

Imperial Brands' contribution to the public consultation

on the Revision of the Tobacco Products Directive and the Tobacco Advertising Directive

Contents

1–2. Purpose and assessment framework	
1. Purpose, scope and structure of this contribution	3
2. Assessment framework	3
2. Options lacking a demonstrated problem-to-intervention chain	
2.1 Reducing nicotine concentration in electronic cigarettes (Question 13)	4
2.2 Leaflets or inserts with quitting information in cigarette and roll-your-own tobacco packs (Question 19)	5
2.3 Standardisation of the form and size of tanks, refill containers and cartridges for electronic cigarettes (Questions 13 and 19)	8
2.4 Further product standards for electronic-cigarette device safety, including leakage, overheating and battery safety (Question 13)	9
2.5 Leaflets or inserts with quitting information for electronic cigarettes, heated tobacco products, nicotine pouches and heated herbal products (Questions 12 and 19)	11
2.6 Additional reporting and testing on product composition, emissions or aerosol constituents for heated tobacco products (Question 13)	13
2.7 Additional reporting and testing on product composition, emissions or aerosol constituents for electronic cigarettes (Question 13)	15
2.8 Reporting and testing on product composition, emissions or aerosol constituents for heated herbal products (Question 13)	16
2.9 Product-design requirements intended to reduce appeal, including restrictions on device appearance, lighting and toy-like features for electronic cigarettes, heated herbal products and heated tobacco (Questions 12 and 13)	17
3. Options lacking justification for changing harmonised requirements	
3.1 Restrictions concerning certain forms of synthetic nicotine and nicotine-like substances (Question 13)	19
3.2 Characterising-flavour determination and ingredient regulation for cigarettes and roll-your-own tobacco (Question 12)	20
3.3 Further ingredient restrictions for electronic cigarettes and refill containers (Question 13)	24
3.4 Plain and standardised packaging, and large pictorial warnings for electronic cigarettes (Questions 13 and 19)	26
3.5 Plain or standardised packaging, and large pictorial warnings for heated tobacco products (Questions 13 and 19)	28
3.6 Plain or standardised packaging, and large pictorial warnings for heated herbal products (Questions 13 and 19)	29
3.7 Plain or standardised packaging, and large pictorial warnings for nicotine pouches (Questions 13 and 19)	30
4. Options lacking demonstration of incremental effectiveness and proportionality	
4.1 Prohibition of flavours in electronic cigarettes and refill containers (Questions 2, 3, 13 and 20)	33
4.2 Mandatory EU-wide plain or standardised packaging for cigarettes and roll-your-own tobacco products (Questions 18 and 19)	36
4.3 Possible maximum unit-packet content restrictions (Question 19)	38
4.4 Standardisation of cigarette sticks (Question 19)	40
4.5 Prohibition of flavours in nicotine pouches (Questions 2, 3, 13 and 20)	41
4.6 Prohibition of flavours in heated herbal products (Question 13)	43
Part II. Procedure	
5. Purpose and applicable procedural framework	45
6. Evaluation-to-Consultation evidential gap	45
7. Limits of the public consultation evidence	46
8. Evidence and causal attribution	47
9. Problem definition and EU added value	47
10. The existing baseline and enforcement	48
11. Consequences for measures introduced or broadened at consultation stage	48
12. Procedural conclusion and option-selection implications	49

1. Purpose, scope and structure of this contribution

This contribution complements Imperial Brands' questionnaire responses. For each option assessed, the analysis reconstructs the applicable legal and regulatory baseline, assesses the case for EU intervention and reaches an explicit conclusion for option selection.

The evidential record includes, with direct quotations where relevant:

- the 2026 Evaluation and its supporting studies,
- European Commission reports on the application of the Tobacco Products Directive and the exercise of delegated powers;
- records of the Commission's Expert Group on Tobacco Policy,
- minutes of the Independent Advisory Panel on characterising flavours in tobacco products,
- European Commission comments and detailed opinions under Directive 2011/64/EU (TRIS Directive),
- The Joint Research Centre and other Commission-commissioned research, and
- the Tobacco Products I to Tobacco Products Directive II preparatory record, including the 2010 consultation and 2012 Impact Assessment.

External evidence is used selectively where it answers a question that this record does not.

The contribution does not follow the sequence of the questionnaire. The measures are organised according to the maturity of the regulatory question they raise, beginning with measures that represent a material step beyond the findings and problem definition of the Evaluation.

The contribution is limited to the consulted options expressly assessed below. No inference should be drawn from an option that Imperial Brands has not addressed. Silence is not endorsement. A “don't know” response in the questionnaire indicates that the question or proposed intervention was not sufficiently clear to support a reasoned answer.

Imperial Brands requests an invitation to a targeted consultation with the Commission to provide additional data, under confidentiality safeguards.

About Imperial Brands

Imperial Brands supports a well-functioning internal market, a high level of health protection, youth-access prevention and robust action against illicit actors. These objectives are mutually reinforcing.

Imperial Brands is a significant participant in the EU's legal, taxed and supervised tobacco and nicotine market. Across the Union, our activities include and support manufacturing, procurement, product stewardship, regulatory compliance, logistics, distribution, innovation and cooperation with retailers and suppliers. In the EU alone, Imperial Brands works with around 100 European suppliers and contributes to employment, including more than 7,000 direct jobs across Europe, as well as tax revenues, investment and the practical implementation of regulatory obligations throughout the legal value chain.

2. Options lacking a demonstrated problem-to-intervention chain

This section assesses options for which the Evaluation identifies no corresponding regulatory deficiency; or it identifies a broader or different concern that does not establish the specific intervention subsequently tested in the consultation.

2.1 Reducing nicotine concentration in electronic cigarettes (Question 13)

Regulatory baseline and EU added value

Article 2(19) of the Directive defines nicotine as “nicotinic alkaloids”. Article 20 establishes a harmonised framework for nicotine-containing electronic cigarettes and refill containers. It requires advance notification of ingredients and emissions, toxicological information, data on nicotine dose and uptake, information on components and production processes, and manufacturer and importer responsibility for product quality and safety. It also requires high-purity ingredients, consistent nicotine delivery under normal conditions of use and a maximum nicotine concentration of 20 mg/ml.

The Directive harmonises the composition, nicotine concentration, notification, purity and product-safety requirements directly engaged by the present measure. Article 24(1) protects the placing on the market of products complying with the Directive against national restrictions based on matters regulated by it. The Court confirms in *Pillbox 38* that Article 20(3), including the 20 mg/ml ceiling, contains rules harmonising the composition of electronic cigarettes and refill containers and is capable of removing obstacles to their free movement.¹

As regards nicotine concentration, the harmonisation is exhaustive. Article 20(3)(b) establishes one maximum concentration for nicotine-containing liquids placed on the Union market.

“The TPD also sets a maximum nicotine concentration of 20 mg/ml and overall this has been implemented.”

European Commission, COM(2021) 249 final | s. 10.1

“Article 20 TPD delivered a substantial harmonisation of the regulatory framework on electronic cigarettes as well as providing enhanced product safety standards.”

Open Evidence, Results of the Study supporting the Evaluation of the Tobacco Control Acquis | p. 34

The Study supporting the Evaluation describes Article 20 as comprehensively harmonising the principal elements of electronic-cigarette regulation, expressly including technical features, maximum nicotine concentration, reporting requirements and the procedure for withdrawing products subsequently found to present a serious health risk.² It further records that 19 of 26 responding Member States regard Article 20 as fully relevant and that national authorities consider it to deliver substantial harmonisation and enhanced product-safety standards.

The 2021 Application Report states that the 20 mg/ml ceiling has, overall, been implemented.

¹ Case C-477/14 *Pillbox 38 (UK) Ltd v Secretary of State for Health* EU:C:2016:324, particularly paras 83–97.

² European Commission, Results of the Study supporting the Evaluation of the Tobacco Control Acquis (study conducted by Open Evidence, Publications Office of the European Union 2026) 34–35.

Article 114(3) TFEU requires the Commission to take a high level of health protection as a basis when preparing an internal-market measure. It does not confer an independent power to replace an already harmonised product requirement merely because a different rule might be regarded as more protective of health. Union action must continue to make a genuine contribution to the establishment or functioning of the internal market.³

Effectiveness and regulatory fit

The evidence does not establish a beneficial population-level effect from reducing the nicotine ceiling. The present 20 mg/ml limit was selected to permit nicotine delivery comparable to that obtained from a standard cigarette while controlling concentration. The Court recognises the legislature's balancing of nicotine-related risks and the use of electronic cigarettes as substitutes for conventional cigarettes.

A lower ceiling may affect product acceptability, compensatory consumption, switching from cigarettes, relapse, continued smoking and demand for non-compliant products. The present record does not establish a net public-health benefit after taking these into account.

Conclusion for option selection

The fully harmonised 20 mg/ml ceiling should be maintained.

2.2 Leaflets or inserts with quitting information in cigarette and roll-your-own tobacco packs (Question 19)

Regulatory baseline and EU added value

Articles 8 to 10 of the Directive establish an extensive harmonised framework for communicating health risks and cessation information on cigarette and roll-your-own tobacco packs. Combined health warnings occupy 65% of the front and back surfaces, rotate annually and include information on smoking-cessation services, such as telephone numbers, email addresses or websites. The no-change baseline therefore already places prominent and recurring cessation information directly on every lawful pack.

The Evaluation does not identify any deficiency. It does not discuss leaflets or inserts, assess their incremental effectiveness or identify their absence as a shortcoming in the current framework. Instead, it concludes that the harmonised combined-warning regime strengthened health protection, raised awareness, helped prevent initiation and supported cessation.⁴ The 2021 Application Report similarly describes compulsory combined warnings as an important improvement and harmonised labelling and packaging as a key success of the Directive.⁵

“Overall, labelling and packaging rules are applied properly across the EU.”

European Commission, COM(2021) 249 final | s. 4.3

“Compulsory combined health warnings covering 65% of the front and back surfaces of tobacco packs was an important improvement of labelling measures.”

European Commission, COM(2021) 249 final | s. 4.1

³ Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* EU:C:2002:741

⁴ European Commission, *Evaluation of the Tobacco Products Directive, Tobacco Advertising Directive and related policies across the EU*, SWD(2026) 111 final, 2 April 2026, pp 62–63 and 66–68.

⁵ European Commission, *Report on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products*, COM(2021) 249 final, s 4.1, pp 6–7.

The implementation chronology points in the same direction. When DG SANTE set out the elements meriting further examination after the Article 28 cycle in December 2021, it identified stronger labelling and plain packaging but not physical cessation inserts.⁶

The Commission's own implementation assessment confirms that the framework is a functioning and mature warning regime. In 2018, it considered the Article 9 information message and the Article 10 text warnings appropriate and effective and regarded adaptation as premature. Article 10(3)(b) had already been used to establish the picture library through Commission Delegated Directive 2014/109/EU; the separate power to adapt that library to scientific and market developments has not been used. The Article 9(5) and Article 10(3)(a) warning-adaptation powers likewise remain unexercised in the subsequent reporting period. The Commission has not identified a failure in the existing warning architecture requiring a new physical information channel.⁷

The internal-market justification is absent. No Member State currently applies a requirement to include a physical cessation leaflet in every cigarette or roll-your-own tobacco pack. One Member State has adopted a prospective requirement, which is not yet in force. The present record does not reveal an established field of divergent national rules requiring approximation at Union level.

The appearance of leaflets or inserts in the present questionnaire therefore represents a material step beyond the findings and problem definition of the Evaluation.

A potential public-health benefit cannot replace that analysis. Article 114(3) TFEU shapes the level of health protection pursued by a measure otherwise supported by the internal-market competence. The present record establishes neither an existing or sufficiently likely obstacle to trade or appreciable distortion of competition nor a genuine contribution by inserts to addressing such an obstacle.

The TPD I to TPD II record reinforces the need for that discipline. The 2010 consultation expressly presented inserts as Option 2c.⁸

The RAND study commissioned to support the Impact Assessment assessed the measure. It found that the evidence base was substantially less developed than supporting other warning measures.⁹ The available Canadian evidence concerned principally notice, recall and perceptions of the information, rather than demonstrated effects on sustained cessation or smoking prevalence. RAND also identified machinery requirements, recurring material costs and reduced factory efficiency as relevant consequences.

Despite that express consultation and substantive assessment, the physical-insert option was not carried into the defined options in the final 2012 Impact Assessment or into the Commission proposal. The selected framework instead placed combined warnings and cessation information directly on the packet.

No new evidence or changed circumstance exists that justifies reviving an option previously examined and filtered out before the proposal stage. The existing harmonised warning regime is not shown to be inadequate, and no incremental behavioural benefit from a physical insert is established.

⁶ European Commission, 3rd Meeting of the Expert Group on Tobacco Policy, Summary Record, 2 July 2015, p. 2; European Commission, DG SANTE, Expert Group on Tobacco Policy meeting, presentation, 2 December 2021, slide 24.

⁷ European Commission, *Report on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2014/40/EU*, COM(2018) 579 final, 8 August 2018, sections 3.3.8–3.3.9, p 5; European Commission, *Report on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2014/40/EU*, COM(2023) 491 final, 17 August 2023, section 4, p 3.; Commission Delegated Directive 2014/109/EU of 10 October 2014 establishing the library of picture warnings to be used on tobacco products

⁸ European Commission, *Possible Revision of the Tobacco Products Directive 2001/37/EC: Public Consultation Document* (2010), s 3.2, Option 2c.

⁹ Jan Tiessen and others, *Assessing the Impacts of Revising the Tobacco Products Directive: Study to Support a DG SANCO Impact Assessment* (RAND Europe, TR-823-EC, 2010), ch 8.

Effectiveness and regulatory fit

The Evaluation support study treats the existing combined warnings as a significant achievement and an effective means of increasing awareness. The 2021 support study nevertheless finds that, after the TPD warnings were introduced, adult smokers reported greater salience but no clear trend in cognitive reactions, including whether the warnings made them more likely to quit, or in reported behavioural reactions, including whether a warning stopped a cigarette that was about to be smoked. Increased attention to an additional message therefore cannot be treated as evidence that a physical insert would produce sustained cessation.¹⁰

The reported EU implementation rate for Articles 11 and 12 of the WHO FCTC is 100%. There is no identified FCTC implementation gap that a mandatory physical insert would address.¹¹

Information exposure is not equivalent to behavioural effectiveness. Findings concerning notice, recall, knowledge, perceived usefulness, intentions or self-reported motivation do not establish an effect on sustained cessation. The present record identifies no such incremental behavioural effect.

Evidence from a non-EU jurisdiction using inserts also cannot be transferred to the present EU baseline. The current Directive already requires large pictorial warnings and cessation information occupying most of both principal packet surfaces. The correct comparator is therefore not an insert against a packet containing limited or outdated information. It is an insert against the present harmonised EU warning system.

Coherence and wider impacts

The requirement may also conflict with efforts to simplify packaging, reduce material use and improve circularity. That burden reinforces the absence of a proportionate case where no material incremental cessation benefit has been established.

Any benefits attributable to the existing warning regime cannot be counted as benefits of inserts. Increased awareness, cessation signposting and the harmonised presentation of health information already form part of the no-change baseline. Only the demonstrable additional effect caused by the physical insert is relevant to the option comparison.

Cessation information printed on the unit packet remains with the pack throughout its use, whereas a separate insert can be removed and discarded. A 2016 roadside litter audit in Canada found Health Canada cigarette-pack inserts to be the most common tobacco-related litter item, accounting for 41.8% of tobacco-product litter, and the third most common branded litter item overall.¹²

Proportionality and less restrictive alternatives

The present record establishes neither a residual behavioural gap, an incremental cessation effect, a material internal-market obstacle nor a proportionate benefit sufficient to justify the recurring operational and environmental burden.

Conclusion for option selection

Mandatory physical leaflets or inserts in cigarette and roll-your-own tobacco packs should be excluded from the retained option set and no change maintained.

¹⁰ European Commission, Directorate-General for Health and Food Safety, Results of the Study supporting the Evaluation of the Tobacco Control Acquis (Open Evidence, manuscript completed October 2025), pp. 44–45; European Commission, Directorate-General for Health and Food Safety, Final Report: Support Study to the report on the application of Directive 2014/40/EU (ICF S.A. and RAND Europe, May 2021), pp. 72–73.

