



Final Report: Support Study to the report on the application of Directive 2014/40/EU

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Executive Summary

This report presents the results of the external Support Study commissioned by the European Commission Directorate-General for Health and Food Safety (DG SANTE) to provide factual input to its report on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products.

Introduction

The 2014 Tobacco Products Directive (TPD) is one of the most relevant pieces of EU legislation on tobacco control, replacing the previous Directive from 2001 (Directive 2001/37/EC). This assessment is rooted in Art. 28 of the TPD and has the general objective of providing an independent evidence base to explore the TPD and its specific articles and provisions through two overarching objectives: assessing TPD implementation and levels of compliance and generating general evidence (through primary and secondary data collection). The purpose of this report is to summarise the evidence collected against the TPD's main articles (Art. 2-24) and more broadly against the five assessment criteria: effectiveness, relevance, efficiency, coherence, and EU added value.

Carried out between October 2019 and May 2021, the assessment collected evidence on impact, benefits, costs, changing circumstances and issues with the legislation. The study team reviewed relevant qualitative and quantitative information gathered from desk research, including an extensive review of peer-reviewed and grey literature sources, as well as mapping and analysis of data from Special Eurobarometer Surveys and Euromonitor International.

The consultation approach sought to collect information and feedback on various aspects of the TPD from several stakeholder groups. The stakeholder consultation was structured around a variety of different sub-tasks, including targeted stakeholder surveys, phone interviews, and workshops.

Additional research tasks included case studies, which examined four key topics related to the TPD in greater detail, and an online mystery shopping exercise.

Findings presented in this report are based on analysis and triangulation of the data gathered from these various sources. A draft report was peer-reviewed by three independent experts, whose suggestions have been accommodated in the final report.

Effectiveness

The structures and procedural arrangements of the TPD have been largely clear on how to transpose the TPD.

Member States found the **transposition guidance for the TPD clear**, and economic operators also found the guidance provided to them to be generally clear.

This study found that Member States broadly fulfilled their obligations to **apply** the TPD, with a few problems and enforcement issues encountered. Issues stemmed from a lack of capacity or scientific or technical expertise for adequate monitoring and enforcement. Art. 7 (ingredients and characterising flavours) and Art. 20 (e-cigarettes) were among the more difficult articles to apply. Some provisions were not applied in a harmonised way.

In terms of compliance, **economic stakeholders generally complied** with the rules and provisions set by the TPD, and for most of the 24 articles examined in the present study, instances of non-compliance were uncommon or were quickly addressed through Member State NCA involvement. However partial non-compliance, such as in Art. 6 (economic operators establish detailed and accurate scientific information about 15 additives) and Art. 18 (age verification systems for cross-border distance sales) impaired effectiveness. There were also cases of economic operators acting in ways that were not strictly non-compliant, but were clearly not in the spirit of the TPD, such as launching legal challenges to obtain a more favourable interpretation.

Prior to the introduction of the TPD in 2014, there were areas of discrepancy between Member States, which limited the functioning of the internal market. The TPD largely resolved these discrepancies.

One key example of the TPD resolving such discrepancies and further facilitating the functioning of the internal market is the clear guidance and regulations on **labelling and packaging**, with a few minor points remaining unclear. A justification for the TPD was that the disparities in labelling of tobacco products were a barrier to the internal market (Recitals 22 and 23), and indeed harmonising labelling and packaging rules was a key success of the TPD, chiefly because it harmonised packaging across the internal market. There were few issues related to Art. 8, 10, and 11, with some minor confusions identified and resolved early on. However, there were a few issues, for example Art. 9(3) was ambiguous about whether or not it was meant to prohibit 'slim' packets of cigarettes, or questions were raised about packets with bevelled edges.

Another success of the TPD was establishing clear guidance and regulations on setting maximum emission levels for **tar, nicotine, and carbon monoxide (TNCO)** in accordance with relevant scientific research and data. However, Member States rarely used the TPD provisions allowing additional measurements methods and thresholds (including for products other than cigarettes).

Some challenging areas were identified, which could threaten the functioning of the internal market, for example ambiguous definitions (Art. 2) or a lack of common standards for classifying novel tobacco products as 'for smoking' or 'smokeless' (Art. 19). The TPD permits Member States to allow or prohibit **cross-border distance sales (CBDS)**: for tobacco products, 19 Member States prohibit them and nine allow them, while for e-cigarettes, 16 Member States prohibit them and 12 allow them¹. Several stakeholders considered CBDS to undermine the functioning of the internal market, public health and fiscal policies in Europe, and felt they should be banned at EU level.

