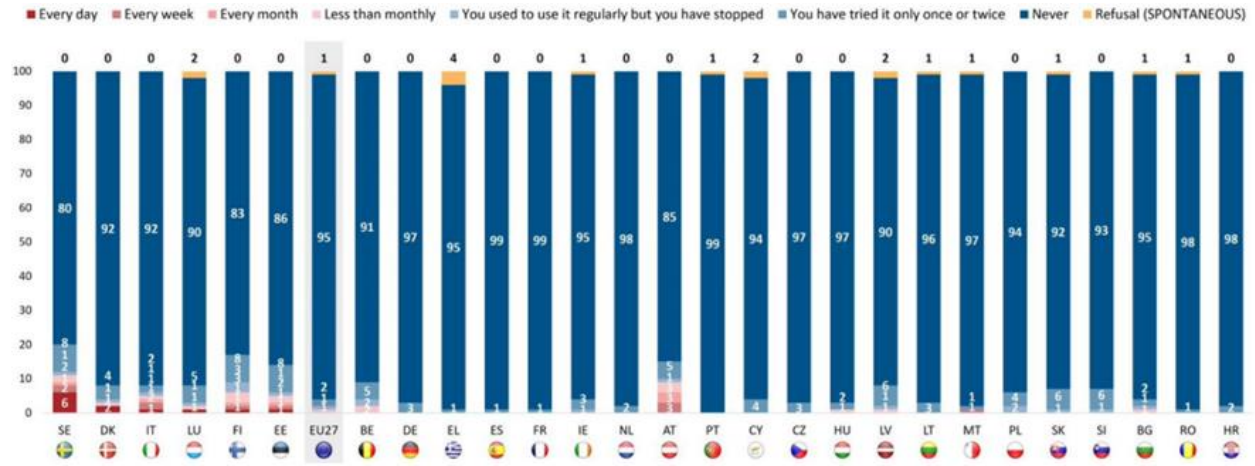
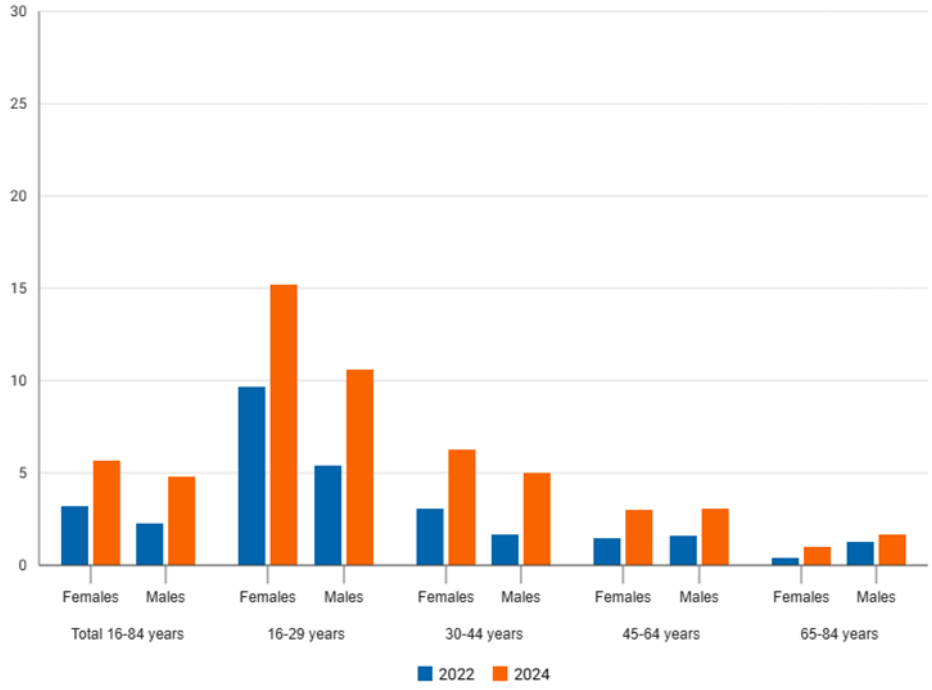


Figure 14: Prevalence of nicotine pouch use by EU Member State (2023)[81]



75 For more information please see "Table 4 Market shares by product category in retail value terms in each country of the EU-27, 2023" in Annex 3 of JRC (2025b) report.
76 Sweden, Finland, Estonia (8% all), https://europa.eu/eurobarometer/surveys/detail/2995.
77 https://europa.eu/eurobarometer/surveys/detail/2995
78 JRC (2025b).
79 Ibid.
80 https://europa.eu/eurobarometer/surveys/detail/2995
81 https://europa.eu/eurobarometer/surveys/detail/2995

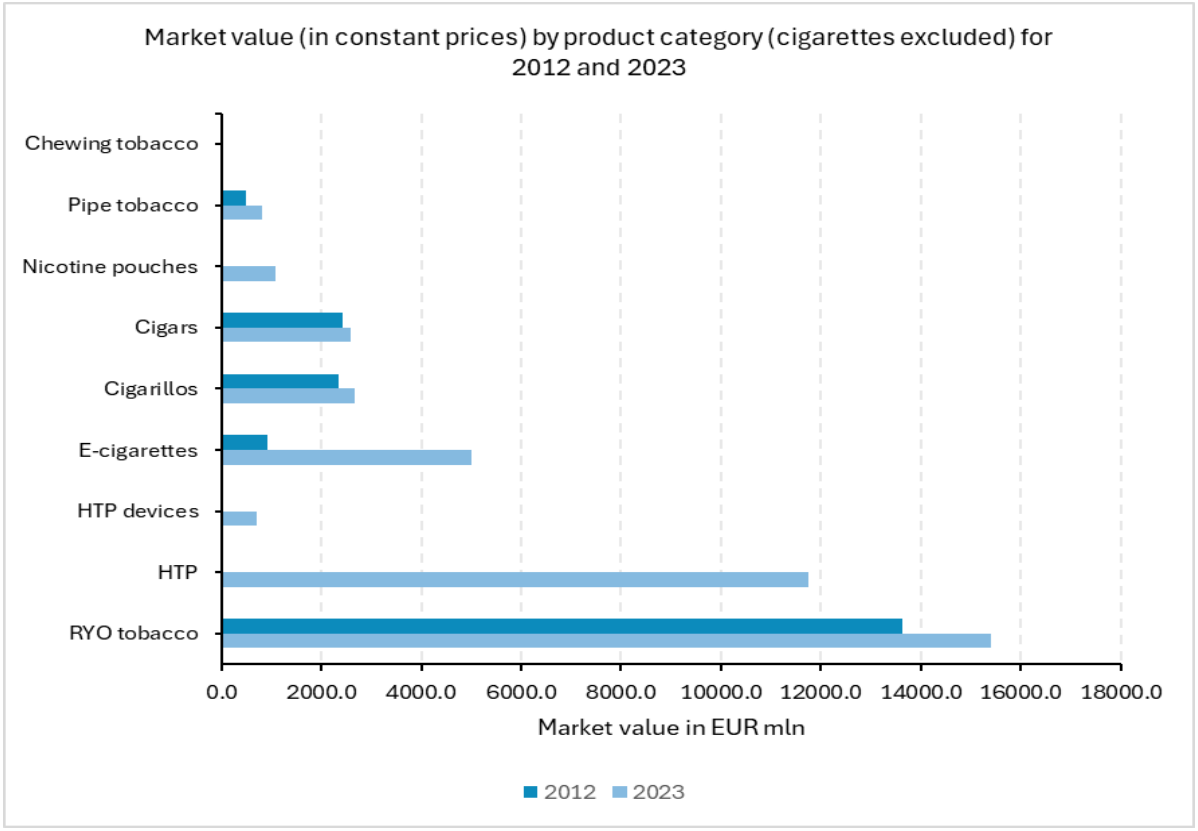
Figure 15: Prevalence of nicotine pouch use in Sweden by age group (2022-2024)[82]

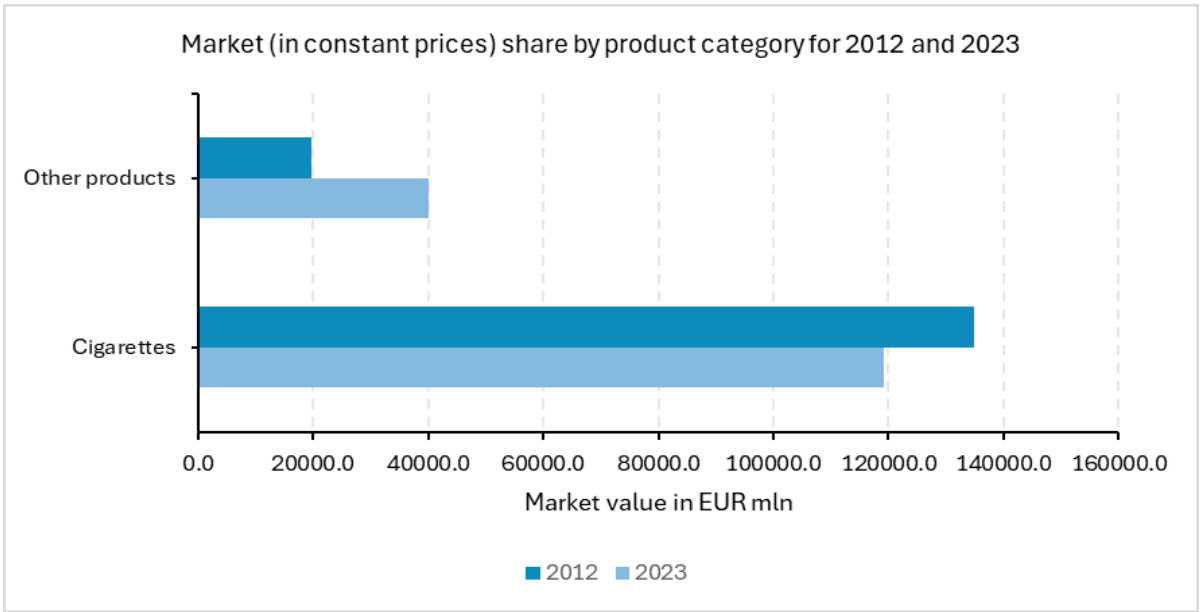


82 https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/living-conditions-and-lifestyle/andtg/tobacco/use-of-tobacco-and-nicotine-products/

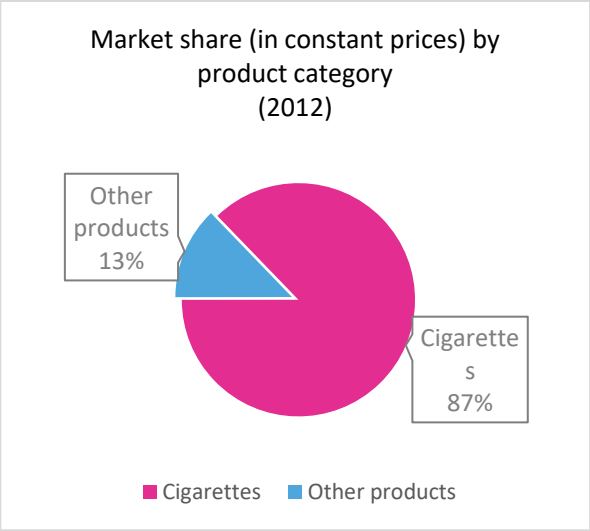
Market developments

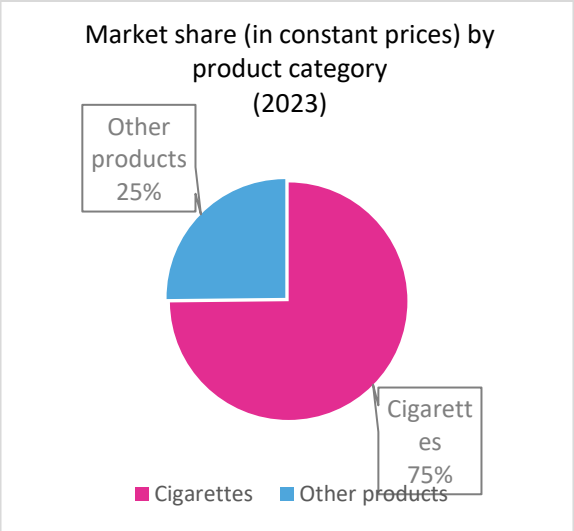
Figures 16-20: Market value and share by product category (2012 and 2023)[83]





[83] Euromonitor International Ltd, Tobacco, 2025 industry edition © All rights reserved. All data in the charts and tables on the following two pages come from the same source. HTPs are tobacco-containing consumables, while HTP devices are the non-tobacco containing devices that enable the consumption of HTPs.





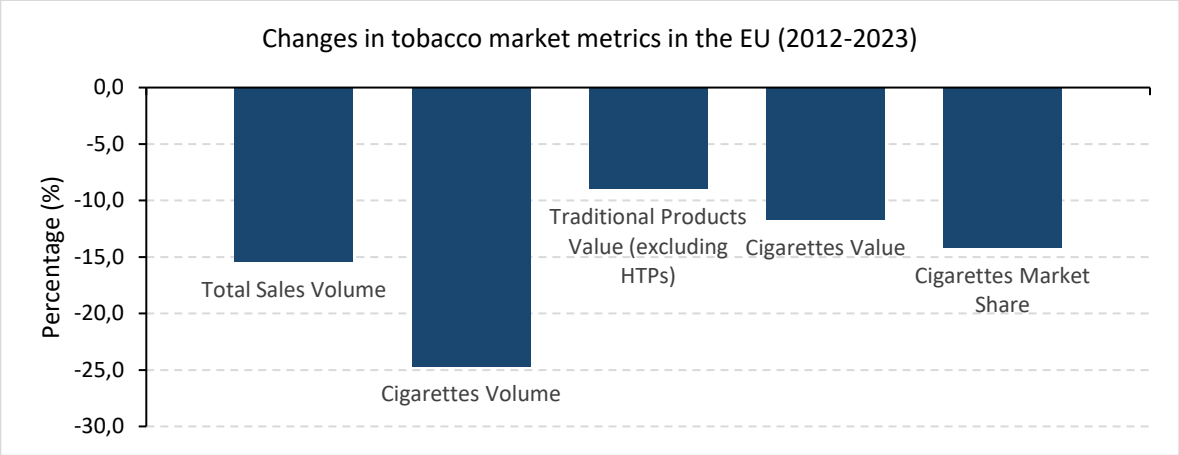


Table 1: Sales value of the EU market for traditional tobacco products[84] (2012-2023)

EU market for traditional tobacco products (excluding HTPs)	2012	2023
Sales value in EUR bln	153.87	140.75

Table 2: Sales value of the EU market for all tobacco and related products (2012-2023)

EU market for all tobacco and related products	2012[85]	2023[86]
Sales value in EUR bln	154.78	159.30

Table 3: Sales value of the EU market for HTPs including the tobacco heating devices (2012-2023)

EU market for HTPs	2012[87]	2013	2023
Sales value in EUR	0	4 mln	12.5 bln

84 Cigarettes, cigarillos, cigars, roll-your-own, pipe tobacco, chewing tobacco.

85 This figure concerns the following products that were reported to Euromonitor in 2012: cigarettes, Cigarillos, cigars, roll-your-own, pipe tobacco, chewing tobacco, and electronic cigarettes. HTPs and tobacco heating devices were not reported in Euromonitor in 2012, as they started appearing from 2013 onwards. Nicotine pouches started being reported to Euromonitor from 2018 onwards.

86 This figure concerns the following products that were reported to Euromonitor in 2023: cigarettes, cigarillos, cigars, roll-your-own, pipe tobacco, chewing tobacco, HTPs, tobacco heating devices, e-cigarettes and nicotine pouches.

87 HTPs and tobacco heating devices were not available on the EU market in 2012. They started being reported to Euromonitor from 2013 onwards.

Table 4: Sales value of the EU market for e-cigarettes (2012-2023)

EU market for e-cigarettes	2012	2023
Sales value in EUR	909 mln	4.99 bln

Table 5: Sales value of the EU market for nicotine pouches (2018-2023)

EU market for nicotine pouches	2018	2023
Sales value in EUR	60.8 mln	1.09 bln

The new landscape of tobacco and nicotine products' advertising

The implementation of EU legislation on the cross-border advertising, and sponsorship of tobacco products, e-cigarettes and refill containers in EU Member States has been good[88]. This, combined with the correct enforcement of the relevant rules across the EU, has contributed to a noticeable decline in the advertising and promotion of tobacco products and e-cigarettes on traditional media channels regulated by the TPD, the TAD, and Audiovisual Media Services Directive (AVMSD), particularly on television, radio, in the press, and in other printed publications.

A 2020 study on e-cigarette advertising in six EU Member States supports this finding, observing a decline in e-cigarettes' advertising, promotion, and sponsorship in several TPD- and AVMSD-regulated channels, especially on television and radio[89]. The same study also noted that e-cigarette advertising was rarely observed on radio, at festivals or sports events, in regular postal mail, e-mails or text messages and in pubs or bars. Another 2021 study corroborates these findings, reporting that advertisements for tobacco products and e-cigarettes in print media, and on TV, and radio were rarely noticed[90].

However, the tobacco industry constantly seeks new platforms to market its products and reach potential consumers[91]. When certain forms of advertising are prohibited, the industry redirects its efforts toward other advertising channels, using creative and indirect ways to promote its products, particularly among younger generations[92]. The digital environment poses the greatest challenge in this regard. The digital promotion of tobacco and related products has expanded globally, including within the EU. Due to the inherently cross-border nature of the internet, content created in one country can easily reach audiences in others. This applies not only to traditional tobacco products but mostly to newer products such as HTPs, e-cigarettes and nicotine pouches, all of which are increasingly marketed via digital media[93].

Adolescents and young adults aged 12 to 29 are the key target groups. Social media, in particular, plays a significant role in reaching this audience, serving as a major platform for promoting new tobacco and nicotine products that appeal to young people. Azagba and Shan (2022) highlighted that 12.9% and 8.3% of the respondents respectively were exposed to tobacco and nicotine products' advertising on social media as well as on TV and streaming services, according to data from the 2020 National Youth Tobacco Survey in the USA[94]. Similarly, according to a study examining illicit advertising on digital channels in France, 72.8% of the 1.066 identified advertisements promoted e-cigarettes' products, especially disposable and rechargeable e-

88 https://op.europa.eu/en/publication-detail/-/publication/68ce81fc-5d55-11ec-9c6c-01aa75ed71a1/language-en, *Report on the implementation of the EU Tobacco Advertising Directive*, COM(2008) 330 final.

89 Impact of the Tobacco Products Directive on self-reported exposure to e-cigarette advertising, promotion and sponsorship in smokers – findings from the EUREST-PLUS ITC Europe Surveys (2020).

90 https://op.europa.eu/en/publication-detail/-/publication/68ce81fc-5d55-11ec-9c6c-01aa75ed71a1/language-en

91 https://exposetobacco.org/wp-content/uploads/F1-Netflix-Driving-Addiction.pdf

92 Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

93 Lazuras, L. (2025), https://www.tobaccoinduceddiseases.org/Promotion-of-heated-tobacco-products-on-social-media-Findings-from-the-United-Kingdom,206315,0,2.html

94 Lazuras, L. (2025).

cigarettes. Social media was the primary advertising platform, accounting for 74.1% of advertisements, with Instagram in the lead[95].

Chu et al. (2018) analysed 3,239 user-generated posts between 2017 and 2018, from the official Twitter account of JUUL, a popular e-cigarette brand. 721 unique Twitter users had shared these posts 1,124 times, with 25% of the users identified as adolescents[96]. While most reposts occurred among adults, 9% were between adolescents, and 11% involved adults reposting adolescent content, suggesting that different age groups invariably use e-cigarette-related content. According to Link et al. (2015), 40% of waterpipe users who share social media posts on waterpipe smoking were young people (18 to 22 years). These findings highlight the role of young population groups as key target groups but also as those producing a high amount of social media posts linked to the use of tobacco and nicotine products.

Streaming services, online or "multiplayer" video games and music videos are also used for digital promotion of tobacco and related products. Tobacco use imagery is present in video games and cartoons, which are particularly appealing to younger populations, such as adolescents. Whereas most of the promotion is driven by industry, some of it is user-generated content with no explicit link to commercial interests[97].

Digital promotion has been identified as a widespread approach that exposes consumers to advertisement for tobacco and nicotine products with more intensity and frequency compared to traditional media outlets[98]. It is highly probable that a significant proportion of online purchases of e-cigarettes and HTPs in Europe are made by younger individuals[99]. Official data from Eurostat confirm a steady increase in the number of individuals engaging in online shopping, as the percentage of online buyers in the EU has steadily increased from 55% in 2012 to 75% in 2022, and further to 77% in 2024, reflecting a sustained upward trend in e-commerce [100]. Public health NGOs have identified social media as a challenge due to its use in promoting and advertising tobacco and nicotine products, and they noted the portrayal of some of these products as cessation devices[101].

Tobacco advertising, promotion, and sponsorship activities (TAPS) involve both commercially driven and non-commercial, user-generated content to facilitate the digital promotion of tobacco and nicotine products. More specifically, digital promotion of tobacco and nicotine products includes the use of social media influencers, user-generated content, and various commercially driven activities. Social media influencers are used to promote a range of tobacco and nicotine products across digital media platforms that are particularly appealing to young people. TAPS contribute to the growing prevalence of use of new products like HTPs, e-cigarettes and nicotine pouches among young people. Additionally, TAPS related to novel tobacco and nicotine products may have a trans-contextual effect and be associated with decisions concerning traditional tobacco products. More precisely, exposure to nicotine products could potentially lead to the initiation of tobacco product use[102]. The WHO acknowledges that contemporary entertainment media, such as

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95 https://www.tobaccoinduceddiseases.org/New-nicotine-products-A-major-illicit-advertising-phenomenon-on-digital-channels,206207,0,2.html

96 Lazuras, L. (2025).

97 Lazuras, L. (2025).

98 Ibid.

99 Vardavas C., *Report on the assessment of the causes, drivers and level of cross-border distance sales in the EU*, 2025 ('Vardavas (2025a)').

100 Ibid.

101 Annex 5: Synopsis report of the different consultation activities.

102 Lazuras (2025).

films and streaming services, music videos, online videos, social media mobile applications, and video games, incorporate tobacco and nicotine imagery in a manner that increases the risk of initiating tobacco use, particularly among young people[103].

Exposure to digital promotions of tobacco and nicotine products is linked to changes in beliefs, such as attitudes, perceived harm and health risks, addictiveness of these products, and social norms. For instance, digital promotions of tobacco and nicotine products often include themes that are designed to appeal to young audiences, such as flavoring cues, cartoons and cartoon-like characters, video and online mobile games, luxury fashion, and other elements that align with young people's lifestyle trends[104].

According to a study on the behavioural effects of engaging with digital marketing in US adolescents, engagement with the digital marketing of tobacco and nicotine products was associated with notable behavioural differences[105]. Among those who engaged with such content, 19.5% reported starting use tobacco and nicotine products, 10.3% reported using them more often, and 5.8% reported using multiple tobacco and nicotine products. In contrast, among those who did not engage with digital marketing, the figures were significantly lower: 11.5% for initiation, 4.4% for increased frequency, and 2.4% for multiple product use. These findings are corroborated by a recent systematic review[106] reporting an odds ratio of more than 2 for reporting lifetime "tobacco use" (covering e-cigarettes, cigarettes, and other (cigars, hookahs, smokeless tobacco)) in people exposed to "tobacco content" on social media, compared with those who were not exposed.

Eliminating exposure to digital promotions of tobacco and nicotine products could result in a 1.5% reduction in the number of people who start using nicotine products, a 7.6% decrease in frequent use of tobacco and nicotine products, a 4.4% reduction in the use of multiple nicotine products, and a 4.8% increase in quitting behaviour[107].

The above evidence suggests that 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, particularly among young people. This, combined with challenges in effectively enforcing the advertising ban for tobacco, e-cigarettes, and refill containers in the digital environment[108] most notably the covert nature of such advertising and the difficulty of identifying and targeting those responsible, especially when they are based in non-EU countries[109] - creates significant public health concerns.

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103 https://fctc.who.int/resources/publications/m/item/tobacco-advertising-promotion-and-sponsorship

104 Lazuras, L. (2025).

105 Ibid.

106 Donaldson, S.I. et al. (2022).

107 Lazuras, L. (2025), Donaldson, S.I. et al. (2022).

108 Example of criminal proceedings related to tobacco advertising and promotion in digital media: Philip Morris France SAS v. National Committee |Tobacco Control Laws

109 See Chapter 4.2 of *Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee on the implementation of the Tobacco Advertising Directive* (2003/33/EC), COM (2008) 330 final.

Health risks associated with novel products

The health risks of novel products are becoming evident, although long-term impacts remain uncertain because these products are relatively new and there has not been enough time to fully assess their long-term impact[110]**.**

E-cigarettes: There is enough evidence to show that e-cigarettes are related to adverse outcomes, mainly linked to the cardiovascular and respiratory systems, and may have some tumorigenic and pregnancy impacts. In particular, evidence from several scientific reports[111] indicates that users of e-cigarettes may experience immediate, short- and medium-term health effects, affecting the cardiovascular system. Nicotine impairs endothelial function through oxidative stress, nitric oxide (NO) depletion, and inflammatory signalling, narrows blood vessels and increases blood pressure[112]. Evidence from scientific reports also associates e-cigarettes with respiratory diseases. E-cigarette users inhale a combination of nicotine, metals, and other substances, some of may be toxic[113].

Scientific reports show that some of the substances e-cigarettes generate are known to cause cancer and, on their own, e-cigarettes are associated with increased risk of lung disorders, poisoning, injuries, burns and immediate nicotine toxicity through inhalation[114]. There is also evidence that chemicals present in e-cigarette aerosols can cause DNA damage and mutagenesis, which supports the biological plausibility that long-term exposure to e-cigarette aerosols could increase risk of adverse reproductive outcomes. E-cigarettes contain nicotine. Nicotine from e-cigarettes is absorbed in a similar way to regular tobacco smoking, with comparable levels of intake[115]. The high addictive potential of nicotine ensures repeated, long-term exposure. Adolescents are especially vulnerable to its neurobiological effects, increasing the risk of lifelong use[116]. Nicotine's negative effect on brain development in children and young people is particularly concerning[117]. In pregnant women, nicotine from e-cigarettes can have similar consequences for the brain development of the foetus[118] as well as other adverse pregnancy outcomes[119].

According to scientific reports e-liquids contain high concentrations of nicotine, and their ingestion can cause acute toxicity and even death. Flavours play a central role in attracting children to e-cigarettes and may increase the likelihood of acute poisoning.

E-cigarettes and HTPs are sometimes marketed as effective for helping people to quit smoking. However, their effectiveness in this regard is highly questionable; the WHO explicitly states that e-cigarettes have not proven effective for smoking cessation[120]. Moreover, the large majority of respondents to the Eurobarometer survey 2023 do not think that e-cigarettes or HTPs can help

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110 JRC (2025a). Unless stated otherwise, the information in this section is taken from this report, as well as the sources indicated therein. In some cases, explicit reference to these sources is made in the document. Forthcoming - expected publication in April 2026.

111 These scientific reports, along with other studies referenced in this section, are cited in the JRC report or in SCHEER 2021 Opinion on electronic cigarettes (regarding the health impact of nicotine-containing e-cigarettes).

112 Munzel (2020), Heiss (2008).

113 https://jaotc.eu/wp-content/uploads/2023/11/M.7.6-Product-classification-based-on-ingredients-emissions-and-product-properties-completed.pdf

114 https://www.who.int/europe/news-room/fact-sheets/item/effects-of-tobacco-on-health

115 Barrington-Trimis, J. L. and Levanthal A. M. (2018).

116 Ibid.

117 Nicotine use among children and young people – Consequences and prevention.

118 https://www.who.int/europe/news-room/fact-sheets/item/effects-of-tobacco-on-health

119 https://www.ncbi.nlm.nih.gov/books/NBK507160/

120 https://www.who.int/news-room/questions-and-answers/item/tobacco-e-cigarettes

smokers to quit traditional tobacco products[121]. Regarding e-cigarettes, only 21% of respondents in the Eurobarometer 2023 survey reported quitting smoking tobacco entirely after switching to e-cigarettes[122]. Available evidence on the evolution of nicotine product use and its association with quitting tobacco smoking, concluded that the dual use of tobacco and e-cigarettes is not linked to efforts to quit tobacco consumption[123]. Dual use, which is common, is at least as dangerous and likely more dangerous than smoking conventional cigarettes or using e-cigarettes alone[124].

In contrast, scientific reports provide evidence that using e-cigarettes increases the likelihood of cigarette smoking, particularly among young people and young adults[125]. One report indicates that e-cigarette use increases the likelihood of starting smoking by about three times, while the WHO indicates that children who use or even try ENDS, are more than twice as likely to smoke cigarettes. E-cigarettes may therefore serve as an initiation into nicotine addiction and smoking/traditional tobacco use, particularly among young people[126]. The 'gateway effect' of e-cigarettes, whereby they end up being a precursor to cigarette smoking, was also the primary concern of the respondents during the call for evidence[127].

Heated Tobacco Products (HTPs): Reports have linked HTPs use to cardiovascular and respiratory diseases, and to pregnancy, reproduction and brain development risks, all potential detrimental effects of nicotine from HTPs. HTPs emit several potentially harmful substances during normal use, and the presence of chemicals with unknown health effects also raises concerns. As these products have been introduced recently into the tobacco market, scientific evidence on their toxicity and long-term health effects is still developing, and the risk of cancer is still largely unknown. However, studies show that carcinogenic substances enter the body when using HTPs[128]. A WHO report suggests that HTPs have similar or greater cardiovascular toxicity when compared to conventional cigarettes[129]. The same report indicates a higher risk of respiratory, cardiovascular and potentially other diseases in non-smokers who use HTPs. No improvement seems to exist for several pulmonary indicators among smokers who have switched to HTPs[130]. Overall, there is insufficient evidence to suggest that HTPs are less harmful than conventional cigarettes[131].

HTPs may expose users to lower levels of some toxicants present in cigarettes, but expose them to higher levels of other toxicants[132]. A lower level of some toxicants does not necessarily mean a lower health risk. According to the WHO, some smokers may switch to HTPs to reduce harmful exposure without quitting traditional tobacco use[133]. However, the data show no improvement in several pulmonary and cardiovascular indicators for smokers who switched to HTPs and a high

121 https://europa.eu/eurobarometer/surveys/detail/2995
122 https://europa.eu/eurobarometer/surveys/detail/2995
123 https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(25)00144-9/fulltext
124 https://www.who.int/europe/news-room/fact-sheets/item/effects-of-tobacco-on-health
125 JRC (2025a), SCHEER 2021 Opinion on electronic cigarettes.
126 JRC (2025a), SCHEER 2021 Opinion on electronic cigarettes, See also recital 43 of the TPD.
127 Evaluation of the tobacco control framework.
128 https://www.dkfz.de/fileadmin/user_upload/Krebspraevention/Download/pdf/Buecher_und_Berichte/2023_Risiken-von-E-Zigaretten-und-Tabakerhitzern.pdf
129 https://www.who.int/publications/i/item/9789240022720
130 Ibid.
131 https://www.who.int/docs/librariesprovider2/default-document-library/4-facts-about-heated-tobacco-products.pdf?sfvrsn=32aced54_1,https://www.who.int/publications/i/item/9789240022720, https://iris.who.int/server/api/core/bitstreams/8372fe0f-2bf7-4272-bb42-9e1428db9ac4/content, https://www.health.govt.nz/system/files/2024-08/Briefings%20and%20aides%20m%C3%A9moire%20heated%20tobacco%20products%20BLACK%20BOX%20watermarked_0.pdf
132 https://www.who.int/publications/i/item/9789240022720
133 https://www.who.int/publications/i/item/9789240022720

prevalence of dual use (with smoking)[134]. HTPs contain and deliver nicotine. As a result, all harmful effects of nicotine that were described in the previous section for e-cigarettes, also apply to HTPs. According to evidence from scientific reports, the absorption of nicotine from their aerosol is comparable to that of cigarettes, suggesting a similar addiction potential[135].

There is insufficient evidence to support claims of HTPs being effective for harm reduction or smoking cessation[136]. Scientific studies find no evidence that HTPs are effective in helping people transition to becoming completely smoke free. In the Eurobarometer survey 2023, a majority of those who said that they smoke or used to smoke tobacco but also use, used or tried HTPs, say HTPs help them to reduce but not necessarily stop their tobacco consumption[137]. To date, there is no conclusive evidence on their usefulness in helping people to transition away from conventional combustible cigarette smoking or other tobacco use, nor on their effectiveness for such a purpose.

Nicotine pouches: Evidence from scientific reports mentions cardiovascular and respiratory impacts from nicotine pouches' consumption. Individuals with cardiovascular diseases are regarded as high-risk if they use nicotine pouches. This is due to the strong effect of nicotine on the cardiovascular system. Nicotine pouches are available in different nicotine levels, and higher doses have been shown to elevate heart rate and systolic blood pressure, particularly in persons who have never used tobacco before[138]. Although nicotine pouches contain fewer toxicants and expose users to fewer harmful constituents than traditional tobacco products, evidence from a WHO (2023) report indicates that nicotine pouches deliver sufficient nicotine to induce and sustain nicotine addiction[139]. This, in turn, increases the likelihood of transitioning to other nicotine or tobacco products, including conventional cigarettes. All harmful effects of nicotine on human health that were described for e-cigarettes and heated tobacco products, including the negative development and reproductive impact, also apply to nicotine pouches.

Synthetic nicotine may include R-nicotine, whose pharmacological and metabolic effects remain largely unknown. Nicotine derived from tobacco can be contaminated with tobacco-specific nitrosamines – known carcinogens – posing further potential health risks[140].

Nicotine pouches are not proven tools for smoking cessation, and it is unknown how their availability will affect overall smoking cessation rates[141]. Additionally, nicotine pouches may cause inflammation in the mouth, giving rise to concerns about long-term oral health impacts[142]. Pregnant and breastfeeding women are considered high-risk due to the effects of nicotine on health during pregnancy. Given that nicotine pouches are relatively new to the market, there has not yet been sufficient time to fully assess their long-term health impacts.