¹¹ WHO Framework Convention on Tobacco Control, Implementation Database, European Union, 2025 reporting cycle, sections 10–11 (Articles 11 and 12), pp. 34–39.

¹² Multi-Materials Stewardship Board, *Newfoundland and Labrador Roadside Litter Audit* (2016), pp. 19, 22–23.

2.3 Standardisation of the form and size of tanks, refill containers and cartridges for electronic cigarettes (Questions 13 and 19)

Regulatory baseline and EU added value

Article 20 already establishes harmonised Union requirements for tanks, cartridges and nicotine refill containers. It limits tanks and cartridges to 2 ml and refill containers to 10 ml and requires a mechanism ensuring leakage-free refilling. Commission Implementing Decision (EU) 2016/586 gives technical effect to that requirement while permitting different compliant technical solutions.

The relevant capacity and refill requirements are already harmonised. Any variation between lawful products is part of the existing harmonised architecture, not a regulatory gap.

Neither the Evaluation nor its supporting study identifies possible variation in the physical form of tanks, refill containers or cartridges as a deficiency in the existing framework. They do not establish that any variation has impaired the application of Article 20, obstructed the movement of compliant products or appreciably distorted competition. The option therefore goes materially beyond the findings of the Evaluation.

“Alignment with the maximum refill volume of 10 mL, as required by Art. 20(3)(a), had also improved significantly, with 94.4% of products in alignment post-implementation as compared to 86.9% pre-implementation.”

ICF S.A. and RAND Europe, Final Report: Support Study to the report on the application of Directive 2014/40/EU | Article 20 assessment, pp. 132–134

The TRIS record for 2012-2026 likewise does not establish a pattern of Member States prescribing competing physical formats for these components.

The TPD I-to-TPD II precedent reinforces the point. The previous revision established common capacity and refill requirements while retaining different lawful product architectures. Decision 2016/586 subsequently implemented that approach by permitting different technical solutions rather than imposing Union-wide physical formats.

The Commission’s 2016 assessment of refillable electronic cigarettes reaches the same regulatory conclusion.¹³ Having assessed the applicable TPD provisions and secondary legislation, it considers the resulting framework adequate and proportionate in light of the scientific knowledge then available. It does not identify physical standardisation of tanks, refill containers or cartridges as a missing component of that framework.

The Commission’s supporting studies also distinguish implementation of the present requirements from any case for further physical standardisation. The 2021 support study records substantial post-implementation alignment with child-resistant and tamper-proof requirements and 94.4% alignment with the 10 ml refill-volume limit. These findings show that the identified issues concern compliance, clarity and the burden of existing limits, not an evidenced need to carry this intervention.¹⁴

The option would change a harmonised framework based on common requirements and different compliant designs. The present record establishes no defect in the existing

¹³ European Commission, *Report on the potential risks to public health associated with the use of refillable electronic cigarettes*, COM(2016) 269 final, conclusion.

¹⁴ European Commission, Directorate-General for Health and Food Safety, Final Report: Support Study to the report on the application of Directive 2014/40/EU (ICF S.A. and RAND Europe, May 2021), pp. 132-134; European Commission, Directorate-General for Health and Food Safety, Results of the Study supporting the Evaluation of the Tobacco Control Acquis (Open Evidence, October 2025), p. 35.

framework, material internal-market problem arising from lawful product variation or incremental contribution from this intervention.

Effectiveness and regulatory fit

The Commission has not demonstrated that lawful variation in the form and size of tanks, refill containers and cartridges causes a problem to the trade of electronic cigarettes and refill containers within the Union. Nor has it identified evidence showing that removal of that variation would improve the functioning of the internal market or produce a measurable public-health outcome.

Coherence

Such intervention would materially constrain manufacturers' freedom to design and develop products, including through patented technologies and registered designs. It would therefore constitute a significant restriction on the freedom to conduct a business and on protected intellectual-property rights.

Proportionality and less restrictive alternatives

The proportionate option is no change. The existing framework already secures common capacity and refill requirements.

Conclusion for option selection

Standardisation of the form and size of tanks, refill containers and cartridges should be excluded from the retained option set and no change maintained.

2.4 Further product standards for electronic-cigarette device safety, including leakage, overheating and battery safety (Question 13)

Regulatory baseline and EU added value

Article 20 of the TPD already establishes harmonised product and safety requirements for nicotine-containing electronic cigarettes and refill containers. Manufacturers and importers must assume responsibility for product quality and safety and notify product components, production processes and specified technical information. Products must be child- and tamper-resistant, protected against breakage and leakage, deliver nicotine consistently under normal conditions of use and provide for leakage-free refilling. Commission Implementing Decision (EU) 2016/586 specifies technical requirements for refill mechanisms.

These harmonised product-specific requirements operate alongside applicable horizontal Union legislation concerning general product safety, electromagnetic compatibility, batteries, chemicals and electrical equipment. Article 20(1) itself requires electronic cigarettes and refill containers to comply with the TPD and all other relevant Union legislation. Commission comments issued through TRIS have similarly treated the TPD and horizontal product-safety legislation as complementary elements of the applicable framework.

The legal baseline is therefore a harmonised and layered Union regime.

Under Article 114 TFEU, additional harmonisation must be directed at removing actual or likely obstacles to trade or appreciable distortions of competition. The requirement in Article 114(3) to ensure a high level of health protection informs the content of a valid

harmonisation measure; it does not replace the need to establish the internal-market problem that warrants Union action.¹⁵

The Evaluation's supporting study describes Article 20 as establishing comprehensive harmonised provisions governing the technical features of electronic cigarettes and refill containers.¹⁶ It records that Member States consider Article 20 to have delivered substantial harmonisation, enhanced product-safety standards and supported the smooth functioning of the internal market.

“Article 20 TPD addresses the specific objectives of harmonising the market for e-cigarettes and their refill containers in the EU. This harmonisation was successful in most aspects.”

Open Evidence, Results of the Study supporting the Evaluation of the Tobacco Control Acquis | p. 34

The recent JRC report recognises that explosions and burns can cause serious injuries, but describes their incidence as low and associates such events with device or battery quality, malfunction, improper storage, modification, mishandling or tampering.¹⁷

The Expert Group record provides direct implementation evidence. In October 2017, when separately sold rechargeable batteries were raised, the record notes that they were in any event covered by the General Product Safety Directive. In October 2019, after the serious US e-cigarette incidents, DG SANTE records that no similar EU cases have been reported through Safety Gate or ICSMS. A further chronology checkpoint appears in December 2021: DG SANTE's list of e-cigarette elements meriting additional examination does not mention leakage, overheating or battery-safety. These points concern risks already addressed through the existing product-safety and surveillance architecture; they do not establish an incremental benefit from this intervention.¹⁸

The Commission's 2016 assessment of refillable electronic cigarettes examined risks arising from ingestion and contact with e-liquids, home mixing, product customisation and untested combinations of devices and liquids. In light of the scientific knowledge then available, it concludes that the TPD, its secondary legislation and applicable national rules provide an adequate and proportionate framework for mitigating the risks identified.¹⁹

“The measures relating to refillable e-cigarettes provided for in the TPD and secondary legislation, combined with national regulation, provide an adequate and proportionate framework for the mitigation of such risks.”

European Commission, Report on the potential risks to public health associated with the use of refillable electronic cigarettes, COM(2016) 269 final

Against that baseline, the Evaluation does not identify the residual internal-market failure to which further leakage, overheating, battery or device-safety requirements would respond. Neither the Evaluation nor its supporting study establishes that Member States apply conflicting technical requirements in these areas, that compliant products must be

¹⁵ Case C-491/01 *British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd* EU:C:2002:741, paras 59–62; Case C-547/14 *Philip Morris Brands SARL and Others v Secretary of State for Health* EU:C:2016:325, paras 57–62; Case C-358/14 *Republic of Poland v European Parliament and Council* EU:C:2016:323, paras 31–35.

¹⁶ European Commission, *Results of the Study supporting the Evaluation of the Tobacco Control Acquis* (Open Evidence, October 2025) 34–35.

¹⁷ A Perez-Cornago and others, *Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches* (Publications Office of the European Union 2026) JRC146139, 43–45.

¹⁸ European Commission, Group of Experts on Tobacco Policy, Summary Record, 9 October 2017, p. 5; Summary Record, 15 October 2019, pp. 3–4; European Commission, DG SANTE, Expert Group on Tobacco Policy meeting, presentation, 2 December 2021, slide 24.

¹⁹ European Commission, *Report on the potential risks to public health associated with the use of refillable electronic cigarettes*, COM(2016) 269 final, sections 3–5, especially the conclusions; see also ICF and RAND Europe, *Support Study to the Report on the Application of Directive 2014/40/EU* (May 2021) 120.

redesigned for different national markets, or that existing differences create material barriers to cross-border trade or appreciable distortions of competition.²⁰

The reviewed TRIS record for 2013–2026 likewise identifies no pattern of Member States prescribing competing technical standards specifically concerning leakage, overheating or battery safety in nicotine-containing electronic cigarettes.

The option therefore goes materially beyond the problem record established by the Evaluation and related implementation materials.

Effectiveness and regulatory fit

That evidence does not establish that any potential hazard results from a deficiency in the harmonised framework, that compliant products present a recurrent residual risk or that Member States are adopting divergent technical responses.

Available implementation evidence instead shows extensive action against non-compliant products.²¹ Member States use withdrawals, fines, compliance notices and other measures concerning notification, composition, capacity, nicotine concentration, labelling and related Article 20 infringements. The support study also records differences in Member-State surveillance resources and technical capacity. These findings point to implementation and enforcement deficiencies, not to a defect in the Union rules.

Coherence and wider impacts

Additional TPD requirements would overlap with the existing Union product-safety, battery, electromagnetic-compatibility, chemical and electrical-equipment framework and risk duplicative or inconsistent obligations.

Requiring modification or withdrawal of products already compliant with Article 20 and relevant horizontal legislation would not produce an internal-market benefit.

Proportionality and less restrictive alternatives

The supporting study identifies implementation and enforcement issues within the existing framework, not a need for this intervention.

Conclusion for option selection

This intervention should be excluded from the retained option set.

2.5 Leaflets or inserts with quitting information for electronic cigarettes, heated tobacco products, nicotine pouches and heated herbal products (Questions 12 and 19)

Regulatory baseline and EU added value

Article 20 of the TPD requires unit packets of electronic cigarettes and refill containers to include a leaflet. Its mandatory content covers instructions for use and storage, contraindications, warnings for specific risk groups, possible adverse effects, addictiveness and toxicity, and contact details. Article 20 establishes a harmonised Union information baseline for those products.

²⁰ European Commission, *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, 51–53 and 66–68; European Commission, *Results of the Study supporting the Evaluation of the Tobacco Control Acquis* (Open Evidence, October 2025) 34–35 and 52–53.

²¹ ICF and RAND Europe, *Support Study to the Report on the Application of Directive 2014/40/EU* (May 2021) 143–146 and 345–346.

Article 20(12) separately empowers the Commission to adapt the wording of the electronic-cigarette health warning; that delegated power remains unexercised. A targeted warning-adjustment mechanism therefore already exists alongside the mandatory leaflet.²²

Heated tobacco products are likewise subject to harmonised TPD labelling requirements according to their legal classification, including cessation information within combined health warnings where those warnings apply. Where a heated tobacco product is classified as smokeless tobacco, Article 12(3) likewise permits adaptation of the health-warning wording to scientific developments; that delegated power remains unexercised.²³

Heated herbal products and nicotine pouches are not governed by the TPD.

Neither the Evaluation nor its supporting study establishes that the harmonised frameworks applicable to electronic cigarettes or heated tobacco products are inadequate.²⁴ In particular, they do not identify the absence of a physical cessation insert for heated tobacco products, or the implementation of the e-cigarette leaflet, as a regulatory deficiency or demonstrate actual or likely national divergence requiring approximation. The option therefore goes beyond the record established in the Evaluation.

The reviewed TRIS record for 2013–2026 likewise identifies no pattern of Member States imposing physical cessation-insert requirements on heated tobacco products, nicotine pouches or heated herbal products.

The TPD I-to-TPD II precedent reinforces that conclusion. TPD II established harmonised labelling for heated tobacco products and expressly introduced a physical leaflet for electronic cigarettes. For these categories, a general objective of increasing health protection cannot itself establish EU added value in a field already harmonised.²⁵

For categories outside the TPD, the absence of harmonisation is not evidence of a product-specific problem, sufficiently likely national divergence or EU added value for physical cessation inserts.

Effectiveness and regulatory fit

For electronic cigarettes, the baseline is Article 20. For heated tobacco products, it includes the applicable classification-dependent labelling framework and, where relevant, combined health warnings containing cessation information. Any benefits attributable to those measures cannot be counted again as benefits of the present option.

For heated herbal products and nicotine pouches, the absence of a TPD labelling framework does not establish that a physical cessation insert would be effective. Those elements cannot be inferred from evidence relating to electronic cigarettes or tobacco products.

Coherence and wider impacts

The material-use, simplification and cumulative implementation consequences of a physical insert are addressed in section 4.4.

Proportionality and less restrictive alternatives

For electronic cigarettes and heated tobacco products, the relevant harmonised Union frameworks already apply. The present record does not establish an internal-market gap that those frameworks fail to address.

²² Directive 2014/40/EU, Article 20(12); European Commission, COM(2018) 579 final, section 3.3.13; European Commission, COM(2023) 491 final, section 4.

²³ Directive 2014/40/EU, Article 12(3); European Commission, COM(2018) 579 final, section 3.3.10; European Commission, COM(2023) 491 final, section 4.

²⁴ European Commission, *Evaluation of the Tobacco Products Directive, the Tobacco Advertising Directive and related policies across the EU*, SWD(2026) 111 final; Open Evidence, *Results of the Study supporting the Evaluation of the Tobacco Control Acquis* (2026).

²⁵ Case C-547/14, *Philip Morris Brands SARL and Others v Secretary of State for Health*, EU:C:2016:325, paras 57–62.

Conclusion for option selection

Physical cessation inserts for electronic cigarettes, heated tobacco products, heated herbal products and nicotine pouches should be excluded from the retained option set.

2.6 Additional reporting and testing on product composition, emissions or aerosol constituents for heated tobacco products (Question 13)

Regulatory baseline and EU added value

Heated tobacco products are novel tobacco products within the TPD. Articles 5 and 19 already establish a harmonised pre-market information framework requiring manufacturers and importers to submit ingredient and emissions information, available scientific studies concerning toxicity, addictiveness and attractiveness, and other relevant product information. Under Article 19(2), Member States may require manufacturers and importers to conduct additional tests or submit additional information.

The public consultation asks whether additional reporting and testing on product composition, emissions or aerosol constituents would be effective. For heated tobacco products, those are not equivalent interventions. Article 19 already provides both a core information baseline and a product-specific power to obtain additional tests.²⁶

The Evaluation identifies neither an operative pattern of conflicting emission levels nor the likely emergence of such levels²⁷. The conditions for preventive harmonisation cannot be supplied merely by the possibility that different national rules might one day emerge. Nor can Article 114(3) TFEU independently justify a new ceiling on public-health grounds. The present record establishes no internal-market problem, inadequacy in the existing Articles 3, 5 and 19 architecture or additional contribution from the proposed limit.

The 2021 support study finds that seven Member States have required additional tests or information for novel tobacco products, principally heated tobacco products.²⁸ Three required emissions testing; other requests concerned aerosol chemistry and emissions data for priority substances. The existing framework therefore already enables authorities to investigate product composition, aerosol chemistry and emissions. The Evaluation does not identify a failure of that intervention.

“Seven Member States required manufacturers and importers of novel tobacco products to carry out additional tests or submit additional/updated information.”

ICF S.A. and RAND Europe, Commission-commissioned Support Study to the report on the application of Directive 2014/40/EU (2021), Article 19(2) assessment, p. 110.