Based on evidence collected for this study, the TPD has improved public health, although it is difficult to conclude the extent to which it is the cause of any changing trends in prevalence of use of tobacco and related products.

Key provisions that seem to have benefitted public health include labelling and packaging provisions (increased awareness of the harmful effects of tobacco and related products), prohibition of ingredients with carcinogenic, mutagenic or reprotoxic properties (for reproduction, stimulants and other substances), and prohibition of characterising flavours in cigarettes and roll-your-own tobacco.

There is some evidence that **awareness of harmful effects of tobacco** and related products has increased (overall and among young people). One of the greatest successes of the TPD has been to improve smokers' awareness and understanding of the various product categories and their overall harmfulness. Colour photographs, bigger health warnings, warning messages and information on ingredients all contributed to increase (quantify) awareness, mainly among smokers and especially among younger people.

The **prevalence of smoking and tobacco related products** overall has generally decreased, although these changes cannot be attributed solely to the TPD.

Similarly, the extent to which decreases in **consumer appeal** (attractiveness) and misperceptions of the harmfulness of tobacco and related products can be attributed to the TPD remains unclear.

Overall, the TPD has achieved significant and beneficial outputs and outcomes, which contributed to the objectives of the TPD. Broadly speaking, the TPD has achieved its intended objectives and created minimum standards in previously problematic areas, such as emissions levels, ingredients, packaging and

¹ This study looks at EU Member States and the UK (Member States).

labelling, flavouring, traceability, and security features. It has also likely significantly impacted public health. Other specific outputs and outcomes are discussed below.

Regulations of tobacco and related products have been **harmonised and coordinated** across Member States, with several problem areas identified. The TPD has created consistency in areas that were not previously harmonised, although some areas lacking harmony impacted the internal market. Additional minor areas included the use of broad terms in Art. 13 to cover a range of promotional packaging and products (lacking specific indications on phrasing permitted or prohibited and creating difficulties with application), divergent national approaches, and legal challenges in several Member States. The TPD leaves certain provisions to Member State discretion. While this can be beneficial to public health by allowing Member States to go beyond the TPD requirements, it can also affect harmonisation. For example, Art. 11 permits Member States to exempt certain products from labelling requirements. This has created inconsistent packaging across Member States, and harmonisation would be improved if there were no such opportunities for exemptions.

Member States made use of opportunities to implement **additional, more restrictive requirements than the minimum standards in the TPD**, which typically did not create obstacles to the successful implementation and harmonisation of TPD standards. The two main examples are prohibiting flavours in e-cigarettes (in four Member States) and plain packaging policies (in eight Member States). Both actions are explicitly left to Member States' discretion in the TPD.

It may be too early to draw conclusions on whether the TPD has established **effective systems to tackle illicit trade**. As provisions on traceability and security features (Art. 15 and 16) have been implemented recently, it remains too early to determine their contribution to the fight against illicit trade.

Similarly, **illicit trade** and smuggling has declined since the implementation of the TPD, but there is insufficient evidence to attribute that trend to the implementation of the TPD and its effects.

Relevance

The specific objectives underlying the TPD proved generally appropriate to address the problems and identified needs. Three specific objectives are discussed in detail below.

Firstly, the TPD has, for the most part, adequately addressed the **availability of illicit tobacco products** in the EU. Art. 15 of the TPD includes measures on traceability of tobacco products, and Art. 16 includes measures on security features, which stakeholders stated would strongly limit the possibility of introducing illicit products. However, it is still too early to assess the exact impact of the systems of tobacco traceability and security features on illicit products in the EU as they have been in place for too short a time. There are some concerns that certain aspects of the traceability system may not be optimal for combating illicit trade in the EU. Examples of potential issues that could hinder the overall ability to address illicit trade include the shared responsibility for the traceability system between multiple national administrative bodies, the complexity of the traceability system, and the capacity and resources required to comply with the system.

Secondly, the TPD has made substantial progress in addressing the **variations in tobacco and related products across Member States**. In particular, it effectively set a minimum standard for regulating health warning labels, packaging formats, maximum emission levels, characterising flavours for cigarettes and roll-your-own tobacco, certain ingredients and additives, traceability and security features, among others. However, variation between Member States still remains, such as e-cigarette flavours and plain packaging. There may be potential for Member States implementing additional measures such as plain packaging to precipitate a 'cascade effect', whereby

evidence from their efforts could be used to justify the adoption of similar legislation in other Member States.