Electronic Non-Nicotine Delivery Systems (ENNDS): The use of ENNDS is not negligible: while 55% of current e-cigarettes users consume nicotine-containing products daily, 14% use nicotine-

134 Ibid.
135 https://iris.who.int/server/api/core/bitstreams/8372fe0f-2bf7-4272-bb42-9e1428db9ac4/content
136 https://www.health.govt.nz/system/files/2024-08/Briefings and aides m%C3%A9moire heated tobacco products BLACK BOX watermarked_0.pdf.
137 https://europa.eu/eurobarometer/surveys/detail/2995
138 https://www.who.int/europe/news-room/fact-sheets/item/effects-of-tobacco-on-health
139 http://files/41/WHO study group on tobacco product regulation report on the scientific basis of tobacco product reg.pdf
140 https://www.who.int/europe/news-room/fact-sheets/item/effects-of-tobacco-on-health
141 WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: ninth report of a WHO study group (2023).
142 https://www.gu.se/en/news/long-term-inflammation-raises-questions-about-white-snus

free e-cigarettes[143]. These products are not harmless although the consequences for long-term effects on morbidity and mortality have not yet been sufficiently studied. Current evidence shows that the aerosol users breathe from ENNDS contain numerous potentially toxic substances. The number, quantity and characteristics of potentially toxic substances in the aerosol emitted by ENNDS are highly variable and depend on product characteristics and how the device is operated by the user[144]. The main substances in the aerosol that raise health concerns are metals, such as antimony, chromium, lead, nickel, glycidol and carbonyls, such as acetaldehyde, acrolein, formaldehyde and glyoxal. Exposure to certain levels of some metals may have serious health effects, such as diseases of the nervous, cardiovascular and respiratory systems. Moreover, ENNDS may contain formaldehyde, which is a human carcinogen (Group 1); acrolein and glycidol, which are probably carcinogenic to humans (Group 2A) acetaldehyde which is possibly carcinogenic to humans (Group 2B); and glyoxal which is harmful if inhaled and suspected of causing genetic defects[145]. Certain flavourings, such as diacetyl, cinnamaldehyde and benzaldehyde, have been cited as a source of health concerns when heated and inhaled. ENNDS aerosol can cause some human cells to malfunction although it is not clear what this means in terms of the long-term consequences of chronic use of ENNDS, but it is possible that it could increase the risk of some diseases, such as cardiovascular disease, cancer and adverse reproductive outcomes. However, the risk is probably lower than from combustible tobacco cigarette smoke. There is moderate evidence that young never-smokers who experiment with ENDS and ENNDS are at least twice more likely to experiment with smoking later. Flavours also seem to play a part in promoting the switch from combustible tobacco products to ENDS and ENNDS. They also play an important role in increasing uptake of ENDS and ENNDS among young people noticeably more significantly than among adults.

4. EVALUATION FINDINGS

4.1. To what extent was the intervention successful and why?

The evaluation matrix in Annex 3 presents the answers to the evaluation questions, organised by evaluation criterion.

The tobacco control framework's success is based on its comprehensive and multifaceted approach, which includes the following measures:

- Obligations for tobacco manufacturers and importers relating to the **reporting of information on tobacco products, including their ingredients** to national competent authorities (Article 5 of the TPD) alongside the creation of the **EU-CEG** (Commission Implementing Decisions (EU) 2015/2183 and 2015/2186).
- The regulation of tobacco products' ingredients, including a **prohibition of placing on the market of cigarettes, RYO tobacco and HTPs with a characterising flavour** (Article 7 of the TPD).
- The introduction of common labelling and packaging requirements for tobacco products, including **combined health warnings for tobacco products for smoking, and traceability and security features for all tobacco products** (Article 8-16 of the TPD).

[143] Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

[144] https://iris.who.int/server/api/core/bitstreams/ae5bfd99-3a25-4fc3-ac12-7f2e24c60ac5/content. The information in this paragraph comes from this WHO report.

[145] https://chem.echa.europa.eu/100.003.160/overview?searchText=glyoxal

- The establishment of the **EU-wide tobacco-traceability system** (Article 15 of the TPD, Commission Implementing Regulation (EU) 2018/574, Commission Delegated Regulation (EU) 2018/573).
- The possibility for EU Member States to **prohibit the cross-border distance sales of tobacco products and e-cigarettes** as well as the obligation of EU Member States to cooperate in order to prevent such sales (Article 18 of the TPD).
- Notification requirements for **novel tobacco products** (Article 19 of the TPD).
- The **regulation of certain aspects related to e-cigarettes and refill containers**, including notification, safety, labelling and packaging requirements, as well as ingredients', advertising and sponsorship restrictions (Article 20 of the TPD).
- The **regulation of certain aspects for herbal products for smoking**, specifically the required health warning, product presentation, and ingredients' reporting (Articles 21-22 of the TPD).
- Rules on **cooperation and enforcement** (Article 23 of the TPD).
- Restrictions on the **tobacco products' advertisement and sponsorship** (Article 3-5 of the TAD).

4.1.1. Facilitating the smooth functioning of the internal market

Both the TPD and the TAD are internal market instruments, as they were adopted on the basis of Article 114 of the TFEU. The Court of Justice has ruled that "when there are obstacles to trade, or it is likely that such obstacles will emerge in the future, because the EU Member States have taken, or are about to take, divergent measures with respect to a product or a class of products such as to bring about different levels of protection and thereby prevent the product or products concerned from moving freely within the European Union, Article 114 TFEU authorises the EU legislature to intervene by adopting appropriate measures, in compliance with Article 114(3) TFEU and with the legal principles mentioned in the FEU Treaty or identified in the case-law, in particular the principle of proportionality"[146].

Before the EU tobacco control framework was adopted, the absence of a harmonised approach to various aspects of tobacco and related products adversely affected the smooth functioning of the internal market and hindered the free movement of goods within the Union. The EU legislature has acknowledged that disparities between national rules concerning, inter alia, the reporting of ingredients and emissions, the traceability of tobacco products, the regulation of ingredients (including characterising flavours), the labelling of tobacco products, the advertising and sponsorship of tobacco products, e-cigarettes and refill containers, the regulation of novel tobacco products, e-cigarettes and refill containers, and herbal products for smoking were barriers to trade and that they have impeded the smooth functioning of the internal market[147]. The legislature has also acknowledged that, in the absence of harmonisation, such obstacles would increase over time.

The harmonisation achieved thanks to the tobacco control framework has improved the functioning of the internal market and removed barriers to trade[148]. In particular, the establishment of uniform rules on: the reporting of information concerning tobacco products; the regulation of ingredients;

[146] Judgment of 4 May 2016, Philip Morris Brands and Others, C-547/14, EU:C:2016:325, paragraph 62. The cases brought before the EU courts concerning the EU tobacco control framework, including those that are relevant to its evaluation and possible update, are described in Annex 3.

[147] Recitals 4, 5, 14, 15, 16, 22, 23, 24, 35, 43 and 49 of the TPD and recitals 1 and 2 of the TAD.

[148] Results of the study supporting the evaluation of EU law on tobacco control, conducted by Open Evidence, 2025.

labelling and packaging requirements; the traceability and security features of tobacco products; the regulation of novel tobacco products, e-cigarettes and refill containers, and herbal products for smoking; the cross-border advertising and sponsorship of tobacco products, e-cigarettes and refill containers; and cooperation on and enforcement of tobacco control rules, have contributed significantly to the smooth functioning of the internal market and enhanced the effectiveness of the tobacco control framework[149].

This assessment was acknowledged by most stakeholder groups participating in the public consultation, with the exception of citizens[150]. In particular, stakeholders considered the harmonisation achieved thanks to the tobacco control framework to be necessary for the proper functioning of the internal market[151].

In this regard, the Court of Justice has held that eliminating existing divergences between national rules, such as those relating to the composition of tobacco products, or preventing those rules from developing in divergent ways, including by means of an EU-wide prohibition, is capable of facilitating the smooth functioning of the internal market[152].

Despite the significant differences in price levels for tobacco products, particularly cigarettes, among EU Member States, the TTD has also contributed, to a certain extent, to the smooth functioning of the internal market. It has done so by introducing rules on EU minimum excise rates, which contributed to mitigating the gap between "high-tax" and "low-tax" EU Member States[153]. The Directive's provisions on minimum excise rates have been moderately effective in raising tax rates and prices in EU Member States, especially in the case of cigarettes and fine-cut tobacco, with particularly noticeable effects in the low-price segment of the market[154].

Today, however, new internal market challenges have emerged as regulatory divergences between EU Member States continue to arise. As described later in this section, EU Member States have adopted divergent rules concerning, inter alia, the regulation of flavours in e-cigarettes, plain packaging requirements, the prohibition of disposable e-cigarettes, tobacco heating devices, nicotine products other than e-cigarettes, and ENNDS. These divergences create obstacles to the free movement of goods and distort competition, as economic operators are subject to different regulatory requirements depending on the EU Member State in which their products are placed on the market. Such divergences result in unequal conditions for the marketing of the relevant products across EU Member States and run counter to the objective of the tobacco control framework, namely the improvement of the functioning of the internal market for tobacco and related products, taking as a base a high level of human health protection, especially for young people. These challenges are further exacerbated by the size of the internal market for tobacco and related products and by the existence of cross-border trade in such products within the EU.

4.1.2. Ensuring a high level of human health protection, especially for young people

Between 2012 and 2023, the total sales volume of tobacco products in the EU declined by 15.45%[155] with the volume of cigarette sales dropping by 24.7% in the same period. The sales value

149 Ibid.
150 Evaluation of the legislative framework for tobacco control.
151 Ibid.
152 Judgment of 4 May 2016, Philip Morris Brands and Others, C-547/14, EU:C:2016:325, paragraphs 125 and 172.
153 https://taxation-customs.ec.europa.eu/system/files/2020-02/10-02-2020-tobacco-taxation-report.pdf
154 Ibid.
155 From 648 274 million sticks to 548 114 million sticks. Source; Euromonitor International Ltd, Tobacco, 2025 industry edition © All rights reserved. The information presented in this paragraph is from the same source.

of the EU market for traditional tobacco products, excluding HTPs, also decreased by approximately 9%, with cigarettes' market value declined by 11.7%. Cigarettes' share of the total EU tobacco and related products market value also fell by about 12.5 percentage points. At the same time, the prevalence of smoking among citizens also decreased from 28% in 2012 to 24% in 2023[156], with a more pronounced reduction among young people aged 15-24, from 29% to 22%[157]. Similarly, the share of daily smokers of traditional tobacco products decreased in the EU between 2014 and 2023 for the overall population over 15 years old (from 25% to 21%). The decrease was even larger among young people aged 15-29 (from 27% to 20%)[158].

The implementation of the tobacco control framework which introduced stricter rules on the manufacture, presentation, advertising and sale of tobacco products contributed to these developments. Although the precise extent to which these effects can be attributed to the framework cannot be fully quantified, evidence from the literature on specific measures of the framework demonstrates its positive impact on health protection. Studies indicate that for example, tobacco advertising and sponsorship bans, such as those introduced by the TAD and the AVMSD, influence smoking behaviour by reducing exposure to marketing cues that encourage people to buy tobacco, thereby contributing to lower smoking prevalence. As explained previously in the report, the advertising bans have contributed to a noticeable decline in the advertising and promotion of tobacco products on television, radio, in the press, and in other printed publications[159]. Such bans are associated with a 20% lower likelihood of smoking and a 37% reduced risk of smoking initiation[160]. Moreover, it is estimated that, independent of other tobacco control interventions, advertising and sponsorship bans reduce tobacco consumption by up to 7%[161]. The TAD was regarded by EU Member States as highly effective in banning tobacco product advertising in the press, non-professional printed publications, and radio programmes[162].

Similarly, evidence on the increased graphic health warnings introduced at national level through the transposition of the TPD - the so-called 'combined health warnings' - indicates that these measures reduce the attractiveness of smoking, particularly among young people, and contribute to declines in smoking prevalence[163]. The literature also shows that health warnings on e-cigarettes may motivate users to quit e-cigarettes use and discourage smoking, with available evidence not supporting the hypothesis that e-cigarette warnings could encourage cigarette smoking[164]. With regard to another measure of the framework, the prohibition of the placing on the market of cigarettes and roll-your-own tobacco with characterising flavours, evidence suggests that this measure also directly affected smokers across the EU, with some of them expected to have quit smoking because of the ban[165].

In tandem with these measures, tobacco taxation initiatives such as the minimum rates established by the Tobacco Taxation Directive and other fiscal measures adopted by EU Member States, have also contributed to the reduction of smoking prevalence, to a certain extent. In particular, evidence

156 Prevalence rates reported by Eurostat as a sustainable development goal indicator (data code sdg_03_30), drawing on Eurobarometers as the primary source. The 4 percent point drop between 2012 and 2023 is in line with the decline (5.1 percent point) that can be derived from the WHO Health or All database (using linear interpolation to address misisng data), with an overall high correlation (98%) between both data-sets on EU smoking in 15+ yo

157 https://europa.eu/eurobarometer/surveys/detail/1060, https://europa.eu/eurobarometer/surveys/detail/2995

158 JRC (2025b).

159 See in Chapter 3, 'Advertisements of tobacco and nicotine products'.

160 Saad C., Cheng B. (2024).

161 Ibid.

162 Annex 5: Synopsis report of the different consultation activities.

163 El-Khoury Lesueur F., Bolze C. (2018).

164 Ibid.

165 Zatoński M., Herbeć A. (2018).

from the evaluation of the TTD indicates that EU minimum rates have supported public health-related outcomes, especially in EU Member States in Eastern Europe[166]. Approximately 40% of the smoking prevalence decline in the EU can be attributed to the impact of taxation policies[167]. The effectiveness of taxing addictive substances in changing behaviour and improving public health is widely recognised, including by the WHO[168].

Evidence on the determinants of cigarette consumption at national level confirms that such measures of the TPD, TAD and TTD (e.g. advertising bans, health warnings, characterising flavours bans, taxation) alongside national policies concerning smoke-free environments, sales arrangements, age-limits for product sales, plain-packaging and support services and programmes for smoking cessation impact the decrease[169].

In short, since 2012 fewer traditional tobacco products - especially cigarettes - have been available on the market, fewer have been sold and fewer people, especially young people, are smoking compared with 2012. This progress has also helped save lives: tobacco-related mortality in the EU fell from approximately 700 000 deaths in 2012 (or around 580 000 deaths adjusted to current EU-27) to about 530 000 in 2023[170], a reduction by 8.6%. This decline represents tangible public health gains[171]. Therefore, the tobacco control framework has contributed, to some extent, to ensuring a high level of human health protection, especially for young people with regard to traditional tobacco products. During targeted interviews concerning the effectiveness of the tobacco control framework, both EU Member States and economic operators recognised that the tobacco control framework has successfully achieved its objectives[172].

The tobacco-control framework has also fulfilled the EU's obligations under the WHO Framework Convention on Tobacco Control (FCTC) and its Protocol to Eliminate Illicit Trade in Tobacco Products by establishing provisions that are aligned with these instruments (see section on coherence with the FCTC)[173].

Other factors affecting consumer behaviour

Reasons preventing smoking initiation

To determine the factors preventing smoking initiation, it is first necessary to understand the factors that influence initiation. The literature indicates that factors influencing smoking initiation include limited knowledge of the harmful health effects of smoking, exposure to tobacco advertising,

166 https://taxation-customs.ec.europa.eu/system/files/2020-02/10-02-2020-tobacco-taxation-report.pdf

167 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

168 https://www.who.int/activities/raising-taxes-on-tobacco

169 See relevant data for Nordic and Baltic countries: https://nordicwelfare.org/wp-content/uploads/2025/03/Use-of-nicotine-products-among-youth-in-the-Nordic-and-Baltic-countries-An-overview.pdf

170 IHME Global Burden of Disease Results Tool

171 There is evidence that health benefits begin to appear relatively soon after people quit smoking. A decline in the prevalence of smoking - even in the short to medium term - can therefore lead to measurable public health gains within a few years. According to the WHO: a year after quitting, the risk of coronary heart disease is about half that of a smoker; between 5 and 15 years after quitting, the risk of a stroke is reduced to that of a non-smoker; 10 years after quitting, the lung cancer death rate is about half the rate of a smoker, and the risk of cancer of the mouth, throat, oesophagus, bladder, kidney and pancreas decreases; and 15 years after quitting, the risk of coronary heart disease is that of a person who never smoked, https://www.who.int/europe/news-room/fact-sheets/item/effects-of-tobacco-on-health

172 Annex 5: Synopsis report of the different consultation activities.

173 WHO, *Two decades of the implementation of the WHO Framework Convention on Tobacco Control in the European Union: progress, challenges and the road ahead*, 2025, https://www.who.int/europe/publications/i/item/WHO-EURO-2025-12743-52517-81148

broader cultural environments that shape attitudes and behaviours including the behaviour of friends and family members, and the normalisation of smoking within social settings[174]. Conversely, factors that could prevent smoking initiation include adequate knowledge and awareness of the health risks of tobacco use, strong anti-smoking norms within families, non-smoking behaviour of friends as well as strict tobacco control policies including advertising bans.

Reasons for quitting smoking

Although high levels of implementation of tobacco control policies, such as those included in the TPD and TAD, tobacco taxation and smoke-free environment policies are associated with lower smoking prevalence and higher smoking cessation ratios in the EU[175], other factors may also play an important role in determining quit success. According to literature, other reasons reported as important for quitting smoking include the perceived harm of smoking to one's own health or to others, the desire to set a good example for children, having a smoking-related illness, and the price of cigarettes[176]. Other factors, such as advice from healthcare professionals and disapproval from friends and family, were also considered as somewhat important reasons for quitting smoking[177]. Socioeconomic factors further influence cessation outcomes. Higher levels of education and household income are associated with successful quitting, whereas lower socioeconomic status is associated with lower likelihood of a successful cessation attempt[178].

Figure 21: Key factors that affect smoking initiation and quitting smoking



174 Lakshmi R., Romate J. (2023).
175 Girvalaki C., Filippidis F. (2020), 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
176 Girvalaki C., Filippidis F. (2020).
177 Ibid.
178 Cheung C., Vardavas C. (2020).

Reasons for the uptake of e-cigarettes and HTPs

According to the 2023 Eurobarometer survey, among the youngest respondents aged 15–24, the most frequently cited factors affecting their decision to start using e-cigarettes were that their friends used them and that they liked the flavours in e-cigarettes. In contrast, respondents aged 55 and over most commonly reported that they started using e-cigarettes to attempt to stop or reduce their tobacco consumption, or because they believed that e-cigarette use is less harmful than smoking cigarettes[179]. The same survey highlights notable differences between EU Member States. France is the only country where more than half of respondents reported starting e-cigarettes in order to stop smoking or smoke less, followed by Cyprus and Denmark. Having friends who used e-cigarettes was cited by at least half of respondents as a reason for starting in Hungary, Germany, and Sweden. The perception that e-cigarettes' use is less harmful than smoking cigarettes is most commonly reported in Cyprus, Slovakia, and Ireland, while liking e-cigarette flavours is cited most often in Ireland, Poland, and France. The perceived "coolness" or attractiveness of e-cigarettes was mentioned most frequently in Poland, Spain, and Italy. Being able to use e-cigarettes in places where smoking is prohibited is most often reported in Bulgaria, Austria, and Hungary. Respondents were most likely to say that e-cigarettes are more socially acceptable than smoking in Austria, Poland, and Slovenia. In contrast to e-cigarettes, users of HTPs most frequently cite the perception that these products are less harmful than smoking tobacco as a key reason for starting to use them.

According to the Eurobarometer 2023 survey, among the youngest respondents aged 15–24, the most frequently cited factor influencing their decision to start using HTPs was that they liked their flavours. In contrast, half of respondents aged 55 and older reported that they started using HTPs because they believed that these products were less harmful than smoking cigarettes. At national level, HTP users are most likely to mention perceived reduced harm compared to the harm done by smoking cigarettes in the case of Portugal, Cyprus, and Greece, and least likely to do so in Sweden, Belgium, and Germany. Having friends who use HTPs was most frequently cited as a reason for starting in Germany, Belgium, and Sweden.

Traditional tobacco products

Despite the considerable progress, smoking prevalence in the EU remains high, particularly among young people and the interim goal of Europe's Beating Cancer Plan to reach the WHO target of a 30% relative reduction in tobacco use by 2025 as compared with 2010 has not yet been reached. Europe ranks first among WHO regions in terms of prevalence of tobacco consumption and is projected to hold that position for years to come[180]. In 2022, 18% of 15-year-old adolescents in the EU reported smoking monthly[181]. People aged 55 and over were also the only age group in which smoking prevalence increased over the evaluation period, rising from 17% in 2012 to 19% in 2023[182]. Traditional tobacco products continue to be widely used and are perceived as the most accessible product category, particularly among young people.

Although tobacco-related deaths in the EU have significantly declined since 2012, tobacco use still imposes a substantial health burden on the society and public health systems. In 2023, tobacco use - including tobacco smoking, tobacco chewing and exposure to second hand smoke - accounted for almost 535 000 deaths and almost 14.5 million Disability-Adjusted Life Years (DALYs) in the EU;

[179] https://europa.eu/eurobarometer/surveys/detail/2995

[180] https://www.who.int/europe/news/item/08-10-2025-who-european-region-has-the-highest-rate-of-tobacco-use-in-the-world--with-an-alarming-rise-in-young-people-using-e-cigarettes--global-report-warns, https://www.who.int/europe/news/item/26-02-2026-tobacco-crisis--who-european-region-projected-to-remain-worst-globally-by-2030

[181] JRC (2025b).

[182] https://europa.eu/eurobarometer/surveys/detail/1060,https://europa.eu/eurobarometer/surveys/detail/2995.

most of this burden is caused by active tobacco smoking (476 000 deaths and 13.4 million DALYs). Second-hand smoking, in turn, accounted for almost 78 000 deaths and nearly 1.8 million DALYs[183].

In 2023, the estimated health-related costs of traditional tobacco consumption were EUR 80.7 billion annually split between direct costs related to medical care expenditure (EUR 40.43 billion) and indirect costs, including informal care and productivity loss (EUR 40.23 billion)[184].

On average, the economic burden of tobacco equates to 0.47% of the EU's GDP, ranging from 0.11% in Luxembourg to 0.68% in Germany. Tobacco-related costs also represent, on average, 2.5% of total healthcare expenditures across the EU.

Novel products

The emergence of novel tobacco and nicotine products poses new challenges to public health. Products such as HTPs, e-cigarettes and nicotine pouches have become very popular, especially among young people, with their use increasing significantly in recent years.

Since 2012, the use of novel tobacco and nicotine products has significantly increased, especially among young people. According to Eurobarometer data, in 2023, 6.4% of young people aged 15–24 were current e-cigarette users, a prevalence higher than in any other age group. Moreover, 18% of individuals in this age group had experimented with e-cigarettes, indicating a significant level of exposure within this vulnerable population. In 2023, e-cigarettes were the first product used by current or former young users aged 15-29 who had used either traditional or novel products. Similarly, HTP use is most prevalent among the youngest age groups (15–24 and 25–39). In the case of nicotine pouches, the 25–39 age group represents the largest share of current users.

In addition, while the sales value of traditional tobacco products (excluding HTPs) declined by 8.5% between 2012 and 2023 (see table 6, in chapter 3), the overall sales value of all tobacco and related products (including HTPs, e-cigarettes and nicotine pouches) increased by almost 3% during the same period (see table 7 in chapter 3). This divergence highlights a marked decline in the popularity and market share of traditional products, especially cigarettes, alongside a significant growth in the market for e-cigarettes, HTPs, and nicotine pouches.

According to Euromonitor passport 2025 data, HTPs [the tobacco containing consumables without the tobacco heating devices], which were absent from the EU market in 2012, accounted for nearly 8% of the total market value in 2023. Between 2013 and 2023, the market volume of heated tobacco products excluding tobacco heating devices increased from 2.5 million sticks to approximately 49 billion sticks, corresponding to an increase greater than 19 000-fold, while the market value rose from around EUR 1 million to EUR 11.7 billion in constant prices over the same period. Including tobacco heating devices, the total HTP market value reached EUR 12.5 billion in 2023, compared with EUR 4 million in 2013. Tobacco heating devices which are the essential components that enable the use of HTPs[185], are key drivers of this growth.

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183 https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/tobacco-smoking_en

184 Salari, P., Maragkoudakis, P.-A. and Wollgast, J., The health-related costs attributable to tobacco in the EU, Publications Office of the European Union, Luxembourg, 2026, https://data.europa.eu/doi/10.2760/5833286, JRC146176JRC ('JRC (2025c)'). The information presented in this paragraph and the following one is taken from the same source.

185 https://iris.who.int/bitstream/handle/10665/331297/WHO-HEP-HPR-2020.2-eng.pdf

E-cigarettes' sales have also rapidly increased. From 2012 to 2023, the EU e-cigarette market grew by 450% in value and 421% in volume[186] with per capita sales increasing by 70% between 2019 and 2023[187]. Nicotine pouches have also had a similar surge with their sales value increasing by 1697% from 2018 to 2023[188]. Despite this rapid growth, these products remain outside the scope of the tobacco control framework.

New marketing practices have made matters even worse. Novel tobacco and nicotine products are increasingly promoted via digital channels, particularly on social media platforms such as Facebook, Instagram, Twitter/X, YouTube and TikTok, often through influencers[189]. These promotional practices which target primarily adolescents and young adults, may fall outside the scope of the tobacco control framework, as explained in the section on advertisement below. Such online promotion, particularly through social media and online marketplaces, has been shown to increase consumer uptake[190], further complicating public health efforts. This demonstrates the strong influence of digital platforms on consumer behaviour in the tobacco and nicotine product market. Given the significant growth in the market share of novel tobacco and nicotine products and the continued increase in online sales, the public health implications are likely to worsen.

Apart from traditional tobacco products the harmful health effects of which have been well documented since the 1950s, emerging evidence highlights the health effects and risks of using novel products. The health risks associated with the use of novel products are described in chapter 3. The call for evidence[191] revealed concerns of many contributors about the negative health effects of substances like nicotine, artificial flavorings, and other chemicals these products contain.

Given the rapid growth in the consumption and sale of novel tobacco and nicotine products among young people, the new digital-driven marketing strategies aggressively targeting this age group and the growing evidence of associated health risks, it is clear that the current tobacco control framework - originally designed to reduce smoking prevalence - falls short in effectively protecting the public, particularly young people's health, from the novel tobacco and nicotine products. As some of these products remain outside the scope of the current tobacco control framework, and others are not adequately regulated by it, as outlined in further detail below, young people are left vulnerable to ongoing harm associated with the use of these products.

The following section outlines, in detail, the gaps and shortcomings in the current tobacco control framework, organised according to the specific regulatory areas they affect, that undermine its overall effectiveness.

Scope

The current tobacco control framework does not have any rules on (non-tobacco) nicotine products other than e-cigarettes. While EU Member States can regulate such products within the remit of their own jurisdiction (and some have already introduced national measures), the absence of EU-wide requirements represents a gap in the tobacco control framework. As explained in chapter 3, nicotine is a toxic and highly addictive substance that poses serious health and safety risks and can serve as a gateway to traditional tobacco smoking for young people. During the public consultation,

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186 With units sold rising from 125 million in 2012 to 649 million in 2023. Source: Euromonitor International Ltd, Tobacco, 2025 industry edition © All rights reserved.

187 Euromonitor International Ltd, Tobacco, 2025 industry edition © All rights reserved.

188 Ibid.

189 Lazuras (2025).

190 Vardavas (2025a).

191 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control_en

NGOs in the public health domain highlighted these risks posed by emerging nicotine products[192]. The WHO has called for the regulation of nicotine products, urging governments to ban all flavours in these products in order to reduce their attractiveness and appeal, and protect youth from nicotine addiction and related diseases[193]. Under Article 5(2) of the WHO FCTC, each party to the Convention is required to adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other parties in developing appropriate policies for preventing and reducing not only tobacco consumption, but also nicotine addiction and exposure to tobacco smoke[194].

EU Member States and civil society organisations that participated in targeted interviews, noted the EU framework's inadequacy for effectively addressing the matter of emerging nicotine products and achieving its public health objectives[195]. Consequently, the lack of EU-wide regulation of all nicotine products undermines the public health efforts to reduce the overall disease burden associated with nicotine use, and protect young people from addiction and the harm it does.

Nicotine pouches are an example of nicotine products currently not regulated by the EU tobacco control framework. EU Member States have taken differing approaches regarding the regulation of nicotine pouches, ranging from complete bans[196], to maximum nicotine content limits[197], regulation of their ingredients[198], age restrictions for their sales[199], labelling and packaging requirements, including mandatory health warnings[200], requirements for their notification to the competent authorities before being placed on the market[201], advertising restrictions[202] as well as restrictions subjecting nicotine pouches to smoke-free environment rules[203]. As these products are relatively new to the EU market, they remain unregulated in some EU Member States. In Bulgaria, Croatia, Cyprus, Greece, Luxembourg, Malta, Poland, and Portugal, nicotine pouches are regulated under consumer laws as "consumer products." In other EU Member States, such as Finland, and Hungary, they are classified as "medicines or pharmaceutical products," while in Belgium and Estonia, they are considered "similar to tobacco products"[204]. In Austria nicotine pouches are classified as both "consumer products" and "medicines"[205].

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192 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation_en

193 https://www.who.int/news/item/30-05-2025-who-calls-for-urgent-action-to-ban-flavoured-tobacco-and-nicotine-products

194 https://iris.who.int/server/api/core/bitstreams/264104b3-241a-4e48-88f9-aa7120779ffc/content

195 Annex 5: Synopsis report of the different consultation activities.

196 Based on information available at the time of preparing this document, this includes the following EU Member States: France, Belgium, the Netherlands and Germany, according to the WHO study group on tobacco product regulation, Report on the scientific basis of tobacco product regulation: ninth report of a WHO study group (2023).

197 Based on information available at the time of preparing this document, this includes the following EU Member States, Denmark, Poland and Hungary.

198 Based on information available at the time of preparing this document, this includes the following EU Member States, Poland and Hungary.

199 Based on information available at the time of preparing this document, this includes the following EU Member States, Latvia, Luxembourg, Czechia, Poland, Romania,Austria.

200 Based on information available at the time of preparing this document, this includes the following EU Member States, Hungary and Luxembourg.

201 Based on information available at the time of preparing this document, this includes the following EU Member State, Hungary.

202 Based on information available at the time of preparing this document, this includes the following EU Member State, Poland.

203 Based on information available at the time of preparing this document, this includes the following EU Member State, the Netherlands.

204 https://iris.who.int/server/api/core/bitstreams/62dd3c46-9bf4-4ebe-a0f6-7bded964c84b/content

205 WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: ninth report of a WHO study group (2023).

This lack of consistent regulation of nicotine products that currently fall outside the scope of the tobacco control framework, leads to market fragmentation and creates barriers that are expected to increase in the coming years, driven by the increasing market share and consumption of these products, as well as their aggressive promotion, particularly to young people via digital channels. 66% of EU Member States that participated in a targeted survey, recognised that the new market developments require EU action rather than national legislation alone[206]. The absence of harmonised rules regulating all nicotine products with the aim of minimising the access, appeal, and initiation among young people, as well as raising awareness about their health risks and potential addictiveness constitutes a significant gap in the current tobacco control framework.

On 16 July 2025, the Commission adopted a proposal for a recast of the TTD[207]. The Commission proposal extends the Directive's scope to explicitly include products, such as smokeless tobacco products (namely, chewing and nasal tobacco for the purposes of the TTD), liquids (nicotine containing and nicotine free) for e-cigarettes, nicotine pouches and other nicotine products. Based on this proposal, the revised TTD would expand its scope beyond that of the TPD and TAD. In particular, the updated TTD would regulate not only tobacco products but also all other nicotine products, including nicotine pouches. This also indicates that the current scope of the tobacco control framework is not sufficiently broad.

ENNDS are also not covered by the current tobacco control framework. This regulatory gap is problematic because it cannot be excluded that certain types of e-cigarettes (particularly the refillable ones) that are intended to be used for the consumption of nicotine-free vapour, can also be used for the consumption of nicotine-containing vapour. Therefore, the nicotine-containing liquid can be used in ENNDS marketed as nicotine-free, allowing these products to circumvent existing restrictions applicable to nicotine-containing e-cigarettes. This poses a significant threat to public health[208], in addition to the health risks associated with the use of ENNDS themselves, as explained in chapter 3. It should be noted that EU Member States which have already prohibited[209] or have recently notified[210] the prohibition of the sale of disposable e-cigarettes containing nicotine have also included a ban on disposable e-cigarettes without nicotine. Overall, the absence of any harmonised rules on ENNDS has led to divergent approaches among the EU Member States[211], creating obstacles to the free movement of goods within the internal market.

There are indications that the market for herbal products is also changing, and the current TPD provisions, including the definition of a 'herbal product for smoking' (Article 2(15) of the TPD), are no longer fully in sync with such market developments. New products, such as those designed for heating rather than smoking[212], have entered the EU market, calling into question the adequacy of the tobacco control framework [213].

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206 Annex 5: Synopsis report of the different consultation activities.

207 https://taxation-customs.ec.europa.eu/taxation/excise-taxes/excise-duties-tobacco/revision-tobacco-taxation-directive-proposal_en

208 See the comments of the European Commission in the following technical regulation information system (TRIS) notifications: https://technical-regulation-information-system.ec.europa.eu/en/notification/26635.

209 Belgium, France and Bulgaria.

210 Austria and Ireland.

211 Study supporting the report on the application of Directive 2014/40/EU.

212 Results of the study supporting the evaluation of the tobacco control acquis, study conducted by Open Evidence, 2025.

213 Study supporting the report on the application of Directive 2014/40/EU, *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 concerning the manufacture, presentation and sale of tobacco and related products*, COM/2021/249 final ('Application Report (2021)').