The Commission’s reports on delegated powers provide a direct official checkpoint concerning the maturity of the standards framework. In 2018, the Commission reported that no FCTC or WHO standard had emerged for maximum emissions from tobacco products other than cigarettes under Article 3(4), and that no corresponding internationally agreed measurement standard had emerged under Article 4(5). It also found no scientific, technical or internationally agreed development justifying adaptation of the existing measurement

²⁶ European Commission, Public consultation on the evaluation and revision of the EU tobacco control framework, questionnaire for companies and business associations (2026), Question 13.

²⁷ European Commission, *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, pp 51 and 67–68 and Annex 5.

²⁸ European Commission, Directorate-General for Health and Food Safety, *Final Report: Support Study to the report on the application of Directive 2014/40/EU* (ICF SA and RAND Europe, May 2021), pp 109–110.

methods under Article 4(3). In 2023, after examining heated-tobacco market developments and acting on the flavour and labelling exemptions applicable to that category, the Commission nevertheless states that the preconditions for exercising the remaining delegated powers have not been met. This establishes that the Commission has not identified the internationally agreed ceiling and measurement architecture contemplated by the existing Directive.²⁹

The TRIS record (2012-2026) identifies no conflicting national emissions levels, obstacle to trade or appreciable distortion of competition. Article 19(2) already accommodates product-specific testing and information requests within the Union framework; differences in such requests are not divergent market-access rules.

Effectiveness and regulatory fit

No legally determinative emission levels or standard exists.

The 2021 support study finds that only a few Member States measure emissions from heated tobacco products, primarily for experimental purposes.³⁰ That evidence does not establish the operational readiness of a Union-wide intervention. A product-specific request under Article 19(2) and an EU-wide intervention have materially different capacity and implementation consequences.

Experimental measurement and surveillance do not establish an internal-market problem or harmonisation need. The record identifies neither conflicting national market-access requirements nor a common legally determinative threshold.

Published studies report substantially lower levels of many measured combustion-related toxicants in heated-tobacco aerosol than in cigarette smoke, while making clear that these products are not risk-free.³¹ Those findings demonstrate that cigarette-smoke limits or constituent priorities cannot be transferred automatically. They do not establish a legally determinative emissions ceiling or an incremental population-level benefit from one. Detection of a constituent is not equivalent to demonstration of a material risk. Analytical detection does not establish a health-based market-access threshold. The present record identifies no such threshold.

Coherence and wider impacts

Information already required under Articles 5 and 19, or capable of being requested under Article 19(2), cannot be treated as a benefit by a new intervention.

Proportionality and less restrictive alternatives

Article 19 already accommodates additional testing and information requests within the Union framework. The record identifies no resulting barrier to trade or additional internal-market value from further Union requirements.

Conclusion for option selection

Emission levels for heated tobacco products should be excluded from the option set.

²⁹ European Commission, COM(2018) 579 final, sections 3.3.2–3.3.4, pp 4–5; European Commission, COM(2023) 491 final, sections 3–4, pp 2–3.

³⁰ European Commission, Directorate-General for Health and Food Safety, *Final Report: Support Study to the report on the application of Directive 2014/40/EU* (ICF SA and RAND Europe, May 2021), p 38.

³¹ M Forster and others, 'Assessment of novel tobacco heating product THP1.0. Part 3: Comprehensive chemical characterisation of harmful and potentially harmful aerosol emissions' (2018) 93 *Regulatory Toxicology and Pharmacology* 14; F Chapman et al., 'Multiple endpoint in vitro toxicity assessment of a prototype heated tobacco product indicates substantially reduced effects compared to those of combustible cigarette', *Toxicology in Vitro* 86 (2023), 105510, doi: 10.1016/j.tiv.2022.105510.

2.7 Additional reporting and testing on product composition, emissions or aerosol constituents for electronic cigarettes (Question 13)

Regulatory baseline and EU added value

Article 20 establishes a harmonised pre-market information and product-control framework for nicotine-containing electronic cigarettes and refill containers. Manufacturers and importers must notify ingredients and emissions, including quantities; toxicological data concerning ingredients and emissions, including when heated; information on nicotine dose and uptake; product components and production processes; and responsibility for product quality and safety. Article 20 also requires high-purity ingredients and provides that ingredients other than nicotine must not pose a risk to human health in heated or unheated form.

The consultation conflates questions concerning information already required through EU-CEG with possible changes, including on emissions levels. Those are not the same intervention.

The Evaluation describes EU-CEG as a useful harmonised monitoring tool while identifying some limitations.³² Those findings concern the operation of the existing system. They do not identify a public health gap and national divergence supporting changes to the current requirements.

“Despite some challenges, the EU-CEG serves as an effective monitoring tool.”

European Commission, SWD(2026) 111 final | p. 62

“By comprehensively harmonising the regulation pertaining to e-cigarettes, Article 20 successfully addresses the need to ensure a smooth functioning of the internal market.”

Open Evidence, Results of the Study supporting the Evaluation of the Tobacco Control Acquis | p. 34

The Commission’s 2021 support study finds that Member-State measurements of emissions from electronic cigarettes are conducted primarily for experimental purposes.³³

“A few Member States performed measurements of emissions of other tobacco products, including emissions of HTPs and e-cigarettes, primarily for experimental purposes.”

ICF S.A. and RAND Europe, Final Report: Support Study to the report on the application of Directive 2014/40/EU | pp. 37–38

The TRIS record reviewed for 2012–2026 likewise does not disclose an operative pattern of Member States adopting emission levels for electronic-cigarette aerosol constituents. It establishes neither existing nor sufficiently likely fragmentation.

Effectiveness and regulatory fit

Published research demonstrates that measured carbonyl and other aerosol yields vary with solvent composition, power, device configuration and use conditions.³⁴ That variability does

³² European Commission, *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, particularly pp 45–46, 60, 62–64, 112–113 and Annex 5

³³ ICF SA and RAND Europe, *Final Report: Support Study to the report on the application of Directive 2014/40/EU* (European Commission, May 2021) 37–38 and the Article 20 assessment. The study records that measurements of HTP and e-cigarette emissions were primarily experimental and identifies laboratory availability, capacity and expertise constraints.

³⁴ L Kosmider and others, ‘Carbonyl Compounds in Electronic Cigarette Vapors: Effects of Nicotine Solvent and Battery Output Voltage’ (2014) 16 *Nicotine & Tobacco Research* 1319; M Sleiman and others, ‘Emissions from Electronic Cigarettes: Key Parameters Affecting the Release of Harmful Chemicals’ (2016) 50 *Environmental Science & Technology* 9644; Y Son and others, ‘Carbonyls and Carbon

not establish a legally appropriate threshold or demonstrate that compliance with any particular ceiling would improve population health. Analytical detection or hazard classification does not establish a health-based market-access threshold.

The evidence does not establish an incremental population-level benefit once compensatory use, continued smoking and demand for products outside the compliant market are taken into account.

Efficiency, implementation feasibility and enforceability

The evidence does not identify a defined regulatory problem that the requirements cannot address.

The Evaluation's findings concern the quality, comparability and use of the existing information. Requiring more data does not remedy those limitations or establish an incremental regulatory benefit either to the internal market or to public health protection.

Coherence and wider impacts

Article 20(3)(e) already addresses ingredient-related risk. Its baseline benefits cannot be attributed to additional interventions.

Proportionality and less restrictive alternatives

EU-CEG data-quality and use limitations are implementation issues within the existing framework; they do not establish the need for changes to the current requirements.

Conclusion for option selection

Emissions levels for electronic cigarettes should be excluded from the retained option set.

2.8 Reporting and testing on product composition, emissions or aerosol constituents for heated herbal products (Question 13)

Regulatory baseline and EU added value

Heated herbal products are not presently subject to TPD notification requirements.

Neither the Evaluation nor its supporting study establishes a need for emission levels in heated herbal products. The Evaluation does not identify a product-specific internal-market problem requiring additional reporting, testing or emissions controls,³⁵ while the supporting study excluded them from substantive analysis.³⁶

“These products are not included in our analysis as, besides not being regulated by the TPD nor TAD, sources were limited in Q3 2023 and Q1 2024.”

Open Evidence, Results of the Study supporting the Evaluation of the Tobacco Control Acquis | p. 21, fn 12

The TRIS record for 2012–2026 likewise identifies no actual or sufficiently likely conflicting national emissions rules, obstacle to trade or appreciable distortion of competition.

Monoxide Emissions from Electronic Cigarettes Affected by Device Type and Use Patterns' (2020) 17 *International Journal of Environmental Research and Public Health* 2767.

³⁵ European Commission, *Evaluation of the Tobacco Products Directive, the Tobacco Advertising Directive and related policies across the EU*, SWD(2026) 111 final, especially pp 51 and 67–68 and Annex 5.

³⁶ Open Evidence, *Results of the Study supporting the Evaluation of the Tobacco Control Acquis* (2026), p 21 and fn 12.

Effectiveness and regulatory fit

A 2025 peer-reviewed assessment funded and performed by Imperial Brands of one tea-based heated-herbal system reports materially lower levels of the nine measured WHO priority analytes than 1R6F reference cigarette smoke, together with lower responses in the in-vitro assays used.³⁷ The authors expressly caution that the findings could not yet be corroborated against other products besides ISENZIA.

Efficiency, implementation feasibility and enforceability

The absence of a category-specific internationally established method is consequential. A method developed for another product category cannot become legally determinative for a non-tobacco substrate.

Conclusion for option selection

Emission levels for heated herbal products should be excluded from the option set.

2.9 Product-design requirements intended to reduce appeal, including restrictions on device appearance, lighting and toy-like features for electronic cigarettes, heated herbal products and heated tobacco (Questions 12 and 13)

Regulatory baseline and EU added value

Article 20 of the TPD regulates specified aspects of electronic cigarettes and refill containers, including components, quality and safety, while horizontal product-safety and electrical rules also apply to their devices. For heated tobacco products, the TPD regulates the tobacco consumable, while the electrical device is governed by horizontal product-safety and consumer law.

As late as March 2024, the Expert Group identifies product attractiveness as an area in which further research was needed. The evidential base is not mature to this intervention.³⁸

“Member States welcomed further research in several areas, such as characterizing flavours and product attractiveness, a better understanding of consumption patterns, and more detail on the long-term health impacts of new nicotine products.”

European Commission, Expert Group on Tobacco Policy, Meeting Minutes, 7 March 2024, p. 3.

The present record does not establish EU added value for this intervention beyond the existing product-safety and consumer-law baseline.

Effectiveness and regulatory fit

Functional indicators serve operational and safety purposes, and their mere presence cannot be treated as a proxy for appeal.

Evidence concerning one device cannot establish the need for such intervention.

Proportionality and less restrictive alternatives

The existing horizontal safety and consumer-law baseline has not been shown insufficient, and the record does not establish a proportionate basis for additional device-design restrictions.

³⁷ A Marinas-Lacasta and others, ‘Assessment of heated herbal products’ tobacco harm reduction potential: pre-clinical and clinical studies’ (2025) 7 *Frontiers in Toxicology* 1589480, DOI 10.3389/ftox.2025.1589480

³⁸ European Commission, Expert Group on Tobacco Policy, Meeting Minutes, 7 March 2024, p. 3.

Conclusion for option selection

The device-design restrictions tested by the consultation should be excluded from the retained option set.

3. Options lacking justification for changing harmonised requirements

This section assesses options that would change existing harmonised requirements or, for products not harmonised under the TPD, extend approaches developed for other categories, without evidence of a failure in the existing requirements, or a product-specific basis for the intervention tested.

3.1 Restrictions concerning certain forms of synthetic nicotine and nicotine-like substances (Question 13)

Regulatory baseline and EU added value

The source-neutral treatment of ordinary nicotine is part of the existing harmonised framework. The Directive defines nicotine by chemical class, not by whether it is extracted from tobacco or produced synthetically. Nicotine falling within the definition of “nicotinic alkaloids” is subject to the same concentration, notification, purity, toxicological-information, dose-consistency and product-safety requirements irrespective of production route.

The Commission confirms that interpretation in the TRIS procedure. In its comments on Luxembourg’s 2024 notification, it objects to a national definition referring to “nicotinic alkaloids and nicotine salts”.³⁹ The Commission explains that the addition risked creating the false impression that nicotine salts are not already nicotinic alkaloids covered by Article 2(19). It subsequently invites Luxembourg to align its definition with the Directive.

The Commission takes the point further in its comments on Spain’s 2025 notification.⁴⁰ Spain proposed to define nicotine as “nicotinic alkaloids and any nicotine derivatives”. The Commission states that the EU definition does not differentiate between tobacco-derived and synthetic nicotinic alkaloids and that synthetic nicotinic alkaloids include nicotine derivatives. It subsequently asks Spain not to add a separate reference to derivatives, because this could falsely imply that they fall outside the existing EU definition.

“That definition does not differentiate between tobacco-derived nicotinic alkaloids and synthetic nicotinic alkaloids, which include also nicotine derivatives.”

– European Commission comments on Spain Notification 2025/0044/ES, C(2025) 2628 final — 24 April 2025, p. 3

These comments establish that, within the scope of “nicotinic alkaloids”, nicotine salts, tobacco-derived nicotine and synthetic nicotine are not separate unregulated typologies. They fall within one source-neutral Union framework. In the Commission’s own words, there is no regulatory gap.

The consultation conflates ordinary synthetic nicotine with chemically distinct substances. The terminology used in the consultation risks reproducing the same uncertainty the Commission identifies when some authority separately refers to “nicotine salts” or “nicotine derivatives”.

Nicotine salts are distinct from chemically different analogues. Salt formation does not, by itself, create a different active substance or remove nicotine from Article 20. The Commission’s Luxembourg comments confirm that nicotine salts are covered by the

³⁹ European Commission comments on Luxembourg Notification 2024/0444/LU, C(2024) 7728 final, 29 October 2024.

⁴⁰ European Commission comments on Spain Notification 2025/0044/ES, C(2025) 2628 final, 24 April 2025.

definition of nicotine. Salt formation does not establish a separate legal category or justify a different concentration ceiling.

The TRIS record (2012-2026) does not identify an established pattern of Member-State rules applying different electronic-cigarette concentration limits according to natural or synthetic origin. More importantly, where Luxembourg and Spain sought to alter the wording of the common definition, the Commission has intervened to preserve the Directive's source-neutral formulation. The TRIS record does not establish an unregulated field requiring changes.

Effectiveness and regulatory fit

The JRC's 2026 evidence synthesis records that the available evidence remains largely confined to short- and medium-term outcomes and that variation in substance content complicates assessment. It does not provide an evidential basis for assigning one common risk profile to ordinary nicotine, nicotine salts and chemically distinct substances.⁴¹

Evidence concerning particular compounds cannot be used to justify restrictions on ordinary nicotine, nicotine salts or source-equivalent synthetic nicotine.

Efficiency, implementation feasibility and enforceability

Article 20 already requires disclosure of ingredients, toxicological information and nicotine dose and uptake. No information gap requiring changes is established.

Coherence and wider impacts

The existing framework treats chemically and pharmacologically equivalent nicotine consistently irrespective of production source. It is the approach the Commission applies when it tells Spain that the EU definition does not differentiate between tobacco-derived and synthetic nicotinic alkaloids.

Conclusion for option selection

A change to the definition of nicotine in the Directive should be excluded from the option set.

3.2 Characterising-flavour determination and ingredient regulation for cigarettes and roll-your-own tobacco (Question 12)

Articles 5 to 7 require ingredient disclosure and toxicological information, provide enhanced reporting for priority additives, prohibit characterising flavours and specified additive categories, and permit action where an additive increases toxicity or addictiveness to a significant or measurable degree.

The architecture also contains targeted mechanisms for implementing and updating certain requirements. Article 5(5) has been used to establish a common submission format in 2015, and Article 6(1) to establish the priority list of additives subject to enhanced reporting in 2016. The Commission has updated neither instrument ever since.⁴²

⁴¹ A Perez-Cornago, A Sarasa-Renedo, C Jarach, J Wollgast and P Maragkoudakis, Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches (Publications Office of the European Union 2026) JRC146139, 3, 5–6 and 75–76.

⁴² Directive 2014/40/EU, Articles 5(5) and 6(1); Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products; Commission Implementing Decision (EU) 2016/787 of 18 May 2016 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations.