Finally, the TPD partially addressed the **problem of smoking in the EU and among vulnerable populations**. The health warning labels, and other labelling and packaging measures introduced through Art. 8-14 of the TPD have been identified as especially relevant to changing perceptions and use of tobacco products, particularly among young people. However, Member States, independent civil society organisations (CSOs) and health experts (HEs) were particularly concerned about the increasing use of e-cigarettes, heated tobacco products (HTPs) and other emerging products by young people. There is some concern that the current scope of the TPD may be inappropriate for products other than cigarettes and roll-your-own tobacco (e.g. packaging and labelling requirements, and characterising flavours). More evidence will be needed to determine how the TPD can remain relevant to addressing the issue of smoking in the EU, particularly among young people and specific vulnerable populations, and in relation to e-cigarettes, HTPs and novel tobacco products. There are also potential issues with the TPD's ability to safeguard young people from accessing tobacco and related products when they are under the legal age, which is not within its scope. The mystery shopping exercise undertaken as part of this study revealed frequent insufficient age verification processes for tobacco and related products bought online through CBDS.

The TPD provisions remain partially relevant to tackle today's reality, and have responded to scientific, economic or technological developments and new products.

Several TPD provisions have **not remained relevant in light of new and emerging sector developments**, which affects the relevance of the TPD. The market has evolved rapidly since the TPD was adopted in May 2014 and it is very challenging for a directive to remain relevant in this context. Overall, the evidence suggests that the TPD forms a strong basis for the regulation of tobacco and related products and remains broadly relevant to address new market developments. However, there are some key areas in which market developments are beyond the current scope of the TPD. Provisions across seven articles (Art. 2, 4, 5, 7, 19, 20 and 21) were perceived to lack relevance in light of scientific and technological developments from the tobacco industry on novel and innovative products, packaging and labelling, marketing and sales methods. In particular, the Directive has faced challenges in keeping pace with the rapidly evolving market and the wide variety of products that are difficult to categorise and/or which fall outside its scope.

Similarly, not all structures and procedural arrangements introduced by the TPD have **adapted sufficiently to new market, scientific, and technological developments** in the tobacco industry and companies producing tobacco related products. The market for tobacco and related products has become more diverse and challenging to regulate, with multiple novel ways of delivering tobacco and nicotine to consumers. New product categories have emerged that circumvent existing regulations such that they cannot be completely addressed by existing provisions in the TPD. This includes products currently within the scope of the TPD, such as HTPs, but also new products that have emerged and are not currently included in the TPD, such as nicotine-free products (e.g. nicotine-free e-liquids), cannabidiol products, and non-tobacco containing nicotine products (e.g. nicotine pouches). Stakeholders viewed this as a contributing factor to the lack of harmonisation across Member States. Specific provisions that have not adapted to new sector developments include definitions, ingredients and emissions, labelling and packaging, novel tobacco products, e-cigarettes and herbal products for smoking.

Finally, the TPD provisions have not fully enabled Member States to **respond quickly and effectively to market developments** and regulator needs, including future needs. During the period 2013-2019, the size of the market for e-cigarettes and HTPs more than quadrupled. Although these products represent a small proportion of the

overall tobacco market, it is an area of substantial expansion and diversification and this appears likely to continue. This has made it challenging for the TPD provisions to remain relevant to this part of the market. There is also some indication that the markets for smokeless tobacco products and herbal products for smoking are also changing and the TPD may not be fully relevant to address these market developments. The evidence suggests that the TPD encompasses many different product types, which may limit its ability to respond in an agile manner to market developments.

Efficiency

Compliance and enforcement costs in most Member States were not outweighed by the direct revenue generated from fees and penalties charged to industry for breaches.

In terms of the **costs versus financial benefits borne by Member States**, the administrative costs borne by regulators to implement the TPD can be grouped into three broad categories: (1) Reviewing submissions to the EU-CEG, (2) Compliance costs, and (3) Enforcement costs. A key driver of all three types of costs was staff time, for example for cost (1), Member States found that reviewing the information submitted to the EU-CEG system created high administrative and technical burdens. Where Member States incur costs associated with implementing the TPD, some charge fees, as permitted by the Directive, to help to recover these costs. However, the costs of implementing the TPD were not outweighed by the direct revenue gained by most Member States.

Overall, **economic stakeholders reported facing a large increase in costs** to implement the TPD, although there is a lack of economic information to make a proper judgement. Economic stakeholders reported, without providing specific quantitative evidence, facing the highest costs for the redesign of packaging, changing the process for printing and packaging, product redesign and testing to meet reporting obligations.