Furthermore, during targeted interviews, EU Member States pointed to a potential regulatory gap regarding whether tobacco heating devices fall within the scope of the current tobacco control framework, when sold separately from the HTP, namely the tobacco containing consumable[214]. The uncertainty arises from the definition of tobacco products under Article 2(4) of the TPD, which defines a tobacco product as a product that "*consist, even partly, of tobacco, whether genetically modified or not*". Since the tobacco heating devices themselves do not contain tobacco, confusion has arisen as to whether the TPD and TAD rules also cover the tobacco heating devices besides the tobacco containing consumable[215]. However, given the sole purpose of tobacco heating devices is to enable the consumption of HTPs and they are not intended for separate use[216], these devices are regarded as also falling within the scope of the TPD and TAD restrictions. Nevertheless, the situation described above has resulted in an inconsistent approach regarding the regulation of tobacco heating devices across EU Member States[217]. These differences between EU Member States' laws impede the smooth functioning of the internal market.

Closely related to the previous issue is the question of whether the current definition of 'tobacco products' in the TPD ('*products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not'*) remains effective. As noted earlier, according to Article 2(4) of the TPD, a product must contain at least some tobacco to be classified as a tobacco product and thus fall within the scope of the tobacco control framework. Consequently, this definition does not explicitly cover non-tobacco containing consumption-related items (e.g. papers, filters devices, items dedicated for the flavouring of tobacco products by the consumer) that are sold and marketed separately from the tobacco-containing product. Given the emergence of new and forthcoming innovative tobacco and nicotine products, the absence of a broader definition encompassing both tobacco-containing items and their separately sold components leaves a gap in the framework[218]. This limitation undermines the framework's effectiveness by making it possible for certain components or accessories to circumvent the framework's restrictions, thereby increasing public health risks by facilitating the use of tobacco products or making them appealing.

Flavours

The tobacco control framework does not contain rules on flavours in e-cigarettes. Flavours other than tobacco significantly contribute to the appeal of e-cigarettes among young people[219] and have played a major role in the recent increase in their use. In particular, sweet and fruity flavours are often a decisive factor in young people's starting to smoke e-cigarettes (see the graph on liquid variants used by e-cigarette users in Chapter 3)[220]. Flavours other than tobacco mask the harshness of the aerosol, create the impression that the product is less harmful than tobacco-flavoured ones[221], make the product more attractive and easier to use, and undermine nicotine cessation efforts. EU Member States which took part in targeted interviews, questioned the rationale for not extending the ban on characterising flavours to e-cigarettes, which are seen as particularly appealing to young people. This view is also shared by the public health NGOs which considered flavoured e-cigarettes a growing public health concern[222]. The absence of common EU rules on flavours in e-cigarettes contributes to regulatory disparities regarding these products and undermines the effectiveness of

214 Annex 5: Synopsis report of the different consultation activities.
215 Application Report (2021).
216 See Heated tobacco products – Summary of research and evidence of health impacts (2023) on the components of HTPs.
217 Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.
218 Tobacco products definitions: Insights from national laws, Tob. Induc. Dis. 2025;23(Suppl 1): A98.
219 https://www.who.int/publications/i/item/9789240112063
220 https://europa.eu/eurobarometer/surveys/detail/2995
221 Study supporting the report on the application of Directive 2014/40/EU
222 Annex 5: Synopsis report of the different consultation activities.

the tobacco control framework in preventing youth uptake of both nicotine and tobacco products (since e-cigarettes can develop into a gateway to traditional tobacco consumption, as explained in chapter 3). In addition, this gap has led to inconsistent national approaches among EU Member States, ranging from full bans[223] to non-regulation, which hinders the smooth functioning of the internal market.

Similarly, flavoured waterpipe tobacco, cigars and cigarillos have emerged in the market and may have increased appeal to young people[224]. Considering the significant size of the EU waterpipe tobacco market and reports from some EU Member States indicating among the highest youth prevalence rates of waterpipe tobacco use, the absence of a prohibition on characterising flavours for waterpipe tobacco and cigarillos point to a potential gap in the current regulatory framework[225].

Another issue is the procedure under Article 7 of the TPD and Commission Implementing Regulation (EU) 2016/779[226] for determining whether a tobacco product has a characterising flavour, and prohibiting its placement on the market. The EU Member States that participated in targeted interviews concerning the effectiveness of the tobacco control framework, consider this process burdensome and resource-intensive[227]. This is because a EU Member State needs to repeat the process if the manufacturer of a tobacco product 'slightly changes' the composition of a previously banned product[228]. The work of the independent advisory panel assisting EU Member States and the Commission in determining whether tobacco products have characterising flavours, does not appear to be adequately adapted to the real market dynamics since manufacturers can modify product compositions faster than the panel can issue an opinion on the presence of characterising flavour in a product. Consequently, the procedure results in delays in removing non-compliant flavoured products from the market, allowing such products to remain on the market and continue to be accessible to EU citizens, including young people, thereby posing serious health risks. EU Member States participating in the public consultation and targeted interviews agree that having a clear ban on flavourings, rather than on the characterising flavours, would be more effective and efficient as it would also save resources[229].

Emissions

The Netherlands has raised concerns about the ISO machine puffing regime, which forms the basis for the measurement methods specified in Article 4(1) of the TPD, used to measure tar, nicotine, and carbon monoxide (TNCO) emissions from cigarettes. In particular, it was noted that these methods do not accurately reflect the amount of harmful substances inhaled by smokers[230]. According to another available method ('WHO intense method') which in the view of the Netherlands, mimic smokers' behaviour better and provide more accurate measurements of the substances they inhale, smokers are exposed to higher levels of TNCO[231]. This would imply that a

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223 According to information available to the Commission at the time this document was being drafted, the EU Member States that have already prohibited flavours in e-cigarettes and refill containers, are: Denmark, Estonia, Finland, Hungary, Lithuania, Latvia, the Netherlands, Slovenia.

224 Study supporting the report on the application of Directive 2014/40/EU, Application Report (2021).

225 Ibid.

226 OJ L 131, 20.5.2016, p. 48.

227 Annex 5: Synopsis report of the different consultation activities.

228 Ibid.

229 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation_en, Annex 5: Synopsis report of the different consultation activities.

230 https://www.rivm.nl/sites/default/files/2021-06/Factsheet%20Methods%20for%20determining%20TNCO%20in%20tobacco%20smoke.pdf

231 https://www.rivm.nl/en/news/smokers-inhale-more-tar-nicotine-and-carbon-monoxide-when-measured-with-who-method

number of cigarettes currently available in the market, would exceed the maximum emission levels when tested using this alternative method, and therefore would not comply with the TPD[232]. This could have significant public health implications, as it could suggest that the current regulatory limits may underestimate the real levels of smokers' exposure to TNCO. This also raises the issue of whether the TNCO maximum emission levels outlined in Article 3(1) of the TPD should be lowered as well as whether maximum levels should be established for other emissions from tobacco products, based on their toxicity or addictiveness, as highlighted in recital 12 of the TPD[233]. In a targeted survey on the relevance of the tobacco control framework, 81% of the participants - including EU Member States' competent authorities, civil society organisations, and economic operators- expressed support for extending the coverage of Article 3(1) of the TPD to other products besides cigarettes, such as HTPs, e-cigarettes, herbal products for smoking, and nicotine pouches[234]. Another concern relates to the enforceability of Article 4(1) of the TPD, given that the ISO standards for measuring the TNCO emissions from cigarettes have not yet been published in the Official Journal of the European Union[235].

EU Common Entry Gate (EU-CEG) IT tool

Furthermore, some EU Member States have raised concerns about challenges in ensuring the submission of complete data by manufacturers and importers in the EU Common Entry Gate (EU-CEG)[236], the IT tool developed to support their reporting obligations under Article 5 of the TPD for ingredients and emissions of tobacco products[237] as well as Article 20 in relation to e-cigarettes and refill containers[238]. In terms of sales data, the system does not allow for collection at the time of initial product notification, as products must be notified prior to market placement. Instead, the system requires the sales volume to be entered when a product is updated after one year. If there is no update, sales data remain incomplete[239]. Retroactive changes to data are possible but can affect data stability. These limitations may hinder the EU-CEG from achieving its full potential as the reporting system designed to provide EU Member States and the Commission with comprehensive

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232 The national Institute for Public Health and the Environment in the Netherlands has measured the amount of tar, nicotine and carbon monoxide (TNCO) in all filter cigarettes sold in the Netherlands with the WHO intense method. The TNCO levels measured with this method were up to 15 times higher than those measured with the legally prescribed ISO method. Source: https://www.rivm.nl/en/documenten/comparison-between-who-intense-method-and-iso-method

233 According to recital 12 of the TPD, 'As regards establishing maximum emission levels, it could be necessary and appropriate at a later date to reduce the emission levels for tar, nicotine and carbon monoxide or to establish maximum levels for other emissions from tobacco products, taking into consideration their toxicity or addictiveness'.

234 Annex 5: Synopsis report of the different consultation activities.

235 https://curia.europa.eu/juris/liste.jsf?num=C-155/24

236 Application Report (2021).

237 Under Article 5 of the TPD this information includes, among other things: (a) a list of all ingredients, and the quantities of them, used in the manufacture of tobacco products, in descending order of the weight of each ingredient; (b) the emission levels referred to in Article 3(1) and (4); (c) if available, information on other emissions and their levels.

238 Under Article 20 of the TPD, this information includes: (a) the name and contact details of the manufacturer, a responsible legal or natural person in the EU, and, if applicable, the importer of the product into the EU; (b) a list of all ingredients in, and emissions resulting from the use of, the product, by brand name and type, including the quantities thereof; (c) toxicological data on the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, among other things, any addictive effect; (d) information on the product's nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions; (e) a description of the product's components; including, where applicable, the opening and refill mechanism of the e-cigarette or refill containers; (f) a description of the production process, including whether it involves series production, and a declaration that the production process ensures that the product fulfils the requirements of this Article; (g) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

239 Application Report (2021).

information on tobacco products, e-cigarettes, and refill containers - information essential for assessing the health impacts associated with these products. Despite its limitations, EU-CEG remains a very useful monitoring tool for regulatory data collection, especially regarding ingredients and emissions, that enables EU Member States to swiftly respond to product evolutions or upcoming 'outbreaks' of newly evolved tobacco products or 'variants of interest' across the EU Member State markets as they emerge[240].

Labelling and packaging

Several EU Member States have already introduced, or are considering introducing plain packaging requirements. Article 24(2) of the TPD allows an EU Member State to introduce further standardisation requirements regarding the packaging of tobacco products, including plain packaging. However, this flexibility contributed to regulatory disparities across the EU since mandatory plain packaging is not yet established in all EU Member States. A mandatory plain packaging requirement is widely recognised as an effective public health measure that contributes to the reduction in tobacco consumption. The WHO recognises that plain packaging enhances the impact of graphic health warnings, reduces the appeal of tobacco products and make the health warnings stand out more across various population groups. According to the WHO, plain packaging for e-cigarettes is also likely to be effective in reducing the appeal of e-cigarettes[241]. Public support for this measure is growing: according to the 2023 Eurobarometer, 52% of EU citizens support the introduction of plain packaging for cigarettes[242]. In this context, the lack of a mandatory plain packaging requirement weakens public health protection. Moreover, it has led to inconsistencies in the presentation of tobacco products, and variations in standardised packaging formats. The use of plain packaging in some EU Member States[243] but not in others is an obstacle to the free movement of goods within the internal market. The Court of Justice has ruled that "by permitting Member States to maintain or introduce further requirements relating to aspects of packaging that have not been harmonised by Directive 2014/40, Article 24(2) does not guarantee that products whose packaging complies with the requirements of the directive may move freely on the internal market"[244].

Another issue within the tobacco control framework that may undermine public health protection regarding novel tobacco products, and in particular HTPs, concerns their health warnings[245]. Under Article 19(4) of the TPD, the applicable labelling provisions for novel tobacco products are determined on the basis of their character as smokeless tobacco products or tobacco products for smoking. As a result, HTPs classified as tobacco products for smoking are required to carry larger[246], combined health warnings consisting of a text warning, pictorial depictions and smoking cessation information whereas smokeless HTPs are required to carry smaller[247] text-based health warnings without any pictorial depiction. Evidence suggests that the combined health warnings are

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240 https://doi.org/10.1136/tobaccocontrol-2021-056548

241 https://www.who.int/publications/i/item/9789240112063

242 https://europa.eu/eurobarometer/surveys/detail/2995

243 According to the study supporting the report on the application of Directive 2014/40/EU, the EU Member States that have adopted plain packaging rules are: Belgium, Denmark, France, Hungary, Ireland, the Netherlands, Slovenia. Finland has also introduced such measures. Some of these EU Member States have also introduced packaging standardisation measures for products other than tobacco products, such as e-cigarettes, refill containers and herbal products for smoking.

244 Judgment of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 79.

245 WHO, *Two decades of the implementation of the WHO Framework Convention on Tobacco Control in the European Union: progress, challenges and the road ahead*, 2025.

246 Covering 65% of both the external front and back surface of the unit packet and any outside packaging.

247 Covering 30% of the surfaces of the unit packet and any outside packaging. That proportion shall be increased to 32% for EU Member States with two official languages and 35% for Member States with more than two official languages.

more effective than text-only warnings in capturing attention, accurately conveying the dangers associated with tobacco use and thereby, deterring people from taking up smoking and helping them to quit smoking[248]. For this reason, manufacturers and importers of HTPs are inclined to describe their HTPs as smokeless tobacco products during the notification process of Article 19 of the TPD[249].

Meanwhile, EU Member States often face challenges in classifying HTPs correctly as either tobacco products for smoking or smokeless tobacco products. The tobacco control framework lacks a definition of 'combustion,' a critical concept for distinguishing smokeless tobacco products (defined in Article 2(5) of the TPD as "*a tobacco product not involving a combustion process*") from tobacco products for smoking (defined in Article 2(9) of the TPD as "*tobacco products other than a smokeless tobacco product*"). This creates a risk of inconsistent application of the TPD across the EU and complicates EU Member States' ability to determine whether HTPs fall under the category of 'tobacco products for smoking' or 'smokeless tobacco products'[250], increasing the possibility that some HTPs and future novel tobacco products are wrongly labelled and marketed with less effective health warnings.

The regulatory distinction in the labelling between smokeless HTPs and HTPs for smoking may mislead consumers into perceiving smokeless HTPs as less harmful than HTPs for smoking[251]. This differentiation lacks clear public health justification and risks extending to future novel tobacco products entering the EU market, thereby exacerbating the issue. It also weakens the ability of EU Member States to use labelling provisions as a tool to reduce the appeal and use of smokeless HTPs, particularly among young people[252]. As a result, the current labelling rules do not offer the same level of public health protection for smokeless novel tobacco products as they do for novel tobacco products for smoking. It is important to note that the provisions of the TPD, including those for novel tobacco products, were drafted before HTPs with their specific characteristics emerged on the EU market.

Furthermore, the TPD provides EU Member States with discretion in applying certain provisions. While this flexibility enables EU Member States to go beyond the TPD minimum requirements and establish higher public health standards, it has also contributed to regulatory disparities across the EU. For example, Article 11 of the TPD permits EU Member States to exempt certain tobacco products from certain labelling requirements. As a result, products like cigars and cigarillos, are subject to these requirements in some EU Member States but not in others. This inconsistency has also created deviations in packaging across EU Member States, directly affecting the functioning of the internal market[253].

Another issue concerning health warnings is that none of the text warnings listed in Annex I to the TPD; the picture library in Annex II; or the health warnings for e-cigarettes set out in Article 20(4)(b)(iii) have been updated since 2014 to reflect the most recent scientific evidence and market developments. As a result, there is a risk that these warnings no longer capture the full range of health risks associated with tobacco and nicotine product use, which may undermine their overall effectiveness in communicating those risks to consumers.

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248 See recital 25 of the TPD, https://www.who.int/publications/i/item/9789240112063.
249 Study supporting the report on the application of Directive 2014/40/EU.
250 Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.
251 Ibid.
252 Conseil d'État, Juge des référés, 07/09/2023, 478518, Inédit au recueil Lebon – Légifrance.
253 Study supporting the report on the application of Directive 2014/40/EU.

Finally, the EU tobacco traceability system has proven to be very resource-intensive for the Commission[254]. Assisting EU Member States in ensuring the correct application and enforcement of the EU tobacco traceability rules, as well as implementing the Commission's responsibilities such as: overseeing the system's functioning; ensuring the independence of ID issuers, providers of repository services and anti-tampering devices, as well as their subcontractors; assessing the suitability of the proposed primary repository providers regarding their independence and technical capabilities, and adopting the necessary Commission Decisions on the approval or rejection of the providers within the required timeframe; appointing by means of a concession contract the secondary repository operator and monitoring the contract's correct implementation demands substantial resources[255]. This administrative and operational burden is significant and would increase further with any planned expansion of the system to cover additional products beyond tobacco products, such as e-cigarettes, imposing considerably heavier burden on the Commission.

Tobacco for oral use

Article 17 of the TPD prohibits the placing on the market of tobacco for oral use (referred to as snus), with the sole exception of Sweden, which was granted a derogation in its Accession Treaty. This derogation was conditional on Sweden taking all necessary measures to ensure that tobacco for oral use is not placed on the market in other EU Member States. Despite this, the use of snus has increased, particularly among young people, in several EU Member States, notably in Sweden's neighbouring countries such as Finland, Estonia, and Denmark[256]. Several factors appear to contribute to this trend, such as: the legal importation of snus by travellers for personal use; the smuggling of snus into these national markets from Sweden[257]; and the circumvention of the snus ban through the marketing of snus-like products as chewing tobacco to gain a legal status[258]. Compounding the issue is the growing presence of nicotine pouches (sometimes referred to as "nicotine snus", "white snus" or only "snus") which are outside the scope of the tobacco control framework. These products closely resemble snus in both appearance and method of use, making it difficult to distinguish between the two. This confusion challenges the enforcement of the snus ban. It is noteworthy that the use of nicotine pouches is particularly high in the EU Member States where the use of snus is present[259]. Therefore, a significant proportion of young people in Finland, Estonia and Denmark are exposed to the health risks of snus which is produced in Sweden and designed to appeal to young people through flavoured variants, slim sachets and brightly coloured packaging[260]. Snus use poses well-documented health risks. It negatively affects cardiovascular health, increases the risk of diabetes and metabolic syndrome, impairs oral health, and poses risks to both pregnant women and their babies. Snus contains at least 28 known carcinogens and nicotine which is a toxic and highly addictive substance that is harmful to human health (see more for nicotine in health risks associated with novel products in chapter 3). Some snus products contain very high nicotine concentrations[261]. Moreover, there is evidence refuting claims about the snus role in harm reduction[262]. The availability and use of snus in EU Member States other than Sweden undermines the effectiveness of Article 17 of the TPD and poses a direct challenge to the tobacco control framework's objective of ensuring a high level of public health protection, especially for young people.

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254 Application Report (2021).

255 Vardavas, C., Report on the analysis of track and trace system and illicit trade in the EU, 2025 ('Vardavas (2025b)').

256 https://pubmed.ncbi.nlm.nih.gov/35309849/, http://urn.fi/URN:ISBN:978-952-408-589-2.

257 https://pubmed.ncbi.nlm.nih.gov/35309849/

258 Application report (2021).

259 https://pubmed.ncbi.nlm.nih.gov/35309849/, JRC (2025b).

260 https://pubmed.ncbi.nlm.nih.gov/35309849/

261 Ibid.

262 Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

Advertisement

Although the tobacco control framework (together with the AVMSD) regulates the advertising of tobacco products, e-cigarettes and refill containers across all media types, there seems to be certain regulatory gaps, raising concerns about its effectiveness. The framework does not cover the advertising of newer nicotine products, such as nicotine pouches. This omission undermines the public health efforts to reduce the use of these products. EU Member States consulted in targeted interviews agreed that, without EU intervention, national bans are insufficient due to the cross-border effects of this type of advertising[263].

There is confusion over whether tobacco heating devices fall within the scope of the advertising restrictions of the TAD when marketed separately from the tobacco containing consumable. This concern was raised during targeted consultations, with some EU Member States highlighting that the TAD's definition of 'tobacco product' does not explicitly include the tobacco heating device. Consequently, differing approaches to the regulation of advertising for these devices have emerged across EU Member States, leading to fragmented advertising rules. This situation poses challenges both for the internal market and for public health[264]. However, it should be noted that the definition of 'advertising' in Article 2 of the TAD is broad, encompassing "any form of commercial communications with the aim or direct or indirect effect of promoting a tobacco product". A commercial communication promoting a device the sole or main function of which is to enable the consumption of a tobacco product, would also have the aim or direct or indirect effect of promoting that tobacco product[265]. This is also supported by the WHO Guidelines for the implementation of Article 13 of the FCTC which make clear that "*any advertising or promotion of a device whose function is to enable the consumption of a tobacco product would have the aim, or the direct or indirect effect, of advertising or promoting that tobacco product itself*," and thus, "*comprehensive bans on advertising, promotion and sponsorship of novel and emerging tobacco products, should, in accordance with national law, include the devices used with them*"[266].

According to a study[267], brand or corporate promotion, as distinct from direct product promotion[268], does not fall under the existing advertising restrictions if such promotion does not have the aim or direct or indirect effect of promoting the tobacco products or e-cigarettes and their refill containers. This can include promotional campaigns carried out under the company's direct name or another logo/initiative, which can be traced back to the tobacco/e-cigarette manufacturer, as long as they do not have the aim or direct or indirect effect of promoting tobacco products or e-cigarettes and their refill containers and thus, constitute 'advertising' within the meaning of Article 2(b) of the TAD. As a result, such promotional activities which may still influence consumer behaviour and encourage the use of tobacco and nicotine products, currently may fall outside the scope of the advertising restrictions, thereby weakening public health efforts.

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263 Annex 5: Synopsis report of the different consultation activities.

264 Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

265 WHO, *Two decades of the implementation of the WHO Framework Convention on Tobacco Control in the European Union: progress, challenges and the road ahead*, 2025.

266 https://fctc.who.int/resources/publications/m/item/guidelines-for-implementation-article-13, Mollet, D., *Digital advertising of tobacco and related products under EU law: A legal mapping of the present scope of regulation*, 2025.

267 Mollet, D. (2025).

268 See Chapter 4.3.4 of the Commission Report on the implementation of the Tobacco Advertising Directive 2003/33/EC: 'One of the remaining common marketing practices is to advertise the tobacco manufacturer with a positive image as a responsible market operator. Even if brands are not directly presented, such corporate promotion is a method of marketing the company's reputation and its products.'

Advertising of tobacco and related products on online platforms is shared both as content sponsored by the industry and as user-generated content without any commercial associations to the relevant industry[269]. User-generated content can fall outside the scope of the tobacco-control framework if it does not constitute a 'commercial communication' within the meaning of Article 2(f) of Directive 2000/31/EC[270]. This happens when the content is not designed to promote, directly or indirectly, a product or a company pursuing a commercial activity, and is conducted in an independent manner without any financial or commercial consideration. In this case, the user generated content is not considered advertising within the meaning of Article 2(b) of the TAD[271]. Consequently, this type of user-generated content that is widely viewed by young people on social media and known to influence their behaviors (as explained in Chapter 3), remains unregulated within the current tobacco control framework (under the conditions explained above). This lack of regulation exposes young audiences to tobacco and nicotine products, potentially encouraging their initiation and use, and undermines the high level of public health protection that the tobacco control framework aims to ensure.

In addition, permitting tobacco advertising intended exclusively for professionals in the tobacco trade and to publications printed and published in third countries under Article 3(1) of the TAD is not in accordance with the standard set by Article 13 of the FCTC, which has among its principles that *'[a] comprehensive ban on tobacco advertising, promotion and sponsorship should include cross-border advertising, promotion and sponsorship. This includes both out-flowing advertising, promotion and sponsorship (originating from a Party's territory) and in-flowing advertising, promotion and sponsorship (entering a Party's territory)*'[272].

The above-presented gaps indicate that the relevant Articles of the tobacco control framework, specifically Article 20(5) of the TPD and the definition of 'advertising' in Article 2(b) of the TAD as well as the limited product scope of the TPD do not fully address the challenges posed by new digital marketing practices for tobacco and nicotine products. These rules were developed before such marketing strategies emerged. 70% of the EU Member States participating in a targeted survey on the effectiveness of the tobacco control framework expressed concerns that the introduction of new products in the market as well as the tobacco and related products' advertisement on social media weakened the effectiveness of TAD in achieving its objectives[273].

New products and market developments

The tobacco control framework lacks the flexibility to keep pace with the rapid market evolution of tobacco products including novel tobacco products unless the stringent conditions of the 'substantial change of circumstances' clause outlined in Article 2(28) are met. These conditions are difficult to fulfil, limiting the possibility of the full application of the TPD's restrictive measures on tobacco products whose market share has been substantially increased. This limitation is also supported by some economic operators that participated in targeted interviews, indicating that the tobacco control framework is no longer able to address new market developments[274].

For e-cigarettes, there is currently no mechanism like that of the withdrawal of (possible) exemptions in case of a 'substantial change of circumstances' provision (see in Articles 7(12) and 11(6) TPD) in the TPD or TAD that would enable the Commission to respond quickly in the event

[269] Lazuras (2025).
[270] OJ L 178, 17.7.2000, p. 1.
[271] Mollet, D. (2025).
[272] Ibid.
[273] Annex 5: Synopsis report of the different consultation activities.
[274] Ibid.

of increasing prevalence of use of these products among young people and/or their growing market sales within the EU.

E-cigarettes use different forms of nicotine, including natural nicotine extracted from tobacco leaves and synthetic nicotine produced in laboratories. Evidence suggests that certain forms of synthetic nicotine may have a faster and/or stronger addictive effect than natural nicotine or result in higher levels of R-nicotine[275] inhalation. This raises questions about the long-term health effects of e-cigarettes containing such forms of synthetic nicotine[276]. The U.S. Food and Drug Administration considers 6-methyl nicotine which is a synthetic derivative of nicotine, as potentially more potent and addictive than natural nicotine[277]. Research also indicates that 6 methyl nicotine increases cytoxicity in human bronchial epithelial cells compared to traditional nicotine[278]. Additionally, evidence shows that even a single e-cigarette's pod using nicotine salts, can contain the nicotine equivalent of 20 cigarettes[279]. In light of this evidence, the current nicotine limit of 20 mg/ml for the nicotine containing liquid of e-cigarettes, as set out in Article 20(3)(b) of the TPD, may no longer adequately account for the various forms of nicotine used in e-cigarettes. This uniform limit which currently applies to all types of nicotine, may therefore be inadequate for newer forms of nicotine, allowing e-cigarettes with faster and/or stronger addictive effect to enter the market and undermining the tobacco control framework's effectiveness in ensuring a high level of public health protection.

In addition, the current tobacco control framework does not include any rules on tobacco-free nicotine products other than e-cigarettes and lacks a definition of a 'nicotine product'. The absence of a flexible and comprehensive definition that can capture both existing and future nicotine products, limits the framework's ability to adapt swiftly to innovations in the nicotine product market and represents a significant regulatory gap hence undermining public health protection. Another issue related to nicotine-containing e-cigarettes concerns the disparity in the regulatory treatment of e-cigarettes compared to tobacco products under the TPD. This includes differences in requirements for health warnings and restrictions on flavours. For example, the TPD requires combined health warnings only for certain tobacco products, whereas e-cigarettes are subject to simple health warnings. Similarly, while the TPD prohibits the placing on the market of certain tobacco products with a characterising flavour, no such prohibition applies to e-cigarettes. These regulatory differences may unintentionally minimise the perceived risks of e-cigarettes, particularly among young people and increase their appeal, thereby weakening public health efforts. This divergence highlights a shortcoming in the current legislation, especially in light of emerging evidence on the health risks associated with nicotine use. Consequently, the current regulation of e-cigarettes falls short of the TPD's objective to ensure a high level of human health protection, particularly for young people. WHO has noted that according to scientific studies, e-cigarettes are not effective for smoking cessation and called on the FCTC Parties to take action to reduce the risks arising from the use of e-cigarettes, paying particular attention to young people[280]. Furthermore, according to 2023 Eurobarometer survey, a majority of those who have never used, or only tried e-cigarettes are in favour of regulating these products as strictly as cigarettes[281].

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275 While naturally occurring, nicotine contains more than 99% of the S-stereoisomer, R-nicotine, the other stereoisomer of nicotine, is formed in non-stereoselective synthesis next to S-nicotine at a rate of 50%. Synthetic nicotine can therefore contain 50% of the R-nicotine isomer, which is toxicologically not well characterised.

276 https://www.who.int/publications/i/item/9789240079410

277 Exclusive: Nicotine-like chemicals in U.S. vapes may be more potent than nicotine, FDA says | Reuters

278 https://www.sciencedirect.com/science/article/pii/S037842742500013X?via%3Dihub

279 https://tobaccocontrol.bmj.com/content/31/e1/e88

280 https://www.who.int/publications/m/item/technical-note-on-call-to-action-on-electronic-cigarettes

281 Attitudes of Europeans towards tobacco and related products – June 2024 – Eurobarometer survey.

Article 24(3) of the TPD allows EU Member States to prohibit a certain category of tobacco or related products on grounds relating to the specific situation in that EU Member State and provided the provisions are justified by the need to protect public health. Belgium[282], and France[283] banned disposable e-cigarettes at national level after their respective national measures notified pursuant to Article 24(3) of the TPD had been approved by the Commission. Similarly, in March 2026 the Commission approved a notification from Bulgaria[284]. In France, the ban applies to disposable e-cigarettes containing nicotine that are intended to be placed on the market in France or are placed on the market in France. Belgium's and Bulgaria's bans cover domestic and imported disposable e-cigarettes containing nicotine. The resulting situation where some EU Member States prohibit the placing on their market of disposable e-cigarettes, while others allow it, undermines the TPD's objective of ensuring the smooth functioning of the internal market and distorts competition between undertakings, placing manufacturers or importers from an EU Member State imposing such prohibitions at a competitive disadvantage.

Disposable e-cigarettes pose significant public health risks. According to the information provided by Belgium and France[285], these products often contain high levels of nicotine with their actual nicotine content often not indicated accurately, increasing the risk of overdose. Nicotine exposure, particularly among adolescents and young people, can cause respiratory inflammation and adversely affect brain development, leading to lasting cognitive and emotional impairments. Early and chronic nicotine use increases the likelihood of addiction, creating a gateway to traditional tobacco smoking. The products' appealing design, variety of flavours, low cost, and aggressive marketing strategies further increase their popularity among young people, who often underestimate their harmfulness. Moreover, the widespread availability of disposable e-cigarettes exacerbates these risks by making them easily accessible to young people.

Similarly, Bulgaria emphasises that young people have a strong urge to experiment, and that electronic cigarettes, especially those containing synthetic substances or drug additives, can cause acute intoxications, severe health incidents, and even death[286].

In 2023, disposable e-cigarettes' devices that are thrown away after use, were used more by those aged 15-24[287]. The prohibition of disposable e-cigarettes in only a few EU Member States, coupled with divergent national approaches to cross-border distance sales, poses significant challenges to public health. For example, while Belgium, France and Bulgaria already prohibit disposable e-cigarettes, their continued availability in other EU Member States undermines efforts to remove them from circulation in the Belgian, French and Bulgarian markets and to reduce their associated health and environmental risks.

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282 https://health.ec.europa.eu/document/download/2c0e24a7-8ea5-4464-9bf6-eecc2f45c42b_en?filename=tobacco_c_2024_1673_en.pdf

283 https://health.ec.europa.eu/document/download/7dfc1451-89e8-41bc-84b7-6ad9ada9027d_en?filename=tobacco_c_2024_6680_en.pdf

284 Commission Implementing Decision of 6.3.2026 concerning national provisions notified by Bulgaria prohibiting the placing on the market of disposable electronic cigarettes, C(2026) 1573 final.

285 Commission Implementing Decision of 18.3.2024 concerning national provisions notified by Belgian authorities prohibiting the placing on the market of disposable electronic cigarettes, C(2024) 1673 final, Commission Implementing Decision of 25.9.2024 concerning national provisions by France prohibiting certain electronic cigarettes, C(2024) 6680 final. All the information in this paragraph is taken from these Decisions.

286 Commission Implementing Decision of 6.3.2026 concerning national provisions notified by Bulgaria prohibiting the placing on the market of disposable electronic cigarettes, C(2026) 1573 final.

287 https://europa.eu/eurobarometer/surveys/detail/2995

Finally, the requirement under Article 18(4) of the TPD for age-verification systems in cross-border distance sales has been largely ineffective in preventing sales to minors[288], as many retailers use relatively weak age verification checks that can be easily circumvented by under-age shoppers to complete purchases[289]. 80% of retailers reviewed use self-reporting as age verification, relying solely on shoppers being honest about their age, and did not verify the age at the point of delivery[290]. As a result, minors continue to have easy access to tobacco products, e-cigarettes and refill containers. This undermines the tobacco-control framework's objective of ensuring a high level of health protection for young people and preventing their initiation into tobacco and e-cigarettes' use.

Notification of national measures

The procedure under Article 24(3) of the TPD is another resource-intensive area. This provision allows an EU Member State to prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that EU 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 the Directive. These national provisions should be notified to the Commission together with the grounds for introducing them. The Commission is then required to approve or reject the provisions within six months of receiving the notification, after verifying whether they are justified, necessary, and proportionate, and ensuring they do not constitute arbitrary discrimination or a disguised restriction on trade between EU Member States. If no decision is taken within six months of the date of receiving the notification, the national provisions are deemed approved. This procedure often runs in parallel with Directive (EU) 2015/1535 procedure[291], which aims to prevent barriers in the internal market before they materialise. In this procedure, EU Member States notify their legislative acts concerning tobacco and related products to the Commission, which then reviews them in light of the EU harmonised legislation and the TFEU provisions. EU Member States also participate in this process and can issue reactions on the notified drafts. In both procedures, the Commission may receive multiple notifications simultaneously, creating significant challenges in terms of resources due to the legal deadlines for issuing comments or a detailed opinion (in the (EU) 2015/1535 procedure) and adopting decisions in accordance with Article 24(3) TPD.