The Evaluation describes EU-CEG as an effective monitoring tool which has improved transparency, regulatory oversight, data analysis and comparability, notwithstanding identified limitations in its operation.⁴³

“The establishment of the reporting obligations, implemented through the EU-CEG system, stands out as a successful initiative, providing a robust monitoring tool to track market changes and facilitate timely policy adjustments.”

Open Evidence, Results of the Study supporting the Evaluation of the Tobacco Control Acquis | p. 8

It also finds that the regulation of ingredients, including the prohibition of characterising flavours, has protected consumers by reducing product appeal and preventing initiation. In its conclusions, the Evaluation identifies the characterising-flavour prohibition among the TPD measures considered to have made the most significant contribution to reducing smoking prevalence.

The Evaluation also identifies the characterising-flavour determination procedure as resource-intensive.⁴⁴ It does not establish that the framework has failed or demonstrate a material internal-market obstacle requiring a change to the model.

The Evaluation does not distinguish the recurring cost of applying the methodology from the one-off costs of developing, validating and extending it. A close analysis shows that the IAP and Technical Group has spent the initial implementation period establishing reference products, sensory and chemical methods, statistical decision criteria and validation requirements. The Commission has continued to revise the methodology through 2025. The relevant baseline for the present Impact Assessment is therefore the methodology in operation, not the aggregate historic cost of creating and extending it.⁴⁵

“The Technical Group performed initial pilot tests with heated tobacco products (HTPs) using the approved IAP methodology. That proved feasible with minor adaptations.”

European Commission, Independent Advisory Panel, 42nd Meeting Minutes | 17 May 2022, item 6

The implementation record further shows that reported delay and resource use have had different causes. In some requests, additional time has been required due to a lack of available evidence or need to perform further testing; in others, concurrent workload has been relevant; and in 2023, there has been temporary delay due to the transition between Technical Group contracts. Evidential safeguards, administrative capacity and temporary procurement constraints are not evidence that the substantive regulatory test is defective.⁴⁶

More importantly, identified implementation shortcomings have been addressed. After the first 18 opinions covering four requests were adopted, the IAP considered streamlining the drafting process and communication with the Technical Group. Concerns raised by a manufacturer concerning practical detail in the approved methodology have also been

⁴³ European Commission, *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, section 4.2, pp 62–63; section 5.1, p 66.

⁴⁴ European Commission, SWD(2026) 111 final, section 4.1.2, “Flavours”, pp. 43–44; “Simplification and burden reduction”, p. 57; and section 5.1, “Conclusions”, p. 66. The evaluation describes the Article 7/Implementing Regulation (EU) 2016/779 procedure as burdensome and resource-intensive, and records it as the least efficient aspect of the TPD.

⁴⁵ European Commission, Independent Advisory Panel on Characterising Flavours in Tobacco Products, minutes of 1st meeting (1 June 2017), section 4; minutes of 9th meeting (27 November 2018), sections 5–7; minutes of 11th meeting (15 March 2019), sections 6–8; minutes of 42nd meeting (17 May 2022), sections 5–6; minutes of 48th meeting (7 February 2023), section 5; minutes of 58th–65th meetings (21 May 2024–19 May 2025), items concerning updates to the chemical and sensory methodology.

⁴⁶ European Commission, Independent Advisory Panel, minutes of 32nd meeting (11 October 2021), section 6; minutes of 53rd meeting (31 July 2023), section 6.

addressed through publication of the underlying Technical Group reports, subject to protection of personal and commercially sensitive information.⁴⁷

“The EU-CEG and the Independent Advisory Panel – are fully operational and functional.”

European Commission, COM(2021) 249 final | s. 3.5

In its 2021 presentation on application of the Directive, the Commission has reported no compliance issues concerning characterising candy or fruit flavours and identified the position as becoming more complex following the menthol prohibition.⁴⁸ Difficulty in particular cases does not establish that the underlying regulatory test is generally ineffective.

DG SANTE has described the IAP and Technical Group architecture as intended to produce a scientifically robust process capable of supporting Member State decisions and withstanding possible court challenge.⁴⁹ The subsequent implementation record does not suggest that the model is particularly burdensome or resource-intensive.

If anything, the implementation record identifies usual administrative burden within an established harmonised framework.

Effectiveness and regulatory fit

A list-based regime would not simplify the characterising-flavour methodology.

The characterising-flavour procedure asks whether the finished product imparts a characterising flavour and reaches that determination through sensory assessment, chemical analysis, reference products, statistical criteria and expert judgment. A list-based regime would instead attach regulatory consequences to specified inputs.

The Commission’s own implementation practice confirms that chemical analysis is not a substitute for the regulatory determination.⁵⁰ The Technical Group performs sensory and, where relevant, chemical assessment, but the IAP states that the conclusion whether a product has a characterising flavour is based primarily on the Panel’s own considerations – not chemical assessment alone.⁵¹ During the recent adaptation of the methodology to heated tobacco products, the IAP again has emphasised that its opinions ultimately rest on the expert judgment of its appointed members.⁵²

“While the actual sensory and chemical test are performed by the TG, the IAP conclusions whether or not a tobacco product has a characterising flavour should be primarily based on the IAP own considerations.”

European Commission, Independent Advisory Panel, 25th Meeting Minutes | 24 February 2021, item 6

“IAP opinions are ultimately based on the expert judgment of the appointed members.”

European Commission, Independent Advisory Panel, 52nd Meeting Minutes | 5 July 2023, item 7

⁴⁷ European Commission, *42nd Meeting of the Independent Advisory Panel on Characterising Flavours in Tobacco Products – Minutes*, 17 May 2022, item 5.

⁴⁸ European Commission, DG SANTE, *Application of Directive 2014/40/EU*, presentation to the Expert Group on Tobacco Policy, 2 December 2021, slide 8, ‘Product regulation – characterising flavours’.

⁴⁹ European Commission, Subgroup on Ingredients, summary record, 6 June 2018, section 3, ‘Determination of characterising flavours’.

⁵⁰ European Commission, Independent Advisory Panel, minutes of 11th meeting (15 March 2019), sections 6–8; *25th Meeting of the Independent Advisory Panel on Characterising Flavours in Tobacco Products – Minutes*, 24 February 2021, item 6; *52nd Meeting...*, 5 July 2023, item 7.

⁵¹ European Commission, *25th Meeting of the Independent Advisory Panel on Characterising Flavours in Tobacco Products – Minutes*, 24 February 2021, item 6.

⁵² European Commission, *52nd Meeting of the Independent Advisory Panel on Characterising Flavours in Tobacco Products – Minutes*, 5 July 2023, item 7.

A regime in which the presence of a listed substance itself determines market access would therefore not simplify the procedure. It would change a product-level assessment informed by several forms of evidence.

The TPD I to TPD II preparatory process is directly relevant. The 2010 public consultation expressly tested both a common positive list and a common negative list of prohibited or restricted ingredients. The Impact Assessment did not carry either model into the final option set. It deferred a common list based on toxicity and addictiveness and did not select the broader option of a general prohibition on additives.⁵³

TPD II subsequently required the Commission to report on the feasibility, benefits and possible impact of an EU system for regulating ingredients, including a Union list of ingredients. In the 2021 Application Report, the Commission has not concluded that such a regime is ready for implementation; instead it identifies its resource requirements as a material consideration. The Commission's own presentation that year likewise treated the feasibility of a list as unresolved.⁵⁴ A list-based regime is not the answer to resource concerns around the characterising-flavour procedure.

The Evaluation identifies no subsequent evidence establishing that a list-based regime delivers increased health protection.

The Commission's formal implementation reports reinforce that conclusion. In 2018, it found that the conditions for exercising the delegated powers under Article 7(11) have not been met. The requisite pattern of Member-State prohibitions had not arisen for additives shown to amplify toxicity or addictiveness. In 2023, the Commission again reiterates that the preconditions for exercising this delegated power have not been met. These findings confirm that the monitoring framework has not generated the substance-specific evidence and pattern of national action contemplated for Union-level intervention.⁵⁵

The Commission's own TRIS practice points in the same direction. In 2015, 2016, 2023 and 2025, the Commission challenged national additive restrictions that extended beyond the harmonised categories or lacked adequate substance-specific justification.⁵⁶ This record is inconsistent with changing the requirements with a list-based regime whose incremental effectiveness has not been established.

“Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products.”

Directive 2014/40/EU text reproduced in Commission observations on Hungary Notification 2015/0529/HU | 17 December 2015

Efficiency, implementation feasibility and enforceability

The 2021 application support study treats the resource and institutional implications of a list-based regime unresolved; it does not describe lists as a self-executing simplification.⁵⁷

⁵³ European Commission, *Possible Revision of the Tobacco Products Directive 2001/37/EC: Public Consultation Document* (DG SANCO, 2010), section 5.2, Options 3a and 3b, pp 9–10; European Commission, *Impact Assessment accompanying the Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products*, SWD(2012) 452 final, policy area 3 on ingredients, pp 55–56.

⁵⁴ *Directive 2014/40/EU*, recital 53 and art 28(2)(d); European Commission, *Report on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products*, COM(2021) 249 final, 20 May 2021, section 3.1, 'Ingredients and emissions'; European Commission, Expert Group on Tobacco Policy, presentation, 2 December 2021, slide 7, 'Product regulation – what worked and what didn't?'.
⁵⁵ *Directive 2014/40/EU*, arts 7(9) and 7(11); European Commission, COM(2018) 579 final, section 3.3.6, p 5; European Commission, COM(2023) 491 final, section 4, p 3.

⁵⁶ European Commission, observations on notification 2015/0529/HU, TRIS/(2015) 03926, 17 December 2015; European Commission, observations on notification 2016/0238/D, TRIS/(2016) 02369, 1 August 2016; European Commission, comments on notification 2023/0544/NL, C(2023) 8526 final, 1 December 2023; European Commission, comments on notification 2024/0610/AT, C(2025) 887 final, 4 February 2025.

⁵⁷ European Commission, Directorate-General for Health and Food Safety, *Final Report: Support Study to the report on the application of Directive 2014/40/EU* (ICF S.A. and RAND Europe, May 2021), pp 51–52.

“Based on current experience, resource needs must be carefully considered when judging the feasibility of establishing, at EU level, a positive list of ingredients and a database.”

European Commission, COM(2021) 249 final — s. 3.3

There is no evidence that changing the methodology with a list-based regime would reduce net administrative burden. Nor does the existence of resource costs under the present system establish an efficiency benefit.

Proportionality

Articles 5 to 7 establish an harmonised framework governing ingredients and characterising flavours. The evidence identifies neither a failure of that framework nor an incremental benefit to change it, either in internal market or public health grounds.

Conclusion for option selection

Changes to the characterising-flavour determination should be excluded from the option set.

3.3 Further ingredient restrictions for electronic cigarettes and refill containers (Question 13)

Regulatory baseline and EU added value

Article 20 establishes a pre-market notification and product-control framework for nicotine-containing electronic cigarettes and refill containers. It requires notification at least six months before intended market placement, qualitative and quantitative information on ingredients and emissions, toxicological data concerning ingredients and emissions, nicotine exposure and uptake information, a description of components and production processes, and a declaration of responsibility for product quality and safety. It also prohibits specified additives, requires high-purity ingredients and provides that ingredients other than nicotine must not pose a risk to human health in heated or unheated form.

The Evaluation finds that Article 20 harmonised previously divergent national rules and strengthened the ability of competent authorities to assess product risks before market placement.⁵⁸ It also identifies operational limitations in EU-CEG. At the same time, it describes EU-CEG as a useful monitoring tool, particularly in relation to ingredients and emissions.

“EU countries have not observed this trend [2019 US EVALI], possibly due in part to the specificities of e-cigarette regulation under the TPD.”

European Commission, COM(2021) 249 final | s. 10.1

The Evaluation does not identify an internal market or public health gap that is not addressed by the requirements. Nor do they establish changes to the ingredient requirements are necessary or that list-based regime would remedy the shortcomings identified.

“To date, no EU Member State has invoked Article 20(11) to prohibit the placing on its market of specific types of e-cigarettes.”

European Commission, SWD(2026) 111 final | p. 54

⁵⁸ European Commission, *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, pp 45-46, pp 62-64, pp 112-113.

The Commission's supporting materials point in the same direction. The 2021 support study records SCHEER's conclusion that there is no consistent data that specific flavourings used in the EU pose health risks following repeated exposure.⁵⁹

The implementation record predating the Evaluation points to the same diagnosis. At the Commission's Expert Group on Tobacco Policy of December 2021, DG SANTE's presentation describes EU-CEG as a valuable single entry point while identifying incomplete mandatory data, limited regulatory use and significant resource demands. Likewise, In October 2019, after the serious US e-cigarette incidents, DG SANTE records that no similar EU cases has been reported through Safety Gate or ICSMS.⁶⁰

"No EU cases similar to those found in the USA have been reported amongst Member States in either Safety Gate (RAPEX) or ICSMS."

European Commission, Expert Group on Tobacco Policy, Summary Record — 15 October 2019, pp. 3–4

The TPD I to TPD II preparatory record is also relevant. The 2010 public consultation identified electronic nicotine-delivery systems as products outside the Directive and described divergent national classification, legal uncertainty and the absence of uniform safety checks as the principal problems. The proposed response comprised safety and quality requirements and ingredient disclosure; it did not include a list-based regime.⁶¹

The 2012 Impact Assessment subsequently assessed an option combining adapted warnings, ingredient reporting and a prohibition of nicotine-containing products with characterising flavours. It did not assess or select a list-based regime for these products.⁶² The final Directive instead adopted the Article 20 framework of advance notification, ingredient and emissions reporting, specified additive prohibitions, purity requirements and risk-based product controls.

Effectiveness and regulatory fit

The Evaluation does not identify a gap in public health protection or on the smooth function of the internal market to justify changes to ingredient requirements. A general concern about ingredients, flavour, attractiveness or national regulatory activity is not an ingredient-specific problem definition.

Article 20 already regulates ingredients through notification, toxicological-information, purity and product-safety requirements. The evidence does not establish an incremental reduction in risk, or a benefit to the internal market, beyond that baseline.

Coherence and wider impacts

The existing baseline also includes horizontal chemicals legislation. In its TRIS comments on Dutch and Danish electronic-cigarette measures, the Commission stressed that the Classification, Labelling and Packaging (CLP) Regulation applies to hazardous e-liquids and pre-filled devices, including relevant packaging and hazard-communication requirements. The combined Article 20 and horizontal chemicals-law baseline leaves no identified residual ingredient or safety problem supporting a new list.⁶³

⁵⁹ European Commission, Directorate-General for Health and Food Safety, Final Report: Support Study to the report on the application of Directive 2014/40/EU (ICF S.A. and RAND Europe, May 2021), p. 335.

⁶⁰ European Commission, Group of Experts on Tobacco Policy, Summary Record, 9 October 2017, p. 5; Summary Record, 15 October 2019, pp. 3–4; European Commission.

⁶¹ European Commission, *Possible Revision of the Tobacco Products Directive 2001/37/EC: Public Consultation Document* (DG SANCO 2010), sections 1.1 and 1.2 concerning the scope of the Directive and electronic nicotine-delivery systems.

⁶² European Commission, *Impact Assessment accompanying the Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products*, SWD(2012) 452 final, section 5.2.1.7 and the corresponding nicotine-containing-products option analysis.

⁶³ European Commission, observations on notification 2014/0324/NL, TRIS/(2014) 02897, 3 October 2014; European Commission, observations on notification 2016/0114/DK, TRIS/(2016) 01638, 3 June 2016.

A restriction that removes notified products without a demonstrated incremental safety benefit may also alter the balance between accountable and non-compliant supply. The record identifies a material risk of displacement towards online, cross-border or illegal products outside EU-CEG reporting and product-stewardship controls. That possibility forms part of the measure's effectiveness and enforceability and should not be treated solely as a commercial consequence.

Proportionality and less restrictive alternatives

Article 20 and applicable horizontal legislation already provide the relevant regulatory baseline. Their insufficiency has not been established.

Conclusion for option selection

Additional changes to the ingredient requirements for electronic cigarettes should be excluded from the option set.