Considering the above limitations, the study was unable to assess the **benefits of the TPD for society in relation to the overall costs faced by all actors**. Key benefits, such as reduced healthcare costs and health gains (people may be encouraged to reduce or quit smoking as a result of the TPD) or reduced law enforcement costs (new tools available to fight the illicit trade in tobacco products) could not be quantified, as the degree to which the TPD impacts on these is complex to determine. Nevertheless, the TPD has several beneficial effects, which, although not included in the cost-benefit analysis, are increasingly identified and recognised by the Member States.

The evidence collected for this study suggests limited flexibility to cater to the needs of SMEs, although evidence is scarce.

In terms of the **flexibility of administrative requirements for SMEs**, the evidence suggests that some Member States provided specific supports for SMEs, including establishing a helpline, disseminating information materials and organising coordination meetings. However, SME stakeholders were generally negative about additional supports and flexibility of Member State authorities in relation to the new TPD requirements. Many suggested that the implementation of the TPD was overly complex and costly for SMEs, and favoured large cigarette companies. General comments were provided by respondents, highlighting that the characteristics of mid-sized and smaller companies were ignored by the TPD.

Several studies highlighted the **costs faced by SMEs and the need for flexibility in administrative requirements**. This is especially relevant in relation to the traceability and security features systems, where SMEs claimed to face a disproportionate level of costs per production unit.

Accordingly, some Member States provided **specific supports to SMEs** affected by the TPD in a variety of forms and to varying degrees. These included technical support to comply with the requirements, information sessions and meetings, and a

helpline/email support. Many economic operators believed that the support provided to implement the TPD was not specifically adapted to SMEs.

Coherence

The TPD provisions broadly complement each other and remain coherent, although minor inconsistencies were reported. The TPD provisions are, for the most part, internally consistent. However, there were a few areas of perceived incoherence. The differing treatment of cigarettes and roll-your-own tobacco versus e-cigarettes and HTPs (based on the scope of the TPD with respect to these categories of products) was seen as inconsistent within the TPD, particularly with respect to regulations on flavours. This discrepancy in how different types of products are treated by the TPD created a perceived lack of coherence in relation to product labelling. Lastly, there are inconsistencies in how tobacco-related products, such as devices and nicotine free e-liquids, are regulated by the TPD.

The TPD provisions are largely coherent with other relevant EU legislation, although there were some perceived inconsistencies that require clarification.

There are many pieces of EU legislation, with which the TPD is generally coherent. One of the main issues identified in terms of a lack of coherence between the TPD and other pieces of EU legislation was in the definitions of tobacco and related products, and definitions of advertising and sponsorship. There was also potential incoherence between pieces of EU legislation and the packaging and labelling requirements set out in the TPD. Lastly, there was a general lack of understanding of how TPD provisions around herbal products for smoking (Art. 21 and 22) interact with other EU-level regulations.

The TPD is generally consistent with WHO FCTC, although some independent stakeholders perceived a lack of coherence with the Illicit Trade Protocol (ITP) of the FCTC.

The WHO FCTC specifies that Parties shall - in setting and implementing their public health policies with respect to tobacco control - protect these policies from commercial and other vested interests of the tobacco industry. However, the traceability measures in Art. 15 of the TPD requires the tobacco industry to carry out certain tasks, which was perceived by some stakeholders (mainly CSOs) as incoherent. Several Member States expressed concern that the ability of Member States to exempt products other than cigarettes, roll-your-own tobacco and waterpipe tobacco from requirements on labelling as per Art. 11(1) of the TPD created issues in complying with WHO FCTC guidelines. Some Member States suggested that these exemptions were based on political pressure from industry, rather than scientific evidence and best practice. Lastly, according to some Member States and stakeholders, ISO standards for measuring TNCO emissions, the use of which is specified by Art. 4(1) of the TPD, may not have kept pace with scientific evidence and best practice in measuring emissions.

EU added value

The legislative framework at EU level has added value to the regulation of tobacco and related products across the EU in a manner that could not have been achieved at national level alone.

It is still too early to draw conclusions on the precise overall effect of the TPD on **public health**, especially since the ban on characterising flavours has only been fully applicable since May 2020. However, some key changes from the TPD were widely regarded by various stakeholders as having positively contributed to protecting EU citizens' health, including the introduction of combined health warnings on tobacco products for smoking and the increase in their size (Art. 10), the ban on characterising flavours in cigarettes and roll-your-own tobacco (Art. 7), the regulation of ingredients and the common reporting obligations (Arts. 5,6 and 7), in particular the prohibition of CMR ingredients, and the presence of the first EU-wide framework for the regulation of e-cigarettes (Art. 20).