Another provision, which allows EU Member States, under specific conditions, to take appropriate provisional measures regarding certain types of e-cigarettes or refill containers, including prohibiting their placement on the market, is Article 20(11) of the TPD. According to this Article, if a competent authority ascertains or has reasonable grounds to believe that specific e-cigarettes or refill containers could present a serious risk to human health, it may adopt provisional measures. The authority must immediately inform the Commission and other EU Member States and provide supporting data. Following notification, the Commission must assess, as soon as possible, whether the provisional measure is justified. If at least three EU Member States have prohibited a specific type of e-cigarette or refill container under this Article, the Commission can adopt a Delegated act extending the ban at EU level. To date, no EU Member State has invoked Article 20(11) to prohibit the placing on its market of specific types of e-cigarettes. Instead, some EU Member States have used Article 24(3) of the TPD to ban disposable e-cigarettes. Given the limited number of overall prohibitions resulting in a small sample size, a consistent rationale for this choice has not been determined. However, it appears that the stringent conditions of Article 20(11), specifically, the need to demonstrate a *serious risk to human health*, may have discouraged these EU Member States

[288] Application Report (2021).

[289] Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

[290] Study supporting the report on the application of Directive 2014/40/EU

[291] 2015/1535 notification procedure - European Commission.

from using it. This is particularly relevant as the health risks associated with the different types of e-cigarettes have become more evident recently, given their relatively limited time on the market. In addition, Article 24(3) does not require evidence of *a serious risk to human health* but allows EU Member States to adopt national provisions if *justified by the need to protect public health* (and under the other conditions described in this Article). This seems to make it a more accessible legal basis for banning specific types of e-cigarettes. Finally, the term "*serious risk*" in Article 20(11) may have caused uncertainty among EU Member States regarding its interpretation, which could also help to explain why this Article has not been used to date for a prohibition. It should be emphasised that, with the exception of the issues related to the availability and use of tobacco for oral use (snus) in EU Member States outside Sweden and the requirement under Article 18(4) of the TPD for age-verification systems, the other issues described above do not stem from a lack of effective enforcement at national level. Rather, they arise from regulatory shortcomings inherent in the design of the EU intervention itself. In particular, when the intervention was designed, certain products either did not exist or had only a limited presence on the market, certain marketing strategies had not yet emerged, or there had been insufficient time for the regulatory framework to reveal its limitations and structural gaps. Some of the shortcomings described above, such as the absence of rules governing nicotine products other than e-cigarettes; issues concerning the definition of "tobacco products" under Article 2(4) of the TPD, and the procedure for determining whether a tobacco product has a characterising flavour and prohibiting its placement on the market; and the lack of a definition of "combustion", are critical to the effective enforcement of existing rules of the TPD and the TAD and have negatively affected enforcement actions undertaken by EU Member States.

Cost-effectiveness of the tobacco control framework

The following analysis of the costs and benefits associated with the tobacco control framework demonstrates that it is a highly cost-effective tool in mitigating the public health and economic burden of tobacco consumption across the EU. Despite the costs required for the framework's implementation, the economic benefits of tobacco control are clear: reducing tobacco consumption results in lower healthcare expenditures, fewer productivity losses and less tobacco-related mortality and morbidity. In 2022, tobacco and nicotine products generated EUR 184.5 billion in GDP across the EU27, with traditional tobacco products generating EUR 100 billion in fiscal revenue[292]. However, the overall economic harm from tobacco consumption – estimated at around EUR 370 billion for the EU[293]in 2012 alone - outweighs these contributions.

Human and financial resources' allocation[294]

Survey responses from 12 EU Member States[295] indicate that, on average, 29.2 Full-Time Equivalent (FTE) staff per country are dedicated to implementing and enforcing the tobacco control framework, amounting to a total of 350 FTEs annually[296]. Financially, these 12 EU Member States spend an average of EUR 730 000 annually on tobacco control implementation, with individual

[292] Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

[293] Based on Goodchild M, et al. Tob Control 2018, Global economic cost of smoking-attributable diseases, assessing the smoking-attributable economic cost for the WHO Europe region in 2012 at 2.5% of GDP or EUR 287 billion for the EU in 2012, equivalent to EUR 370 billion in 2025 EUR value.

[294] The information comes from a targeted survey on the administrative efforts to implement the tobacco control framework. The results of this survey are described in Annex 5: Synopsis report of the different consultation activities.

[295] These EU Member States are Belgium, Bulgaria, Czechia, Ireland, Italy, Cyprus, Luxembourg, Malta, Netherlands, Romania, Slovenia and Finland.

[296] Annex 5: Synopsis report of the different consultation activities.

expenditures ranging from EUR 350 000 to 1.3 million [297]. The total annual cost across these 12 EU Member States amounts to EUR 8.76 million.
Roughly extrapolating these averages to the EU27 leads to the following estimated total resource allocation:
Human resources: 29.2 FTE × 27 EU Member States = approx. 790 FTEs
Financial cost: EUR 730 000 × 27 EU Member States = approx. EUR19.7 million annually

A reliable assessment of industry compliance costs proved challenging. The available data was too limited, scattered, and often inconsistent, with self-reported figures varying significantly across companies and lacking independent verification. Economic operators considered most TPD-related compliance costs proportionate, although over 40% expressed concerns about the cost burden associated with the implementation of labelling and packaging, and traceability provisions[24]. In particular, significant investment was needed to adapt production lines for manufacturers of tobacco products other than cigarettes[298]. Regarding the TAD, all stakeholder groups (namely, EU Member States' competent authorities, civil society organisations, and economic operators in the tobacco industry or related) agreed that the implementation costs were proportionate and assumable.

The table below presents the estimated costs per relabelled/repackaged product for the economic operators that responded to the cost template. The wide variation in these costs suggests significant differences in how companies experienced and complied with TPD requirements. The highest costs were typically associated with packaging redesign and changing the process for printing and packaging.

Table 6: Overview of labelling and packaging costs faced by industry – costs per relabelled/repackaged product[299]

Activities relating to change in labelling/packaging of products	Overview of replies
Understanding of labelling and packaging provisions	EUR 45 to 2 178 per product
Redesigning packages	EUR 108 to 1 370 per product
Redesigning labels	EUR 64 to 400 per product
Changing the process for printing or packaging	EUR 40 to 3 409 per product
Changing the materials or suppliers used for printing or packaging	EUR 45 to 137 per product

Cost-benefit comparison
Reducing tobacco consumption results in lower healthcare expenditures, fewer productivity losses, reduced tobacco-related mortality and morbidity, less informal care burden, and reduced socio-economic health disparities. Measures such as those related to health warnings or flavour bans, next to measures related to pricing or smoking bans, are associated with lower tobacco consumption[300].

297 The varying wage levels in individual EU Member States should be taken into account in this respect.
298 Study supporting the report on the application of Directive 2014/40/EU.
299 Ibid.
300 Akter, S., Rahman, M. M., Rouyard, T., Aktar, S., Nsashiyi, R. S., & Nakamura, R., 'A systematic review and network meta-analysis of population-level interventions to tackle smoking behaviour', *Nature Human Behaviour, Vol. 8, Issue* 12, 2024, pp. 2367–2391, https://www.nature.com/articles/s41562-024-02002-7.

Health-related costs linked to smoking may have decreased over time, although estimates differ depending on the study and methodology used. These figures are also influenced by long time lags and changes in the cost of healthcare technologies. In 2012, estimated smoking health-related costs in the EU amounted to around EUR 130 billion[301] while for 2023, another study estimated the health-related costs of traditional tobacco consumption (linked to direct health expenditure and indirect costs, including productivity losses and informal care) at EUR 80.7 billion per year across the EU[302], suggesting a notable decline. This suggests that the tobacco control framework has also generated savings for the EU Member States, allowing resources to be redirected toward other public health priorities.

Broader social benefits also apply. Smoking prevalence in the EU declined by around 14% between 2012 and 2023[303], reflecting a mix of cessation, reduced initiation, and demographic changes. Assuming that 60% of this decline is due to quitting[304], this suggests millions fewer smokers. Evidence from long-term cohort studies[305] indicates that cessation is associated with life expectancy gains of about 3 to 10 years, depending on the age of quitting. Applying a conservative estimate of 3 life-years gained per quitter, a value of EUR 52 000 per life-year in line with standard appraisal methods[306], and a 3% social discount rate[307] yields benefits associated with smoking cessation between 2012 and 2023 of roughly EUR 750 billion. While sensitive to underlying assumptions, these figures suggest that declining smoking prevalence generates substantial health and social benefits in the EU. Moreover, benefits due to people not taking up smoking are not included in these figures.

As referenced in section 4.1.1., the implementation of the EU tobacco-control framework, together with taxation and other fiscal measures, has contributed to a reduction in overall smoking prevalence; a decline in tobacco-related deaths and likely a considerable reduction in the health-related costs associated with the consumption of traditional tobacco products, as well as significant broader social benefits from smoking cessation. This indicates that tobacco control measures arguably have contributed to significant cost savings for the EU Member States and public health systems.

Given that the estimated benefits from both reduced healthcare costs and broader social gains from smoking cessation vastly outweigh the total estimated annual implementation cost of the tobacco-control framework (approximately 19.7 million EUR versus likely annual effects in the tens of billions), the cost-benefit outcome is highly positive.

Feedback from EU Member States and stakeholders further supports the conclusion that the tobacco control framework is cost-effective. EU Member States that participated in a targeted survey on the administrative efforts for the implementation of this framework, generally view the implementation costs as acceptable or lower than expected. The only exception is the procedure

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301 Based on Goodchild M, et al. Tob Control 2018, Global economic cost of smoking-attributable diseases, notably presented cost estimates for the WHO Europe region in 2012, covering direct healthcare costs and labour market productivity losses due to smoking-related disability. Adjusting for inflation would put the estimate at EUR 165 billion (2023 EUR value)

302 JRC (2025c).

303 Eurostat data on Smoking prevalence in the population 15 years old or older

304 See for instance Nigar Nargis et al., 2020, *Declining trend in cigarette smoking among U.S. adults over 2008–2018: A decomposition analysis*

305 Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. BMJ. 2004;328:1519.

306 European Commission, 2012, *A study on liability and the health costs of smoking*

307 European Commission, 2025, *Better Regulation Toolbox*, Chapter 8. A 20-year lead time is assumed for life expectancy outcomes.

for the determination of "characterising flavours", which 42% of respondents found too costly. EU Member States also considered compliance costs to be acceptable for economic operators and consumers, with 54% also considering the burden on public authorities to be appropriate[308]. Among the 10 EU Member States[309] which evaluated implementation efficiency, the areas of 'labelling and packaging', 'advertising', 'notifications', and 'tobacco traceability' were rated as the most efficient. Conversely, the area that required the smallest amount of human and financial resources ('characterising flavours') was identified by the EU Member States as the least efficient area.

It should also be noted that the provisions of the TTD have been efficient in reducing the cost of decreasing smoking prevalence, enhancing the benefits in terms of lives saved and reduced healthcare and productivity costs[310].

Simplification and burden reduction

The implementation of Article 7 of the TPD and Commission Implementing Regulation (EU) 2016/779 which concerns the procedure for determining whether a tobacco product has a characterising flavour, is considered the least efficient aspect of the TPD. The EU Member States that participated in a targeted survey on the administrative efforts for implementing the tobacco control framework identified the provisions on characterising flavours as costly, burdensome and inefficient[311]. In particular, the administrative process for assessing tobacco products flagged by EU Member States as potentially non-compliant and suspected of having a characterising flavour, was perceived as inefficient, ineffective[312] and particularly onerous, especially in terms of the time required for the assessment[313]. In this regard, the capacity of any of the existing agencies to carry out any tasks related to the ingredients of tobacco and related products does not appear to have been adequately considered[314]. From the Commission perspective, the same procedure is highly resource-intensive[315]. The Commission acts as the secretariat for the independent advisory panel assisting EU Member States and the Commission in determining whether tobacco products have a characterising flavour, and all activities related to the application of Commission Implementing Decision (EU) 2016/786. This includes providing administrative support to facilitate the efficient functioning of the Panel and to monitor compliance with the Panel's rules of procedure. The Commission organises the Panel's meetings, and serves as the intermediary between the EU Member States and the Panel for every request concerning the determination of a characterising flavour under Article 7 of the TPD. Additionally, the Commission is responsible for appointing the members of the Panel and overseeing their independence. 65 meetings of the Independent Advisory Panel took place until May 2025. All these tasks require substantial Commission resources. In addition, economic operators described the process of reporting through the EU-CEG, the IT tool developed to support the reporting obligations under Article 5 of the TPD for ingredients and emissions of tobacco products as well as Article 20 for e-cigarettes and refill containers, as 'complex' and 'time-consuming', although quantitative data on these claims remain limited[316]. EU

[308] Annex 5: Synopsis report of the different consultation activities.
[309] Czechia, Denmark, Italy, Cyprus, Latvia, Luxembourg, Romania, Slovenia, Finland and Sweden.
[310] https://taxation-customs.ec.europa.eu/system/files/2020-02/10-02-2020-tobacco-taxation-report.pdf
[311] Annex 5: Synopsis report of the different consultation activities.
[312] Ibid.
[313] Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.
[314] Application Report (2021).
[315] Ibid.
[316] Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

Member States also raised concerns regarding the IT design and operation of the EU-CEG system[317]. The EU-CEG system is also costly and resource-intensive for the Commission[318].

4.1.3. Coherence of the tobacco control framework

Coherence between TPD and TAD

Both Directives share the common objectives of ensuring the smooth functioning of the internal market and a high level of public health protection, especially for young people but they differ in scope regarding their advertising provisions, reflecting distinct yet interlinked roles within the framework. The TPD regulates the manufacture, presentation, and sale of tobacco and related products, and includes provisions on the advertising and sponsorship of e-cigarettes and refill containers. The TAD is focused specifically on regulating the advertising and sponsorship of tobacco products. This difference does not undermine their coherence but rather demonstrates how the Directives complement each other by addressing different regulatory needs. The differing definitions of "tobacco products" in the two Directives does not undermine this alignment[319].

The TPD mirrors the TAD's provisions on advertising in printed media, information society services, radio, and on sponsorship of events, extending them to e-cigarettes and refill containers. In doing so, the TPD addressed a regulatory gap, namely the lack of EU level advertising and sponsorship restrictions for e-cigarettes and refill containers, which were not present on the EU market at the time of the TAD's adoption in 2003. This extension demonstrates that the TPD indirectly updated the TAD to reflect developments in the tobacco and nicotine products' market.

However, the coexistence of two separate Directives applying the same advertising and sponsorship restrictions to tobacco products, e-cigarettes and refill containers creates unnecessary regulatory complexity. The TPD already regulates several aspects of tobacco products but does not cover their advertising. This issue has raised concerns among stakeholders, with the majority of respondents to the public consultation indicating that this is not the most effective means to achieve the legislative objectives of tobacco control legislation[320].

In addition, the differing treatment of cigarettes, roll-your-own tobacco and heated tobacco products versus e-cigarettes, particularly with respect to the regulation of flavours and labelling and packaging provisions, was seen as inconsistent within the TPD[321].

Despite these issues, stakeholder feedback noted the internal alignment of the framework. According to a targeted survey on the coherence of the tobacco control framework, all stakeholders groups agreed that the framework is internally and external coherent. Furthermore, 73% of EU Member States considered the provisions of the TPD internally coherent, and the TAD was similarly viewed as coherent, both in itself and in relation to TPD[322].

Coherence of the TPD and TAD with the Tobacco Taxation Directive

The TPD, TAD, and Tobacco Taxation Directive (TTD) form a cohesive legislative triad each addressing different dimensions of tobacco control. While each instrument operates independently

317 Ibid.
318 Application Report (2021).
319 Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.
320 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation_en
321 Study supporting the report on the application of Directive 2014/40/EU.
322 Annex 5: Synopsis report of the different consultation activities.

within its respective scope, all three Directives contribute to the shared objectives of ensuring the proper functioning of the internal market and a high level of public health protection. Together, they also support the implementation of the EU's international obligations under the FCTC and its Protocol to Eliminate Illicit Trade in Tobacco Products[323].

The TTD provides a harmonised framework for the structure and rates of excise duty applied by EU Member States to 'manufactured tobacco', including cigarettes, cigars, cigarillos, and other 'smoking tobacco'. This harmonisation is intended to prevent distortions of competition and barriers to the free movement of these products within the EU. Moreover, as the WHO has recognised, taxation is an effective and important tool which can be utilised in order to reduce tobacco consumption, particularly among young people[324]. While the TPD, TAD and TTD differ in the way they define tobacco products, this difference reflects the distinct scope of each Directive and does not result in their inconsistent application[325]. The fact that the TPD refers to the TTD for the definitions of 'cigarette' and 'cigar' further illustrates their integrated functioning. The TPD has a broader regulatory scope, covering not only cigarettes, RYO tobacco, cigars and cigarillos, but also smokeless tobacco products, and e-cigarettes and refill containers. The absence of explicit reference to novel tobacco products in the TTD is explained by the fact that those products were not on the market in 2011 and does not contradict the TPD[326].

However, it is important to note that on 16 July 2025, the Commission adopted a proposal for a recast of the TTD[327]. On the same day, the Commission also proposed a new own resource for the EU budget based on the minimum tobacco excise duty for manufactured tobacco and other tobacco products. This revision aims to modernise the current legal framework for tobacco excise duties by better aligning the taxation of tobacco and related products with public health objectives. The Commission proposal extends the Directive's scope to explicitly include products, such as smokeless tobacco products (namely, chewing and nasal tobacco for the purposes of the TTD), liquids (nicotine containing and nicotine free) for e-cigarettes, nicotine pouches and other nicotine products. The Commission proposal harmonises the tax rules and introduces minimum rates for these products. Additionally, raw tobacco is included in the TTD's scope to improve monitoring of its movement within the EU and thereby contribute to the fight against illicit tobacco trade.

On the basis of the Commission proposal, the revised TTD would expand its scope beyond that of the TPD and TAD regarding the tobacco and nicotine products covered by these Directives. In particular, the updated TTD would regulate not only tobacco products and e-cigarettes (from the nicotine products) but also all other nicotine products, including nicotine pouches which are currently not regulated by the TPD and TAD.

Coherence of the TPD and TAD with the Audiovisual Media Services Directive

The Audiovisual Media Services Directive (AVMSD) 2010/13/EU[328] regulates advertising bans for tobacco products, e-cigarettes and refill containers, thereby supporting the broader EU-wide restrictions on advertising for these products. Its scope is limited to 'audiovisual media services' and in this regard, it complements the advertising provisions of the tobacco control framework, which covers other forms of advertising (with cross-border effects) beyond audiovisual media.

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323 https://fctc.who.int/protocol

324 https://www.who.int/publications/i/item/9789240032095

325 Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

326 Ibid.

327 https://taxation-customs.ec.europa.eu/taxation/excise-taxes/excise-duties-tobacco/revision-tobacco-taxation-directive-proposal_en

328 Directive - 2010/13/EU - EN - EUR-Lex.

When comparing the tobacco control framework with AVMSD, some differences arise in the definitions of '*tobacco products', 'advertising', and 'sponsorship'*[329]. However, these minor differences are attributable to the different scopes and objectives of the two frameworks. For example, the AVMSD does not include a definition of 'tobacco products', as its primary focus is on regulating audiovisual media services and their content. The Directive defines '*television advertising'* and '*audiovisual commercial communications'* within the context of audiovisual media. The AVMSD includes provisions related to advertising time limits, sponsorship identification, and user protection (including minors), all tailored to the audiovisual media context. Its definition of 'sponsorship' is similarly framed in the context of audiovisual media services.

Some EU Member States participating in targeted interviews raised concerns about a potential misalignment between the TAD and AVMSD, particularly regarding gaps in regulating social media advertising[330]. However, it should be noted that the term '*information society services*' in the TPD and TAD covers digital advertising, including advertising on social media platforms[331].

An inconsistency between the tobacco control framework and the AVMSD arises in how depictions of brand names and corporate promotions are addressed. Under the tobacco control framework, such content is not permitted, only if the depictions of brand names and other corporate promotions are considered to have the aim or direct or indirect effect of promoting the tobacco products or e-cigarettes and their refill containers. In contrast, Article 11(4)(a) of the AVMSD prohibits programmes "*to contain product placement*[332] *of cigarettes and other tobacco products, as well as electronic cigarettes and refill containers, or product placement from undertakings whose principal activity is the manufacture or sale of those products*". Additionally, Article 9(1)(d) AVMSD indicates that 'all forms of audiovisual commercial communications for cigarettes and other tobacco products, as well as e-cigarettes and refill containers shall be prohibited'. This suggests that the AVMSD takes a stricter stance on non-product-specific communications brought forward by undertakings whose principal activity is the manufacture or sale of tobacco products, e-cigarettes and refill containers[333]. As a result, a regulatory misalignment emerges between the AVMSD and the tobacco control framework, weakening the overall consistency of EU-level advertising restrictions.

Coherence of the TPD and TAD with the FCTC

The measures of the tobacco control framework are in line with the relevant provisions of the WHO FCTC[334]. In fact, the tobacco-control framework has significantly contributed to the consistent

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329 European Commission, Directorate-General for Health and Food Safety, *Study on smoke-free environments and advertising of tobacco and related products: final report*, 2021, Publications Office, https://data.europa.eu/doi/10.2875/802479.

330 Annex 5: Synopsis report of the different consultation activities.

331 Mollet, D. (2025). Most social media platforms appear to fulfil the conditions of an information society service under Article 1(1)(b) of Directive 2015/1535, but a case-by-case analysis of each social media platform as a service provider is required.

332 Product placement is defined in Article 1(m) of the AVMSD as '*any form of audiovisual commercial communication consisting of the inclusion of, or reference to, a product, a service or the trade mark thereof so that it is featured within a programme or a user-generated video in return for payment or for similar consideration'*.

333 Mollet, D. (2025).

334 The FCTC introduces several obligations for the parties to it to adopt and implement measures concerning, among other things: a) protection from exposure to tobacco smoke (Article 8 of the FCTC); b) regulation of the contents of tobacco products (Article 9 of the FCTC); c) regulation of tobacco product disclosures (Article 10 of the FCTC); d) the packaging and labelling of tobacco products (Article 11 of the FCTC); e) tobacco advertising, promotion and sponsorship (Article 13 FCTC); f) illicit trade in tobacco products (Article 15 of the FCTC); and g) sales to and by minors (Article 16 of the FCTC).

implementation of the WHO FCTC by the EU. In this regard, the TPD introduced provisions that contributed to the implementation of the FCTC provisions concerning the regulation of the content of tobacco products (Article 9), their disclosure (Article 10), packaging and labelling (Article 11), the illicit trade in tobacco products (Article 15), and the promotion of research, surveillance, and information exchange (Article 20). Similarly, the TAD contributed to the implementation of the FCTC provision on the tobacco advertising, promotion and sponsorship (Article 13)[335]. Additionally, the Council Recommendation on Smoke- and Aerosol-Free Environments supports the implementation of Article 8 of the FCTC. 93% of the EU Member States participating in a targeted survey on the added-value of the tobacco control framework, believe that the TPD supports and supplements the FCTC policies[336]. Importantly, it enabled the consistent implementation of FCTC obligations by both the EU and its Member States, something that fragmented national efforts could not have achieved.

However, not all FCTC provisions are fully reflected in the EU framework. A gap concerns Article 5(3) FCTC, which requires Parties to protect their public health policies from the tobacco industry interference. Relevant provisions in the tobacco control framework include Article 4(2) of the TPD, which requires that laboratories verifying emissions are not owned or controlled directly or indirectly by the tobacco industry, as well as Article 35 of Implementing Regulation (EU) 2018/574, which sets out requirements to ensure the independence of entities participating in the EU tobacco traceability system. Although some EU Member States have adopted national measures to implement Article 5.3 of the FCTC[337], the approaches vary significantly, resulting in inconsistent levels of protection across the EU.

Another issue relates to the implementation of Article 19 of the FCTC, which addresses the liability of tobacco manufacturers for harm caused by their products. The EU tobacco-control framework contains no liability provisions for the harm caused by the tobacco and related product use. However, both the TPD and TAD establish provisions related to penalties and enforcement of the tobacco control framework. More specifically, the two Directives require EU Member States to set rules on penalties for infringements of national laws adopted under these Directives and to take all measures that are necessary to ensure that these penalties are enforced. The penalties must be effective, proportionate and dissuasive (see Article 23(3) of the TPD and Article 7(1) of the TAD). These provisions are also considered as measures that contribute to the implementation of Article 19 of the FCTC[338].

Coherence of the TPD with the CLP Regulation

CLP Regulation requires companies to classify, label, and package their chemicals in accordance with its legally binding rules. The CLP Regulation's labelling and packaging requirements may apply to products that are also subject to the TPD labelling and packaging requirements. The parallel application of the CLP Regulation and the TPD has created challenges for the competent authorities of the EU Member States, who are responsible for enforcing these regulatory frameworks[339]. This situation demonstrates the need for reflection on a more clearly defined allocation of regulatory roles between the two instruments in order to allow for better enforcement.

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335 WHO, *Two decades of the implementation of the WHO Framework Convention on Tobacco Control in the European Union: progress, challenges and the road ahead*, 2025.

336 Annex 5: Synopsis report of the different consultation activities.

337 https://globaltobaccoindex.org/report-summary

338 https://storage.googleapis.com/who-fctc-cop11-source/Main%20documents/fctc-cop11-6-en.pdf

339 https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/8539fae6-ff2b-4a87-8698-4c60dfbe4939/details, https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/3ee3232b-3028-4c48-a5df-a37a4caeea03/details

4.2 How did the EU intervention make a difference?

The EU intervention has provided significant added value in the field of tobacco control by introducing harmonised rules that facilitated the proper functioning of the internal market for tobacco and related products, while ensuring a high level of human health protection; and supported the EU's compliance with the FCTC and its Protocol to Eliminate Illicit Trade in tobacco products, and enhanced the cooperation among EU Member States. In the absence of harmonised EU rules, differing national laws would lead to market fragmentation and legal uncertainty, creating barriers to trade and undermining market cohesion.

The EU rules achieved results that could not have been attained by individual EU Member States acting alone, particularly considering diverging national regulations and varying levels of commitment to tobacco control. EU-level legislation established a framework for facilitating the functioning of the internal market and contributed to the implementation of stronger tobacco control measures despite tobacco industry's opposition and/or threat of legal challenges[340]. The framework established a uniform regulatory environment that delivered tangible benefits to a wide range of stakeholders, including consumers, and in particular young people, EU Member States' competent authorities and public health systems, economic operators and the Commission.

Notable regulatory advances include:

- The introduction of harmonised ingredient and emission reporting format and requirements by the TPD, Commission Implementing Decision (EU) 2015/2186[341] and Commission Implementing Decision (EU) 2015/2183[342] has improved transparency and regulatory oversight. National authorities and the Commission benefitted from enhanced data analysis and comparability, while tobacco products' manufacturers and importers benefited from streamlined, common reporting procedures. The creation of EU-CEG by the Commission facilitated the reporting of information on tobacco products and e-cigarettes. EU-CEG allows EU Member States and the Commission to process, compare, analyse and draw conclusions from the information received. Despite some challenges, the EU-CEG serves as an effective monitoring tool, enabling EU Member States to swiftly respond to product evolutions or upcoming 'outbreaks' of newly evolved tobacco products or 'variants of interest' across the EU MS markets as they emerge[343].
- The regulation of ingredients under the TPD - including the prohibition of specific additives in tobacco products and of characterising flavours in cigarettes, RYO tobacco, and HTPs, as well as flavourings in any of their components – protected the health of consumers and in particular young people, by reducing the appeal of tobacco products and preventing tobacco initiation[344]. As highlighted in Chapter 3, flavours other than tobacco significantly influence young people to use tobacco and nicotine products.
- The introduction of harmonised labelling and packaging rules under the TPD, including combined health warnings with a text warning, a colour photograph depicting medical conditions associated with smoking, and smoking cessation information, strengthened health protection and benefitted consumers. The health warnings changed the perception

340 Study supporting the report on the application of Directive 2014/40/EU
341 OJ L 321, 27.11.2015, p. 5.
342 OJ L 309, 26.11.2015, p. 15.
343 https://doi.org/10.1136/tobaccocontrol-2021-056548
344 Ibid, p. 199.

and use of tobacco products among young people by raising awareness of the health risks[345], reducing the products' attractiveness, preventing initiation and supporting cessation efforts. Harmonising packaging and labelling was a key success of the tobacco control framework[346], as it also established uniform presentation of tobacco products across the internal market, thereby ensuring consistency.

- The development of an EU-wide traceability system for tobacco products under the TPD and Commission Implementing Regulation (EU) 2018/574[347], undertaken to implement Article 8 of the Protocol to Eliminate Illicit Trade in Tobacco Products, has been crucial in strengthening the integrity of the tobacco products' supply chain. The system provides an unprecedented amount of data on the legal supply chain of tobacco products, from the point of manufacture to the last economic operator before the first retail outlet. The system assists EU Member States in identifying instances where traceability requirements have not been met. There was no significant change in the post-2019 slope in illicit trade in Europe indicating that the pre-existing rate of decline in illicit trade continued after the traceability system was introduced. It is therefore likely that the system has contributed to the maintenance of the overall downward trend in illicit trade across the EU since it became operational in 2019[348].
- The TPD also empowered EU Member States to prohibit cross-border distance sales of tobacco products, e-cigarettes and refill containers, while also requiring their cooperation to prevent such sales so that these products are not sold in EU Member States where cross-border distance sales are banned. In addition, the TPD require retail outlets engaged in cross-border distance sales to operate an age verification system, which verifies that the purchasing consumer complies with minimum age requirements provided for under the national law of the EU Member State of destination. These provisions of the Directive have contributed to limiting consumer access to tobacco products, e-cigarettes, and refill containers by reducing cross-border distance sales[349].
- The TPD introduced the concept of 'novel tobacco products' with a date-based definition that captures all tobacco products placed on the EU market after a specific date. In this way, any new tobacco products are subjected to the TPD restrictions, thereby protecting consumers' human health while ensuring a level playing field for these products. Additionally, the 'substantial change of circumstances' mechanism established by the TPD empowers the Commission to withdraw certain exemptions for tobacco products that have undergone such a change. As a result, restrictions, such as a ban on characterising flavours and stricter labelling requirements, may be imposed if significant changes occur in sales volumes or consumption patterns among young people. In this way, the TPD provides an extra layer of protection for this age group.
- The TPD requirement for manufacturers and importers to notify novel tobacco products to the national competent authorities six months before the intended placing on the market enhanced regulatory preparedness and allowed for the EU Member States' timely health risk assessments of new products. This facilitates informed decision-making by national authorities and prevents the introduction of products that are not compliant with the rules of the TPD, including those related to prohibited ingredients[350].

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345 Study supporting the report on the application of Directive 2014/40/EU, Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

346 Application Report (2021), Support study to the report on the application of Directive 2014/40/EU.

347 OJ L 96, 16.4.2018, p. 7.

348 Vardavas (2025b).

349 Support study to the report on the application of Directive 2014/40/EU.

350 Results of the study supporting the evaluation of the tobacco control *acquis*, study conducted by Open Evidence, 2025.

- The TPD also established a harmonised framework for e-cigarettes and refill containers, setting among others, a requirement for notification before their intended placing on the market, maximum nicotine limits for the nicotine-containing liquid, regulation of their ingredients, labelling and packaging requirements, and advertising and sponsorship restrictions. These rules harmonised previously divergent national regulations, ensuring consistent regulatory standards across the internal market. EU Member States recognised this and reported that the TPD introduced requirements for e-cigarettes that previously some EU Member States reported not having, and it was a good starting point for their regulation[351]. In addition, these provisions enhanced consumer safety by reducing exposure to e-cigarette advertising, particularly on radio, television, in the press and other printed publications, minimising the risk of accidental consumption of high doses of nicotine and ensuring the provision of sufficient and appropriate information on the use of e-cigarettes. These rules also strengthened regulatory preparedness by enabling timely health risk assessments by national competent authorities.
- The TPD rules on cooperation and information exchange between EU Member States, and between EU Member States and the Commission, together with the Market Surveillance Regulation (EU) 2019/1020[352], strengthened the market surveillance, implementation and enforcement of tobacco control measures[353]. This facilitated a more consistent application of the rules, supported EU Member States' enforcement efforts and contributed to collective progress toward public health objectives. Many EU Member States reported benefitting from these rules, especially those with less technical expertise and fewer resources available. Initiatives such as the Joint Action on Tobacco Control (JATC) and the Group of Experts on Tobacco Policy have been instrumental in this regard, fostering information exchange and capacity building that underpin the effective implementation of the tobacco control framework across EU Member States.
- Cross-border advertising and sponsorship of tobacco products were brought under unified EU regulation, closing gaps in national laws and limiting the advertising, promotion and sponsorship of these harmful products, particularly through traditional media channels such as television, radio, the press, and other printed (non-professional) publications[354]. Before the adoption of the TAD, Directive 98/43/EC regulated tobacco products' advertising and sponsorship but was annulled by the Court of Justice in Case C-376/98 Federal Republic of Germany v European Parliament and Council of the European Union. This left a regulatory gap, and differences in EU Member States' laws on tobacco advertising and sponsorship created barriers to the free movement of products and services supporting such advertising and sponsorship.
- In addition, the TAD provisions, through their obligations on the EU Member States, enabled the enforcement of stricter advertising controls. As a result, consumers benefited from better protection against harmful marketing practices, while public health authorities gained stronger tools for regulation. EU Member States that participated in a targeted survey on the added value of the tobacco control framework, reported that the TAD enable them to implement effective tobacco control policies in the area of tobacco advertising and sponsorship compared to what they could have done alone, with 78% of civil society organisations considering EU-level action essential to meet public health objectives[355].

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351 Annex 5: Synopsis report of the different consultation activities.

352 OJ L 169, 25.6.2019, p. 36.

353 https://op.europa.eu/en/publication-detail/-/publication/9ce15083-b931-11eb-8aca-01aa75ed71a1/language-en. The information presented in this paragraph is taken from the same source.