3.4 Plain and standardised packaging, and large pictorial warnings for electronic cigarettes (Questions 13 and 19)

Regulatory baseline and EU added value

Article 20 establishes a harmonised information, presentation and health-warning framework for electronic cigarettes and refill containers. Unit packets and outside packaging must carry specified product information and one of the two warnings prescribed by the Directive, presented in accordance with common Union requirements. Article 20 also applies specified restrictions on misleading and promotional presentation. The Commission is empowered to adapt the wording of the warning.

The Commission itself confirms that the Article 20 health warning is a binding element of that harmonised framework. In its comments on Slovenia's 2023 TRIS notification, the Commission requires the national rules to ensure that electronic cigarettes and refill containers carry the warning prescribed by Article 20(4)(b)(iii).⁶⁴ It takes the same position on Spain's 2025 TRIS notification, warning that national definitions must not permit circumvention of the Article 20 warning requirement.⁶⁵

Neither the Evaluation nor the reviewed TRIS record (2012-2026) identifies any Member State requiring pictorial health warnings for electronic cigarettes, or any actual or likely divergence in that field.⁶⁶ A pictorial-warning requirement would therefore not approximate divergent national laws. It would change an existing harmonised and product-specific text-warning framework. Article 114(3) TFEU informs the level of health protection once the conditions for harmonisation are met; it cannot supply the missing internal-market case.⁶⁷

Article 20(12) empowers the Commission to adapt the wording of the electronic-cigarette warning. The Commission's own implementation record does not identify a failure of the electronic-cigarette warning. In 2018, it considered adaptation under Article 20(12) premature because it regarded the existing message as "appropriate and effective".⁶⁸ Its 2023 report again records that the preconditions for exercising this delegated power had not been met. The power remains unexercised.⁶⁹

⁶⁴ European Commission, Comments on notification 2023/0636/SI, C(2024) 755 final, 1 February 2024, 2–3.

⁶⁵ European Commission, Comments on notification 2025/0044/ES, C(2025) 2628 final, 24 April 2025, 5.

⁶⁶ European Commission, *Evaluation of the Tobacco Products Directive, the Tobacco Advertising Directive and other related tobacco-control policies across the EU*, SWD(2026) 111 final, 2 April 2026, section 4.1.2 and conclusions at 66–68.

⁶⁷ Consolidated Version of the Treaty on the Functioning of the European Union [2016] OJ C202/47, art 114(1) and (3); Case C-547/14 *Philip Morris Brands SARL and Others v Secretary of State for Health* EU:C:2016:325, paras 58–62.

⁶⁸ European Commission, *Report on the exercise of the power to adopt delegated acts conferred pursuant to Directive 2014/40/EU*, COM(2018) 579 final, 8 August 2018, 3 and 6, section 3.3.13.

⁶⁹ European Commission, *Report on the exercise of the power to adopt delegated acts conferred pursuant to Directive 2014/40/EU*, COM(2023) 491 final, 17 August 2023, 1–3.

Plain and standardised packaging presents a separate case that the evidence does not establish. Some Member States have introduced or notified requirements standardising the visual presentation of electronic cigarettes packs. Those regimes do not demonstrate a common national trend towards standardising pack dimensions, shape or construction. Any divergence is therefore narrower than the consultation's broad reference to "plain or standardised packaging" suggests. The Evaluation refers to divergent "plain-packaging" requirements for electronic cigarettes as part of wider internal-market difficulties.⁷⁰ The Evaluation does not identify the number or materiality of the electronic-cigarette regimes concerned, quantify the resulting obstacle to trade or isolate their effect from other national packaging rules.

The TPD I to TPD II process reinforces the distinction. The previous revision assessed a tailored text-warning regime for nicotine-containing products, while large pictorial warnings and plain packaging were considered principally for conventional tobacco products. TPD II ultimately selected the product-specific Article 20 warning and presentation framework for electronic cigarettes.⁷¹ Applying plain packaging or large pictorial warnings to that category would constitute a new intervention for which no product-specific problem, evidence or internal-market justification is established.

Effectiveness and regulatory fit

Increasing perceived harm is not itself a public-health outcome, misperceived harm may itself influence the behaviour of consumers with outcomes contrary to public health objectives. Evidence suggests that relative harm perceptions of electronic cigarettes are worsening.⁷² The present evidence does not establish a beneficial overall behavioural effect once initiation, smoking, switching, relapse and displacement are considered. That requires examination of initiation, continued smoking, complete switching, dual use, relapse and movement towards non-notified or illegal products. The Evaluation does not demonstrate that large pictorial warnings or plain and standardised packaging for electronic cigarettes would produce an incremental population-level benefit beyond the warning, mandatory information and presentation controls required by Article 20.

Nor does the evidence establish that removing lawful product differentiation would address under-age access. The present record does not identify lawful packaging used by notified manufacturers as the source of supply through non-compliant online sellers, informal channels or illegal retail.

Efficiency, implementation feasibility and enforceability

The present record does not establish that greater uniformity among notified products would facilitate enforcement while products outside the Article 20 framework remain identifiable only through inspection, testing and supply-chain investigation.

The option assessment should also address the existing interaction between the TPD and the Classification, Labelling and Packaging (CLP) Regulation. The Commission-commissioned 2021 support study records stakeholder reports that the two regimes create practical difficulties in accommodating mandatory information on electronic-cigarette packaging. Any additional requirement should therefore be assessed against this and should not further constrain the space necessary to comply with CLP requirements.

⁷⁰ European Commission, SWD(2026) 111 final, section 4.1.2, 'Labelling and packaging', 46.

⁷¹ European Commission, *Possible Revision of the Tobacco Products Directive 2001/37/EC: Public Consultation Document* (2010), section 3.2, option 3; European Commission, *Impact Assessment accompanying the Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products*, SWD(2012) 452 final, 50–54 and 84–96; European Commission, *Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products*, COM(2012) 788 final, arts 9–11 and 17–19; Directive 2014/40/EU, art 20.

⁷² Action on Smoking and Health (ASH), *Use of vapes and other novel tobacco and nicotine products among adults in Great Britain* (July 2026).

Coherence and wider impacts

Any benefits cannot be counted across plain packaging, large pictorial warnings and packaging standardisation. Their incremental effects are not established, while their burdens would overlap on the same limited packaging space and draw on the same artwork, supplier, notification and transition capacity.

The assessment must further consider whether removing lawful product differentiation could make electronic cigarettes less distinguishable or less acceptable to adult smokers who might otherwise switch away from cigarettes. Reduced product appeal cannot be treated as an unqualified public-health benefit without assessing its effect on switching, continued smoking, dual use and relapse.

Proportionality and less restrictive alternatives

Maintaining the current framework would not leave electronic-cigarette packaging unregulated. Article 20 already prescribes a health warning, mandatory product information and leaflet content and applies restrictions on misleading and promotional presentation.

For large pictorial warnings, the present record identifies neither a failure of the harmonised Article 20 warning nor an internal-market problem requiring replacement of that warning. The option should therefore be excluded.

For plain packaging, a limited number of national regimes do not establish a material Union-wide obstacle, the necessity of an EU-wide prohibition of lawful product presentation or the inadequacy of the existing Article 20 framework.

Conclusion for option selection

Large pictorial warnings and plain and standardised packaging for electronic cigarettes should be excluded from the retained option set.

3.5 Plain or standardised packaging, and large pictorial warnings for heated tobacco products (Questions 13 and 19)

Regulatory baseline and EU added value

Heated tobacco consumables contain tobacco and are already subject to the Tobacco Products Directive's labelling and product-presentation rules according to their legal classification. Articles 8 to 13 establish the applicable warning framework, while Article 19 applies to novel tobacco products. The regulatory baseline is therefore an existing harmonised regime.⁷³

Where a heated tobacco product is classified as smokeless tobacco, Article 12(3) separately empowers the Commission to adapt the wording of the health warning to scientific developments. That delegated power remains unexercised. This existing targeted mechanism is relevant to proportionality: any demonstrated warning deficiency should first be defined and tested against the product-specific baseline before moving to cigarette-style pictorial warnings.⁷⁴

The consultation groups plain or standardised packaging with large pictorial warnings even though they have different pathways, legal effects and implementation consequences.

The Evaluation identifies difficulties in classifying heated tobacco products for warning purposes. That issue does not establish that branding removal or large pictorial warnings

⁷³ Directive 2014/40/EU, in particular Articles 8–13 and 19; Commission Delegated Directive (EU) 2022/2100 concerning heated tobacco products.

⁷⁴ Directive 2014/40/EU, in particular Articles 8–13 and 19; Commission Delegated Directive (EU) 2022/2100 concerning heated tobacco products.; European Commission, COM(2018) 579 final, section 3.3.10; European Commission, COM(2023) 491 final, section 4

are necessary or effective. A classification issue is not resolved by plain or standardised packaging and large pictorial warnings.⁷⁵

The evidence establishes no incremental internal-market case for plain packaging or large pictorial warnings beyond the existing classification-dependent TPD framework.

Effectiveness and regulatory fit

There is little published post-implementation evidence demonstrating the effect of plain packaging on initiation, continued use or switching behaviour for heated tobacco products. The evidence developed for cigarettes cannot be transposed without accounting for different product characteristics, user populations, warning baselines and possible substitution effects.

No evidence establishes large pictorial warnings as necessary or effective for heated tobacco products. This intervention could communicate equivalence with cigarettes by presentation rather than improve product-specific risk understanding.

The JRC's recent synthesis does not establish a basis for risk equivalence. It distinguishes reduced exposure to some constituents from demonstrated reduction in disease risk and records that long-term health impacts, absolute risk and relative risk remain uncertain. It also reports that some toxicants may be present at lower levels and others at higher levels than in cigarette smoke.⁷⁶

Coherence and wider impacts

Equalising the presentation of heated tobacco products and cigarettes could obscure lawful product differences and weaken the product-specific risk communication that the classification exercise is intended to address. It could also reduce the visible information available to adult consumers to distinguish product types.

Proportionality and less restrictive alternatives

No change is the proportionate comparator for these additional packaging interventions.

The present record does not establish a proportionate basis for removing lawful brand presentation or imposing large pictorial warnings on heated tobacco products.

Conclusion for option selection

Plain or standardised packaging and the application of large pictorial warnings to heated tobacco products should be excluded from the retained option set.

3.6 Plain or standardised packaging, and large pictorial warnings for heated herbal products (Questions 13 and 19)

Regulatory baseline and EU added value

Nicotine-containing heated herbal products use a non-tobacco substrate that is heated in a device to generate an inhalable nicotine-containing aerosol. They are not presently regulated as a distinct product category under the Tobacco Products Directive.

The absence of a current TPD framework does not establish the necessity, effectiveness or EU added value of plain packaging, standardised packaging or large pictorial warnings for the category.

⁷⁵ European Commission, public consultation questionnaire for companies and business associations, 2026, Questions 15, 18, 19, 19.1 and 19.2; European Commission, Evaluation of the Tobacco Products Directive, Tobacco Advertising Directive and related policies across the EU, SWD(2026) 111 final, pp. 66–68.

⁷⁶ A Perez-Cornago and others, Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches (European Commission, Joint Research Centre, JRC146139, 2026), pp. 58–68.

The evidential baseline is particularly weak. The study supporting the Evaluation excludes heated herbal products from its substantive analysis because the available sources were limited.⁷⁷ It describes them, at the time of the research, as a niche category with close-to-zero prevalence.

The TRIS record for 2012–2026 does not identify Member States applying conflicting plain- or standardised-packaging requirements to heated herbal products; competing requirements for large pictorial warnings; labelling being redesigned to comply with different national specifications; or a material labelling- or packaging-related obstacle to cross-border trade. Nor does it establish sufficiently developed national initiatives from which such obstacles can be shown to be likely.

Effectiveness and regulatory fit

No product-specific evidence has been identified demonstrating that plain packaging reduces initiation, continued use or switching behaviour for nicotine-containing heated herbal products. Nor has evidence been identified demonstrating that variation in the physical characteristics of the packaging causes a material public-health problem or that large pictorial warnings would improve risk comprehension or behaviour for this category.

Applying large pictorial warnings to a tobacco-free product without evidence of its accuracy or behavioural effect could communicate equivalence with cigarettes by presentation. The evidence record does not establish a basis for such equivalence.

Coherence and wider impacts

The absence of a present product-information framework cannot be counted as a benefit associated with plain or standardised packaging or pictorial warnings. The present record establishes no incremental benefit from those restrictions.

Conclusion for option selection

No change. Plain or standardised packaging and pictorial warnings for heated herbal products should be excluded from the retained option set.

3.7 Plain or standardised packaging, and large pictorial warnings for nicotine pouches (Questions 13 and 19)

Regulatory baseline and EU added value

The general regulatory baseline and evidence concerning nicotine pouches are addressed in section 3.3 and are not repeated here. This section concerns the incremental case for three distinct interventions: restrictions on branding and visual presentation; standardisation of the physical can or product format; and large pictorial warnings.

The Evaluation records heterogeneous national requirements concerning labelling, packaging and health warnings, but does not identify the measures concerned, distinguish visual plain packaging from standardisation, quantify a packaging-specific obstacle to trade or assess a pictorial-warning regime.⁷⁸ A general finding that the category is regulated differently across Member States cannot establish the EU added value, effectiveness or proportionality of each intervention.

⁷⁷ European Commission, *Results of the Study supporting the Evaluation of the Tobacco Control Acquis* (Open Evidence, 2026), p 21 and n 12.

⁷⁸ European Commission, *Evaluation of the Tobacco Products Directive, the Tobacco Advertising Directive and related tobacco-control policies across the EU*, SWD(2026) 111 final, 2 April 2026, pp 51 and 66–68

The TPD I to TPD II record does not provide a precedent for applying plain packaging, physical packaging standardisation or large pictorial warnings to nicotine-containing products as part of the framework adopted for them.⁷⁹

For nicotine pouches, the absence of a prior Union framework does not supply a packaging-specific problem or incremental benefit sufficient to justify these restrictions.

National divergence does not determine the content of a Union rule or establish that the most restrictive national intervention is the necessary harmonising response. Harmonisation is not a ratchet through which the most restrictive national first mover determines the Union rule.

The TPD I to TPD II process reinforces the same distinction. Combined health warnings were developed for specified tobacco products for smoking, while separate text-warning architectures were retained for smokeless tobacco products and nicotine-containing products. The precedent demonstrates that regulation within one legislative instrument does not require identical warning regimes across materially different product categories.

The consultation also obscures the distinction between plain and standardised packaging. Removing or prescribing elements of visual presentation is not equivalent to controlling the physical characteristics of the can or pouch.

Effectiveness and regulatory fit

The most directly relevant experimental evidence does not establish a meaningful overall effect from standardised nicotine-pouch packaging. A randomised online experiment involving 2,967 UK adults finds little significant overall effect on interest in trying nicotine pouches or on perceptions of their harm relative to cigarettes. In one standardised-packaging condition, incorrect relative-harm perceptions were more common among participants who had never smoked. The study did not measure purchasing, initiation, sustained use or other real-world behaviour.⁸⁰

A warning is not effective merely because it is alarming or increases perceived harm. Large pictorial warnings cannot be justified by increased alarm or perceived harm where the depicted causal relationship is not established. Large pictorial warnings associated with cigarettes could imply that nicotine-pouch use causes smoking-related diseases, without evidence establishing that relationship. Such an intervention would risk replacing product-specific risk communication with risk equalisation through presentation.

Coherence and wider impacts

General considerations concerning the effects of branding restrictions, intellectual property and cumulative presentation requirements are addressed in section 4.1 and are not repeated here.

The available packaging surface is also already constrained by existing regulatory requirements. Where the applicable classification requires it, nicotine-pouch packaging must accommodate CLP hazard labelling, including prescribed pictograms and hazard statements. In some Member States, unit packets must additionally carry national excise stamps or banderoles. The space need to preserve sufficient space for those existing mandatory elements should be preserved.

⁷⁹ European Commission, *Impact Assessment accompanying the Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products*, SWD(2012) 452 final, especially pp 54 and 84–96; European Commission, *Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products*, COM(2012) 788 final, arts 9–13 and 17–19; Directive 2014/40/EU, arts 10, 12, 19 and 20.