The TPD has helped to achieve **harmonisation** across the Member States and contributed to better functioning of the internal market. This can be seen in particular in the rules on packaging and labelling (Art. 8-14), where divergences were clearly noticeable prior to the TPD and where the TPD provides a high level of harmonisation and clear guidance on health warning labels, with a few minor clarity issues. That is also the case for rules on e-cigarettes (Art. 20), where no common legal framework existed prior to the TPD. The rules on emissions and ingredients (Art. 3-7), on traceability and security features (Art. 15 and 16), and on novel tobacco products (Art. 19) were also reported as having contributed to the better functioning of the internal market, although these are not without fault or implementation challenges.

Another key outcome was the EU's **coordinator role**, facilitating the achievements of the objectives of the TPD. The TPD has allowed Member States to cooperate more closely with one another and to benefit from the coordination efforts and support provided by the European Commission. Most Member States reported benefitting, especially those with less technical expertise and fewer resources available, which sometimes struggled to meet their obligations under the TPD. Most stakeholders, including CSOs and HEs, saw this cooperation and coordination as one of the great successes of the TPD. An example often cited was the Joint Action on Tobacco Control (JATC), which was welcomed by Member States as a useful initiative to help them to assess, treat and share information received on ingredients and emissions, and for enforcement purposes. Most Member States also expressed strong satisfaction with the Group of Experts on Tobacco Policy and the guidance it provided on transposition of the Directive.

In conclusion, **the TPD has generated significant outcomes that would not have been achieved through Member States acting alone**. This is particularly true in respect of the better functioning of the internal market and better coordination between Member States. These are objectives that, by definition, can only be achieved through action at EU level. There is reason to believe that a degree of public health protection similar to that provided by the TPD would not have been achieved by Member States acting alone. The political willingness to enact strict tobacco control measures can vary between Member States, sometimes to a considerable extent. Action at the EU level helped to mainstream the level of protection for all EU citizens and residents, and helped certain Member States to overcome domestic political opposition. Action at EU level also helped Member States wishing to enact stricter tobacco control measures but who were rebutted by tobacco companies' opposition and/or threat of legal challenges. Finally, there is an inherent value in having one overarching piece of legislation regulating tobacco and related products in terms of coherence and effectiveness of tobacco control.

Abbreviations used in the report

Abbreviation	Full term or description
AVMSD	Audio-visual media services Directive DIRECTIVE 2010/13/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audio-visual media services (Audiovisual Media Services Directive) ²
CAS numbers	Chemical Abstract Service numbers
CBDS	Cross-Border Distance Sales
CI	Canadian Intense
CLP	Classification, Labelling and Packaging
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ³
CMR properties	Carcinogenic, mutagenic or reprotoxic properties
CSO	Civil Society Organisation
DG SANTE	The Directorate-General for Health and Food Safety
E-cigarette	Electronic cigarette
ECJ	European Court of Justice
E-liquid	Liquid solution in e-cigarettes
EU-CEG	EU Common Entry Gateway
EUREST	European Regulatory Science on Tobacco
Euromonitor International	Euromonitor International; Tobacco Industry Edition (2021 unless otherwise specified)
FCTC	World Health Organisation Framework Convention on Tobacco Control ⁴
HE	Health expert
HETOC	Health Effects Tobacco Composition
HTP	Heated Tobacco Product
IARC	International Agency for Research on Cancer

² The European Parliament and the Council of the European Union. (2013). DIRECTIVE 2010/13/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive). Available at: <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:095:0001:0024:EN:PDF>

³ The European Parliament and the Council of the European Union. (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1272>

⁴ World Health Organisation Framework Convention on Tobacco Control. (2003). WHO Framework Convention of Tobacco Control. WHO. Available at: <https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf?sequence=1>

Abbreviation	Full term or description
ISO	International Organization for Standardization
ITP	World Health Organisation Protocol to Eliminate Illicit Trade in Tobacco Products ⁵
JATC	Joint Action on Tobacco Control ⁶ .
JATC WP	JATC Work Package
Market Surveillance Regulation	REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ⁷
MSREP	Member States Reporting Tool
NCA	National Competent Authority
REACH	Regulation (EC) No 1907/2006 - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ⁸
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks ⁹
SUP / Single Use Plastics Directive	DIRECTIVE (EU) 2019/904 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 on the reduction of the impact of certain plastic products on the environment ¹⁰
Tobacco Advertising Directive (TAD)	DIRECTIVE 2003/33/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products ¹¹
TNCO	Tar, nicotine, and carbon monoxide
TPD (occasionally referred to by Member States as TPD2)	Tobacco Products Directive DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States