354 *Study on smoke-free environments and advertising of tobacco and related products*, European Commission (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC7526780/pdf/ckaa055.pdf

355 Annex 5: Synopsis report of the different consultation activities.

4.3 Is the intervention still relevant?

The tobacco control framework has been essential in ensuring, to a certain extent, the proper functioning of the internal market for tobacco and related products. In the absence of harmonised EU rules, differing national laws would lead to market fragmentation and legal uncertainty, creating barriers to trade and undermining market cohesion. Furthermore, the framework has enabled the EU and its Member States to implement their international obligations under the WHO FCTC and its Protocol to Eliminate Illicit Trade in a consistent and coordinated manner.

Tobacco remains one of the most serious public health threats in the EU, causing addiction, severe illnesses, and premature death. In this context, the tobacco control framework remains relevant as ever today given the rapid market evolution of tobacco and nicotine products, and its absence would likely result in significantly worse public health outcomes. As explained in section 4.1.2., between 2012 and 2023, the EU saw: a decline in tobacco products' total sales' volume and value, particularly cigarettes. These declines were accompanied by a reduction in overall smoking prevalence, with an even sharper decrease among young people aged 15 to 24. Importantly, these improvements have translated into a reduction in tobacco-related deaths, clearly demonstrating the life-saving impact of the EU tobacco control framework.

These positive developments are the result of comprehensive measures introduced under the tobacco control framework, including restrictions on the manufacture, presentation, sale, and advertising of tobacco and related products. Without these measures, cigarettes and other tobacco products would be more widely available, more easily and aggressively marketed, and consumed by a higher number of people, particularly by young people.

In addition, the health-related costs associated with smoking have also decreased. In 2012, the economic burden of smoking on EU Member States, including direct healthcare costs and productivity losses due to disability, was cautiously estimated to be around EUR 130 billion. By 2023, these costs had declined to an estimated EUR 80.7 billion per year across the EU. Without the tobacco control framework, these costs would likely have remained significantly higher, placing greater strain on national budgets and health systems.

As the tobacco and nicotine products' market continues to evolve with the introduction of new products the relevance of the framework becomes even more pronounced. Thanks to the existing rules, products such as e-cigarettes and HTPs, are regulated under the framework, ensuring that they are subject to appropriate requirements. These measures ensure that the public, and especially young people, continue to be protected from the harmful effects of these products. Additionally, other novel tobacco products beyond HTPs that may emerge in the future, will also fall within the scope of the EU tobacco control framework and be subject to its restrictions. The growing use of aggressive digital marketing strategies targeting young people[356] makes the tobacco control framework more essential than ever. Without a strong and adaptive EU regulatory framework, the market would be vulnerable to widespread exposure to new tobacco and nicotine products, threatening to reverse the progress achieved in reducing smoking and tobacco-related harm.

The tobacco control framework has been key in ensuring the smooth functioning of the internal market for tobacco and related products, while ensuring a high level of human health protection by significantly contributing to the reduction in tobacco consumption, smoking-related diseases and deaths, as well as the relevant economic burden on EU Member States. It has also supported the

[356] Lazuras (2025).

Union in fulfilling its obligations under the WHO FCTC. Without this framework, tobacco use, especially among young people, would be significantly higher resulting in more tobacco-related deaths and higher public health costs. The objectives, provisions and scope of the framework remain highly relevant, as the use of tobacco and nicotine products persists in the EU. Maintaining and where necessary, further strengthening this framework, particularly in relation to novel tobacco and nicotine products, is not only necessary but essential to safeguard the proper functioning of the internal market, while continuing to ensure a high level of public health protection in the EU, especially for young people.

5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED?

5.1. CONCLUSIONS

The tobacco control framework introduced several measures that have contributed, to some extent, to the smooth functioning of the internal market and to a decline in smoking prevalence, alongside the TTD, the AVMSD and national tobacco control policies and legislation in areas not harmonised by the framework, such as smoke-free environment policies and plain packaging requirements. Other EU legislation such as the Market Surveillance Regulation, the CLP Regulation and external factors including those described in Section 4.1.2 may have also contributed to these outcomes. Approximately 40% of the decline in smoking prevalence in the EU is associated with taxation policies.

The TPD and TAD introduced provisions that contributed to increased public awareness of the harmful effects of traditional tobacco products, reduced their appeal and uptake, influenced young people's attitudes toward smoking, supported cessation efforts and enhanced the cooperation and information exchange between EU Member States. The TPD provisions also supported the implementation of the FCTC by both the EU and its Member States, notably regarding the regulation of the content of tobacco products (Article 9), their disclosure (Article 10), packaging and labelling (Article 11), the illicit trade in tobacco products (Article 15), and the promotion of research, surveillance, and information exchange (Article 20). Similarly, the TAD, together with Article 20(5) of the TPD and the AVMSD, have reduced the advertising and promotion of tobacco products and e-cigarettes across traditional media channels such as television, radio, the press, and other printed publications. The TAD also contributed to the implementation of the FCTC provisions on the tobacco advertising, promotion and sponsorship (Article 13). Among these measures, the TPD provisions prohibiting characterising flavours in cigarettes, RYO tobacco and HTPs, and any of their components, the TAD ban on tobacco advertising and sponsorship and the TPD requirement for combined health warnings on cigarettes, RYO tobacco, waterpipe tobacco and HTPs are considered to have made the most significant contribution to the reduction of smoking prevalence and the tobacco-related deaths.

In view of the considerable social benefits associated with smoking cessation, the EU tobacco control framework is a cost-effective tool for reducing the economic burden of tobacco consumption. However, the implementation of Article 7 of the TPD and Commission Implementing Regulation (EU) 2016/779 on the determination of a tobacco product with a characterising flavour is considered the least efficient aspect of the Directive. EU Member States regarded this procedure as costly, burdensome, and time-consuming. In addition, economic operators described the reporting through EU-CEG as complex and time-consuming, despite the absence of quantitative evidence.

The framework's key components work cohesively and complement each other, reflecting their distinct but complementary regulatory roles. Overall, the framework aligns well with the TTD

although under the Commission's proposed revision the TTD would expand its scope beyond that of the tobacco control framework, and this would create a misalignment -in terms of scope- between the tobacco control framework and the TTD. While the framework is mostly coherent with the AVMSD, inconsistencies in addressing brand depictions and corporate promotions create a misalignment, weakening the overall consistency of the EU advertising restrictions. 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 tobacco industry interference and liability.

Despite the positive aspects, the analysis reveals that the smoking prevalence in the EU remains high, particularly among young people, and that the current framework is not aligned with recent market developments, consumption trends and digital marketing practices as certain provisions of it have been superseded by such developments, and in particular: a) the emergence and widespread popularity of novel tobacco and nicotine products, such as e-cigarettes, HTPs, and nicotine pouches, especially among young people (while the health risks of these products are becoming clearer, their long-term impact remain uncertain); b) the rapid evolution of digital marketing of tobacco and nicotine products, which significantly influences their use, in particular among young people.

Regulatory shortcomings undermine the framework's effectiveness

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

Divergent regulation across EU Member States of flavours in e-cigarettes, disposable e-cigarettes, nicotine pouches, plain packaging requirements for tobacco products and e-cigarettes, tobacco heating devices and ENNDS create serious distortions to the smooth functioning of the internal market. While the scope of the tobacco control framework covers all tobacco products, it does not sufficiently cover all nicotine products and ENNDS thereby creating a coherence gap with the Commission proposal for the revision of the TTD. In addition, new types of herbal products are also excluded from the framework's scope.

The procedure for determining whether a tobacco product has a characterising flavour leads to significant delays in removing non-compliant flavoured products from the market. Moreover, the framework makes it difficult for EU Member States to determine whether HTPs fall under the category of 'tobacco products for smoking' or 'smokeless tobacco products', increasing the risk that some HTPs and future novel tobacco products are labelled with less effective health warnings. In addition, the current labelling rules do not offer the same level of protection for smokeless novel tobacco products as for novel tobacco products for smoking. Moreover, the health warnings have not been updated since 2014 to reflect the latest scientific evidence. As a result, there is a risk that these warnings no longer capture the full range of health risks associated with tobacco and nicotine product use, potentially undermining their effectiveness in communicating those risks to consumers.

Certain limitations within the EU-CEG prevent it from reaching its full potential as reporting tool. Furthermore, the availability and use of snus in EU Member States outside Sweden undermine the effectiveness of the relevant ban in Article 17 of the TPD. The age-verification requirements under Article 18(4) of the TPD have also largely been ineffective in preventing sales to minors. The nicotine limit of 20 mg/ml for the nicotine containing liquid of e-cigarettes may be inadequate for

newer forms of nicotine, allowing e-cigarettes with faster and/or stronger addictive effects to enter the market.

Although the TAD, TPD and AVMSD appear to have contributed to reducing the advertisement and promotion of tobacco products and e-cigarettes through traditional media channels, there are still notable shortcomings. These include limitations in the scope of products covered by the advertising provisions and legal loopholes that allow certain promotional practices to persist via digital means. For instance, brand or corporate promotion that does not have the aim or direct or indirect effect of promoting the tobacco products or e-cigarettes and their refill containers, as well as independently created user-generated content not designed to promote, directly or indirectly, a product or a company pursuing a commercial activity, seem to fall outside the scope of the current regulatory framework.

Finally, the implementation of certain provisions of the tobacco control framework has proven to be highly resource intensive for the EU Member States and the Commission. These provisions concern the procedure on the determination of characterising flavours in tobacco products, the EU tobacco traceability system, the procedure of Article 24(3) of the TPD and the EU-CEG system.

5.2. LESSONS LEARNED

The EU tobacco control framework has contributed to a high level of public health protection, particularly for young people, and the smooth functioning of the internal market for the products it was designed to regulate. This contribution is widely acknowledged by EU Member States and economic operators, and is supported by evidence concerning the decrease in the prevalence of the use of traditional tobacco products and the number of tobacco-related deaths.

However, the framework was developed in a market environment that is considerably different from today's. Many novel products did not exist or had very limited market presence and prevalence, especially among young people, when the framework was introduced. Nor was the framework designed to address the scale and nature of today's digital marketing, which has resulted in an increased uptake of these products by young people through diverse promotional channels. While the framework remains largely effective in regulating traditional tobacco products, these developments reveal its limited capacity to achieve its objectives with respect to novel products, in particular in terms of new public health challenges. At the same time, evolving product categories, fragmented data availability, and the interaction between EU-level and national measures have made it increasingly difficult to clearly attribute observed changes in use patterns and health outcomes to specific regulatory interventions.

As the market continues to evolve and diversify rapidly, an increasing number of new products that are likely to emerge and appeal to young people, will fall outside the scope of the tobacco control framework. The framework's continued effectiveness in supporting the smooth functioning of the internal market for all tobacco and related products, and ensuring a high level of public health protection, particularly for young people, depends on its capacity to contribute to a further decrease in smoking prevalence in line with the objectives of Europe's Beating Cancer Plan, and to address the rising use of novel products and associated public health challenges by adapting to evolving market trends, consumption patterns, and digital promotion practices.

ANNEXES

ANNEX 1: PROCEDURAL INFORMATION

1. Lead DG, Decide Planning/CWP references

The evaluation of the Tobacco Products Directive[357] (TPD) and the Tobacco Advertising Directive[358] (TAD) was prepared under the lead of the Directorate-General for Health and Food Safety. In the Decide Planning of the Commission, the process is referred to under item PLAN/2021/12253. The evaluation of the tobacco control legislative framework was mentioned in Commission work programme 2026[359].

This is an evaluation of the TPD and TAD. In this context, the provisions of the following implementing and delegated acts that were adopted on the basis of the TPD, were also assessed, to the extent possible: Commission Implementing Regulation (EU) 2016/779, Commission Delegated Directive (EU) 2022/2100, Commission Implementing Decision (EU) 2015/2186, Commission Implementing Decision (EU) 2016/786, Commission Implementing Decision (EU) 2016/787, Commission Delegated Directive 2014/109/EU, Commission Implementing Decision (EU) 2015/1842, Commission Implementing Decision (EU) 2015/1735, Commission Implementing Regulation (EU) 2018/574, Commission Delegated Regulation (EU) 2018/573, Commission Implementing Decision (EU) 2018/576, Commission Decision (EU) 2019/691, Commission Implementing Decision (EU) 2016/586, Commission Implementing Decision (EU) 2015/2183.

2. Organisation and timing

The evaluation is based on the following consultation activities:

- a call for evidence[360] that was open from 20 May 2022 to 17 June 2022 and resulted in 24 359 contributions, mostly from EU citizens (93%);
- a public consultation[361] that was open from 21 February to 16 May 2023 and resulted in more than 17 000[362] contributions. The majority of the responses (89%) came from EU and non-EU citizens, while the remaining contributions (11%) were submitted by companies, business associations, academic institutions, NGOs, consumer organisations, public authorities and other stakeholders;
- a targeted survey[363] of key stakeholders other than EU citizens (namely Member States' competent authorities, civil society organisations and economic operators in the tobacco industry or related) that was carried out in June-July 2023 and resulted in 64 responses.
- a second targeted survey[364] addressing the administrative efforts related to the implementation of the tobacco control framework, was carried out between October 2024 and February 2025. It was distributed to 29 European countries (the 27 EU Member States

357 OJ L 127, 29.4.2014, p. 1
358 OJ L 152, 20.6.2003, p. 16
359 Commission work programme 2026 Europe's Independence Moment, COM/2025/870 final.
360 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control_en
361 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation_en
362 Initial number of submissions: 17 773.
363 Annex 5: Synopsis report of the different consultation activities
364 Annex 5: Synopsis report of the different consultation activities.

plus Iceland and Norway) via the Expert Group on Tobacco Policy and was analysed by the Commission's Joint Research Centre (JRC). .

- targeted interviews[365] of key stakeholders other than EU citizens that were carried out in July 2023 and resulted in 26 completed interviews of 30 stakeholders (eight EU Member States, 10 economic operators and 12 civil society Organisations).

An Inter-service Coordination Group (ISCG) was created in 2022 and assisted DG Health and Food Safety in the evaluation process. The ISCG included Commission services of Directorate-Generals AGRI, GROW, RTD, JUST, ENV, EISMEA, EAC, CNECT, TRADE, BUDG, INTPA, TAXUD, OLAF, JRC and the Commission's Secretariat General and Legal Service. In total, four meetings were held in relation to the evaluation of the tobacco control framework, with the final meeting taking place on 8 October 2025. During this meeting, the ISCG discussed the key findings and conclusions of the evaluation. Several Directorate-Generals provided written comments on the evaluation documents, namely the Staff Working Document ('SWD') and its Annexes. These services agreed with the revised version of the document and the conclusions of the evaluation.

3. Consultation of the Regulatory Scrutiny Board

The draft SWD on the evaluation and all supporting documents were submitted to the Regulatory Scrutiny Board ('RSB') on 10 November 2025, in view of a meeting on 9 December 2025. The draft SWD was reviewed by the RSB which issued a negative opinion on 12 December 2025. The opinion includes key issues of the draft SWD and recommendations on how the SWD could be improved and which were addressed as explained below:

Table 1: How recommendations of the RSB have been addressed.

Recommendations of the RSB	**Modifications in the SWD on the evaluation in response to the Board's recommendations**
(1) Given that the two Directives and the Tobacco Taxation Directive (TTD) share the same objectives of ensuring a functioning internal market and a high level of health protection in relation to tobacco products, the evaluation should analyse the contribution of tobacco taxation, building on the evidence from earlier evaluations and impact assessments of TTD, to ensure coherence.	Contribution of tobacco taxation to the objectives of facilitating the smooth functioning of the internal market (section 4.1.1.), ensuring a high level of human health protection, especially for young people (section 4.1.2.) and to the cost-effectiveness of the tobacco control framework was added, drawing on the evidence from the evaluation and impact assessment of TTD. This contribution was also highlighted in the conclusions (section 5.1).
(2) The report should clearly describe which products are in scope of the covered legislation, and where the existing legislation falls short on new and emerging products. The report should provide a comprehensive overview of the evolution of prevalence	A table describing the products that fall within and outside the scope of the TPD and TAD, was included in Section 2.1. A new figure concerning the evolution of prevalence for heated tobacco products was added (next to those already included for

[365] Annex 5: Synopsis report of the different consultation activities

related to all products over the evaluation period, including on young people and 55+.	smoking products and electronic cigarettes) in section 3. For all figures of section 3 concerning the trends in the prevalence of use of the different products, the overviews provide information for all available age groups, including young people and those aged 55 and over. In section 2.2, a reference to the 55 and over age group was added to the paragraph concerning the situation in 2012.
(3) The report should better distinguish between the intervention covered by the evaluation and other factors impacting consumer behaviour, for example, price and changing consumer preferences; it should better analyse what factors are driving any changes in the consumption of tobacco. The report should substantiate the effectiveness analysis with evidence regarding individual measures foreseen in the Directives and analyse underlying factors that may reduce their effectiveness. The report should also improve the analysis of the extent to which the effects on health protection can be attributed to these two Directives.	Explanations have been added in sections 2.1 and 4.1.2 to clearly distinguish the intervention of the TPD and TAD from other EU legislation and external factors. In addition, a separate subsection has been introduced in section 4.1.2 on external factors that impact consumer behaviour. This subsection outlines the reasons preventing smoking initiation, the reasons for quitting smoking, and the reasons for the uptake of e-cigarettes. A visual graph illustrating the key factors influencing smoking initiation and cessation has been included in section 4.1.2. to provide a clear overview of the different factors, including measures of the TPD and TAD, contribute to health protection. Furthermore, evidence relating to specific measures of the TPD and TAD (the tobacco advertising and sponsorship bans, combined health warnings and the prohibition of placing on the market tobacco products with characterising flavours) was added in section 4.1.2 to strengthen the effectiveness assessment. Additional factors that may limit the effectiveness of the two Directives have been included in the section addressing gaps and shortcomings in the current tobacco control framework.
(4) The report should analyse different situations, measures and policies of the Member States and explain how these have affected the overall effectiveness of the EU level framework. The report should also analyse to what extent observed problems affecting effectiveness are due to the design of the intervention or are related to enforcement at Member State level. The analysis on the internal market should be further elaborated, in particular regarding the impact of harmonisation on the effectiveness of tobacco policies.	New figures on the prevalence of use of different products by Member State have been added in section 3. Additional information on national tobacco control policies and measures beyond those provided for under the TPD and TAD - such as rules on smoke-free environments, sales arrangements, and age limits - has been included in sections 2.1 and 4.1.2 of the report. Explanations clarifying the extent to which observed gaps and shortcomings in the TPD and TAD affecting effectiveness are attributable to the design of the intervention

	or to enforcement at Member State level have been added to section 4.1.2. The analysis of the internal market in section 4.1.1 has also been strengthened to better illustrate its impact on the effectiveness of tobacco policies.
(5) The conclusions on effectiveness and efficiency should not go beyond what is supported by evidence and analysis. They should reflect uncertainties of analysis on the contribution of the legislation to reducing the smoking prevalence of traditional products and on the health impacts of novel products and on the impact of other measures such as taxation.	The conclusions on effectiveness and efficiency in section 5.1 have been revised to better reflect the uncertainties in the analysis regarding the TPD and TAD contribution to reducing the prevalence of traditional tobacco products, as well as the health impacts of novel products. The revised text also more clearly highlights the influence of other measures, such as taxation.
(6) The report should analyse to what extent the data provided by monitoring and evaluation framework allow to build a sufficient evidence base to evaluate effectiveness, efficiency, coherence and relevance, and draw related lessons.	Explanations of the limitations of the analysis based on data derived from the monitoring and evaluation framework have been added to section 1.3.
(7) The conclusions and lessons learned should provide a clear account of lessons related to products in scope, including effectiveness of packaging requirements, traceability and other measures related to illicit trade, age verification, requirements related to toxicity, advertisement.	An overview of both the positive elements and the regulatory shortcomings related to specific measures of the TPD and TAD that affect the smooth functioning of the internal market, as well as the objective of ensuring a high level of public health protection, particularly for young people, has been added to the conclusions in Section 5.1.

4. Sources of evidence and expertise used

This evaluation draws on a broad and diverse evidence base, including a supporting study conducted by an external contractor. This study was submitted to the Commission in March 2024. Additionally, from autumn 2024 to summer 2025, the Commission contracted four external experts, who provided reports on the following matters:

- the EU tobacco traceability system and the illicit trade in tobacco products in the EU;
- the assessment of the causes, drivers and level of cross-border distance sales in the EU;
- the use and impact of digital promotion of tobacco and nicotine products, in particular the current marketing practices and behavioural effects related to the digital promotion of tobacco and nicotine products;
- the advertising of tobacco and related products, with particular focus on whether the current scope of EU tobacco control legislation adequately covers all forms of digital advertising and promotion.

During the same period, JRC provided expert reports on the following issues:

- the health-related costs attributable to tobacco use in the EU;

- trends and patterns of use of tobacco and nicotine products in the EU;
- health outcomes associated with the use of e-cigarettes, heated tobacco products and nicotine pouches.

The JRC also provided an analysis of the Member States' administrative tasks in relation to TPD and TAD implementation, in particular the human and financial resources allocated to the implementation of these two Directives. This was done on the basis on new data provided by Member States on their use of Full-Time Equivalents (FTE) for TPD and TAD implementation. This information was obtained by the Commission through a questionnaire sent to the Expert Group on Tobacco Policy in autumn-spring 2024-2025. In the questionnaire, Member States were also asked to assess the effectiveness and efficiency of their activities in relation to the TPD and TAD implementation on a scale from 1 to 5. The JRC converted the FTE to monetary costs by means of Eurostat data on the annual wages in Member States and analysed the scores on effectiveness and efficiency. This analysis supported the assessment of the effectiveness and efficiency.

The evaluation also incorporated findings from expert studies, scientific reports, surveys and other documents addressing, among others, the following issues:

- The implementation of WHO 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 implementation, application and impact of the TPD and TAD;
- The attitudes of EU citizens towards tobacco and related products, in particular the prevalence of tobacco and nicotine products use in the EU;
- The sales value and volume of tobacco and related products;
- The characteristics of novel tobacco and nicotine products;
- The relationship between EU tobacco control legislation and other relevant areas of EU law.

Furthermore, the evaluation integrates quantitative and qualitative data from the following sources of evidence:

- Epidemiological and behavioural surveys, such as Eurobarometer (2012, 2020, 2023), EHIS, HBSC and ITC (2016–2022);
- Market data analytics, such as Euromonitor passport 2025 data.

Where possible, indicators were disaggregated by age, and Member State to support equity-aware assessments.

The main data sources used across the different sections of the evaluation are listed in Annex 3.

ANNEX 2: METHODOLOGY AND ANALYTICAL MODELS USED

1. Purpose and Scope of Annex 2

This Annex sets out the methodological framework and analytical foundations for the evaluation of the Tobacco Products Directive 2014/40/EU[366] (TPD) and the Tobacco Advertising Directive 2003/33/EC[367] (TAD). It underpins the accompanying evaluation and ensures full transparency of the evidence base and evaluative processes used.

The purpose of this Annex is to document:

- What has been done and by whom, for this evaluation, including a description of the process as well as details relating to the methodologies applied;
- The limitations of this evaluation and mitigation measures taken, including how uncertainties in the analytical results were addressed;
- An assessment of the work carried out by the external contractors;
- The steps taken to assure the quality of the analytical results presented in the evaluation.

This Annex serves as the technical backbone of the evaluation and is intended to be read alongside it. Each chapter of the evaluation references corresponding components described in this Annex.

2. What has been done and by whom, for this evaluation, including a description of the process as well as details relating to the methodologies applied

2.1. Evaluation process

2.1.1. Evaluation questions

The evaluation answers the following questions in the manner presented below:

- ***What was the expected outcome of the intervention?***

The evaluation explains the rationale for the EU tobacco control intervention at the time it was adopted. In short, the expected outcome of the intervention was to ensure the smooth functioning of the internal market for tobacco and related products while taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the Union under the WHO Framework Convention for Tobacco Control ('FCTC'). To provide further clarity, the evaluation report includes a visual depicting the objectives, outputs, results and impacts of the tobacco control legal framework drawing on the impact assessment report for the TPD[368], a[369] and the recitals of the TPD and TAD. It also refers to the points of comparison against which the EU intervention was assessed.

366 OJ L 127, 29.4.2014, p. 1
367 OJ L 152, 20.6.2003, p. 16
368 https://health.ec.europa.eu/document/download/4feef42c-f49f-49ac-864f-edae2a24c0c7_en?filename=com_2012_788_ia_en.pdf
369 Report on the implementation of the EU Tobacco Advertising Directive, COM(2008) 330 final

- ***How has the situation evolved over the evaluation period?***

The evaluation provides a factual overview of the progress made in implementing the tobacco control intervention, both from a legal perspective and in practice. Specifically, it examines the situation of tobacco and related products in the EU since 2012, including trends in prevalence and consumption, market developments (such as the value and volume of the different product categories in 2012 and 2023), and the overall sales value of the EU market for both traditional and novel tobacco products and nicotine products in those years. The trends showcase the emergence and growing popularity of new products in the EU market, alongside a decline in the use of traditional tobacco products. The evaluation also analyses how the advertising and promotion of tobacco and nicotine products have evolved over the evaluation period and describes the health risks associated with the use of novel products. The trends are clear: social media has emerged as a rapidly growing platform for the promotion of tobacco and nicotine products.

- ***To what extent was the intervention successful and why?*** *[criteria to be assessed: effectiveness, efficiency, coherence]*

The evaluation compares the expected situation (What did we expect to achieve?) with the actual situation (How have things changed over the evaluation period?). 'Success' is assessed based on the extent to which the intervention has achieved its objectives: effectively, efficiently, and in a coherent manner. The evaluation outlines the positive aspects while also identifying gaps and shortcomings in the tobacco control framework that undermine its overall effectiveness. The analysis of efficiency includes a review of the costs and benefits associated with the framework. Additionally, the evaluation examines the internal and external coherence of the tobacco control framework.

- ***How did the EU intervention make a difference?*** *[criterion to be assessed: EU added value]*

The evaluation provides a detailed assessment of the EU added value of the tobacco control framework's intervention for citizens, Member States' competent authorities and public health systems, and economic operators within the EU. The evaluation explains who has benefited from the EU intervention.

- ***Is the intervention still relevant?*** *[criterion to be assessed: relevance]*

The evaluation looks at the objectives of the tobacco control framework's intervention and see how well they addressed during the evaluation period and most importantly, they still address current and future needs.

- ***What are the conclusions and lessons learned?***

The evaluation includes:

- a summary of the positive elements of the tobacco control framework's intervention as well as of the gaps and shortcomings that limit the framework's effectiveness;
- a presentation of credible evidence-based lessons learnt.

2.1.2. Evaluation criteria

The evaluation applied the Better Regulation Framework, assessing the tobacco control framework against five criteria:

Criterion	Key Focus
Effectiveness	*To what extent the tobacco control framework has met its objectives*
Efficiency	*Whether these objectives were achieved at a reasonable cost*
Relevance	*Whether the tobacco control framework remains fit for purpose given market and scientific development and evolving market trends*
Coherence	*Internal and external consistency with relevant EU legislation and WHO FCTC*
EU Added Value	*What could only be achieved through EU action rather than national initiatives*

Each criterion was assessed by combining quantitative, qualitative, legal, and scientific evidence. This structure enabled the integration of diverse inputs, including stakeholder consultations, legal mapping, and prevalence surveys.

2.1.3. Indicators to assess the evaluation criteria and questions

Certain quantitative and qualitative indicators were used to address the above-mentioned evaluation criteria and questions. The indicators per evaluation criterion include the following:

- **Effectiveness:**
    - sales value and volume of tobacco and related products;
    - prevalence of the use of traditional tobacco products;
    - share of daily smokers;
    - prevalence of the use of novel tobacco and nicotine products;
    - death and disease burden from the use of tobacco products in the EU;
    - impact of novel tobacco and nicotine products on human health;
    - tobacco-related healthcare costs and productivity losses;
    - degree of digital advertising and promotion of tobacco and related products, and its influence on consumer behaviour;
    - level of advertisement and promotion of tobacco products and related products on television, radio, in the press, and in other printed publications;
    - level of harmonisation of the internal market for tobacco and related products;
    - level of Member States' implementation of the WHO FCTC;
    - stakeholders' views on whether the tobacco control framework ensures the smooth functioning of the internal market;

    - stakeholders' views on whether the tobacco control framework ensures a high level of public health protection, especially for young people;
    - contribution of individual measures of the tobacco control framework to its effectiveness;
    - contribution of other EU legislation, national measures and policies and external factors to the overall effectiveness of the framework.
- **Efficiency:**
    - Member States' allocation of Full-Time Equivalent (FTE) staff and monetary costs for the tobacco control framework's implementation and their assessment of the relation between the resources spent and the results reached;
    - economic costs from tobacco consumption in the EU;
    - Member States' views on the most efficient areas of the tobacco control framework;
    - economic operators' views on the perceived financial burden of implementing the tobacco control framework;
    - Commission's assessment as to the most resource intensive areas of the tobacco control framework.
- **Relevance:**
    - Relation between the needs that the tobacco control framework intended to address and the measures proposed to address them;
    - Ability of the existing tobacco control framework to keep responding to market, scientific and international developments.
- **Coherence**
    - Coherence between the two Directives within the tobacco control framework, as well as between the framework and other relevant EU legislation;
    - Coherence between the tobacco control framework and the WHO FCTC.
- **EU added value**
    - Effect of measures taken by individual Member States before the tobacco control framework was adopted versus effect of EU action.

2.2. Details relating to the evaluation methodologies

Analytical Methods and Models

A range of analytical models and evaluation tools were applied to ensure scientific validity and coherence with the Better Regulation requirements. Some of these models and evaluation tools, along with the specific studies in which they were applied, are described below:

- **Legal gap analysis regarding the advertising provisions of the TPD and TAD**

A structured mapping was carried out to assess the gaps and shortcomings in the relevant provisions of the TPD and TAD, as well as to assess the compatibility and coherence of these provisions with:

- Article 13 of the WHO FCTC Article 13;
- the Audiovisual Media Services Directive (AVMSD).

The analysis used doctrinal legal methods, platform policy review, and Member State reporting on the enforcement of the provisions concerning the advertising and sponsorship of tobacco products and electronic cigarettes. The findings of this study indicated certain regulatory gaps in online marketing practices.

- **Behavioural review on digital marketing**

A PRISMA-compliant systematic review was conducted on the behavioural impacts of tobacco and nicotine product marketing in digital environments. It included:

- Experimental and observational studies (2017–2023);
- Pathway analysis of exposure - susceptibility - uptake among youth;
- Special focus on influencer-based and algorithm-driven marketing.

The evidence was triangulated with stakeholder consultation input and the JRC trends and patterns of use report.

- **Analysis on cross-border distance sales**

The study on the cross-border distance sales of tobacco products combined:

- ITC survey data on cross-border purchases and motivations;
- Eurobarometer 2012–2023 trends on retail sources;
- A scoping review of academic and grey literature;
- Platform and product search mapping via structured Google scans.

- **Analysis on the EU tobacco traceability system and illicit trade in the EU**

The study on the EU tobacco traceability system and illicit trade in the EU of tobacco products combined:

- A scoping review of academic and grey literature using PRISMA-ScR guidelines;
- Public and private data sources relevant to the Tobacco Products Directive (TPD) and illicit tobacco trade in the EU. This includes data extracted from reports submitted to the Framework Convention on Tobacco Control (FCTC), the Protocol to Eliminate Illicit Trade in Tobacco Products, Euromonitor Passport data, Eurobarometer 2012–2023 and data available through Statista.

- **Administrative burden assessment**

Efficiency and enforcement analyses were based on:

- Implementation reports from Member States;
- Targeted interviews with competent authorities;
- Resource estimates (staff FTEs, enforcement tools, cross-agency coordination).

Variability in administrative structures and mandates was flagged as a limiting factor for coherence and efficiency assessments.

- **Health outcomes risk analysis**

A cross-cutting synthesis was conducted to assess the risks associated with the use of nicotine-cigarettes and other emerging products across the following domains: cardiovascular risk, respiratory impact, cancer risk, toxicological exposure, and reproductive and developmental effects.

Scenario and Comparative Baseline

The evaluation did not model alternative regulatory frameworks but instead assessed the performance of the TPD and TAD against established baselines and evolving policy benchmarks. This retrospective approach is appropriate for determining whether the TPD and TAD achieved their goals of ensuring the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the Union under the WHO Framework Convention for Tobacco Control ('FCTC').

Legal and Policy Baselines

The evaluation was anchored to two legal baselines:

- **Directive 2014/40/EU (TPD)** – including the Implementing and Delegated acts adopted on its basis.
- **Directive 2003/33/EC (TAD)**.

Additionally, implementation progress was compared to **WHO FCTC obligations**.

The evaluation also mapped the Directives against other relevant EU legislation, such as the Tobacco Taxation Directive[370], the Audiovisual Media Services Directive[371] and the WHO FCTC[372].

Rationale for No Counterfactual Scenario Modelling

Unlike an impact assessment, this retrospective evaluation did not construct alternative scenarios of what might have occurred in the absence of the TPD or TAD. This choice was justified because the evaluation aimed to assess current performance and identify implementation gaps and regulatory insufficiencies, rather than predict potential future impacts.