⁸⁰ Taylor, E. et al. (2026), "Investigating the Appeal of Nicotine Pouch Packaging, Flavour, and Nicotine Descriptors Among Adults in the UK: An Online Experiment", *Nicotine & Tobacco Research* 28(2), 251–259, DOI 10.1093/ntr/ntaf072. Data were collected in 2024 and the article was first published online in 2025.

Proportionality and less restrictive alternatives

No change with respect to these packaging interventions is the relevant comparator. The present record does not establish that lawful visual differentiation, physical can design or the absence of large pictorial warnings are justified.

Conclusion for option selection

No change. Plain or standardised packaging and large pictorial warnings for nicotine pouches should be excluded from the retained option set.

4. Options lacking demonstration of incremental effectiveness and proportionality

This section assesses options that pursue policy objectives through categorical or highly prescriptive restrictions, but for which the evidence does not establish that the intervention tested would deliver an incremental benefit or that the restriction chosen is necessary and proportionate.

4.1 Prohibition of flavours in electronic cigarettes and refill containers (Questions 2, 3, 13 and 20)

Regulatory baseline and EU added value

Article 20 requires advance notification, ingredient and emissions information, toxicological data, product-safety and quality information, and manufacturer and importer responsibility. Member-State age-of-sale and retail-enforcement rules operate alongside that framework.

National flavour rules diverge. That fact does not establish the necessity, effectiveness or proportionality of a blanket Union prohibition on flavours, and the evidence does not demonstrate that the most restrictive national model is required for the functioning of the internal market.

The Commission itself draws the same distinction. When Finland, Hungary and Estonia proposed broad flavour prohibitions, the Commission has acknowledged the stated youth- and health-protection objectives but has not accepted a general proposition about appeal as sufficient grounds for banning all flavours.⁸¹

Any divergence must also be assessed through subsidiarity. Article 20 harmonised a substantial part of the regulatory framework for electronic cigarettes without establishing an EU-wide flavour requirement, leaving Member States regulatory space in this area. The fact that Member States have exercised that competence, and have done so differently, does not by itself establish that Union intervention is necessary, still less that the appropriate Union response is a blanket flavour prohibition.

The 2021 application support study concludes that the population-level effect of flavour restrictions remains unresolved. The JRC's 2026 synthesis records that some adult smokers report that flavours in products such as e-cigarettes contribute to their efforts to stop or reduce cigarette use. The evidence does not establish a beneficial net population effect of prohibition across cessation, complete switching, dual use and relapse.⁸²

The Commission's dedicated cross-border-distance-sales study identifies product availability, alongside price, as one of the principal causes likely to drive cross-border distance purchasing. For electronic cigarettes, it records evidence that the unavailability of the desired nicotine strength and flavours leads users to purchase from foreign online sellers, and notes more generally that unavailability or prohibition in the home market can drive cross-border purchasing. Such sales may occur through lawful cross-border sellers, but may also redirect demand towards unregulated or illegal online channels. The study cautions that the direct evidence is limited and often uses online or cross-border purchasing as a proxy. That limitation prevents quantification of the effect of an EU flavour ban, but it

⁸¹ European Commission, observations on notification 2015/0490/FIN, TRIS/(2015) 03597, 19 November 2015; European Commission, observations on notification 2015/0723/HU, TRIS/(2016) 00785, 11 March 2016; European Commission, observations on notification 2016/0648/EE, TRIS/(2017) 00599, 3 March 2017.

⁸² European Commission, Directorate-General for Health and Food Safety, Final Report: Support Study to the report on the application of Directive 2014/40/EU (ICF S.A. and RAND Europe, May 2021), section 5.10, pp. 333–344; A Perez-Cornago and others, Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches (European Commission, Joint Research Centre, JRC146139, 2026), pp. 51–55.

does not remove the displacement pathway: eliminating lawful domestic availability may create precisely the condition the study associates with cross-border purchasing, including distance sales via unregulated markets and/or illegal channels.⁸³

“The primary motivations for cross-border purchases were lower prices (56.3%), the need for tobacco while visiting another country (44.6%), and the unavailability or prohibition of the desired products in their home country (2.9%).”

C Vardavas, Report on the assessment of the causes, drivers and level of cross-border distance sales in the EU | 2025, scoping review

The TPD I to TPD II preparatory process is relevant. The 2012 Impact Assessment assessed, but did not select, an option combining adapted warnings, ingredient reporting and a prohibition of nicotine-containing products with characterising flavours.⁸⁴ The final Directive instead adopted the Article 20 regulated-market framework without introducing an EU flavour rule. A Union-wide prohibition of flavours would therefore go materially beyond the model adopted following that assessment.

Effectiveness and regulatory fit

The scientific evidence does not establish the net population-health benefit from a blanket prohibition. Reviews report heterogeneous findings and limited certainty when comparing flavours in relation to smoking cessation and smoking outcomes.⁸⁵ Professional and public-health bodies have also recognised that a range of flavours may support complete switching for some adults, while stressing that electronic cigarettes are not risk-free.⁸⁶ Evidence indicates flavours are favoured by both adults and youth and may contribute to youth appeal and experimentation, but the available gateway literature does not establish that flavour availability causes progression to regular smoking. A 2025 peer-reviewed review, funded by Imperial Brands, also found no basis for treating non-tobacco flavours as a single toxicological risk category and identified product and supply-channel substitution as a relevant consequence of prohibition.⁸⁷ The present record does not establish a beneficial net effect once initiation, complete switching, dual use, relapse and product and supply-channel substitution are taken into account.

“More evidence is needed to determine whether flavour bans would have a negative impact on adult smoking cessation, and if so, whether it could be mitigated by a selective ban on e-cigarette flavours.”

ICF S.A. and RAND Europe, Final Report: Support Study to the report on the application of Directive 2014/40/EU — Case study 2, pp. 333–344

Evidence from the Netherlands indicates continued access through foreign, online and illegal channels, limited movement towards the permitted flavour and significant

⁸³C Vardavas, Report on the assessment of the causes, drivers and level of cross-border distance sales in the EU (European Commission, Directorate-General for Health and Food Safety, October 2025), pp. 35–41.

⁸⁴ European Commission, Commission Staff Working Document, 'Impact Assessment accompanying the Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products' SWD(2012) 452 final, policy area concerning nicotine-containing products

⁸⁵ C Meernik et al., 'Impact of non-menthol flavours in e-cigarettes on perceptions and use: an updated systematic review', *BMJ Open* 9 (2019), e031598, doi: 10.1136/bmjopen-2019-031598; N Lindson et al., 'An exploration of flavours in studies of e-cigarettes for smoking cessation: secondary analyses of a systematic review with meta-analyses', *Addiction* 118(4) (2023), 634–645, doi: 10.1111/add.16091; AC Liber et al., 'The role of flavored electronic nicotine delivery systems in smoking cessation: a systematic review', *Drug and Alcohol Dependence Reports* 7 (2023), 100143, doi: 10.1016/j.dadr.2023.100143.

⁸⁶ Lindson et al. (2022), secondary analysis of the Cochrane review of electronic cigarettes for smoking cessation; Liber et al. (2023), systematic review of flavoured electronic nicotine-delivery systems and cessation; Meernik et al. (2019), systematic review of non-menthol flavours. Royal College of Physicians, "E-cigarettes and harm reduction: an evidence review" (2024); Office for Health Improvement and Disparities, "Nicotine vaping in England: 2022 evidence update"; Public Health England, "Vaping in England: 2021 evidence update".

⁸⁷ Fearon et al. (2023), "Curiosity and intentions to use myblu e-cigarettes and an examination of the 'gateway' theory"; Beard et al. (2022), time-series analysis of electronic-cigarette use and regular smoking in England; Parnham et al. (2022), multistate transition modelling in UK youth; Hajat et al. (2022), analysis of methodological limitations in electronic-cigarette epidemiology. Fearon, Stevenson and Nahde (2025), "Flavoured Vaping Products in Tobacco Harm Reduction: A Regulatory Perspective", *Cureus* 17(8), e89196, DOI 10.7759/cureus.89196.

enforcement difficulty. Consumer surveys and prevalence trends cannot establish the counterfactual effect of the prohibition by themselves, but they identify displacement pathways inconsistent with assuming that legal prohibition eliminates demand.⁸⁸

National implementation material reviewed alongside the TRIS record for 2012-2026 points in the same direction. Following Denmark's 2022 restriction, reported electronic-cigarette use among people aged 15 to 29 has increased from 7% to 12% by 2024. These findings suggest that a flavour prohibition is ineffective to eliminate access to, or demand for, the prohibited flavour profiles.⁸⁹

Efficiency, implementation feasibility and enforceability

The Dutch and Danish experience, amongst others, indicates that prohibited products and flavour profiles may remain available after restrictions enter into force. That experience identifies continuing illegal and cross-border supply and does not establish that a prohibition directed at compliant operators reduces, rather than displaces, the enforcement burden.

The Commission's 2021 support study documents comparable enforcement consequences in Finland: foreign online sellers outside the competent authority's control; insufficient resources to act on potentially non-compliant notifications; and little literature from which to quantify the measure's effect. It also cautions that the ban's impact could not readily be isolated where other tobacco-control measures are introduced at the same time.⁹⁰

"There is little literature investigating the impact of the Finnish e-cigarette flavour ban on e-cigarette (and tobacco products) availability, perceptions and use."

ICF S.A. and RAND Europe, Final Report: Support Study to the report on the application of Directive 2014/40/EU | Case study 2, Finland

Coherence and wider impacts

A measure that removes a substantial part of the notified lawful offer while demand continues to be served through non-notified, online or cross-border channels may reduce the proportion of products subject to EU-CEG reporting, quality controls and market surveillance.

The present record also does not establish consistency with the objective of moving adult smokers away from combustion. An intervention intended to reduce youth appeal may have adverse effects if it reduces the acceptability of non-combustible alternatives for adults, encourages relapse to smoking or shifts purchases to products outside the regulated supply chain. Those effects cannot be treated as secondary implementation issues; they form part of the measure's net public-health effect.

Proportionality and less restrictive alternatives

When electronic cigarettes were brought within the Directive, the Union selected a regulated-market model rather than a general prohibition of one of its principal product characteristics, allowing Member States to exercise their competence and discretion around flavours. A blanket flavour ban would materially alter that balance.

⁸⁸ Netherlands Food and Consumer Product Safety Authority (NVWA), "Inspection Results for the Flavoured Vapes Ban (January–June 2024)", ; NVWA, "NVWA neemt 80.000 illegale vapes in beslag", 10 July 2025, ; Tweede Kamer, Kamerstuk 32 011, no. 116, "Lijst van vragen en antwoorden", 12 August 2024, answers 27–32; Statistics Netherlands, "Leefstijl; persoonskenmerken", StatLine, ; ACVODA, "Enquête onder Nederlandse dampers over de gevolgen van het online verkoop- en smaakverbod", 30 August 2024.

⁸⁹ Denmark, Law No 2071 of 21 December 2020, Section 3(13), introducing Section 25a of the Act on electronic cigarettes, etc., and Section 7(2) and (11). See also Danish Director of Public Prosecutions, Circular No 9523 of 8 July 2024, Section 4.5, pp. 16–17; Stine Arp and Lotus Sofie Bast, *Danskernes Rygevaner 2024*, Statens Institut for Folkesundhed, University of Southern Denmark, prepared on behalf of the Danish Health Authority, 24 February 2025, Figure 8.1.3, p. 57, and Section 8.3 and Figures 8.3.1–8.3.2, pp. 60–62.

⁹⁰ European Commission, Directorate-General for Health and Food Safety, Final Report: Support Study to the report on the application of Directive 2014/40/EU (ICF S.A. and RAND Europe, May 2021), section 5.10, pp. 338–344.

Conclusion for option selection

A blanket prohibition of flavours in electronic cigarettes should be excluded from the option set.

4.2 Mandatory EU-wide plain or standardised packaging for cigarettes and roll-your-own tobacco products (Questions 18 and 19)

Regulatory baseline and EU added value

The Directive establishes extensive harmonised requirements governing health warnings, cessation information, product presentation and the appearance and contents of unit packets. Article 24(2) permits Member States, subject to justification on public-health grounds and proportionality, to maintain or introduce further requirements concerning the standardisation of tobacco packaging.

Some Member States have exercised that discretion. The resulting differences are part of the architecture expressly permitted by Article 24(2) and do not establish that mandatory EU-wide plain and/or standardised packaging is necessary, effective or proportionate.

The Evaluation describes “plain packaging” as widely recognised as effective and treats differences between national regimes as an obstacle to the free movement of goods.⁹¹ Those are distinct propositions. The existence of different national rules does not establish a material obstacle to trade, the public-health effectiveness of one particular EU-wide design or its necessity and proportionality.

In fact, the present divergence is not simply an unforeseen regulatory gap. Different national choices are a foreseeable consequence of the architecture adopted by the Union legislature in TPDII. It cannot by itself be treated as evidence that the framework has failed or that mandatory EU-wide plain and/or standardised packaging is necessary.

The TPD I to TPD II preparatory record is directly relevant. The 2010 public consultation presented generic or plain packaging as a separate policy option.⁹² The 2012 Impact Assessment assessed full plain packaging alongside a less restrictive option based on enlarged warnings and harmonisation of certain packet features.⁹³ Full plain packaging was not carried into the Commission proposal, and the final Directive combined an extensive harmonised baseline with national discretion under Article 24(2).

The present record identifies no new evidence establishing that the existing architecture is inadequate. Evidence concerning a public-health objective does not establish a material internal-market obstacle. Conversely, evidence of national divergence does not establish the incremental effectiveness or proportionality of an EU-wide requirement.

Effectiveness and regulatory fit

The Evaluation itself assesses tobacco-control outcomes against a combination of EU, national and other measures. The available record does not isolate an additional effect attributable specifically to plain and/or standardised packaging from the effects of multiple interventions.

⁹¹ European Commission, SWD(2026) 111 final, section 4.1.2, “Labelling and packaging”, p. 46. The evaluation states that mandatory plain packaging is widely recognised as an effective public-health measure and that divergent national regimes create inconsistencies and an obstacle to the free movement of goods.

⁹² European Commission, *Possible Revision of the Tobacco Products Directive 2001/37/EC: Public Consultation Document* (DG SANCO 2010), section 3.2, Option 3, ‘Introduce generic or plain packaging’.

⁹³ European Commission, *Impact Assessment accompanying the Proposal for a Directive concerning the manufacture, presentation and sale of tobacco and related products*, SWD(2012) 452 final, packaging policy area and preferred-option analysis.

The Commission's 2021 support study itself illustrates the attribution problem. It describes the French evidence as concerning plain packaging in combination with the larger combined health warnings required by the TPD; records that evidence from newer implementing Member States was not yet available; and reports that a systematic review of the United Kingdom evidence found limited evidence of effects on smoking behaviour. The available evidence does not establish a durable consumption effect caused specifically by this intervention.⁹⁴

Efficiency, implementation feasibility and enforceability

The consultation merges “plain packaging” and “standardised packaging” into a single option, although they involve materially different restrictions and implementation consequences. That formulation prevents respondents from assessing the necessity, effectiveness and impacts of each intervention separately.

The 2021 support study identifies packaging redesign, changes to printing and packing processes, product redesign and testing among the highest costs reported by economic stakeholders, while stating that the quantitative evidence was insufficient for a complete assessment. The absence of a Commission-wide cost estimate is not evidence that conversion costs are immaterial.⁹⁵

Coherence and wider impacts

Competition, trade marks and lawful product differentiation are relevant to proportionality. Removing a principal means of lawful differentiation imposes restrictions on competition and commercial communication for which the present record establishes no corresponding necessity.

Any benefits produced by the existing framework cannot be attributed to standardised or plain packaging. Common health warnings, cessation information, traceability requirements, security features and controls on presentation already apply under the no-change baseline.

Proportionality and less restrictive alternatives

The relevant option comparison is between mandatory EU-wide plain and/or standardised packaging and no change. No change does not mean the absence of regulation. It would maintain the extensive harmonised requirements already contained in the Directive, the national discretion established by Article 24(2), and the existing rules on warnings, presentation, traceability and security features.