⁵ WHO. (2013). Protocol to Eliminate Illicit Trade in Tobacco Products. Available at: https://www.who.int/fctc/protocol/illicit_trade/protocol-publication/en/

⁶ Joint Action on Tobacco Control (n.d.) Available at: <https://jaotc.eu/>

⁷ The European Parliament and the Council of the European Union. (2008). REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R0765>

⁸ European Agency for Safety and Health at Work. (2006). Regulation (EC) No 1907/2006 - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Available at: <https://osha.europa.eu/en/legislation/directives/regulation-ec-no-1907-2006-of-the-european-parliament-and-of-the-council>

⁹ European Commission. (n.d.) SCIENTIFIC COMMITTEE ON HEALTH, ENVIRONMENTAL AND EMERGING RISKS (SCHEER). Available at: https://ec.europa.eu/health/scientific_committees/scheer_en

¹⁰ The European Parliament and the Council of the European Union. (2019). DIRECTIVE (EU) 2019/904 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 June 2019 on the reduction of the impact of certain plastic products on the environment. Available at: <https://eur-lex.europa.eu/eli/dir/2019/904/oj>

¹¹ The European Parliament and the Council of the European Union. (2003). Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32003L0033>

Abbreviation	Full term or description
	concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/ ¹²
TP-ID	<i>In EU-CEG, product IDs are assigned by the submitter to each of its products. For tobacco products this product ID is known as a 'TP-ID'.</i>
The Tobacco Taxation Directive	COUNCIL DIRECTIVE 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco ¹³
UIs	Unique Identifiers
WHO	World Health Organisation

¹² The European Parliament and the Council of the European Union. (2014). Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 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 and repealing Directive 2001/37/EC. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014L0040&rid=6#d1e40-1-1>

¹³ The Council of the European Union. (2011). Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco. Available at: <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32011L0064>

1 Introduction

This is the Final Report of the Support Study commissioned by the European Commission Directorate-General for Health and Food Safety (DG SANTE) to provide a factual input to its report on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products.

1.1 Study aim

The study explores the Tobacco Products Directive (TPD) and its specific articles and provisions through two overarching objectives:

- **Assessing TPD implementation and levels of compliance:** exploring the achievements and successes of the Directive, as well as hindering factors and shortcomings encountered by various stakeholders (the European Commission, Member States, Civil Society Organisations (CSOs), Health Experts (HEs), economic operators and organisations representing consumers of tobacco and related product¹⁴s);
- **Generating general evidence** (through primary and secondary data collection): in particular on the inputs, outputs, outcomes and impacts of the TPD, with the aim to assess its overall relevance, effectiveness, efficiency, coherence and EU-added value.

1.2 Purpose of this report

The purpose of this report is to summarise the evidence collected against the Directive's main articles (Art. 2-24) and more broadly against the five-assessment criterion. This report includes:

- A summary of the methodological approach (section 2);
- Findings by TPD article (section 3) and five-assessment criterion (section 4);
- Conclusions framed against the evaluation criteria (section 5)

The first overarching objective is supported with an assessment of the implementation of specific articles and provisions. The second overarching objective has been achieved through an overall assessment of the TPD. The two assessments are distinguished as Tier 1 (implementation of specific articles and provisions) and Tier 2 (overall assessment of the Directive). See Annex 1 for the Tier 2 analytical framework. The two assessments are interlinked such that the evidence generated in the Tier 1 assessment has fed into the Tier 2 assessment.

This report is supported by a number of annexes:

- Annex 1 Analytical Frameworks
- Annex 2 Template used for document review
- Annex 3 Eurobarometer data analysis
- Annex 4 Euromonitor International data analysis
- Annex 5 Substantial change of circumstances
- Annex 6: EU-CEG notification information
- Annex 7: Economic operator survey respondent information
- Annex 8: Field Research – additional data analysis
- Annex 9: Case studies
- Annex 10: Mystery shopping task
- Annex 11 Market developments, public health and perception information of HTPs
- Annex 12: Bibliography used in this study.

¹⁴ Where relevant, organisations with possible links or financial support from the tobacco and related industries were distinguished

2 Methodology

This section summarises the methodological approach taken as part of this study.