3. Limitations in terms of data and mitigation measures taken

Limitations	Mitigation measures
Lack of quantitative data on the costs incurred by certain Member States.	15 Member States were not able to provide a complete estimate of the administrative burden, in full-time equivalents (FTE), because the implementation of the tobacco-control framework is often spread across multiple ministries and

370 OJ L 176, 5.7.2011, p. 24.
371 OJ L 95, 15.4.2010, p. 1.
372 https://fctc.who.int/resources/publications/i/item/9241591013

	departments. To overcome this constrain, the comparative analysis draws on the quantitative input from the remaining 12 Member States that replied fully to the questionnaire, supplemented by qualitative information provided by all Member States. This input was gathered through the targeted surveys .
Lack of quantitative data on the costs incurred by economic operators in complying with the tobacco-control framework.	Extensive efforts were made to obtain quantitative data on the costs incurred by economic operators in implementing and applying the tobacco-control framework. However, the quantitative data were very limited, with only a small number of economic operators providing concrete estimates of the financial costs. In addition, the quality and reliability of the data collected could not be verified, as there was no opportunity to validate the information provided. The views of economic operators and qualitative input on the costs were used in the analysis.
Quantification of the benefits resulting from the implementation of the tobacco control legislation has proven challenging. This limits the ability to fully assess the economic impact of the tobacco control framework.	To assess the cost-effectiveness of the tobacco control framework, the analysis compares the estimated annual implementation costs of the tobacco control framework with some likely quantitative benefits resulting from its implementation. In particular, the analysis takes into account reductions in direct healthcare expenditure related to tobacco-related illnesses and indirect costs, including productivity losses . In addition, a high-level estimate of total population health benefits due to smoking cessation is presented, including through valuating future life years saved However, the cost-benefit analysis does not take into account other probable cost reductions linked to the implementation of the tobacco control framework, most notably: • Benefits from lowered smoking initiation rates. • Reductions in health burden or monetary losses attributable to second-hand smoke-related mortality and morbidity. While it is difficult to quantify the additional cost reductions related to decreased health burden due to the lack of comparable data since 2012, it is reasonable to assume that the estimated decline in tobacco-related deaths over the past decade has contributed to a significant reduction in costs related to these broader categories. For this reason, the analysis acknowledges that, despite the absence of precise figures, these wider impacts should be considered in the overall cost-benefit assessment of

	the framework. To further strengthen the analysis, stakeholder input was also incorporated.
Quantification of the economic burden of tobacco consumption in the EU has proven challenging due to the many factors involved, and the fact that no study provides only a single figure.	To assess the economic costs from the tobacco consumption in the EU, the analysis took into account the following estimated costs: Direct healthcare expenditure related to tobacco-related illnesses; Indirect costs, including productivity losses and informal care; Value of years of life lost to disability or premature death from smoking; Losses attributable to second-hand smoke-related mortality and morbidity.
Determining the quantitative contribution of individual measures of the tobacco control framework as well as the effects of other EU legislation and external factors on the reduction of smoking prevalence and smoking related mortality and morbidity, has proven very challenging. No data was available to clearly quantify the specific impact of all these factors on the relevant outcomes.	In the absence of quantitative data, it was not possible to make a clear distinction between the specific contributions of the TPD and TAD measures. The analysis therefore considers that both sets of measures have contributed to the observed benefits, without specifying the precise extent of each contribution. However, the conclusions indicate which measures appear to have had the most significant influence based on qualitative input. The evaluation also explicitly recognises the contribution of other relevant legislation, such as the Tobacco Taxation Directive (TTD)[373], national fiscal measures, the Market Surveillance Regulation, and national tobacco control measures, where appropriate. Regarding external factors, while some may have influenced trends such as the reduction in smoking prevalence, this evaluation focuses on assessing the effects of the EU tobacco control measures rather than analysing all external determinants of tobacco use.
The simplification and burden reduction aspect primarily reflect the perspectives of Member States and the Commission.	A core objective of the tobacco control framework is to ensure a high level of public health protection, particularly for young people. This objective can sometimes be incompatible with all simplification efforts aimed at economic operators, as easing regulatory requirements could undermine public health protection. For example, reducing or further simplifying the industry reporting will limit monitoring capabilities in a rapidly evolving market, hindering the Member States' and Commission's timely responses to emerging health risks. This highlights the unique nature of tobacco control legislation, which prioritises protecting public health over easing conditions for the tobacco industry. For this reason, simplification was not included as a key aspect in the consultation activities.
The data from the monitoring and evaluation framework do not allow for quantitative	This evaluation recognises that factors beyond the tobacco control measures established by the TPD and

[373] OJ L 176, 5.7.2011, p. 24.

attribution of observed consumption trends to the individual factors influencing them.	TAD, may have influenced consumer behaviour and contributed to the observed decline in smoking prevalence during the evaluation period. These additional factors are presented in sections 2.1 and 4.1.2. Accordingly, the evaluation does not attribute the observed positive outcomes exclusively to the implementation of the EU tobacco control framework. While the data provided by monitoring and evaluating the tobacco control framework allow for an assessment of its effectiveness, efficiency, coherence and relevance, they do not permit a quantitative attribution of outcomes to individual policy measures or other factors impacting consumer behaviour. As a result, the evaluation focuses on assessing the performance of the TPD and TAD within the limits of the available evidence.

It should also be noted that the health-related cost information presented in the evaluation is limited to traditional tobacco products. Reliable data on the healthcare costs associated with emerging tobacco and nicotine products, such as electronic cigarettes and heated tobacco products, are not yet available. Since tobacco-related diseases generally develop long after tobacco use, and the long-term health effects of cumulative exposure to these novel products remain uncertain, it is currently impossible to accurately predict their economic impact.

While this evaluation was grounded in a broad and diverse evidence base, certain limitations were identified across data collection, analytical models, and stakeholder input. These limitations were transparently acknowledged and mitigated to the extent possible, in line with Better Regulation standards.

Other data limitations include:

Data Availability and Consistency

- Fragmented implementation reporting across Member States limited the ability to make fully comparable assessments, especially in areas like labelling enforcement, cross-border distance sales, and digital advertising oversight.
- Proprietary platform data (e.g. on tobacco advertising reach, user engagement on Meta or TikTok) were unavailable, making it difficult to precisely quantify youth exposure to digital promotion.

Methodological Constraints

- Much of the behavioural and prevalence data were derived from cross-sectional studies, limiting the ability to infer causal relationships (e.g. between marketing exposure and product uptake). However, triangulation with ITC's longitudinal cohorts provided complementary insights.
- In some areas, proxy indicators were used as a methodological necessity, such as treating online purchasing as a surrogate for cross-border sales activity. These proxies were applied in both internal Commission assessments and external technical studies.

Consultation-Related Biases

- The Call for Evidence and Public Consultation showed clear patterns of campaign-driven responses from a few Member States (notably Romania and Italy), which risked skewing representativeness. This was mitigated by thematic weighting and consultation analysis methods.
- Underrepresentation was observed in some key stakeholder categories, including:
    - Youth-led organisations; Environmental NGOs; Digital platforms and advertisers.

This may have limited the scope of perspectives gathered on specific topics.

Market and Product Evolution

- The tobacco and nicotine product market has evolved faster than the current regulatory framework.
- Dual and poly-use patterns are not consistently tracked across datasets.

Measures to Address Uncertainty

To manage and reduce uncertainty, the evaluation included the following mitigation strategies:

- Triangulation across evidence domains (legal, behavioural, health);
- Sensitivity analysis in the SHS and LCA models to define upper and lower bounds;
- Use of conservative assumptions in economic modelling to avoid overstatement of impacts;
- Internal expert validation of external contributions and analytical approaches.

Summary of Technical Limitations from Supporting Studies

In addition to the systemic and strategic limitations discussed above, a number of study-specific technical constraints were identified in the commissioned analytical reports. These issues do not invalidate the studies' contributions but may affect how their findings should be interpreted within the evaluation context:

- Reliance on proxy indicators in the cross-border distance sales study, such as online purchase behaviour and self-reported cross-border activity, limited the precision of regulatory circumvention estimates.
- Use of cross-sectional survey designs in behavioural and sales studies restricted causal inference and may have introduced recall bias into self-reported data.
- Health risk modelling was constrained by inconsistent toxicological protocols, limited long-term data on ENDS and HTPs, and poor tracking of poly-use behaviour across datasets.
- Legal mapping efforts faced challenges due to lack of real-world enforcement data from digital platforms, and fragmented national legal definitions that hampered EU-wide comparability.

These limitations were transparently acknowledged and, where feasible, mitigated through triangulation, qualitative evidence, conservative assumptions, and internal validation. The overall methodology is considered sufficiently robust to support the evaluation’s findings, conclusions, and recommendations.

Despite the above-mentioned limitations, the evidence gathered is reliable to support the evaluation of the tobacco control framework. The conclusions drawn in this evaluation are based on evidence from multiple sources and therefore present consistent and well-supported findings.

4. An assessment of the work carried out by the external contractor

The evaluation benefitted from the work of several external experts and contractors who produced thematic studies and technical reports under the direction of the European Commission. Their contributions were independently reviewed for methodological quality, alignment with the Terms of Reference, and suitability for triangulation within the broader evaluation framework.

4.1. Scope of External Contributions

Key external studies included the following:

- **Assessment of Digital Marketing of Tobacco and Nicotine Products**
  – Provided systematic mapping of online advertising exposure, youth targeting risks, and regulatory gaps.
- **Digital Advertising of Tobacco and Related Products under EU Law: A Legal Mapping**
  – Examined the alignment of TAD and TPD with AVMSD, DSA, and WHO FCTC Article 13.
- **Cross-Border Sales**
  – Used ITC and Eurobarometer data to estimate the causes, drivers and level of cross-border distance sales in the EU.
- **Open Evidence study supporting the evaluation of the EU Tobacco Control Acquis**
- **Report on the track and trace system and illicit trade in the EU**.

4.2. Evaluation of Methodological Quality

The Commission assessed the contractors' reports against three primary benchmarks:

Benchmark	**Findings**
Scientific and Legal Soundness	All studies employed recognised methodological standards (e.g. PRISMA for literature reviews, doctrinal legal mapping). The legal and epidemiological models were validated through peer comparison and internal expert panels.
Consistency with Terms of Reference	Thematic reports corresponded to timelines and deliverables outlined in the Terms of Reference.
Data Integration and Transparency	All studies provided metadata on sources, assumptions, and modelling approaches. The Commission ensured comparability across datasets and inclusion of sensitivity analyses where relevant.

4.3 Quality Appraisal of External Studies and Study-Specific Limitations

This subsection evaluates the methodological strengths and limitations of the external contributions commissioned for this evaluation. The studies addressed core topics such as second-hand smoke, cross-border distance sales, legal coherence of TPD and TAD with other relevant EU legislation, and health outcomes of novel products. Each report was assessed for scientific rigour, alignment with the Terms of Reference, and relevance to the evaluation's objectives.

Strengths:

- The studies followed internationally recognised standards and methodologies, including PRISMA (systematic reviews), LCA (environmental modelling), and doctrinal legal analysis.
- Most incorporated conservative assumptions and transparent models to avoid overstatement of results.
- Evidence was consistently triangulated with other sources (e.g. stakeholder consultation, ITC data), reinforcing internal validity.
- The contributions enabled coverage of new or complex topics (e.g. social platform marketing of tobacco and related products, emergence of novel tobacco and nicotine products).

Study-Specific Limitations

- **Cross-Border Distance Sales Study**
    - Relied on proxy indicators (e.g. online purchases) due to the absence of direct CBD transaction tracking.
    - Used a cross-sectional design, limiting causal inference; recall bias may have influenced self-reported purchasing behaviour.
    - Limited detail on product types and national differences constrained granularity.
- **Health Outcomes Report**
    - Long-term risks from emerging products remain uncertain due to limited follow-up data.
    - Difficulty disaggregating effects from dual/poly-use behaviour or distinguishing ENDS from ENNDS.
- **Report on the health-related costs attributable to tobacco use**
    - Given the relative novelty of HTPs, electronic cigarettes, nicotine pouches and ENNDS, limitations remain regarding available data on long-term effects and the economic consequences of their use on the society, and as such, it was not possible to estimate a cost for these products.

- **Legal Mapping Study**
    - Assessment was constrained by limited access to real-world platform advertising data (e.g. Meta, TikTok).
    - Legal fragmentation across Member States (e.g. in definitions of "advertising" and "emerging products") complicated horizontal analysis.

These limitations were taken into account when interpreting each study's findings and were mitigated, where possible, through sensitivity testing, cross-validation, and expert review.

5. The steps taken to assure the quality of the analytical results presented in the evaluation.

To ensure that the integration of new evidence did not compromise the methodological integrity of the evaluation, several additional safeguards were implemented:

- A cross-team internal quality review process was set up to validate the consistency of evidence integration across the evaluation report and its annexes.
- Targeted expert interviews were conducted to fill thematic and stakeholder-specific evidence gaps[374].
- Sensitivity analyses were applied to key models (e.g. SHS burden) to assess uncertainty bounds and ensure conservative estimates.
- Thematic weighting of stakeholder responses[375] was introduced, particularly in response to the overrepresentation of campaign-driven contributions from certain Member States.
- Triangulation strategies were reinforced across legal, behavioural, and epidemiological domains to mitigate any residual bias or gaps.

To ensure robustness, the evaluation adopted a multi-dimensional triangulation strategy, covering four key evidence domains:

- **Epidemiological and Behavioural Evidence**
  This included data from Eurobarometer surveys, ITC Project, the European Health Interview Survey (EHIS), and reports of the Joint Research Centre (JRC).
- **Health Economic Modelling**
  Primary sources were the by disease prevalence rates and risk estimates used to calculate attributable health and economic burdens supplemented by SHS Cost Model (from the SHS Addendum).
- **Legal Consistency Assessment**
  Legal mapping compared the coherence of the TPD and TAD with other EU relevant legislation such as the Audiovisual Media Services Directive and the Tobacco Taxation Directive, and international standards (WHO FCTC).
- **Stakeholder and Public Input**
  These comprised findings from the public consultation (more than 17 000 responses), the call for evidence (more than 24 000 responses), 26 structured interviews with national

[374] Study Supporting the Evaluation of the Tobacco Control Acquis: Synopsis Report
[375] Open Evidence study supporting the evaluation of the EU Tobacco Control Acquis.

authorities, NGOs, academics, and industry representatives, a targeted survey with key stakeholders and a second targeted survey that was distributed to 29 European countries via the Expert Group on Tobacco Policy.

Where direct data were lacking, proxy indicators were used:

- Online purchase behaviour was used as a proxy for cross-border distance sales;
- Platform transparency policies substituted for unavailable advertising exposure data.

Each method was cross-validated using PRISMA-compliant literature reviews, administrative reporting, and structured expert interviews to increase consistency and mitigate bias.

Justification for the Mixed-Methods Approach

The combination of retrospective evaluation (e.g. implementation progress, market effects) and prospective elements (e.g. relevance of TPD/TAD in light of new product types, consumption trends and digital marketing practices) necessitated a hybrid methodological model. In addition, this approach allows us to triangulate questions to ensure higher validity to the analysis conclusion. This allowed:

- Integration of evidence across internal market, public health, digital, legal and policy domains
- Responsiveness to recent market developments.

ANNEX 3

This Annex does not provide exhaustive answers to the evaluation questions and is intended to complement, and be read in conjunction with, the main body of the document, in particular Section 4. The references for all evidence cited in this Annex are provided in section 4 of the main document and not repeated here.

I. Evaluation matrix

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
To what extent was the intervention successful and why?	**Effectiveness, efficiency, coherence**	***Relevant to effectiveness criterion*** The EU tobacco-control's intervention was successful because: **a)** it **succeeded, to a certain extent,** in ensuring a high level of human health protection, especially for young people. **Between 2012 and 2023:** - the total sales volume of tobacco products in the EU declined by 15.45% with the volume of cigarettes dropping by 24.7%. - The sales value of the EU market for traditional tobacco products, excluding HTPs, was decreased by approximately 9%, with cigarettes' market value declined by 11.7%.	• Addadi, A., Alnaimat, T., Al-Uar, L., Al Nahar, J., Alzawawi, M., et al., 'Tobacco products definitions: Insights from national laws', *Tobacco Induced Diseases*, Vol. 23, Suppl. 1, 2025, p. A98, https://www.tobaccoinduceddiseases.org/Tobacco-products-definitions-Insights-from-national-laws,206198,0,2.html • Akter, S., Rahman, M. M., Rouyard, T., Aktar, S., Nsashiyi et al., 'A systematic review and network meta-analysis of population-level interventions to tackle smoking behaviour', *Nature Human Behaviour*, Vol. 8, Issue 12, 2024, pp. 2367–2391, https://www.nature.com/articles/s41562-024-02002-7 • Barrington-Trimis, J. L. and Leventhal A. M., 'Adolescents' Use of "Pod Mod" E-Cigarettes - Urgent Concerns', *New England Journal of Medicine*, Vol. 379, No. 12, 2018, pp. 1099-1102, https://doi.org/10.1056/nejmp1805758

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		- Cigarettes' share of the total EU tobacco and related products market value fell by about 12.5 percentage points. - Smoking prevalence among citizens also decreased from 28% in 2012 to 24% in 2023, with a more pronounced reduction among young people aged 15-24, from 29% to 22%. - The share of daily smokers of traditional tobacco products decreased in the EU between 2014 and 2023 for the overall population over 15 years old (from 25% to 21%). The decrease was even larger among young people aged 15-29 (from 27% to 20%). - Based on reported mortality numbers, a decline by 8.6% in mortality due to tobacco use in the EU is assumed. Advertising and promotion of tobacco products and e-cigarettes declined significantly across traditional media channels regulated by the TPD, the TAD, and the AVMSD, including TV, radio, press, and printed publications. Stakeholder feedback confirms this success: In targeted interviews, both Member States and economic operators acknowledged that the tobacco control framework has effectively achieved its objectives.	• Berlingieri, F., Casabianca, E. and Vlachos, S., Trends and patterns of use of tobacco and nicotine products in the EU, Publications Office of the European Union, Luxembourg, 2026, https://data.europa.eu/doi/10.2760/3233096, JRC143862 • Brennan, M. M., Bower, A. K., Sheridan, A., Doyle, F., Boland, F. et al, 'Evolution of nicotine product use in Ireland 2015–2023, and associations with quit intentions and attempts: an analysis of nationally representative repeated cross-sectional surveys', *The Lancet Regional Health - Europe*, Vol. 55, 2025, 101352, https://doi.org/10.1016/j.lanepe.2025.101352 • Cheung, C. M., Vardavas, C. I. and Filippidis, F. T., 'Factors associated with abstinence after a recent smoking cessation attempt across 28 European Union member states', Tobacco Prevention and Cessation, Vol. 7, 2021, 5, https://doi.org/10.18332/tpc/132123. • Doll, R., Peto, R., Boreham, J. and Sutherland, I., 'Mortality in relation to smoking: 50 years' observations on male British doctors', *BMJ*, Vol. 328, 2004, p. 1519, https://doi.org/10.1136/bmj.38142.554479.AE. • Donaldson, S. I., Dormanesh, A., Perez, C., Majmundar, A. and Allem, J.-P., 'Association

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		The tobacco-control framework has also successfully contributed to the EU's fulfilments of its obligations under the WHO Framework Convention on Tobacco Control (FCTC) and its Protocol to Eliminate Illicit Trade in Tobacco Products by establishing provisions that are fully aligned with the relevant provisions of these instruments. **Despite these achievements, the EU intervention faces certain limitations as:** - Smoking prevalence in the EU continues to remain high, particularly among young people. - Tobacco use still imposes a significant health burden on the society and public health systems. - The market for novel products (e.g. e-cigarettes, Heated Tobacco Products (HTPs), nicotine pouches, Electronic Non-nicotine Delivery Systems (ENNDS)) has grown rapidly. Growing evidence indicates adverse health effects from these products. - New advertising and promotion practices further exacerbated the problem. Tobacco and nicotine products are increasingly promoted via digital channels, particularly on social media platforms, often through influencers, undermining existing advertising restrictions. - **Gaps and shortcomings in relation to the scope, flavours, the EU Common Entry Gate (EU-**	Between Exposure to Tobacco Content on Social Media and Tobacco Use: A Systematic Review and Meta-analysis', *JAMA Pediatrics*, Vol. 176, 2022, pp. 878–885, https://doi.org/10.1001/jamapediatrics.2022.2223. • El-Khoury Lesueur, F., Bolze, C., Gomajee, R., White, V. and Melchior, M., 'Plain tobacco packaging, increased graphic health warnings and adolescents' perceptions and initiation of smoking: DePICT, a French nationwide study', *Tobacco Control*, Vol. 28, Issue e1, 2019, e31, http://dx.doi.org/10.1136/tobaccocontrol-2018-054573. • World Health Organization. Regional Office for Europe, 'Electronic nicotine and non-nicotine delivery systems: a brief', WHO/EURO:2020-4572-44335-62638, 2020, https://iris.who.int/handle/10665/350474. • Eschenbrenner, A., Poincet, C., Béguinot, E. and Gallopel-Morvan, K., 'New nicotine products - A major illicit advertising phenomenon on digital channels in France', *Tobacco Induced Diseases*, Vol. 23, Suppl. 1, 2025, p. A101, https://www.tobaccoinduceddiseases.org/New-nicotine-products-A-major-illicit-advertising-phenomenon-on-digital-channels-in-France,206214,0,2.html.

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		CEG) IT tool, labelling and packaging, advertising and other aspects of the tobacco-control legislation undermine the framework's overall effectiveness, in particular with regard to novel tobacco and nicotine products. **b) it** succeeded, to a certain extent, in ensuring the smooth functioning of tobacco and related products within the EU by harmonising several aspects regarding their manufacture, presentation, sale and advertising. However, diverging national rules concerning, inter alia, the regulation of flavours in electronic cigarettes, plain packaging requirements, the prohibition of disposable electronic cigarettes, tobacco heating devices , nicotine products other than electronic cigarettes, and ENNDS disrupt the internal market. ***Relevant to efficiency criterion*** The EU tobacco-control framework's appears to be a highly cost-effective tool in mitigating the public health and economic burden of tobacco consumption across the EU. Costs of the EU intervention:	• Euromonitor International, 'Passport', Euromonitor International website, 2025, https://www.euromonitor.com/solutions/passport. • European Commission, 'Special Eurobarometer 239: Attitudes of Europeans towards Tobacco', 2006, https://europa.eu/eurobarometer/surveys/detail/1060. • European Commission, 'Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes', 2021, https://europa.eu/eurobarometer/surveys/detail/2995. • European Commission: Directorate-General for Health and Food Safety, ICF S.A. and RAND Europe, *Support study to the report on the application of Directive 2014/40/EU: Final report*, Publications Office of the European Union, Luxembourg, 2021, https://op.europa.eu/publication-detail/-/publication/9ce15083-b931-11eb-8aca-01aa75ed71a1. • European Commission: Directorate-General for Health and Food Safety, IVO, RAND, ICF, Beaujet, H. et al., *Study on smoke-free environments and advertising of tobacco and related products: Final report*, Publications Office of the European Union,

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		Survey responses from 12 Member States indicate that, on average: • 29.2 Full-Time Equivalent (FTE) staff per country are dedicated to implementing and enforcing the tobacco-control framework, totalling approximately 350 FTEs across these countries. • Financially, these Member States spend an average of EUR 730 000 annually, with individual expenditures ranging from EUR 350 000 to EUR 1.3 million. • The total reported annual cost across these 12 countries is 8.76 million EUR. **Extrapolated Costs for the EU27** Applying these averages across all 27 Member States provides the following estimates: • Human resources: 29.2 FTE × 27 = approximately 790 FTEs • Financial cost: EUR 730 000 × 27 = approximately 19.7 million EUR annually A reliable assessment of industry compliance costs proved challenging. The available data was too limited, scattered, and often inconsistent, with self-reported figures varying significantly across companies and lacking independent verification. Cost-benefit comparison	Luxembourg, 2021, https://data.europa.eu/doi/10.2875/802479 • Effah, F., Sun, Y., Friedman, A. and Rahman, I., 'Emerging nicotine analog 6-methyl nicotine increases reactive oxygen species in aerosols and cytotoxicity in human bronchial epithelial cells', *Toxicology Letters*, Vol. 405, 2025, pp. 9–15, https://doi.org/10.1016/j.toxlet.2025.01.007 • Girvalaki, C., Filippidis, F. T., Kyriakos, C. N., Driezen, P., Herbeć, A. et al., 'Perceptions, Predictors of and Motivation for Quitting among Smokers from Six European Countries from 2016 to 2018: Findings from EUREST-PLUS ITC Europe Surveys', *International Journal of Environmental Research and Public Health*, Vol. 17, Issue 17, 2020, 6263, https://doi.org/10.3390/ijerph17176263 • Goodchild, M., Nargis, N. and Tursan d'Espaignet, E., 'Global economic cost of smoking-attributable diseases', *Tobacco Control*, Vol. 27, Issue 1, 2018, pp. 58–64, https://doi.org/10.1136/tobaccocontrol-2016-053305. • Heiss, C., Amabile, N., Lee, A. C., Real, W. M., Schick, S. F. et al., 'Brief Secondhand Smoke Exposure Depresses Endothelial Progenitor Cells Activity and Endothelial Function: Sustained Vascular Injury and Blunted Nitric Oxide Production', *Journal of the American College of*

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		The implementation of the EU tobacco-control framework, alongside other EU legislation, national tobacco-control measures, taxation and fiscal policies, and additional external factors, has contributed to: • A reduction in smoking prevalence; • A decline in tobacco-related mortality and morbidity; • A reduction in health-related costs associated with traditional tobacco product consumption. The estimated annual economic cost of tobacco consumption in the EU includes: • Direct healthcare costs associated with tobacco use, including smoking-related diseases and the increased health risks caused by tobacco consumption (e.g. hospitalisations, medical visits and medication costs): 40.43 billion EUR • Indirect healthcare costs associated with tobacco use (e.g. productivity losses and informal care costs): 40.23 billion EUR Costs at baseline (economic burden of smoking on EU Member States) including direct healthcare costs and productivity losses due to disability, were cautiously estimated to be around 130 billion EUR for the EU in 2012.	*Cardiology*, Vol. 51, Issue 18, 2008, pp. 1760–1771, https://doi.org/10.1016/j.jacc.2008.01.040. • Hoffman, S. J. and Tan, C., 'Overview of systematic reviews on the health-related effects of government tobacco control policies', *BMC Public Health*, Vol. 15, 2015, 744, https://doi.org/10.1186/s12889-015-2041-6. • Kahnert, S., Driezen, P., Balmford, J., Kyriakos, C. N., Demjén, T. et al., 'Impact of the Tobacco Products Directive on self-reported exposure to e-cigarette advertising, promotion and sponsorship in smokers—findings from the EUREST-PLUS ITC Europe Surveys', *European Journal of Public Health*, Vol. 30, Suppl. 3, 2020, pp. iii55–iii61, https://doi.org/10.1093/eurpub/ckaa055. • Perez-Cornago, A., Sarasa-Renedo, A., Jarach, C., Wollgast, J. and Maragkoudakis, P., Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches, Publications Office of the European Union, Luxembourg, 2026, https://data.europa.eu/doi/10.2760/0061469, JRC146139 • Prochaska, J. J., Vogel, E. A. and Benowitz, N., 'Nicotine delivery and cigarette equivalents from vaping a JUULpod', *Tobacco Control*, Vol. 31, Issue e1, 2022, pp. e153–e155,

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		In addition, a high-level estimate of total population health benefits due to smoking cessation is presented, including through valuating future life years saved. Related social benefits associated with smoking cessation between 2012 and 2023 are estimated to amount to roughly EUR 750 billion. ***Simplification and burden reduction*** The implementation of Article 7 TPD and Commission Implementing Regulation (EU) 2016/779 which concerns the procedure for determining whether a tobacco product has a characterising flavour, is considered the least efficient aspect of the TPD. The Member States that participated in a targeted survey on the administrative efforts for implementing the tobacco control framework identified the provisions on characterising flavours as costly, burdensome and inefficient. In particular, the administrative process for assessing tobacco products flagged by Member States as potentially non-compliant and suspected of having a characterising flavour, was perceived as particularly onerous, especially in terms of the time required for the assessment. From the Commission perspective, the same procedure is highly resource-intensive. The Commission acts as the secretariat for the independent advisory panel assisting Member States and the Commission in determining whether tobacco products	https://doi.org/10.1136/tobaccocontrol-2020-056367. • Lakshmi, R., Romate, J., Rajkumar, E., George, A. J. and Wajid, M., 'Factors influencing tobacco use behaviour initiation – From the perspective of the Capability, Opportunity, Motivation- Behaviour (COM-B) Model', *Heliyon*, Vol. 9, Issue 6, 2023, e16385, https://doi.org/10.1016/j.heliyon.2023.e16385. • Lazuras L., Assessment of the use and impact of digital marketing of tobacco and nicotine products, 2025 • Mollet D., Digital advertising of tobacco and related products under EU law: A legal mapping of the present scope of regulation, 2025 • Münzel, T., Hahad, O., Kuntic, M., Keaney, J. F., Jr, Deanfield, J. E. et al., 'Effects of tobacco cigarettes, e-cigarettes, and waterpipe smoking on endothelial function and clinical outcomes', *European Heart Journal*, Vol. 41, Issue 41, 2020, pp. 4057–4070, https://doi.org/10.1093/eurheartj/ehaa460. • Nargis, N., Xue, Z., Asare, S., Bandi, P. and Jemal, A., 'Declining trend in cigarette smoking among U.S. adults over 2008–2018: A decomposition analysis', *Social Science & Medicine*, Vol. 328, 2023, 115982, https://doi.org/10.1016/j.socscimed.2023.115982.

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		have a characterising flavour, and all activities related to the application of Commission Implementing Decision (EU) 2016/786. This includes providing administrative support to facilitate the efficient functioning of the Panel and to monitor compliance with the Panel's rules of procedure. The Commission organises the Panel's meetings, and serves as the intermediary between the Member States and the Panel for every request concerning the determination of a characterising flavour under Article 7 TPD. Additionally, the Commission is responsible for appointing the members of the Panel and overseeing their independence. All these tasks require substantial Commission resources. In addition, economic operators described the process of reporting through the EU-CEG, the IT tool developed to support the reporting obligations under Article 5 TPD for ingredients and emissions of tobacco products as well as Article 20 for e-cigarettes and refill containers, as 'complex' and 'time-consuming', although quantitative data on these claims remain limited. Member States also raised concerns regarding the IT design and operation of the EU-CEG system. The EU-CEG and the EU tobacco traceability systems have proven to be very resource-intensive for the Commission. ***Relevant to coherence criterion***	• Results of the study supporting the evaluation of the tobacco control acquis, study conducted by Open Evidence, 2025. • European Commission, '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 concerning the manufacture, presentation and sale of tobacco and related products', COM/2021/249 final, 2021, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:249:FIN. • Commission of the European Communities, 'Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee - Report on the implementation of the tobacco advertising directive (2003/33/EC)', COM/2008/0330 final, 2008, https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52008DC0330. • World Health Organization: Framework Convention on Tobacco Control, 'Liability (Article 19 of the WHO FCTC): Report by the Expert Group', FCTC/COP/11/6, 2025, https://storage.googleapis.com/who-fctc-cop11-source/Main%20documents/fctc-cop11-6-en.pdf

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		Internal coherence Both Directives share the common objectives of ensuring the smooth functioning of the internal market while taking as a base a high level of public health protection, especially for young people. However, the Directives differ in scope regarding their advertising provisions, reflecting distinct yet interlinked roles within the framework. The TPD regulates the manufacture, presentation, and sale of tobacco and related products, and includes provisions on the advertising and sponsorship of e-cigarettes and refill containers. The TAD is focused only on regulating the advertising and sponsorship of tobacco products. This difference does not undermine their coherence but rather demonstrates how the Directives complement each other by addressing different regulatory needs. While there are some differences in definitions of common terms between the two, these do not affect their overall coherence. Nevertheless, the coexistence of two separate legal instruments applying the same advertising and sponsorship restrictions to tobacco products, e-cigarettes and refill containers creates unnecessary regulatory complexity. Despite this issue, stakeholder feedback confirms the internal alignment of the framework. 73% of Member States considered the provisions of the TPD internally coherent, and the TAD	• European Commission, 'Revision of the Tobacco Taxation Directive (proposal)', European Commission website, 2024, https://taxation-customs.ec.europa.eu/taxation/excise-duties/excise-duties-tobacco/revision-tobacco-taxation-directive-proposal_en. • Saad, C., Cheng, B. H., Takamizawa, R., Thakur, A., Lee, C. et al., 'Effectiveness of tobacco advertising, promotion and sponsorship bans on smoking prevalence, initiation and cessation: a systematic review and meta-analysis', *Tobacco Control*, 2024, https://doi.org/10.1136/tc-2024-058903 • Salari, P., Maragkoudakis, P.-A. and Wollgast, J., The health-related costs attributable to tobacco in the EU, Publications Office of the European Union, Luxembourg, 2026, https://data.europa.eu/doi/10.2760/5833286, JRC146176 • Salokannel, M. and Ollila, E., 'Snus and snus-like nicotine products moving across Nordic borders: Can laws protect young people?', *Nordic Studies on Alcohol and Drugs*, Vol. 38, Issue 6, 2021, pp. 540–554, https://doi.org/10.1177/1455072521995704. • Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), 'Opinion on electronic cigarettes', 2021,

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		was similarly viewed as coherent, both in itself and in relation to the TPD. Coherence with other relevant EU legislation: Overall, the EU tobacco-control framework works well with other relevant EU legislation, notably the Tobacco Taxation Directive (TTD) and the Audiovisual Media Services Directive (AVMSD). More specifically: Coherence with the TTD The TPD, TAD and TTD form a cohesive legislative triad each addressing different dimensions of tobacco control. While each instrument operates independently within its respective scope, all three Directives contribute to the shared objectives of ensuring the proper functioning of the internal market while taking as a base a high level of public health protection, especially for young people. Together, they also support the implementation of the EU's international obligations under the FCTC and its Protocol to Eliminate Illicit Trade in Tobacco Products. While the TPD, TAD and TTD differ in the way they define 'tobacco products', this difference reflects the distinct scope of each Directive and does not result in their inconsistent application. The TPD has a broader regulatory scope compared with the TAD and TTD. The absence of explicit reference to 'novel tobacco	https://health.ec.europa.eu/publications/electronic-cigarettes_en • Study Supporting the Evaluation of the Tobacco Control Acquis: Synopsis Report • National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, Centers for Disease Control and Prevention (US), Atlanta (GA), 2014, https://www.ncbi.nlm.nih.gov/books/NBK179276/. • Vardavas C., Report on the assessment of the causes, drivers and level of cross-border distance sales in the EU, 2025 • Vardavas C., Report on the analysis of the track and trace system and illicit trade in the EU, 2025. • Vardavas, C. I., 'European Tobacco Products Directive (TPD): current impact and future steps', *Tobacco Control*, Vol. 31, Issue 2, 2022, pp. 240–241, https://doi.org/10.1136/tobaccocontrol-2021-056548. • World Health Organization, *WHO report on the global tobacco epidemic 2021: addressing new and emerging products*, World Health Organization, Geneva, 2021,