Products and production systems are already adapted to TPDII packaging requirements and, in some markets, national plain-packaging regimes. A different Union standard would require a second conversion in those markets, including replacement of compliant artwork, printing tools, inspection settings, technical documentation and stock. The relevant comparison is therefore not between fragmented national rules and cost-free EU uniformity. It is also between maintaining the present architecture and the one-off and recurring effects of replacing national regimes with a new Union standard.

The present record establishes neither an additional public-health benefit attributable specifically to mandatory EU-wide plain and/or standardised packaging nor a material internal-market obstacle to justify replacing the Article 24(2) architecture.

Conclusion for option selection

No change. Mandatory EU-wide plain and/or standardised packaging should be excluded from the retained option set and no change retained.

⁹⁴ European Commission, Directorate-General for Health and Food Safety, Final Report: Support Study to the report on the application of Directive 2014/40/EU (ICF S.A. and RAND Europe, May 2021), section 5.12, pp. 368–377, especially pp. 368–369, 371–372 and 377.

⁹⁵ European Commission, Directorate-General for Health and Food Safety, Final Report: Support Study to the report on the application of Directive 2014/40/EU (ICF S.A. and RAND Europe, May 2021), pp. 5 and 190–203.

4.3 Possible maximum unit-packet content restrictions (Question 19)

Regulatory baseline and EU added value

Article 14 of the Directive establishes minimum unit-packet contents of 20 cigarettes and 30 grams of roll-your-own tobacco. It does not establish a maximum. The no-change baseline therefore permits lawful variation above the harmonised minimum, subject to the Directive's packaging, warning, traceability and security-feature requirements.

Neither the Evaluation nor the consultation expressly formulates a maximum unit-packet content as a separate option. The possible measure arises only by inference from broader references to standardised packaging. A response to those broader questions should not be treated as evidence that a maximum content rule has been consulted upon, supported or assessed. The undefined measure cannot be treated as having been consulted upon or assessed as a discrete option.

“Overall, labelling and packaging rules are applied properly across the EU.”

European Commission, COM(2021) 249 final | s. 4.3

“This article appears to be implemented in full compliance with the TPD in the Member States, although there were some minor initial difficulties which were subsequently resolved.”

ICF S.A. and RAND Europe, Final Report: Support Study to the report on the application of Directive 2014/40/EU | Article 14 assessment, pp. 80–81

The TPD I to TPD II record reinforces that distinction. The 2010 consultation referred to the possible regulation of packet size and shape but did not propose maximum packet contents.⁹⁶ The 2012 Commission proposal dealt expressly with packet quantity by prescribing minimum contents of 20 cigarettes and 40 grams of roll-your-own tobacco. The final Directive retained the 20-cigarette minimum and set the roll-your-own minimum at 30 grams.

The present record identifies no new problem or evidence justifying replacement of the harmonised floor with a rule that excludes lawful formats above a prescribed ceiling.

National divergence cannot simply be assumed. An analysis of TRIS Notifications (2012–2026) does not establish a pattern of conflicting national maximum-content requirements or quantify a resulting obstacle to trade or appreciable distortion of competition. The formal creation of a common rule is not by itself evidence that the rule is necessary for the functioning of the internal market.

Effectiveness and regulatory fit

The Commission's 2021 support study found Article 14 to be implemented in full compliance, with only minor initial difficulties that had largely been resolved. It also cautioned that observed changes following the United Kingdom's introduction of minimum packet sizes and plain packaging could not isolate the effect of packet size because the measures were introduced together; the associated surveys identified price as the principal purchasing driver. That experience does not establish a causal basis for a maximum-content rule from the effects of a regulatory minimum.⁹⁷

⁹⁶ European Commission, *Possible Revision of the Tobacco Products Directive 2001/37/EC: Public Consultation Document* (2010), section 3.2, Option 3.

⁹⁷ European Commission, Directorate-General for Health and Food Safety, *Final Report: Support Study to the report on the application of Directive 2014/40/EU* (ICF S.A. and RAND Europe, May 2021), pp. 80–81.

A maximum unit-packet content limits the quantity contained in one packet. It does not limit the number of packets that an adult may purchase, the quantity bought in one transaction or the frequency of purchase. The available evidence does not establish a durable reduction in tobacco consumption rather than a change in the number and size of packets purchased.

The principal direct experimental evidence compared cigarette packs of 20 and 25 in two 14-day intervention periods.⁹⁸ Participants smoked an estimated 1.3 fewer cigarettes per day when using packs of 20. This does not establish an effect on cessation, smoking prevalence or long-term consumption. The study's authors also cautioned that translation of the observed effect into population-level outcomes was uncertain and likely to be small. Nor does it assess purchasing behaviour in an ordinary retail market, where consumers may buy multiple packets, switch brands or obtain tobacco through other channels.

No evidence exists that markets in which packs containing more than 20 cigarettes are available have higher smoking prevalence or daily consumption than markets limited to packs of 20.

The available evidence does not account adequately for multiple-packet purchasing, increased purchase frequency, switching between products or price points, cross-border purchasing and illegal supply. The legal breadth of a maximum does not establish that its intended effect would survive those substitution pathways.

Evidence concerning cigarette packets also cannot establish the effect of a maximum weight for roll-your-own tobacco. The categories differ in use, packaging, price structure and consumer purchasing behaviour. Evidence concerning cigarette packets cannot supply the missing causal or effectiveness case for a maximum roll-your-own pouch weight.

Efficiency, implementation feasibility and enforceability

Enforcement of the packet specification within the notified legal market is not the same as achieving the intended behavioural outcome. Consumers could lawfully purchase several compliant smaller packets, while cross-border and illegal suppliers could continue offering non-compliant formats. Compliance with the packet rule would not establish effectiveness in reducing consumption.

The consultation does not define the ceiling or permitted formats sufficiently to assess the scale, cost or feasibility of implementation. That defect cannot be deferred until after option selection.

Coherence and wider impacts

Operational evidence from Australia shows that removing larger formats may change upfront prices, unit prices, price architecture and purchase frequency and may shift demand towards cheaper cigarette brands, roll-your-own tobacco or products outside the lawful market. The present record does not establish a beneficial net effect after those responses.

The measure would compound contemplated changes to plain or standardised packaging, health warnings, inserts and packet construction, increasing line-conversion, stock-transition and material burdens.

Proportionality and comparison with no change

The present record establishes neither a durable public-health benefit attributable to a maximum nor a material internal-market obstacle arising from larger lawful formats.

Concerns about youth access, affordability or illegal supply do not establish that packet quantity itself materially causes the identified problem or justify a maximum-content rule.

⁹⁸ I Lee et al., 'Cigarette pack size and consumption: a randomized cross-over trial', *Addiction* 118(3) (2023), 489–499, doi: 10.1111/add.16062.

Conclusion for option selection

No change. A maximum unit-packet content for cigarettes or roll-your-own tobacco should be excluded from the option set.

4.4 Standardisation of cigarette sticks (Question 19)

Regulatory baseline and EU added value

The Directive regulates the presentation of tobacco products, including elements and features appearing on the tobacco product itself. It also prohibits flavourings in components such as cigarette paper and filters and establishes extensive requirements governing the unit packet and its health warnings. It does not prescribe a single cigarette length or diameter.

The 2026 Evaluation does not revisit slim cigarettes or identify cigarette dimensions as a deficiency in the effectiveness, efficiency, relevance, coherence or EU added value of the existing framework.⁹⁹ Nor does it formulate dimensional standardisation as a possible response. This is therefore not an unexamined regulatory gap. It is an issue that was specifically monitored under Article 28 but was not carried forward as an identified problem in either the 2021 Application Report or the subsequent Evaluation.

The Commission's 2021 Application Report expressly examined slim cigarettes on the basis of a dedicated study. It recorded a long-term decline in the EU slim-cigarette market, notwithstanding increases in retail volume in some eastern Member States, and alleged evidence concerning attractiveness and perceived harmfulness.¹⁰⁰ It did not, however, identify a causal effect of cigarette length or diameter on initiation, consumption or cessation, a material internal-market obstacle arising from dimensional variation, or a need to introduce one EU length, diameter or permitted range.

“The extent to which decreases in consumer appeal (attractiveness) and misperceptions of the harmfulness of cigarettes (including those with a diameter of less than 7.5mm, i.e. slim cigarettes) can be attributed to the TPD is not fully clear.”

ICF S.A. and RAND Europe, Final Report: Support Study to the report on the application of Directive 2014/40/EU | evaluation findings on product presentation

The TPD I to TPD II preparatory record is directly relevant. The 2012 Commission proposal would have deemed cigarettes with a diameter below 7.5 mm misleading.¹⁰¹ The Union legislature did not adopt that provision. It instead required the Commission, under Article 28(2)(e), to report on market developments concerning cigarettes below 7.5 mm and consumer perceptions of their harmfulness and misleading character.

The present record identifies no new evidence or changed market circumstance justifying reopening the issue. Broad references to inconsistencies in product presentation or standardised packaging cannot substitute for a measure-specific problem definition or bridge the gap between the completed evaluation record and a general dimensional requirement.

⁹⁹ European Commission, SWD(2026) 111 final.

¹⁰⁰ European Commission, 'Report on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products' COM (2021) 249 final, s 10.1, 15–16.

¹⁰¹ European Commission, 'Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products' COM (2012) 788 final, 2012/0366 (COD), art 12(2).

The record identifies no specific obstacle to trade or appreciable distortion of competition created by existing lawful cigarette formats. The formal creation of one common format is not itself evidence that the measure is necessary for the functioning of the internal market.

Effectiveness and regulatory fit

The effects of cigarette-stick standardisation cannot be inferred from evidence concerning packaging generally. Evidence that packet appearance might influence perceptions does not establish that cigarette length or diameter affects initiation, consumption or cessation.

The present record identifies no causal pathway from cigarette dimensions to a durable public-health outcome under ordinary market conditions.

A dimensional rule changes the physical format of the cigarette. It does not limit the number of cigarettes purchased or consumed. The present record does not demonstrate that removing dimensional variation would reduce initiation, consumption or continued smoking rather than produce substitution.

Efficiency, implementation feasibility and enforceability

The technical scope is not defined sufficiently to assess feasibility, cost or enforceability and cannot be deferred until after option selection.

A common external format would not simplify compliance with the Directive's other product requirements or establish a regulatory benefit sufficient to justify the measure.

Coherence and wider impacts

The public-health, internal-market and enforcement benefits attributable to the Directive's existing product-presentation, reporting, traceability and security requirements form part of the no-change baseline. They cannot be counted as incremental benefits of dimensional standardisation.

Proportionality and comparison with no change

The relevant comparison is between cigarette-stick standardisation and no change. No change would retain the Directive's existing controls on product presentation, component flavourings, packet warnings, traceability and security features. It would not mean the absence of regulation.

The Article 28(2)(e) monitoring process identified no evidence establishing that the present framework is insufficient.

The present record does not establish that dimensional variation itself materially causes the identified harm. A single format should not be used as an indirect proxy for attractiveness or appeal.

Conclusion for option selection

No change. Cigarette-stick length and diameter standardisation should be excluded from the retained option set.

4.5 Prohibition of flavours in nicotine pouches (Questions 2, 3, 13 and 20)

Regulatory baseline and EU added value

Nicotine pouches are tobacco-free, non-combustible oral products. They are not presently regulated under the Tobacco Products Directive. Their use, uptake of nicotine via oral mucosa, composition, packaging and enforcement characteristics differ from those of electronic cigarettes and tobacco-containing oral products. The present record does not

establish a pouch-specific problem requiring a flavour prohibition, and evidence from another product category cannot supply that missing basis.

The consultation groups electronic cigarettes and nicotine pouches in a common question concerning a flavour prohibition, although it separately recognises that nicotine pouches are products outside the EU framework that have entered the market since 2012.

Member States have adopted or proposed different flavour restrictions, or none. Divergence does not establish that a blanket flavour prohibition is necessary or that the most restrictive national model should determine Union action.

Effectiveness and regulatory fit

The available evidence does not establish a flavour-ban case across materially different patterns of experimentation, regular use, prior nicotine use and switching, or across distinct concerns relating to presentation and under-age access.

The recent JRC evidence reinforces the need for a product-specific assessment. It estimates daily nicotine-pouch use at 0.3% of the EU population in 2023, with pronounced concentration in Sweden and use below 0.5% in most Member States. Among current or former users of tobacco and novel products aged 15-29, only 1% or less reported nicotine pouches as the first product used regularly, although Sweden was an outlier. The JRC's health-outcomes review separately finds no long-term evidence for nicotine pouches, only one reviewed organisational report addressing possible smoking initiation and one addressing cessation, and concluded that the category lacks sufficient evidence because of its limited time on the market. It also records that nicotine pouches expose users to fewer harmful constituents than conventional tobacco products.¹⁰²

Available European surveillance remains limited and uneven. The most developed evidence comes from Great Britain and the Nordic and Baltic countries. The available evidence from those markets indicates that reported nicotine-pouch use remains at low population levels and is concentrated among people with prior or concurrent experience of cigarettes, electronic cigarettes or other nicotine products. Nicotine-naïve young users appear to represent a comparatively small part of current use.¹⁰³

The evidence also does not establish that nicotine pouches act as an entry point to cigarette smoking. Population studies generally find that nicotine pouches are adopted after or alongside other tobacco/nicotine use. Some evidence also reports their use in connection with smoking reduction or cessation attempts. Cross-sectional evidence of concurrent use cannot establish which product was used first or whether nicotine-pouch use caused later smoking.¹⁰⁴

Evidence concerning the specific role of flavours is also limited. Available studies indicate that flavour affects product acceptability, but do not establish that flavours are the principal cause of youth uptake. Available studies report substantial experimentation and comparatively limited evidence of established regular use among nicotine-naïve young people.¹⁰⁵ Those findings do not establish that flavours are the principal cause of regular uptake among nicotine-naïve young people or support a blanket prohibition.

¹⁰² F Berlingieri, E Casabianca and S Vlachos, Trends and patterns of use of tobacco and nicotine products in the EU (European Commission, Joint Research Centre, JRC143862, 2026), pp. 20–26; A Perez-Cornago and others, Health outcomes associated with the use of e-cigarettes, heated tobacco products, and nicotine pouches (European Commission, Joint Research Centre, JRC146139, 2026), pp. 69–76.

¹⁰³ L S Brose, L Bunce and H Cheeseman, study of nicotine-pouch awareness and use in Great Britain, *Nicotine & Tobacco Research* 28(2), 213–222; H Tattan-Birch and others, 'Oral nicotine pouch use in Great Britain: a repeat cross-sectional study, 2020–25' (2026) 11 *Lancet Public Health* e26–e34; Nordic Welfare Centre, *Use of Nicotine Products among Youth in the Nordic and Baltic Countries* (2025); European Commission, Eurobarometer evidence concerning tobacco and nicotine-product use.

¹⁰⁴ Brose, Bunce and Cheeseman (2025), *Nicotine & Tobacco Research* 28(2), 213–222; Tattan-Birch et al. (2026), *Lancet Public Health* 11, e26–e34; Nordic Welfare Centre (2025), "Use of nicotine products among youth in the Nordic and Baltic countries"; European Commission Eurobarometer on attitudes towards tobacco and electronic cigarettes.

¹⁰⁵ Havermans et al. (2021), *Drug and Alcohol Dependence* 229, 109136; Vogel et al. (2025), *Tobacco Control* 34(3), 315–322; Mathur Gaiha et al. (2023), *Addictive Behaviors* 139, 107597; Travis et al. (2025), *Nicotine & Tobacco Research* 27(4), 598–610.

Efficiency, implementation feasibility and enforceability

The present record establishes no enforcement benefit from a flavour prohibition sufficient to offset the risk of redirecting demand towards products and suppliers outside the supervised market. A measure directed mainly at compliant manufacturers and retailers cannot be assumed to address supply originating outside those channels.

Removing or substantially narrowing lawful and accountable supply without addressing illegal channels may redirect demand towards products for which product standards cannot readily be verified. That displacement risk forms part of the measure's effectiveness and cannot be treated solely as a consequence.

Coherence and wider impacts

The evidence does not establish a net population-health benefit once the potential effects on adult smokers, switching, continued use of combustible products and substitution between nicotine categories are taken into account.