2.1 Task 1: Inception

The main objectives of the inception task were to capture lessons from the documentation review and key informant interviews to inform the study design and to refine our suggested methodological approach. In the inception phase, the study team undertook the following activities: a kick-off meeting, rapid document review¹⁵, key informant scoping interviews with stakeholders at EU and international level (including EU institutions, industry and civil society), refining the study approach (including the analytical framework), and the inception report and meeting.

2.2 Task 2: Desk research

The desk research task focused on taking stock of all relevant documentation (EU studies, reports, research) and data (market share, consumption trends, sales) pertaining to the TPD and related issues, analysing them in view of our analytical framework, and informing subsequent study tools. The desk review did not include information or research funded by the tobacco industry.

This task consisted of four components, described below.

2.2.1 Legal assessment: complementing the conformity assessment and reviewing European Court of Justice (ECJ) case law

As part of this task, documentation was examined to explore whether there are any legal issues, either due to a lack of conformity or because one or more of the provisions of the Directive are being / have been legally challenged, which may also be affecting its implementation in practice.

2.2.2 Documentation review and analysis

A range of sources were relied upon to extract relevant information in the document review, including peer-reviewed literature, documentation from the EC, notably minutes of Group of Experts on Tobacco Policy and other official working groups, and position statements and evidence reports from stakeholder associations. Most of the literature used was identified through a 'snowball' search, based on the bibliography provided in the Terms of Reference, and documents provided by DG SANTE. Relevant documentation was also found through a variety of sources, including discussions with the Steering Committee; internal discussions with study experts; reference mining using bibliographies of highly relevant studies previously identified; targeted literature searches to fill gaps, and recommendations from the focus groups and stakeholder event participants.

After reading documents and extracting information for each appropriate assessment question, each document was rated in terms of its relevance to the questions at hand; see Table 1 for a summary of these ratings.

Table 1. Relevance of documents in document review

Relevance	Peer-reviewed literature	Grey literature	Total
High	8	22	30
Medium	13	29	42

¹⁵ Documents in the rapid document review included Implementation Documents, Meeting Minutes, Legislation, Implementation reports, Implementation Documents, Legal analysis, Reports, Information Sheets, and Conference proceedings.

Low	32	45	77
Total	53	96	149

Documents were analysed thematically, using a template based on the revised analytical framework including mapping to specific TPD articles and the overall evaluation criteria. See Annex 2 for the template used for extraction: each document was read, and relevant notes were recorded by assessment area and TPD articles, with most documents having notes related to more than one assessment area and more than one article. See Table 2 for a summary of how many documents were analysed by assessment area.

Table 2. Document analysis by assessment area

Assessment area	Peer-reviewed literature	Grey literature	Total
Effectiveness	46	87	133
Relevance	17	27	44
Efficiency	3	13	16
Coherence	6	9	15
EU added value	1	3	4

2.2.3 Data mapping and analysis

The study team carried out an analysis of data gathered through the Special Eurobarometer Surveys (2014, 2017 and 2020 waves) and Euromonitor International (2013-2019). The Eurobarometer data were used to examine prevalence of smoking overall and for those between 15-25 years of age by Member State. The 2020 wave includes several new questions on Heated Tobacco Products (HTPs) and herbal products and allowed for a more robust trend analysis of prevalence and frequency of smoking and use of tobacco related products. The indicators available from the Euromonitor International were mapped to our assessment objectives and the three specific types of analysis we undertook: market share, assessing consumer views and behaviours, and assessing substantial change in circumstances¹⁶. Eurobarometer and Euromonitor International data were used to answer the evaluation questions in Tier 1 and Tier 2; see Annexes 3 and 4 for detailed information on Eurobarometer and Euromonitor International data, respectively, and see Annex 5 for the substantial change of circumstances calculations.

DG SANTE also provided information on the number of notifications provided in the EU Common Entry Gateway (EU-CEG) (in accordance with Art. 5) disaggregated by Member State and product type as of January 2021 (see Annex 6 for detailed data). This information has been integrated into the relevant sections of Tier 1.

2.2.4 Verification workshop

A verification workshop was held on 10 December 2019 in Brussels, to set the scene and engage relevant stakeholders represented at EU level with the objectives and purpose of the assessment and to present preliminary findings emerging from the

¹⁶ The criteria used to assess a substantial change in circumstances were: (1) An increase of the sales volumes by product category by at least 10% in at least five Member States based on sales data transmitted in accordance with Article 5(6); and (2) The sales volume of the product category at retail level must exceed 2.5 % of total sales of tobacco products at Union level. Note that due to inconsistencies in the units used to measure retail volume across products, it was not possible to determine the second criteria for a substantial change of circumstances. See Section 5.2 for more information.

document review. Due to the differing aims and motivations of the stakeholder groups, the study team organised two separate sessions: one in the morning with representatives from CSOs and HEs, and an afternoon session with representatives from the tobacco industry. DG SANTE attended the workshops as an observer. The workshop was also used to start developing 'lines of enquiries' and findings to test during the field research and allowed the study team to understand where the current gaps in evidence lie.