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		products' in the TTD is explained by the fact that those products were not on the market in 2011 and does not contradict the TPD. On 16 July 2025, the Commission adopted a proposal for a recast of the TTD. Under this proposal: • The revised TTD would expand its scope beyond that of the TPD and TAD. • It would explicitly include products previously excluded, such as smokeless tobacco products (namely, chewing and nasal tobacco for the purposes of the TTD), liquids (nicotine containing and nicotine free) for e-cigarettes, nicotine pouches and other nicotine products. Regarding the coherence with AVMSD: The Audiovisual Media Services Directive (AVMSD) 2010/13/EU supports EU-wide advertising restrictions by regulating advertising bans for tobacco products, e-cigarettes, and refill containers specifically within the scope of audiovisual media services. In doing so, it complements the tobacco control framework, which regulates advertising (with cross-border effects) across a broader range of media channels. Certain differences exist in how the tobacco-control framework and AVMSD define key terms such as 'tobacco products', 'advertising', and 'sponsorship'. These minor differences are attributable to the different scopes and objectives of the two frameworks.	https://www.who.int/publications/i/item/9789240032095. • World Health Organization. Regional Office for Europe (ed.), *Two decades of the implementation of the WHO Framework Convention on Tobacco Control in the European Union: progress, challenges and the road ahead*, World Health Organization. Regional Office for Europe, Copenhagen, 2025, https://www.who.int/europe/publications/i/item/WHO-EURO-2025-12743-52517-81148. • World Health Organization, *WHO report on the global tobacco epidemic, 2023: protect people from tobacco smoke*, World Health Organization, Geneva, 2023, https://www.who.int/publications/i/item/9789240077164. • World Health Organization, *WHO report on the global tobacco epidemic, 2025: warning about the dangers of tobacco*, World Health Organization, Geneva, 2025, https://www.who.int/publications/i/item/9789240112063. • World Health Organization, *WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: ninth report of a WHO study group*, World Health Organization,

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		Some Member States participating in targeted interviews raised concerns about potential misalignment between the TAD and AVMSD, particularly regarding gaps in regulating social media advertising. An inconsistency between the tobacco control framework and the AVMSD arises in how depictions of brand names and corporate promotions are addressed. Under the tobacco control framework (TPD and TAD), such content falls within its scope, only if the depictions of brand names and other corporate promotions are considered to have the aim or direct or indirect effect of promoting the tobacco products or e-cigarettes and their refill containers. In contrast, Article 11(4)(a) AVMSD prohibits the product placement (defined in Article 1(m) AVMSD as "*any form of audiovisual commercial communication consisting of the inclusion of, or reference to, a product, a service or the trade mark thereof so that it is featured within a programme or a user-generated video in return for payment or for similar consideration*") of "cigarettes and other tobacco products, as well as electronic cigarettes and refill containers, or product placement from undertakings whose principal activity is the manufacture or sale of those products". Additionally, Article 9(1)(d) AVMSD indicates that 'all forms of audiovisual commercial communications for cigarettes and other tobacco products, as well as electronic cigarettes and refill containers shall be	Geneva, 2023, https://www.who.int/publications/i/item/9789240079410. • World Health Organization, *Technical note on the call to action on electronic cigarettes*, World Health Organization, Geneva, 2023, https://www.who.int/publications/m/item/technical-note-on-call-to-action-on-electronic-cigarettes • World Health Organization, *WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: eighth report of a WHO study group*, World Health Organization, Geneva, 2021, https://www.who.int/publications/i/item/9789240022720 • World Health Organization. Regional Office for Europe (ed.), *Two decades of the implementation of the WHO Framework Convention on Tobacco Control in the European Union: progress, challenges and the road ahead*, World Health Organization. Regional Office for Europe, Copenhagen, 2025, https://www.who.int/europe/publications/i/item/WHO-EURO-2025-12743-52517-81148. • Zatoński M., Herbeć A. Zatónski W., Przewoźniak K., Janik-Koncewicz K., et al., 'Characterising smokers of menthol and flavoured cigarettes, their

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		prohibited'. This suggests that the AVMSD takes a stricter stance on non-product specific communications brought forward by undertakings whose principal activity is the manufacture or sale of tobacco products, electronic cigarettes and refill containers. Coherence with the WHO FCTC: The measures of the tobacco-control framework are in line with the provisions of the WHO FCTC. In fact, the framework has significantly contributed to the consistent implementation of WHO FCTC by both the EU and its Member States. However, not all FCTC provisions are fully reflected in the EU framework. The most notable gap concerns Article 5(3) FCTC, which requires Parties to protect their public health policies from the tobacco industry interference. Relevant provisions in the tobacco control framework include Article 4(2) TPD, which requires that laboratories verifying emissions are not owned or controlled directly or indirectly by the tobacco industry, as well as Article 35 of Implementing Regulation (EU) 2018/574, which sets out requirements to ensure the independence of entities participating in the EU tobacco traceability system. Although some Member States have adopted national measures to implement Article 5.3 FCTC, the approaches vary significantly, resulting in inconsistent levels of protection across the EU.	attitudes towards tobacco regulation, and the anticipated impact of the Tobacco Products Directive on their smoking and quitting behaviours: The EUREST-PLUS ITC Europe Surveys', *Tobacco Induced Diseases*, Vol. 16, Suppl. 2, 2018, p. A4, https://doi.org/10.18332/tid/96294 • Zauraiz L., 'Promotion of heated tobacco products on social media: Findings from the United Kingdom, Ireland, and Germany', *Tobacco Induced Diseases*, Vol. 16, Suppl. 2, 2025, p. A4, https://www.tobaccoinduceddiseases.org/Promotion-of-heated-tobacco-products-on-social-media-Findings-from-the-United-Kingdom,206315,0,2.html • World Health Organization, 'Heated tobacco products: information sheet', 2nd edition, WHO/HEP/HPR/2020.2, 2020, https://iris.who.int/bitstream/handle/10665/331297/WHO-HEP-HPR-2020.2-eng.pdf. • European Commission, 'Evaluation of the legislative framework for tobacco control', European Commission website, 2023, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control_en. • European Commission, 'Public consultation: Evaluation of the legislative framework for tobacco

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		Another issue relates to the implementation of Article 19 FCTC, which addresses the liability of tobacco manufacturers for harm caused by their products. The EU tobacco-control framework contains no liability provisions for the harm caused by the tobacco and related product use. However, both the TPD and TAD establish provisions related to penalties and enforcement of the tobacco control framework.	control', European Commission website, 2023, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation_en. • World Health Organization, 'WHO calls for urgent action to ban flavoured tobacco and nicotine products', World Health Organization website, 2025, https://www.who.int/news/item/30-05-2025-who-calls-for-urgent-action-to-ban-flavoured-tobacco-and-nicotine-products. • Public Health Agency of Sweden, 'Use of tobacco and nicotine products', Public Health Agency of Sweden website, 2024, https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/living-conditions-and-lifestyle/andtg/tobacco/use-of-tobacco-and-nicotine-products/. • RIVM, 'Smokers inhale more tar, nicotine and carbon monoxide when measured with WHO method', RIVM website, 2018, https://www.rivm.nl/en/news/smokers-inhale-more-tar-nicotine-and-carbon-monoxide-when-measured-with-who-method. • Global Center for Good Governance in Tobacco Control, 'Global Tobacco Industry Interference

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How did the EU intervention make a	**EU added value**	The EU intervention has provided significant added value in the field of tobacco control by introducing harmonised rules that strengthened public health protection, contributed to the proper functioning of the	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
difference and to whom?		internal market for tobacco and related products, supported the EU's compliance with the FCTC and its Protocol to Eliminate Illicit Trade in tobacco products, and enhanced the cooperation in the field of tobacco control between the Member States. In the absence of harmonised EU rules, differing national laws would lead to even greater market fragmentation and legal uncertainty, creating barriers to trade and undermining market cohesion. The EU rules achieved results that could not have been attained by individual Member States acting alone, particularly considering diverging national regulations and varying levels of commitment to tobacco control. EU-level legislation helped to establish a common standard of protection for all EU citizens and enabled some Member States to overcome domestic political resistance to stronger tobacco control legislation. The framework established a uniform regulatory environment that delivered tangible benefits to a wide range of stakeholders, including consumers, in particular young people, Member States' competent authorities and public health systems, economic operators and the Commission. Notable regulatory advances include: • The introduction of harmonised ingredient and emission reporting format and requirements by the TPD, Commission Implementing Decision (EU)	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		2015/2186 and Commission Implementing Decision (EU) 2015/2183 has improved transparency and regulatory oversight. National authorities and the Commission benefitted from enhanced data analysis and comparability, while tobacco products' manufacturers and importers experienced reduced administrative burdens due to the simplification of reporting procedures benefited from streamlined, common reporting procedures. • The creation of EU-CEG by the Commission facilitated the reporting of information on tobacco products and e-cigarettes. EU-CEG allows Member States and the Commission to process, compare, analyse and draw conclusions from the information received. Despite some challenges concerning its functioning, the EU-CEG serves as an effective monitoring tool, enabling Member States to swiftly respond to product evolutions or upcoming 'outbreaks' of newly evolved tobacco products or 'variants of interest' across the EU MS markets as they emerge. • The regulation of ingredients under the TPD - including the prohibition of specific additives in tobacco products and of characterising flavours in cigarettes, RYO tobacco, and HTPs, as well as flavourings in any of their components - protected the health of consumers and in particular young	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		people, by reducing the appeal of tobacco products and preventing tobacco initiation. • The introduction of harmonised labelling and packaging rules under the TPD, including combined health warnings, strengthened public health protection and benefitted consumers, particularly young people. The health warnings changed the perception and use of tobacco products among young people by raising awareness of the health risks, reducing the products' attractiveness, preventing initiation and supporting cessation efforts. Harmonising packaging and labelling was a key success of the tobacco control framework, as it also established uniform presentation of tobacco products across the internal market, thereby ensuring consistency. • The development of an EU-wide traceability system for tobacco products under the TPD and Commission Implementing Regulation (EU) 2018/574, undertaken to implement Article 8 to the Protocol to Eliminate Illicit Trade in Tobacco Products, has been crucial in strengthening the integrity of the tobacco products' supply chain. The system offers an unprecedented amount of data on the legal supply chain of tobacco products, from the point of manufacture to the last economic operator before the first retail outlet. The system assists Member States in identifying instances where	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		traceability requirements have not been met. Evidence suggests that the system has likely contributed to the maintenance of the overall downward trend in illicit trade across the EU since it became operational in 2019, despite other factors such as rising prices of tobacco products. • The TPD also empowered Member States to prohibit cross-border distance sales of tobacco products, e-cigarettes and refill containers, while also requiring their cooperation to prevent such sales so that these products are not sold in Member States where cross-border distance sales are banned. In addition, the TPD require retail outlets engaged in cross-border distance sales to operate an age verification system, which verifies that the purchasing consumer complies with minimum age requirements provided for under the national law of the Member State of destination. These provisions of the Directive have contributed to limiting consumer access to tobacco products, e-cigarettes, and refill containers by reducing cross-border distance sales. • The TPD introduced the concept of 'novel tobacco products' with a date-based definition that captures all tobacco products placed on the EU market after a specific date. In this way, it protects consumers' human health by subjecting any new tobacco products to the TPD's requirements, thereby	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		protecting consumers' human health while ensuring a level playing field for these products. Additionally, the 'substantial change of circumstances' mechanism established by the TPD empowers the Commission to withdraw certain exemptions for tobacco products that have undergone such a change. As a result, a ban on characterising flavours and stricter labelling requirements, may be imposed if significant changes occur in sales volumes or consumption patterns among young people. In this way, the TPD provides an extra layer of protection for this age group. • The TPD requirement for manufacturers and importers to notify novel tobacco products to the national competent authorities six months before the intended placing on the market enhanced regulatory preparedness and allowed for the Member States' timely health risk assessments of new products. This facilitates informed decision-making by national authorities and prevents the introduction of products that are not compliant with the rules of the TPD, including those related to prohibited ingredients. • The TPD also established a harmonised framework for e-cigarettes and refill containers, setting among others, a requirement for notification before their intended placing on the market, maximum nicotine	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		limits for the nicotine-containing liquid, regulation of their ingredients, labelling and packaging requirements, and advertising and sponsorship restrictions. These rules harmonised previously divergent national laws, ensuring consistent regulatory standards across the internal market. Member States recognised this and reported that the TPD introduced requirements for e-cigarettes that previously some Member States reported not having, and it was a good starting point for their regulation. In addition, these provisions enhanced consumer safety by reducing exposure to e-cigarette advertising, particularly on radio, television, in the press and other printed publications, minimising the risk of accidental consumption of high doses of nicotine and ensuring the provision of sufficient and appropriate information on the use of e-cigarettes. These rules also strengthened regulatory preparedness by enabling timely health risk assessments by national competent authorities. • The TPD rules on cooperation and information exchange between Member States, and between Member States and the Commission, together with the Market Surveillance Regulation (EU) 2019/1020, strengthened the market surveillance, implementation and enforcement of tobacco control measures. This facilitated a more consistent application of the rules, supported Member States'	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		enforcement efforts and contributed to collective progress toward public health objectives. Many Member States reported benefitting from these rules, especially those with less technical expertise and fewer resources available. Initiatives such as the Joint Action on Tobacco Control (JATC) and the Group of Experts on Tobacco Policy have been instrumental in this regard, fostering information exchange and capacity building that underpin the effective implementation of the tobacco control framework across Member States. • Cross-border advertising and sponsorship of tobacco products were brought under unified EU regulation, closing gaps in national laws and limiting the advertising, promotion and sponsorship of these harmful products, particularly through traditional media channels such as television, radio, the press, and other printed (non-professional) publications. Prior to the adoption of the TAD, Directive 98/43/EC regulated tobacco products' advertising and sponsorship but was annulled by the Court of Justice in Case C-376/98 Federal Republic of Germany v European Parliament and Council of the European Union. This left a regulatory gap, and differences in Member States' laws on tobacco advertising and sponsorship created barriers to the free movement of products and services supporting such advertising and sponsorship.	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		• In addition, the TAD provisions, through their obligations on the Member States, enabled the enforcement of stricter advertising controls. As a result, consumers benefited from better protection against harmful marketing practices, while public health authorities gained stronger tools for regulation. Member States that participated in a targeted survey on the added value of the tobacco control framework, reported that the TAD enable them to implement effective tobacco control policies in the area of tobacco advertising and sponsorship compared to what they could have done alone, with 78% of civil society organisations considering EU-level action essential to meet public health objectives.	
Is the intervention still relevant?	Relevance	From the internal market perspective, the tobacco control framework has been essential in ensuring, to a certain extent, the proper functioning for tobacco and related products. In the absence of harmonised EU rules, differing national laws would lead to market fragmentation and legal uncertainty, creating barriers to trade and undermining market cohesion. Furthermore, the framework has enabled the EU and its Member States to implement their international obligations under the WHO FCTC and its Protocol to Eliminate Illicit Trade in a consistent and coordinated manner.	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		Tobacco remains one of the most serious public health threats in the EU, causing addiction, severe illnesses, and premature death. In this context, the tobacco control framework remains highly relevant, and its absence would likely result in significantly worse public health outcomes. Between 2012 and 2023, the EU saw: a decline in tobacco products' total sales' volume and value, particularly cigarettes. These declines were accompanied by a reduction in overall smoking prevalence, with an even sharper decrease among young people aged 15 to 24. Importantly, these improvements have translated into a reduction in tobacco-related deaths, clearly demonstrating the life-saving impact of the EU tobacco control framework. . These positive developments are the result of comprehensive measures introduced under the tobacco control framework, including restrictions on the manufacture, presentation, sale, and advertising of tobacco and related products. Without these measures, cigarettes and other tobacco products would be more widely available, more easily and aggressively marketed, and consumed by a higher number of people, particularly young people. In addition, the costs associated with smoking have also decreased. In 2012, the economic burden of smoking on EU Member States, including direct healthcare costs	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		and productivity losses due to disability, was cautiously estimated to be around 130 billion EUR. By 2023, these costs had declined to an estimated 80.7 billion EUR per year across the EU. Without the tobacco control framework, these costs would likely have remained significantly higher, placing greater strain on national budgets and health systems. As the tobacco and nicotine products' market continues to evolve with the introduction of new products the relevance of the framework becomes even more pronounced. Thanks to the existing rules, products such as e-cigarettes and HTPs, are regulated under the framework, ensuring that they are subject to appropriate requirements. For instance, HTPs with characterising flavours are prohibited throughout the EU, and both HTPs and e-cigarettes must carry health warnings informing consumers about their health risks. These measures ensure that the public, and especially young people, continue to be protected from the harmful effects of these products. Additionally, other novel tobacco products beyond HTPs that may emerge in the future, will also fall within the scope of the EU tobacco control framework and be subject to its restrictions. The growing use of aggressive digital marketing strategies targeting young people makes the tobacco control framework more essential than ever. Without a	

Evaluation question	Evaluation criterion to be assessed	Answers to evaluation questions	Main data sources used (for all sections)
		strong and adaptive EU regulatory framework, the market would be vulnerable to widespread exposure to new tobacco and nicotine products, threatening to reverse the progress achieved in reducing smoking and tobacco-related harm. The tobacco control framework has been key in ensuring a high level of human health protection by significantly contributing to the reduction in tobacco consumption, smoking-related diseases and deaths, as well as the relevant economic burden on Member States. It has also supported the EU in fulfilling its obligations under the WHO FCTC. Without this framework, tobacco use, especially among young people, would be significantly higher resulting in more tobacco-related deaths and higher public health costs. The objectives and scope of the framework remain highly relevant, as the use of tobacco and nicotine products persists in the EU.	

II. Court cases related to tobacco control framework

Several cases have been brought before the Union Courts concerning the EU tobacco control framework. These include challenges to the validity of specific provisions of the TPD[376], the TAD[377] and Delegated Directive (EU) 2022/2100 on the withdrawal of certain exemptions in respect of HTPs[378]. Other cases addressed the validity of the EU tobacco traceability system[379], the use of a photograph in a library of warnings with pictures to be used for tobacco products[380] and the prohibition on the sale of tobacco products to minors[381]. In addition, the Court of Justice of the European Union (CJEU) was requested to interpret specific provisions of the tobacco control framework, including the definitions of 'chewing tobacco' and 'tobacco for oral use' of Articles 2(6) and 2(8) TPD[382], the concept of 'placing on the market' in the context of various provisions of the TPD[383], the notion of 'images' of unit packets and any outside packaging of Article 8(8) TPD[384], the measurement methods referred to in Article 4(1) of TPD[385] and certain requirements for e-cigarettes[386].

Case C-665/24[387] concerns the interpretation of the enforcement provision of Article 23(2) TPD, read in conjunction with Article 2(40) defining the term "placing on the market", and Article 20(4)(b)(i) concerning a packaging requirement for electronic cigarettes and refill containers. The key issue is whether the obligation for Member States to prevent non-compliant products (products with inaccurate indication of nicotine content) from being placed on the market covers not only the sale of products by the retailer to a consumer but also their supply by the distributor to a retailer. In its judgment of 11 December 2025, the Court held that "*Article 23(2) of Directive 2014/40/EU, read in conjunction with Article 2(40) and Article 20(4)(b)(i) of that directive, must be interpreted as meaning that the obligation on Member States to ensure that refill containers for electronic cigarettes the unit packets of which do not include an accurate indication of their nicotine content are not placed on the market is not limited to the stage at which those refill containers are supplied by a retail outlet to the consumer*". The Court further ruled that

[376] Case C-477/14 Pillbox 38 (UK) Ltd v Secretary of State for Health, Case C-547/14 Philip Morris Brands SARL and Others v Secretary of State for Health, Case C-358/14, Republic of Poland v European Parliament and Council of the European Union, Case C-220/17 Planta Tabak-Manufaktur Dr. Manfred Obermann GmbH & Co. KG v Land Berlin, Case T-298/17 Adrian Iordăchescu and Others v European Parliament and Others, Case C-151/17 Swedish Match AB v Secretary of State for Health, Case C-160/20 Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Case T-791/22, Broad Far (Hong Kong) and M21 v Commission.

[377] Case C-380/03, Federal Republic of Germany v European Parliament and Council of the European Union.

[378] Case T-706/22 RENV, Nicoventures Trading and Others v Commission (this case was referred back to the General Court following the judgment of 18 December 2025 in Case C-731/23P Nicoventures Trading and Others v Commission), Case T-791/22, Broad Far (Hong Kong) and M21 v Commission, Case C-759/23 PJ Carroll and Nicoventures Trading.

[379] Case C-553/19 P – ITSA v Commission, Case T-396/18 ITSA v European Commission.

[380] Case T-654/19, FF v Commission.

[381] Case C-452/20 PJ v Agenzia delle dogane e dei monopoli.

[382] Case C-425/17 Günter Hartmann Tabakvertrieb GmbH & Co. KG v Stadt Kempten.

[383] C-356/22 Pro Rauchfrei eV v JS e.K. II, Case C-717/23 Bundesminister für Gesundheit, Case C-665/24 Staatssecretaris Jeugd, Preventie en Sport v Diamond Flavours BV and UEG Holland BV.

[384] C-370/20 Pro Rauchfrei eV v JS e.K.

[385] Case C-160/20 Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Case C-155/24 Nederlandse Voedsel- en Warenautoriteit and Others.

[386] C-448/24 British American Tobacco Belgium and Nicoventures Holdings, C-449/24 DSE International.

[387] EUR-Lex - 62024CN0665 - EN - EUR-Lex

"*Article 23(3) of Directive 2014/40 must be interpreted as precluding national legislation which provides for an administrative fine of a criminal nature to penalise an economic operator which has placed on the market refill containers whose unit packets do not include correct information on their nicotine content, even though that information corresponds to that in the notification made within the meaning of Article 20(2) of the directive by the 'manufacturer' or 'importer' from which that operator acquired those containers, where the amount of that fine cannot be adjusted according to the seriousness of the breach, taking into account the individual circumstances of the case*"[388].

A related matter was addressed in Case C-717/23[389] which also involved the interpretation of Article 23(2) in conjunction with Article 2(40) and Article 13(1)(c) TPD. The case examined whether the prohibition on placing tobacco products on the market in unit packets with elements or features relating to taste applies solely to sales by retailers to consumers, or also to supply by wholesales to retail outlets. The Court ruled "*the obligation of the Member States to ensure that tobacco products whose unit packet labelling infringes the requirements relating to their presentation are not placed on the market is not limited to the stage at which those products are supplied by a retail outlet to the consumer*"[390].

Pending Court cases may further clarify the interpretation of key TPD provisions and reveal areas in need of revision. Case C-155/24[391] (among others) concerns the consequences of non-publication of the ISO standards referred to in Article 4(1) TPD in the Official Journal for the enforceability of that provision.

In his Opinion in Case C-759/23[392], Advocate General Emiliou emphasised that a legislative act harmonising national rules on the manufacture, presentation, and sale of tobacco and related products "*might require regular revisions over time, since the market is constantly evolving (existing products may change, new products are placed on the market and consumers' preferences shift) and new scientific studies become available*". Accordingly, the Advocate General underlined the importance of the EU legislature potentially revising this legal framework - *"as regards both the general principles and definitions, and the more specific rules on obligations, exemptions and withdrawal of exemptions - in order to adapt those rules to, inter alia, the specificities of tobacco products that have entered the market after the adoption of Directive 2014/40/EU"*. This Opinion underlines the importance of a robust consideration of the need for an update of the EU tobacco control framework, in particular in light of market developments

388 https://infocuria.curia.europa.eu/tabs/affair?lang=EN&publishedId=%22C-665%2F24%22&searchTerm=%22C-665%2F24%22

389 EUR-Lex - 62023CN0717 - EN - EUR-Lex

390 https://curia.europa.eu/juris/document/document.jsf?text=&docid=299641&pageIndex=0&doclang=DE&mode=lst&dir=&occ=first&part=1&cid=732241

391 Case C-155/24 Nederlandse Voedsel- en Warenautoriteit and Others. The Advocate General Opinion was delivered in 4 September 2025, https://infocuria.curia.europa.eu/tabs/affair?lang=en&sort=AFF_NUM-DESC&searchTerm=%22C-155%2F24%22&publishedId=C-155%2F24.

392 CURIA - Documents

ANNEX 4 – OVERVIEW OF COSTS AND BENEFITS

This Annex does not provide exhaustive answers to the evaluation questions and is intended to complement and be read in conjunction with the Staff Working Document, in particular Section 4.

Affected stakeholder	Costs	Benefits
Citizens/consumers	The implementation and enforcement of the tobacco-control framework do not result in any direct or indirect costs for citizens or consumers.	Improved well-being of EU citizens/consumers. In particular, the implementation of the framework has contributed to: - a reduction in smoking prevalence across the EU population, particularly among young people; - a decline in tobacco-related mortality and morbidity. For example, the regulation of ingredients under the Tobacco Products Directive 2014/40/EU - including the prohibition of specific additives in tobacco products, and of characterising flavours in cigarettes, roll-your-own tobacco, and Heated Tobacco Products (HTPs), as well as flavourings in any of their components – protect the health of consumers and in particular young people, by reducing the appeal of tobacco products and prevent tobacco initiation. Other relevant measures under the Tobacco Products Directive and the Tobacco Advertising Directive 2003/33/EC with similar effects are described in the Staff Working Document.
Member States/national health systems	The implementation and enforcement of the tobacco-control framework requires human and financial resources from the Member States. Survey responses from 12 Member States indicate that, on average: • 29.2 Full-Time Equivalent (FTE) staff per country are	The implementation of the EU tobacco-control framework has generated significant economic benefits for Member States by contributing to a measurable reduction in smoking-related costs. In 2012, estimated smoking health-related costs in the EU amounted to around EUR 130

Affected stakeholder	Costs	Benefits
	dedicated to implementing and enforcing the tobacco-control framework, totalling approximately 350 FTEs across these countries. • Financially, these Member States spend an average of EUR 730 000 annually, with individual expenditures ranging from EUR 350 000 to 1.3 million EUR. • The total reported annual cost across these 12 countries is 8.76 million EUR. Extrapolated costs for the EU27: Applying these averages across all 27 Member States provides the following estimates: • Human resources: 29.2 FTE × 27 = approximately 790 FTEs • Financial cost: EUR 730 000 × 27 = approximately 19.7 million EUR annually	billion while for 2023, another study estimated the health-related costs of traditional tobacco consumption (linked to direct health expenditure and indirect costs, including productivity losses and informal care) at 80.7 billion EUR per year across the EU, suggesting a notable decline. This suggests that the tobacco control framework has also generated savings for the Member States, allowing resources to be redirected toward other public health priorities. Broader social benefits also apply. Smoking prevalence in the EU declined by around 14% between 2012 and 2023, reflecting a mix of cessation, reduced initiation, and demographic changes. Assuming that 60% of this decline is due to quitting, this suggests millions fewer smokers. Evidence from long-term cohort studies indicates that cessation is associated with life expectancy gains of about 3 to 10 years, depending on the age of quitting. Applying a conservative estimate of 3 life-years gained per quitter, a value of EUR 52 000 per life-year in line with standard appraisal methods, and a 3% social discount rate yields benefits associated with smoking cessation between 2012 and 2023 of roughly EUR 750 billion. While sensitive to underlying assumptions, these figures suggest that declining smoking prevalence generates substantial health and social benefits in the EU. Moreover, benefits due to people not taking up smoking are not included in these figures.

Affected stakeholder	Costs	Benefits
		Harmonisation of reporting requirements regarding tobacco product ingredients and emissions has enhanced regulatory oversight. Member States benefit from access to comprehensive data covering multiple national markets, enabling improved data analysis and comparability. This facilitates timely responses to product evolutions or upcoming 'outbreaks' of newly evolved tobacco products or 'variants of interest' across the EU MS markets as they emerge. The development of an EU-wide traceability system for tobacco products under the TPD and Commission Implementing Regulation (EU) 2018/574, undertaken to implement Article 8 to the Protocol to Eliminate Illicit Trade in Tobacco Products, has been crucial in strengthening the integrity of the tobacco products' supply chain. The system provides an unprecedented amount of data on the legal supply chain of tobacco products, from the point of manufacture to the last economic operator before the first retail outlet. The system assists Member States in identifying instances where traceability requirements have not been met. The TPD requirement for manufacturers and importers to notify novel tobacco products to the national competent authorities six months before the intended placing on the market enhanced regulatory preparedness and allowed for the Member States' timely health risk assessments of new products. This facilitate

Affected stakeholder	Costs	Benefits
		informed decision-making by national authorities and prevent the introduction of products that are not compliant with the rules of the TPD, including those related to prohibited ingredients. The TPD rules on cooperation and information exchange between Member States, and between Member States and the Commission, together with the Market Surveillance Regulation (EU) 2019/1020, strengthened the market surveillance, implementation and enforcement of tobacco control measures. This facilitated a more consistent application of the rules, supported Member States' enforcement efforts and contributed to collective progress toward public health objectives. Many Member States reported benefitting from these rules, especially those with less technical expertise and fewer resources available. Initiatives such as the Joint Action on Tobacco Control (JATC) and the Group of Experts on Tobacco Policy have been instrumental in this regard, fostering information exchange and capacity building that underpin the effective implementation of the tobacco control framework across Member States. By harmonising rules on the manufacture, presentation, sale, and advertising of tobacco and related products, the framework has eliminated divergent national approaches, removing obstacles to the internal market. This streamlining of previously varied national rules supports the free

Affected stakeholder	Costs	Benefits
		movement of tobacco and related products across the EU and enhances overall market efficiency. The tobacco-control framework has strengthened the Member States' ability to comply with their international obligations under the WHO Framework Convention on Tobacco Control (FCTC) and its Protocol to Eliminate Illicit Trade in Tobacco Products. These benefits cannot be quantified, as there are no precise quantitative data establishing a causal link between the implementation of the tobacco-control framework and these benefits.
Economic operators	A reliable assessment of industry compliance costs proved challenging. The available data was too limited, scattered, and often inconsistent, with self-reported figures varying significantly across companies and lacking independent verification. Economic operators considered most TPD-related compliance costs proportionate, although over 40% expressed concerns about the cost burden associated with the implementation of labelling and packaging, and traceability provisions18. In particular, significant investment was needed to adapt production lines for manufacturers of tobacco products other than cigarettes. Regarding the TAD, all stakeholder groups (namely, Member States' competent authorities, civil society organisations, and economic operators in the tobacco industry or related) agreed that the implementation costs were proportionate and assumable.	By harmonising rules on the manufacture, presentation, sale, and advertising of tobacco and related products, the framework established a uniform regulatory environment, creating a level playing field for economic operators. These rules provided tobacco manufacturers and importers with clear and consistent regulatory benchmarks, eliminating discrepancies between national practices and removing the need to navigate 27 different regulatory systems. Additionally, common reporting procedures, such as those for ingredients and emissions of tobacco products, were simplified, reducing the administrative burden on economic operators. This benefit cannot be quantified, as there are no precise quantitative data establishing a causal link between the implementation of the

<table>
<tr><th>Affected stakeholder</th><th>Costs</th><th>Benefits</th></tr>
<tr><td></td><td>The table below presents the estimated costs per relabelled/repackaged product for the economic operators that responded to the cost template. The wide variation in these costs suggests significant differences in how companies experienced and complied with TPD requirements. The highest costs were typically associated with packaging redesign and changing the process for printing and packaging.

<table><tr><th>Activities relating to change in labelling/packaging of products</th><th>Overview of replies</th></tr><tr><td>Understanding of labelling and packaging provisions</td><td>EUR 45 to 2 178 per product</td></tr><tr><td>Redesigning packages</td><td>EUR 108 to 1 370 per product</td></tr><tr><td>Redesigning labels</td><td>EUR 64 to 400 per product</td></tr><tr><td>Changing the process for printing or packaging</td><td>EUR 40 to 3 409 per product</td></tr><tr><td>Changing materials or suppliers used for printing or packaging</td><td>EUR 45 to 137 per product</td></tr></table></td><td>tobacco-control framework and this benefit.</td></tr>
</table>

ANNEX 5

Synopsis report of the different consultation activities

Disclaimer: *This document includes contributions in the context of a call for evidence, a public consultation, and successive targeted consultation activities. It cannot in any circumstances be regarded as the official position of the Commission or its services. Responses to the consultation activities cannot be considered as a representative sample of the EU population.*

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Introduction

This document represents the Synopsis report of the consultation activities conducted in the context of the **Study supporting the Evaluation of the Tobacco Control Acquis,** (the Tobacco Products Directive (TPD) 2014/40/EU, the Tobacco Advertising Directive (TAD) 2003/33/EC, and relevant tobacco control policies at EU and national level).

The objective of the multiple consultations was to gather the views of stakeholders to inform the evaluation of the tobacco control acquis while ensuring that the policy work is carried out in an open and transparent manner, backed by the comprehensive involvement of stakeholders. In particular, the consultations covered the evaluation criteria of relevance, effectiveness, efficiency, coherence, complementarity, EU added value, sustainability, coordination, and acceptability of the legal framework.

Overview of the consultation activities and the consultation strategy

The consultation strategy has been designed to address comprehensively different stakeholder groups by means of tailored tools, questionnaires, and different consultation activities. The overall approach to the consultation activities is fully in line with the principles of the Better Regulation Guidelines, such as participation, openness and accountability, effectiveness and coherence. All relevant input and evidence will be taken into account, including data sources, data about costs and societal impact, as well as data on the potential benefits and detriments of the initiative. The results from these consultations activities constitute an important component of the evaluation of the tobacco control acquis, which will be complemented with evidence obtained from other sources, such as desk research.

The following table provides an overview of the objectives and targets of each consultation activity.