Proportionality and less restrictive alternatives

The absence of a common Union framework does not make a flavour prohibition proportionate or establish its incremental benefit either to the internal market or public health protection.

Conclusion for option selection

A blanket prohibition of flavours in nicotine pouches should be excluded from the option set.

4.6 Prohibition of flavours in heated herbal products (Question 13)

Regulatory baseline and policy issue

Nicotine-containing heated herbal products use a non-tobacco substrate that is heated in a device. They are not cigarettes, electronic cigarettes, herbal products for smoking or heated-tobacco consumables. Evidence from those other categories cannot supply the missing product-specific causal case for a flavour prohibition.

These products are not presently regulated as a distinct category under the Tobacco Products Directive.

Evidence relating to other product categories, either regulated by the TPD or not, cannot establish the likely effects of a prohibition for a non-tobacco heated substrate without demonstrating the relevant product-specific causal pathway. Nor can the internal-market contribution of a prohibition be inferred from rules applying to other product categories.

The Evaluation support study confirms the absence of a mature evidential base. It excludes heated herbal products from its substantive analysis because available sources were limited in late 2023 and early 2024. It describes the category as a niche product with close-to-zero prevalence and relies principally on market-intelligence material to identify possible future growth. The Commission's 2021 support study similarly describes the herbal-products market as new and changing and recorded classification difficulties for heated herbal sticks because they involved neither tobacco nor combustion. Those findings do not establish the role of flavours or likely effect of a category-wide prohibition either to the smooth function of the internal market or to public health protection.¹⁰⁶

¹⁰⁶ European Commission, Directorate-General for Health and Food Safety, Results of the Study supporting the Evaluation of the Tobacco Control Acquis (Open Evidence, manuscript completed October 2025), pp. 21–22 and footnote 12; European Commission, Directorate-General for Health and Food Safety, Final Report: Support Study to the report on the application of Directive 2014/40/EU (ICF S.A. and RAND Europe, May 2021), pp. 146–152.

Effectiveness and regulatory fit

Neither the Evaluation nor consultation materials provide product-specific evidence establishing prevalence, regular use, uptake among nicotine-naïve minors, user history or the effect that a flavour prohibition would have on initiation, switching or substitution. Nor do they establish that flavours in heated herbal products are a problem.

Imperial's Czech Actual Use behavioural research concerning adjacent heated-product use provides a plausible indication that flavour may be relevant to adult switching, with more than half of the observed switchers selecting flavour products.¹⁰⁷ That evidence does not establish the effect of flavour availability specifically for heated herbal products or at population level. It identifies switching as a plausible effect inconsistent with assuming that removing flavours would affect only product appeal to minors.

Efficiency, implementation feasibility and enforceability

Any benefits attributable to other regulatory measures cannot be attributed to the flavour prohibition. The evidence identifies no separate benefit attributable specifically to a flavour prohibition in heated herbal products

Proportionality and less restrictive alternatives

The absence of a common framework does not establish the necessity or proportionality of a flavour prohibition.

Conclusion for option selection

A blanket prohibition of flavours in heated herbal products should be excluded from the option set.

¹⁰⁷ Russell C, Barnard G, Marza V, Notley S, Nahde T, Fitzpatrick M, Malt L, Stevenson M, Weaver S, McKeganey N. Switching and substantial reductions in cigarette consumption concurrent with use of a heated tobacco product among adults who smoke in Czechia: an actual use study. *Harm Reduct J.* 2025 Aug 14;22(1):138. doi: 10.1186/s12954-025-01293-x. PMID: 40814051; PMCID: PMC12351828.

Part II - Procedure

5. Purpose and applicable procedural framework

The public consultation can legitimately map concerns and test possible interventions. Its evidential function is limited. The fact that a measure appeared in the questionnaire, or attracted support in a closed response, does not establish the measure-specific regulatory failure, causal pathway, incremental benefit or internal-market case relied upon to justify retaining that measure.

Part I addresses those questions against the Commission's own record. This Part II addresses some procedural aspects that affect what the consultation and surrounding process can add to that record for option selection.

6. Evaluation-to-Consultation evidential gap

The Regulatory Scrutiny Board issued a negative opinion on the original Evaluation. It identified shortcomings in scope, evidence, effectiveness analysis, treatment of Member State measures, monitoring and the distinction between legislative design and enforcement.

The revised Evaluation continues to acknowledge limitations in quantitative data, attribution and the assessment of newer product categories.¹⁰⁸ DG SANTE has also stated that the questionnaire was based on the results of the Evaluation and that the Evaluation evidence and results 'guided the propositions'.¹⁰⁹

The Commission may consult on emerging problems or options not examined in the Evaluation. That does not give the consultation proposition evidential status of its own. Where Part I identifies an intervention that goes materially beyond the problem definition established in the Evaluation, and the current record does not independently establish the missing regulatory problem, appearance in the questionnaire does not cure the gap.

Consultation responses may record stakeholder views on such a proposition. They do not retrospectively create an Evaluation finding, establish a causal pathway or demonstrate incremental benefit. Where the present record does not establish the measure-specific case identified in Part I, the measure should not be retained on the strength of consultation testing.

This is particularly important because the public consultation introduction is expressed in relatively conclusive terms. It states that the legislation has not kept pace with market developments, consumption trends and digital marketing practices and that certain provisions have been outpaced by newer products. Those propositions may be relevant hypotheses, but they do not identify, for each intervention, the existing rule that has failed, the scale and cause of the failure, or whether the appropriate response is implementation, enforcement, guidance, targeted amendment or broader harmonisation.¹¹⁰

¹⁰⁸ European Commission, 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, 8 April 2026, in particular the methodological limitations and conclusions, https://health.ec.europa.eu/document/download/4913f646-f22d-463f-8678-3a82c3e84fc2_en?filename=tobacco_wd-evaluation_en.pdf.

¹⁰⁹ European Commission, Directorate-General for Health and Food Safety, reply concerning the design of the public consultation on the revision of the EU tobacco rules (Initiative 17612), SANTE.R.1.001/ML, 15 July 2026, p. 2, https://acvoda.nl/wp-content/uploads/2026/07/CONTACTED_02_Reply-complaint-23-06-2026_SG-clean-1.pdf.

¹¹⁰ European Commission, public consultation questionnaire for businesses and companies on the revision of the EU tobacco control legislation, June 2026, Introduction. The consultation materials are available through the Commission's Have Your Say initiative page: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/17612-Tobacco-products-and-tobacco-advertising-revision-of-EU-rules_en.

7. Limits of the public consultation evidence

Grouped products and grouped interventions

Several questions group materially different products and interventions. Question 13 asks respondents to assess numerous measures for nicotine and non-nicotine products as a combined field; Question 19 presents labelling and packaging measures without consistently identifying the product to which an answer relates; and Question 20 groups electronic cigarettes and nicotine pouches within a single flavour-ban proposition.¹¹¹

DG SANTE has also clarified that the products under consideration carry risks 'to varying degrees', while the consultation was not intended to differentiate between levels of risk 'at this stage'. An aggregate answer collected on that basis cannot establish that the same intervention is appropriate for each product category.¹¹²

Support for one product or one element cannot be transposed to another product or intervention appearing in the same question. The resulting aggregate cannot therefore provide product-specific affirmative evidence for a measure where the questionnaire did not isolate the object of the response.

Definition of young people

The questionnaire defines 'young people' as persons aged 10 to 24. That category combines minors with adults and materially different legal and behavioural contexts. A response concerning 'young people' therefore does not, without more specific underlying evidence, establish an effect on minors. This matters directly where protection of minors is relied on as the justification for product-design, flavour, packaging or access restrictions.¹¹³

Effectiveness scales and undefined measures

Agreement scales can map stakeholder views; they are not empirical estimates of effectiveness. Questions 19, 19.1 and 19.2 illustrate the problem: respondents are asked whether listed measures are 'effective', while economic operators are separately asked about technical operation and adjustment costs. A numerical balance of agreement and disagreement cannot turn the asserted benefit of an undefined intervention into demonstrated effectiveness.¹¹⁴

The same caution applies to 'don't know' answers. They may reflect lack of evidence, lack of respondent competence or an intervention that is insufficiently specified to support a reasoned answer. Treating those responses as neutrality would overstate the certainty of the consultation record.

Silence, reservations and uploaded contributions

Question 23 describes the questionnaire as the 'essential input' and the uploaded document as an optional complement, while DG SANTE has confirmed that uploaded documents allow differentiated or substantiated views and will be analysed within the consultation. Where an uploaded contribution qualifies or contradicts a closed answer, the closed answer cannot be treated as freestanding support for the measure.¹¹⁵

¹¹¹ European Commission, public consultation questionnaire for businesses and companies on the revision of the EU tobacco control legislation, June 2026, Questions 13, 19 and 20, available through https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/17612-Tobacco-products-and-tobacco-advertising-revision-of-EU-rules_en.

¹¹² European Commission, Directorate-General for Health and Food Safety, reply concerning the design of the public consultation on the revision of the EU tobacco rules (Initiative 17612), SANTE.R.1.001/ML, 15 July 2026, p. 2, https://acvoda.nl/wp-content/uploads/2026/07/CONTACTED_02_Reply-complaint-23-06-2026_SG-clean-1.pdf.

¹¹³ European Commission, public consultation questionnaire for businesses and companies on the revision of the EU tobacco control legislation, June 2026, definition of 'young people' as persons aged 10 to 24, available through https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/17612-Tobacco-products-and-tobacco-advertising-revision-of-EU-rules_en.

¹¹⁴ European Commission, public consultation questionnaire for businesses and companies on the revision of the EU tobacco control legislation, June 2026, Questions 19, 19.1 and 19.2, available through https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/17612-Tobacco-products-and-tobacco-advertising-revision-of-EU-rules_en.

¹¹⁵ European Commission, public consultation questionnaire for businesses and companies on the revision of the EU tobacco control legislation, June 2026, Question 23; and European Commission, Directorate-General for Health and Food Safety, reply concerning the

8. Evidence and causal attribution

Evidence must match the proposition

The measures assessed in Part I repeatedly turn on the difference between evidence of a concern and evidence for a particular intervention. Prevalence, appeal, chemical detection, temporal association or the existence of national rules may be relevant facts, but none by itself establishes causation, incremental effectiveness or the net effect of a specified Union measure. Evidence from one product category cannot fill an evidential gap in another where route of use, regulatory baseline, exposure or market behaviour differs.

Limits of the current Commission evidence

The Commission's own supporting material illustrates those limits. The Evaluation support study did not assess the cost-effectiveness of individual tobacco-control policies; the 2021 support study could not determine whether the TPD's societal benefits outweighed its overall implementation costs because important benefits and the Directive's contribution could not be quantified; and the JRC aggregate cost study excludes emerging products and does not compare regulatory options. Those sources therefore do not provide comparative evidence in favour of the specific new measures now under consideration.¹¹⁶

The Commission's 2025 track-and-trace analysis likewise cautions that much of the underlying evidence is observational or cross-sectional, limiting causal attribution, and that changes in recorded illicit trade can reflect changes in detection and reporting. The same limitation applies to national policy examples: a change observed after a national restriction is not, without an adequate counterfactual, evidence that the restriction caused the change or that an EU-wide version would have the same effect.¹¹⁷

Objectives such as protecting minors, reducing initiation, informing consumers or improving the internal market are not measured benefits of every intervention that invokes them. A generic expected benefit cannot supply the missing measure-specific evidence for several independent restrictions operating on the same population or pathway.

9. Problem definition and EU added value

General objectives do not establish a measure-specific problem

A general concern about youth use, product attractiveness, information, enforcement or market development is not equivalent to a regulatory problem for each measure tested in the questionnaire. The relevant evidential question is whether the present record establishes the specific failure that the intervention is said to address. Where Part I finds no such failure, the broader policy objective does not supply it.

The distinction is equally important for product scope. In areas already harmonised, national activity does not by itself establish a residual failure in the field governed by the Union rule. For products outside the current harmonised framework, a possible case for bringing a category within common rules is analytically distinct from a case for a particular flavour, packaging, ingredient or device restriction. One does not establish the other.

design of the public consultation on the revision of the EU tobacco rules (Initiative 17612), SANTE.R.1.001/ML, 15 July 2026, p. 2, https://acvoda.nl/wp-content/uploads/2026/07/CONTACTED_02_Reply-complaint-23-06-2026_SG-clean-1.pdf.

¹¹⁶ European Commission, Results of the Study supporting the Evaluation of the Tobacco Control Acquis, study conducted by Open Evidence, manuscript completed October 2025, pp. 55-57; ICF and RAND Europe, Support Study to the report on the application of Directive 2014/40/EU, May 2021, pp. 190 and 203; P. Salari, P.-A. Maragkoudakis and J. Wollgast, The health-related costs attributable to tobacco use in the EU, JRC146176, 2026, pp. 4 and 7.

¹¹⁷ European Commission, Report on the analysis of the track and trace system and illicit trade in the EU (October 2025), pp. 42-44.

10. The existing baseline and enforcement

The existing framework is part of the evidence

The baseline is not an absence of regulation. For many measures in Part I it includes harmonised TPD requirements, implementing acts, EU-CEG, applicable horizontal legislation and national enforcement. Evidence that a risk, infringement or undesirable outcome still occurs despite that framework is not the same as evidence that the legal rule is missing or defective.

Enforcement failure is not design failure

That distinction is expressly present in the Regulatory Scrutiny Board opinion, which required the Evaluation to distinguish problems of legislative design from problems of Member State enforcement.¹¹⁸

Where conduct is already unlawful, involves non-notified or illegal products, or occurs outside supervised channels, the existence of that conduct does not establish a case for imposing a new substantive obligation on compliant operators. Recasting an enforcement problem as a regulatory gap would overstate the evidence for intervention.

For measures where Part I finds the existing baseline operative and the alleged shortcoming unproven, the procedural record therefore reinforces the no-change conclusion.

11. Consequences for measures introduced or broadened at consultation stage

Part I identifies two recurring situations: measures for which the Evaluation does not contain a corresponding problem finding, and measures that are materially broader than the issue actually evidenced. Both raise the same threshold problem. The consultation can record views on a proposed intervention, but it cannot make the missing causal or regulatory link true.

The weakness is especially acute where the proposed measure remains undefined. A respondent cannot provide empirical evidence of the effectiveness of an intervention whose regulated unit, scope or technical content is unspecified. An aggregate agreement score for such a proposition has no stable regulatory object and cannot justify retention.

The same applies where the evidence concerns a different product, a narrower intervention or only a general policy objective. Extending that evidence to a broader measure would substitute analogy for measure-specific proof.

Where the current record falls into any of these categories, the measure should be excluded from the retained option set rather than preserved as a placeholder for later design or evidence gathering.

¹¹⁸ European Commission, Regulatory Scrutiny Board Opinion on the Evaluation of the Tobacco Products Directive (2014/40/EU), the Tobacco Advertising Directive (2003/33/EC) and other related tobacco control policies across the EU, SEC(2026) 111 final, 8 April 2026, pp. 1–2, <https://ec.europa.eu/transparency/documents-register/detail?lang=en&ref=SEC%282026%29111>.

12. Procedural conclusion and option-selection implications

The public consultation is a source of stakeholder evidence, not a plebiscite on regulatory necessity. On the present design, it cannot support treating appearance in the questionnaire as evidence of need; grouped answers as product-specific support; stakeholder agreement as demonstrated effectiveness; responses concerning persons aged 10 to 24 as evidence specifically about minors; national divergence as a sufficient internal-market case; or non-compliance as proof of a legislative-design failure.

Conclusion for option selection

These are not requests for further process or for a better-designed route to the same measures. They are limits on what the present record can establish.

Accordingly, where Part I concludes that an option lacks a defined regulatory problem, product-specific evidence, a causal pathway, incremental benefit over the existing baseline or a material internal-market case, the procedural record reinforces exclusion. The consultation does not cure those deficiencies and does not provide an independent basis for retaining the measure.

No measure should be retained merely because it appeared in the questionnaire, attracted aggregate support, would eliminate national divergence or can be described as simplifying the framework. On the present record, options resting on those propositions lack sufficient evidential basis to proceed.