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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 8 April 2026

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

Subject: Regulatory Scrutiny Board: 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

Delegations will find attached document SEC(2026) 111 final.

Encl.: SEC(2026) 111 final



EUROPEAN COMMISSION

Brussels, 8.4.2026
SEC(2026) 111 final

REGULATORY SCRUTINY BOARD OPINION

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

{SWD(2026) 111 final/2}
{SWD(2026) 112 final/2}



EUROPEAN COMMISSION
REGULATORY SCRUTINY BOARD

Brussels,
Ares(2025)

Opinion

Title: Evaluation of the tobacco products directive, the tobacco advertising directive and other related tobacco control policies across the EU

Overall opinion: NEGATIVE

(A) Policy context

This report evaluates the Tobacco Products Directive (TPD) relating to manufacture, presentation and sale of tobacco and related products, and the Tobacco Advertising Directive (TAD) relating to the advertising and sponsorship of tobacco products. The main objective of these Directives is to ensure a smooth functioning of the internal market while striving for a high level of health protection.

(B) Key issues

The Board notes the additional information provided and commitments to make changes to the report.

However, the Board gives a negative opinion, because the report contains the following serious shortcomings:

- (1) The scope of the evaluation and the products covered is too limited to allow for a comprehensive analysis of the tobacco control measures in the EU. The report does not sufficiently analyse the coherence, in particular with the tax measures.
- (2) The evidence base is insufficient to draw informed conclusions on evaluation criteria. The analysis of effectiveness is not robust. The report is not clear on the extent to which the effects on health protection can be attributed to the two Directives only.
- (3) The Member States' specific tobacco control measures and their interplay with the overall effectiveness of the EU level framework are not sufficiently analysed.
- (4) The report does not draw lessons regarding the monitoring and evaluation framework.

(C) What to improve

(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

This opinion concerns a draft evaluation/fitness check which may differ from the final version.

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taxation, building on the evidence from earlier evaluations and impact assessments of TTD, to ensure coherence.

(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 related to all products over the evaluation period, including on young people and 55+.

(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.

(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.

(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.

(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.

(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.

Some more technical comments have been sent directly to the author Service.

(D) Conclusion

The lead Service must revise the report before launching the interservice consultation. The lead Service may resubmit to the Board a revised version of this report.

Full title	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
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