Table 1 - Consultations activities, objectives, and audience

Consultation activity	Consultation objectives	Targeted stakeholders
Call for evidence	To gather feedback from interested stakeholders and collect their relevant input and evidence on the potential benefits and detriments of the initiative.	➢ All stakeholders and citizens.
Public consultation	➢ To ensure broadest public validation. ➢ To extend the finding from the call for evidence.	➢ All stakeholders and citizens.
Targeted surveys	➢ To conduct a focused interaction and dialogue with expert stakeholders, taking into account stakeholders views from the public consultation.	➢ Member States competent authorities, Civil Society Organisations, and Economic Operators in the tobacco industry or related.

Consultation activity	Consultation objectives	Targeted stakeholders
Targeted interviews	➢ To fine-tune the evidence gathered so far and complements the submissions coming from surveys. ➢ To collect additional evidence.	➢ Selected Member States competent authorities, Civil Society Organisations, and Economic Operators in the tobacco industry or related. ➢ Selection from stakeholders replying to the survey.

Call for evidence

On 20 May 2022, the European Commission launched a Call for Evidence (CFE) titled "Evaluation of the legislative framework for tobacco control". Published on the https://health.ec.europa.eu/tobacco/evaluation-legislative-framework-tobacco-control_en web portal, the consultation activity aimed at gathering feedbacks from interested stakeholders on the TPD, TAD and relevant tobacco control policies.

The evaluation covered the areas of product regulation, advertising, promotion and sponsorship. It also evaluated the extent to which the legislative framework reached its objectives and whether it supported the target of the Europe's Beating Cancer Plan of a "tobacco-free generation" by 2040.

Between the 20th of May and the 17th of June, the CFE received 24 334 contributions. EU Citizens were the most involved respondent, with 93% of submissions. They were followed by economic operators[393] (3%), civil society organisations[394] (<1%), and public authorities (<0.1%). Campaigns were identified coming from Romania (26% of all citizens' feedback) and Italy (18% of all citizens' feedback). The campaigns were identified through an algorithmic assessment which proved that the majority of these feedbacks had the same content and were provided in the same timeframe.

Public consultation

The public consultation was open from the 21st of February to the 16th of May 2023 on the online https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation_en. More than 17 000 submissions were received via this website[395]. Citizens[396] were the most represented category, accounting for 89% of the total contributions, followed by economic operators[397] (9%), civil society organisations[398] (1%) and public bodies (>1%). Responses have been received from the general public and stakeholders from all EU Member States. The countries with greater participation were Germany (32%), Italy (12%) and Greece (9%). The

393 Including Company/business and business associations
394 Including academic/research institutions, NGOs, and consumer organisations
395 Initial number of submissions: 17 773.
396 Including both EU and non-EU Citizens
397 Including Company/business and business associations
398 Including academic/research institutions, NGOs, and consumer organisations

number of responses received largely exceeds the average for Public Consultation showing a significant public interest in the subject.

To identify overrepresentation through campaigns, profiling questions were added to the public consultation. The results from these questions show how 72% of respondents are users of emerging products, while the prevalence through random sampling shows this to stand at 3.6%[399] in the EU. Furthermore, campaigns coming from organisations linked to e-cigarette use were also identified (see example https://www.sovape.fr/tpd-participez-a-la-consultation-publique-sur-les-produits-de-reduction-des-risques/).

Targeted survey

A targeted survey was carried out through an online questionnaire, available in English through an external platform. 80 stakeholders were identified and targeted to take part in this consultation activity. The selected stakeholders were contacted on the 12th of June 2023 to notify they had been identified as relevant recipients for this consultation. The survey was open for 3 weeks (21st June – 14th July 2023). Fifteen responses were received outside of this deadline, but before the 21st of July, allowing to be included. In total, the achieved response rate was 78%, with 62 stakeholders submitting the survey (93% of Member States, 65% of invited civil society organisations, and 74% of invited economic operators in the tobacco industry or related).

The questionnaire was prepared on the following basis:

- The questionnaires have a **common structure** to facilitate the comparability of results.
- **Questions are tailored,** through three different questionnaires focusing on the most relevant aspects for each stakeholder group.
- **Closed ended question are preferred** as they provide easily comparable data. However, respondents have also the possibility to further elaborate through open text.

Each stakeholder was assigned a unique ID and a unique survey link. The length of the questionnaire varied among the different stakeholder groups and ranged from 47 questions for Member States to 31 questions for economic operators. All closed-ended survey questions were mandatory to answer, as the questionnaire contained only questions relevant to the respondent and their area of expertise. Nevertheless, respondents had the possibility to explicitly select *don't know/can't answer* when necessary and open text questions were non-compulsory.

Overall, the survey received 64 valid responses across the three stakeholder groups, with a response rate of 80%. As shown in figure 1, the stakeholder group with the highest number of respondents was the *Member States competent authorities* group representing 41% of the total replies (26 respondents) followed by the *economic operators* group representing 31% of the total responses (20 respondents). The stakeholder group with the lowest number of respondents was *the civil society organisations* group with 28% of the total responses (18 respondents). Figure 2 shows the response rats for each stakeholder group. *Member States* engagement was of 96%, with only 1 Member State failing to submit their response to the questionnaire. 69% (18 out of 26) of the targeted civil society organisations and 74% (20 out of 27) of economic operators responded to the survey.

[399] European Health Interview Survey (2019)

Figure 1 - Profile of respondents (64 respondents)

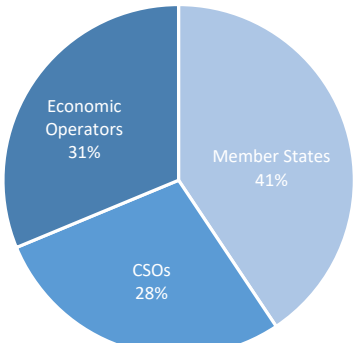
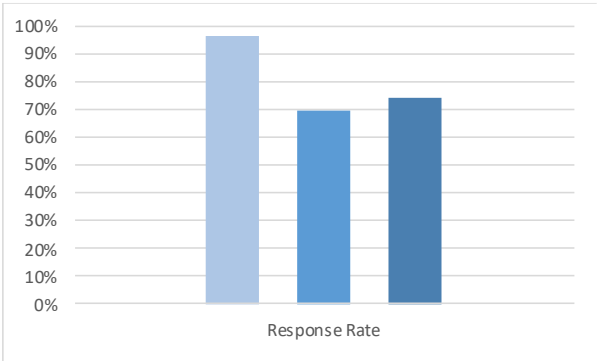


Figure 2 – Response rates (Per group)



not shared ahead of the interviews, with a list of points of discussion being available upon request. Two economic operators submitted responses in written in lieu than a video interview.

The stakeholder selection was based on findings from the survey and ensured that the entire data collection had a **balanced representation** of stakeholders, taking into account all interests (e.g., MS interests, public health, commercial, etc.). The following factors were considered when allocating interview slots:

- **Level of detail on the survey contribution:** the more developed and vary were the response to the survey, the more significant is the added value to have a follow-up interview to further investigate survey contributions and explore particular topics.
- **Motivation, interest, and grouping of views:** stakeholders that pro-actively expressed interest in the consultation and represented a variety of stakeholders (e.g., associations, interest groups, etc.) were preferred to increase the coverage of the consultation.
- **Expertise and knowledge**: stakeholders with experience and thematic expertise on the subject matter were considered to provide better further insight into the topic, also considering the variety in the scope of the chosen stakeholders.
- **EU wide organisations** were preferred as they were able to provide the broader perspective. On the other hand, the selection of **Member States** took into consideration geographically localised views.

Considering survey responses and the previous three points, interviews were distributed as follows: (i) target of 8 interviews for Member States competent authorities, (ii) target of 10 interviews for economic operators, and (iii) target of 12 interviews for civil society organisations, including 2 consumer organisations.

Overall comments on the outreach and results of the consultation strategy

The consultation strategy was successful in terms of reaching nearly all Member States, involving key actors in the EU public health civil society sector, and the main actors in the economic sector. The consultation strategy achieved a robust coverage with a response rate of 80% in the survey and a complete achievement of the interview targets.

Approach to data analysis

All the data have been categorized and managed through Qualtrics. Quantitative data from the survey was presented through tables and figures, while qualitative data coding was applied to data collected via the interviews and open questions to the survey. While the contributions to the call for evidence and public consultation cannot be considered as a representative sample of the EU population, the good response rate achieved of in all targeted data collection activities, an exhaustive comparison of the results by stakeholder group made it possible to identify trends for the three main stakeholder groups.

In-depth analysis

Call for evidence

The results of the Call for Evidence showed an higher number of responses with arguments against the tobacco control policies than those in favour of such policies. . This could be expected due to the identified campaigns and the nature of the consultation, which attracts those that do not support the attainment of benefits from this public health initiative either to commercial or other interests.

In terms of responses by the type of respondents, the contributions from **NGOs and Public Authorities** were generally s**upportive of the current legislative framework for tobacco control** and highlighted relevant challenges faced by the current framework in the current market scenario. In contrast, the majority of the feedbacks submitted by citizens, consumer organisations, companies and business associations raised concerns about potential negative consequences of tobacco control policies.

The most common arguments in favour of tobacco control legislation concerned **the importance of addressing novel tobacco products, particularly heated tobacco products, and other nicotine products not currently covered by the framework (e.g., nicotine pouches**). The primary concern was related to the so-called '**gateway effect'**, which was also used as an argument when showing concerns about e-cigarettes. This behavioural argument emphasizes the risk that **e-cigarettes, novel tobacco products, and other nicotine products may be the first nicotine-based products for many users**, especially teenagers, and may **increase the likelihood of consuming traditional tobacco products** in the future, including cigarettes. Therefore, respondents feedback suggests

I. the need to include more complete definitions,
II. harmonisation of rules for all inhaling devices,
III. stricter sales restrictions,
IV. to expand the focus of the directive to tobacco and nicotine products,
V. extending advertisement bans to cover all products,
VI. the consequences of not having harmonised plain packaging in the TPD.

In addition, many contributors expressed concerns about **the negative health effects of substances like nicotine, artificial flavourings**, and other chemicals contained in these products. It has also been highlighted how the tobacco industry is taking advantage of regulation gaps, overwhelming the markets with novel tobacco products and other emerging products that they advertise or name as "less harmful", "safe", or as effective cessation aids.

With regards to the **arguments against the current tobacco control framework**, which englobes most responses to this call for evidence, a wide range of contributions provided the

counterargument that **novel tobacco products and nicotine products can have important benefits**. These arguments were based on the idea that products such as e-cigarettes and HTPs might help current smokers to switch to '**less harmful' alternatives** and restrictions would cause current users of these products to go back to smoking cigarettes. In this line, many contributors argued that these products might eventually increase quitting rates among current smokers. **Business organisations and business associations**, in addition to the previous points, also emphasized the **negative economic impact restrictions** on the tobacco have on the economy, particularly SMEs and family businesses.

Public consultation

The use of the profiling question for citizens in the public consultation questionnaire has allowed the identification of trends in the views of different types of users. Table 2 below shows the distribution by use pattern of traditional tobacco products and emerging products. This self-identification question is used to interpret the responses from citizens to the public consultation.

Table 2 Respondents self-reported tobacco and emerging products use patterns

Non-User	User of traditional tobacco products	User of emerging products	Dual user
12.94%	14.67%	29.13%	43.26%

Overview

Overall responses to the **public consultation vary considerably based on the type of stakeholder.** Citizens, the vast majority of respondents (89%) as self-defined, disagree with the need of EU policies to ensure a higher level of human health protection and satisfied, similarly with the views of consumer organisations that responded as civil society organisations. This result can be explained by the **overrepresentation of respondents that are users of emerging products on and traditional tobacco products** (representing 87% of the total citizen responses). On the other side of the opinion spectrum of the CSO group there are NGOs in the public health area highlighted the risk posed by emerging products, including e-cigarettes, to public health in the EU. **Public authorities**, particularly those competent authorities from Member States, provided a **very low number of feedbacks**. This might be explained by their awareness on the following steps (targeted consultations). Nevertheless, they confirmed the success achieved so far by the TPD in protecting public health but underlined the necessity for action to address a series of identified deficiencies. Finally, economic operators evaluated positively the impact of the TPD policies on the protection of public health in the EU. This positiveness was also extended to the relevance related questions of both TPD and TAD legislations. **This could indicate that economic operators favour the *status quo* and keeping the legislation framework as it is now.**

Tobacco Product Directive: key findings and stakeholders´ positions

While citizens were generally negative about the success of the TPD in improving public health, all other stakeholder groups considered most of the provisions of the TPD to be adequate to facilitate the smooth functioning of the internal market and to protect public health in the EU.

With regards to the **ban on characterising flavours**, citizens showed **particularly negative** attitudes about their contribution to improving public health. This was the case also with economic operators, believing that it was also **inadequate to facilitate the internal market**, while civil society organisations responded that although they were adequate to protect public health, they were inadequate to facilitate the internal market. Interpretation of these findings, highlighting the inadequacy of TPD article 7 depends on each stakeholder. While it could be interpreted that for economic operators it would have been preferable to market products with flavouring, for public authorities the implementation of this measure would be costly and hard to enforce in some cases, making it preferable for the later to include a full ban on flavouring than the complex mechanism of charactering flavours. For CSOs, it could be interpreted as a barrier to the internal market as some countries went further to ban flavouring for all products while others follow strictly the wording of the TPD, creating de-harmonisation. Packaging and labelling were also a challenging area in the views of stakeholders due to the de-harmonisation. While it is possible that each stakeholder group would address this differently, **plain packaging** seems to be one of the most common measures in which Member States have decided or are considering going beyond TPD requirements. This has a clear impact on the functioning of the internal market but also for which economic operators show a strong view against. Further challenges were reported for the **traceability and security features** of the TPD. Civil society organisations responding to the public consultation considered it to be ineffective, with economic operators reporting significant difficulties with the implementation of these provisions.

Tobacco Advertisement Directive: key findings and stakeholders´ positions

Compared to the TPD, it appears that the TAD is perceived as less challenging and more widely accepted by respondents participating to the Public Consultation. Similarly, also provisions on e-cigarettes advertising (Art. 20(5) TPD) do not raise concerns.

Citizens, particularly those **users of traditional tobacco products**, consider the current framework (i.e. advertisement ban) to be **"too restrictive".** A particularly explicit disagreement from this user type can be explained by the exclusion on some types of emerging products from the advertisement bans, which therefore, would mean that users of these products that defend their use might consider the framework to be effective and relevant. Indeed, while in aggregate civil society organisations do not raise any issues with the current framework, **public health NGOs do highlight some challenges which include the use of social media** to promote and advertise tobacco and nicotine products, the lack of regulation of some nicotine products, the use of social **corporate responsibility schemes** by the tobacco industry, and the portrayal of some products as **cessation** devices. Importantly, they highlighted the challenges caused by the **outdated definitions** contained in the TAD.

Other relevant policies and overall coherence

With regards to policies outside of the scope of the TPD and TAD, which are nonetheless contained in the WHO FCTC to which all Member States and the European Commission are parties, there were some differences in the views of the different stakeholder group. For citizens, we see also differences between users of emerging products or non-users with regards to the users of traditional tobacco products or dual users. The former is considerably less likely to disagree the statement that 'the established restrictions were enough'. This could be interpreted as, in the views of emerging product users, promotion of emerging products could

support users of traditional tobacco products to quit while, nevertheless, believing that traditional tobacco products should not be promoted.

Civil Society organisations respondents did not express major concerns about the fragmentation of national and EU regulations. Overall, traditional tobacco products were perceived as the most threatening product category whose **accessibility**, especially for the youth, should be reduced through further **restrictions on points of sales near schools** and stricter rules on their **visibility at points of sale**. A considerable number of economic operators highlighted the fragmentation of tobacco control policies in the EU, which is a challenge they face when operating across the EU single market, with different Member States having different restrictions. Furthermore, a majority of respondents do not believe that the split of the TPD and TAD into two directives is the most effective mean to achieve the legislative objectives of the tobacco control legislation.

Targeted survey: key findings

Perception of the problem and its relevance

The first section of the targeted survey focused on the relevance of the EU Tobacco Framework and its capacity to tackle today's reality and address new product development in the market.

According to Member States inputs, **most of TPD definitions remain relevant and do not pose any challenge.** However, there are some important exceptions, mostly caused by rise of emerging products. **The definition of smokeless tobacco appears to be most challenging,** as the majority of Member States pointed out. Similar results also emerged from the survey to **CSOs.** This might be explained because emerging products are not fully captured by the current definition, especially HTPs and e-cigarettes. Other challenging definitions are **"tobacco for oral use", "characterising flavour" and "e-cigarettes".** Remarkably, all these definitions are directly impacted by emerging products. Indeed, **amongst CSOs respondents**, the most challenging definition is **"novel tobacco products**" which again confirm the difficulties of TPD definition to keep up with the market development. **Most of economic operators believe that no definition pose challenges.**

With regards to emission limits, 81% of participants supported extending the coverage to other tobacco products, such as heated tobacco products (HTPs), e-cigarettes, herbal products for smoking, and nicotine pouches. Respondents from civil society organisations believed that the majority of the definitions contained in the TPD are not problematic, except for those of **characterising flavour** and **novel tobacco products**, which were reported to pose challenges by 50% and 67% of the participants, respectively. Finally, respondents gave an overall negative opinion of the adequacy of the TPD in addressing the challenges posed by e-cigarettes, HTPs, nicotine pouches, and nicotine-free surrogates. Economic operators were generally of the opinion that definitions in the TPD were still relevant, with a 30% of respondents believing there is an issue with the definition of **market placement**. They were also of the believe that no matter the policy actions, the new products will continue growing.

With regards to the TAD, respondents from Member States and civil society organisations generally believe that the rise of new products and the use of social media have undermined the TAD objectives. 66% of **Member States recognized that new market developments require EU action rather than relying solely on national legislation**. The opposite is the case for economic operators, which support the idea that the TAD is still relevant to address

recent developments. However, there was uncertainty about the TAD's relevance in addressing products portrayed as quitting tools.

Effectiveness and efficiency

Roughly 45% of Member States believed that the **fragmentation of the EU tobacco control framework and diverging national policies hindered the TPD's effectiveness**. The effectiveness of the combined health warnings for tobacco products was reported to be affected to a certain extent by the fact the users of waterpipe tobacco do not see those product labels. The **divergence of national tobacco control policies was considered even more problematic**, with 61% believing that it impacted negatively the effectiveness of the TPD. In addition, more than 65% of the participants believed that the unclarity of the TPD provisions had **unintended consequences**. To a lower degree (reported by 45-50% of the sample) issues related to the excessive administrative burden and the lack of specific regulatory approaches were also reported.

CSOs results tend to be aligned with Member States, with 50% of the respondents believing that the degree of fragmentation characterizing the EU tobacco control framework had a negative impact on the achievement of the objectives of the initiative, against 17% who provided a positive evaluation. Furthermore, CSOs reported that the TPD did not fully address the problem of tobacco initiation among the youth nor issues related to the rise of emerging products.

Radically different opinions were reported by **Economic Operators** as they consistently highlighted **the administrative burden of the TPD as excessive**, with between 60% and 70% of participants feeling that the provisions of the TPD were excessively restricting or unclear. Specific provisions on tobacco products, such as cross-border sales of distance, the ban on oral tobacco use, traceability and security features of unit packages, and labelling and packaging of tobacco products, were also seen as particularly problematic by this stakeholder group. No concern over unclear provisions reported as the majority of Economic Operator believes that the **TPD still effectively regulate the current landscape.**

In terms of efficiency, Member States considered that most provisions of the **TPD had been implemented with adequate or lower than expected costs**, except for the procedure for determining **characterizing flavours, which was considered too costly by 42% of respondents.** Member States also considered compliance costs to be adequate for economic operators and consumers, with 54% also considering the burden on public authorities to be adequate.

Overall, **economic operators** considered the costs of the **TPD provisions proportionate**. However, over 40% of respondents believed that the **provisions on labelling and packaging** of tobacco products and those on **traceability** and security features of unit packages introduced were **an excessive economic burden to them**.

With regards to the **TAD**, which is seen **as highly effective in banning tobacco product advertisement** in press, non-professional printed publications, and on radio programs, 73% of Member States believed that its **effectiveness is hindered by the introduction of emerging products** and, to a lesser extent, by fragmentation in the EU tobacco control framework**. Civil society organisations agree**, except for the ban on the sponsorship of tobacco products in events having cross-border effects and the ban on the free distribution of tobacco products at

events, that the TAD was effective. With 70% of economic operators reporting that it was effective. **In terms of costs, there are no major negative impacts,** with all stakeholder groups agreeing that they were proportionate and assumable.

Coherence

Overall, **all Stakeholders Groups agree that the EU Tobacco Acquis is internally and externally coherent**.

73% of Member States believed that the **TPD provisions are internally** coherent while their views on coherence between the TPD and other EU initiatives were mixed. More than 40% of the respondents thought the **TPD and the Tobacco Taxation Directive are coherent with each other only to a limited extent**. In contrast, higher level of consistency was reported between the TPD and other initiatives, including the TAD and the Council Recommendation on Smoke-Free environments.

CSOs provided considerable no responses to this question, of the 39% that replied 80% believed it was internally coherent while this percentage is reduced to 45% in the case of EOs. Member States supported that the TPD was seen to have limited coherence with the Tobacco Taxation Directive by more than 40% of respondents, while higher consistency was reported with other initiatives and Europe's Beating Cancer Plan. Civil society organisations believed the TPD had limited coherence with other EU legislation and national policies. This was shared by 70% of EOs which believed that the TPD lacked coherence with national-level tobacco control policies, especially regarding labelling and packaging.

Overall, all Stakeholders Groups agree that the EU Tobacco Acquis is internally and externally coherent.

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The TAD was generally regarded as coherent, internally and with other EU legislation, including the TPD. However, civil society organisations (44%) believed that the TAD missed an opportunity to further support Member States initiatives.

EU Added Value and complementarity, and coordination

In terms of coordination efforts, 61% of civil society organisations reported poor coordination levels between Member States.

With regards to the complementarity of the EU legal framework, 93% of Member States believed that the TPD supports and supplements policies and guidelines set by the WHO FCTC framework, with over 70% of them reporting that their countries implemented different national tobacco control policies supporting the WHO FCTC objectives.

For Member States, the TAD was perceived to allow them to develop effective tobacco control policies compared to what they could have done alone, with 78% of CSOs considered EU level action essential to meet public health objectives.

Targeted interviews: key findings

Overall, the interviews provided a great opportunity to further explore the topics previously raised by stakeholder through the different consultation activities. The different stakeholder groups were divided by the positions previously explored through the preceding consultations. Public authorities interviewed highlighted consistently deficiencies in both the TPD and the TAD, most of them shared by NGOs in the civil society organisations stakeholder group, and also advocated for the need of stronger and more developed EU action in the area.

Perception of the problem and its relevance

This topic area addressed primarily the relevance evaluation criteria aimed at identifying the current and future needs and problems in the EU and the objectives of the intervention. In this regard, stakeholders complemented the previously issues highlighted in the survey. An issue raised by **MS competent authorities and CSOs was the inadequacy of the legislative framework to address emerging nicotine products**, which could not allow for the legislation to meet its objectives. Particularly, a repeated product mentioned was **nicotine pouches**. Indeed, Member States and public health NGOs agree that the **ban on tobacco for oral use is outdated due to this development** and needs to be extended to cover nicotine for oral use products. Furthermore, these stakeholder groups raised the need to address **social media**, which also challenges the relevance of the TPD and TAD to deal with the current scenario. **Public health NGOs denounced the use of social media, websites, and influencers to promote tobacco and related products to youth**. This later issue was also discussed with Member States public authorities, in some cases they indicated how in their Member States measures have been taken to prevent **online advertisement**, but it is very challenging to implement the ban when visiting websites or platforms from other Member States. Without EU intervention, their national bans are not effective enough due to the cross-border effects of this type of advertisement. Some economic operators and consumer organisations in the civil society organisations group presented a different opinion, defending that the TAD is still relevant as differentiation of rules across products with different risk-profiles is necessary. However, some economic operators, pointed out that while tobacco products are clearly covered by the TAD, they cannot say the same for emerging products for which there is a considerable increase in the number of advertisements. Therefore, in their view, the TAD is no longer able to address new market developments.

Furthermore, relevance issues were raised with regards to the **characterising flavour ban** as Member States believe that it no longer makes sense to ban characterising flavours in tobacco products but not for e-cigarettes, which they consider to be a particular threat due to their **attractiveness** to young people. This is agreed by public health NGOs, while economic operators did not raise any issues of relevance with this TPD article. Further discussion on characterising flavours is covered under the effectiveness criterion.

Finally, **definitions** present considerable relevance issues according to Member States and public health NGOs targeted in this consultation activity. Definitions **of 'tobacco product' in the TAD does not cover heated tobacco products nor their devices**, with some Member States reporting that they had to act unilaterally but this has caused considerable challenges when the advertisement is across their border. '**Smokeless tobacco product' is the term that poses more challenges according to Member States and public health NGOs**. A Member State also mentioned an issue with heated herbal products, which they report now are having

nicotine added to them and can be used to circumvent the flavour ban on heated tobacco products. Public health NGOs highlighted the importance of making definitions future proof. In their view, the TPD and TAD definitions were not made fit-for-purpose for such an evolving market. Consumer organisations pointed out challenges with the definition of tobacco products, which they consider to be too broad.

Effectiveness and efficiency

With regards to the effectiveness of the legal framework, **Member States and economic operators** were the most positive stakeholders believing that the TPD and TAD were able, overall, **to successfully meet its objectives**. **Civil society organisations were more hesitant to affirm this**. Nevertheless, all stakeholders highlighted some challenging aspects that affected the full effectiveness of the framework. With regards to efficiency, there are no doubts with regards to the benefits outweighing the costs, with only **economic operators challenging the costs of the traceability and security features, and Member States highlighting the costs associated with reviewing the notification of products**.

Member States reported **challenges with the effectiveness of the ban on characterising flavours** (TPD article 7) due to the vagueness of the term and the '**endless cycle of proving that the tobacco product has a flavour in it**' that it causes Member States. They also pointed out the challenges with regards to loopholes, as a Member State would have to repeat the process if the manufacturer of a tobacco product '**slightly changes' the composition of a previously banned product**, making the cycle very burdensome. Member States seem to agree that having a clear ban on flavourings, instead of characterising flavours, would be not only more effective, but also more efficient as it would save them resources.

Economic operators supported the claim that differentiation across products is needed and those products with decreasing market shares should not be targeted by flavour ban. Public health NGOs believe that economic operators benefit from this characterising flavouring term, and consumer organisations call for product differentiation to facilitate switching.

Notifications of novel tobacco products (TPD article 19) and **notifications of e-cigarettes** (TPD article 20(2)) also raised some challenges due to the notification system that Member States need to deal with. Member States raised the issue of notifications coming from third countries and the contact provided for the EU market being unresponsive or non-existent. As well, when a notification if removed by the Member State, the notifier re-submits the application giving additional burdens on the Member State.

Other challenges raised by stakeholders included the **labelling of e-cigarettes**, the lack of an effective ban on tobacco for oral use in bordering nations with Sweden, the effectiveness challenges faced by Member States implementing plain packaging in the internal market, and also with the definition of 'placing in the market'.

Coherence and complementarity

Very few points were raised by stakeholders with regards to challenges related to the coherence and complementarity of the legal framework. Some Member States reported some degree incoherence with the WHO FCTC, as it also covers protection from nicotine use, and incoherence with the audio-visual media service directive, as it leaves with the TAD a gap on social media advertisement that should covered. Other points mentioned by Member States,

which was also mentioned by public health NGOs, was the misalignment of the traceability requirements with the WHO FCTC as it involves economic operators in the process of printing codes and conducting the checks at different steps of the value chain. Some mentions were also made that to resolve current and future incoherence, it could be beneficial to have TPD and TAD in one single directive.

Scope of EU Action and EU Added Value

The EU tobacco control framework has provided considerable added value to Member States. For instance, they report that it introduced requirements for e-cigarettes that previously some Member States reported not having, and it was a good starting point on their regulation. It also served to harmonise requirements, which was particularly needed in Member States with little action in tobacco control. Member States report, however, that there is further scope for action and it is particularly important that it comes from the EU as Member States face considerable challenges to implement tobacco control measures by themselves. As well, measures on the environment are missing from the TPD, and it would be important to incorporate them.

Coordination and Acceptability

In terms of coordination, Member States and public health NGOs reported a lack of availability of research, as well as a lack of an easily accessible portal with the research being conducted by other Member States or public health NGOs and researchers. Having a better 'complete view' would be beneficial to improve harmonising and support public health.

All stakeholders considered the current framework to be acceptable. Stakeholders consider harmonisation to be positive and needed for the internal market. Some stakeholders, from all groups, did point out of the benefits of having a single tobacco directive, also to make it 'more widely known to the public'.

Conclusions and highlights

- Throughout the whole consultation activities, it appeared evident that **stakeholders views and position are inherently influenced by irreconcilable interests** (i.e. industry objectives and public health needs). This led to polarised opinions and the impossibility to analyse aggregated results.
- The **overrepresentation of tobacco and related product users** in the Call for Evidence and Public Consultation must be taken into account when assessing the respective results.
- Overall, it appears that stakeholders' views on EU Tobacco Control are more favourable than negative. All stakeholders group **acknowledged the benefits of having an EU streamlined approach to Tobacco Control**.
- The **rise of emerging products is arguably the most significant challenge** to a legislative framework which - overall - remain relevant to the needs and its objective.
- Overall, the **legislative framework is perceived as effective,** even though certain provisions (i.e. flavour ban, notification of new products) are perceived burdensome and complex to implement. Overall, **respondents believe that the EU Tobacco Acquis' benefits exceed its costs**, even though some stakeholders group highlighted higher costs than expected (Member States and Economic Operators).
- All stakeholders tend to agree that **EU intervention was necessary to achieve harmonisation amongst national regulatory framework.** On the other hand, some

stakeholders group (CSOs and Economic Operators) believe **that further coordination amongst national policies** is needed.

Addendum to the Synopsis Report

Targeted survey on the administrative efforts to implement the legislation

Background and objectives

Between October 2024 and February 2025, the Commission carried out a targeted consultation, in the form of a questionnaire distributed to 29 European countries (the 27 EU Member States plus Iceland and Norway), via the Tobacco Control Expert Group.

The objective of the consultation was to collect data on the administrative efforts related to the implementation of the Tobacco Products Directive and the Tobacco Advertising Directive. The questionnaire covered six aspects of implementation ('questions'): *Characterising flavours, Track and trace, Packaging and labelling, Cross-border distance sales, Advertising* and *Notifications.*

For each area of implementation, data was requested from the participating countries on Full-Time Equivalent staff allocated, Effectiveness (ability to achieve the desired result) and Efficiency (ability to achieve the desired result with adequate and economical use of resources). In addition, for each implementation area, responding countries had the opportunity to provide comments in free- text boxes. The analysis was performed in-house by the Commission's Joint Research Centre (JRC).

Responses

Out of the 29 responding countries, two Member States and a third country (Austria, Germany and Iceland) provided only narrative replies. As such, the analysis of Full-Time Equivalent staff allocated, Effectiveness and Efficiency was performed for 26 countries, while the comments section analysis also includes Germany (27 countries). Twelve countries replied fully for all six implementation areas as regards FTE allocation, and 10 countries replied fully for all six implementation areas as regards Effectiveness and Efficiency; as such, the comparative analysis for FTEs (and cost), effectiveness and efficiency were based on the above. For the individual implementation areas, all responses were taken into account.

Key findings summary

FTE allocation and financial cost for implementing the directives

The 12 EU Member States that replied to all questions on FTEs dedicated a total of 350 FTEs for the implementation of the directives per year, with an average of 29.2 per country. Differences were observed among the total allocation of FTEs for the implementation of the directives in different countries, ranging from approx. 70 FTEs annually in some countries to around 10 in others. The allocation of FTEs across the six implementation areas (questions) also varied considerably. "Packaging and labelling" had the highest total FTEs (81) allocated and the highest average per country (6.8); "Monitoring compliance with EU labelling and packaging requirements" was the activity requiring most FTEs under this implementation area. A high number of FTEs were also required for the "Track and Trace" and "Advertising" implementation areas (74 and 71 FTEs respectively); for the former "Ensuring manufacturers and importers accurately and timely submit required data" was the most FTE-intensive activity,

while for the latter it was "Enforcing advertising regulations" and "Ensuring compliance with advertising regulations". The lowest FTEs allocation was reported for the "Characterising Flavours" implementation area (30 FTEs, 2.5 average per country).

To estimate costs, Eurostat's data on annual earnings in EUR (median earnings) in individual Member States was used. The total cost of implementing the legislation for these 12 countries was estimated at EUR 8 761 749; the average cost per country was EUR 730 146, and the average cost per implementation area per country was EUR 121 691. The cost per country depends not only on the number of FTEs allocated but also on the median salary, which differs significantly across countries. As such, significant variation was observed in total absolute administrative costs for the implementation of the directives among the analysed countries, ranging from approx. EUR 1 300 228 to 349 38.

Effectiveness and Efficiency of implementing the directives

The 10 EU Member States that replied to all six implementation areas attributed an average score of 3.3 (out of five) regarding the effectiveness of implementing the directive; variations were observed among the replying countries, ranging 4.5 to 2.7. The average effectiveness scores across the different implementation areas of the directive varied slightly; "Notifications" had the highest score with 3.7, followed by "Packaging and labelling" (3.5), while "Cross-border distance sales" (3.1) and "Characterizing flavours" (2.7) had the lowest.

The 10 EU Member States that replied to all six implementation areas attributed an average score of 3.3 (out of five) regarding the efficiency of implementing the directive; variations were observed among the replying countries, ranging 4.4 to 2.3. The average efficiency scores across the different implementation areas of the directive varied slightly; "Packaging and labelling" and "Advertising" had the highest scores with 3.5, followed by "Notifications" (3.4), while "Characterizing flavours" (2.8) had the lowest.

Considering both effectiveness and efficiency, and based on these 10 Member States replies, the "Notifications" implementation area seems to be the more efficient and effective, albeit only slightly compared to the others; on the other hand, the "Characterising flavours" implementation area seems to be the least effective and efficient.