2.2.5 Detailed methodology report

Following from the information gathered in Task 2, and building on the inception report, a detailed methodology report was produced and submitted on 09 April 2020.

2.3 Task 3: Field research

Task 3 focused on gathering additional data and insights from all relevant stakeholder groups, in view of adding to the evidence base of this study. As a result, a series of detailed consultations with various stakeholders relevant for the TPD took place, described below.

2.3.1 Stakeholder groups

There are five stakeholder groups which represent the complex landscape of the tobacco industry, and whom were the focus of this field research task:

- (1) **government regulators:** stakeholders with a deep involvement in implementing the TPD at either a national or European level (e.g. the WHO, Member State Competent Authorities).
- (2) **economic stakeholders:** these comprise of individuals within the tobacco industry that work across the supply chain including retailers, manufacturers, distributors, suppliers and importers of tobacco and related products.
- (3) **CSOs:** these are not for profit organisations, advocacy or policy groups who are expected to have reasonable knowledge of the TPD and its provisions. A clear distinction was made between the views of independent organisations and those with possible conflict of interest.
- (4) **HEs:** these include academics or scientists within the health sector with a focus on tobacco or related products. HEs are not expected to have in-depth knowledge of the TPD but a broader understanding of tobacco within the health sector.

(5) **Organisations representing consumers of tobacco and related products:** These are organisations who could provide information on the impact of the TPD on consumers. Where relevant, organisations with possible links or financial support from the tobacco and related industries were distinguished.

2.3.2 Stakeholder surveys

Three surveys were sent to 487 stakeholders from the following key stakeholder groups:

- Member States and the UK (henceforth Member States);
- Economic stakeholders;
- CSOs, HEs, and organisations representing consumers of tobacco and related products.

The surveys were conducted between 23rd April 2020 and 17th June 2020 with a response of 120 stakeholders (a response rate of 24%). The surveys provide in-depth information on the state of implementation across EU Member States, alongside perceptions of various stakeholders regarding the TPD objectives, provisions and any patterns or trends over time. The surveys were all based on the analytical frameworks but were targeted to assess concerns specific to each stakeholder group. The surveys to Member States and manufacturers and importers (a subcategory of economic

stakeholders) were accompanied by a cost-data template excel file with specific questions on costs and fees for implementation of the TPD.

Therefore, findings are available from:

- **an offline questionnaire sent to the 28 Member States;** 25 Member States (all except EL¹⁷, MT and RO) replied to the survey.
- **an online survey of 52 economic stakeholders** within the industry for tobacco and related products across the Member States. An offline article-specific survey was additionally sent to manufacturers and importers; see Annex 7 for information about offline respondents.
- **an online survey of 21 CSOs and 18 HEs** across the Member States. The same survey was sent to **four organisations representing consumers** of tobacco and related products, across the Member States and the UK¹⁸. Overall data for CSOs, HEs, and organisations representing consumers has been analysed in aggregate categorised as CSOs and HEs. However, comments and perspectives from these respondents are cited with a specification of if the respondent is a HE, CSOs, or organisation representing consumers.
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See Table 3 for a summary of responses to the stakeholder surveys.

Table 3. Stakeholder survey responses

Stakeholder group	Online survey responses	Offline (word document) responses	Offline (cost data) responses
Member States + UK	N/A	25	20
Economic operators	52	19	9
CSOs	21	N/A	N/A
HEs	18	N/A	N/A
Organisations representing consumers of tobacco and related products	4	N/A	N/A
Total	91	44	29

The Member State survey followed the format of asking a question, often with the response options of Yes / No / To some extent, and then asking for elaboration. In the present report, the Yes / No / To some extent responses are summarised semi-quantitatively through descriptive terms¹⁹, and this is followed by a discussion of the specific points discussed by Member States.

A similar approach was taken for the other stakeholder groups: responses to closed-ended questions are discussed quantitatively, and further points are summarised

¹⁷ Note Greece did contribute to the factual check exercise; see section 2.3.9 for further information.

¹⁸ Two of these organisations represent consumers of e-cigarettes, one represents businesses and professionals related to e-cigarettes, and the fourth advocates harm reduction in general, and many of their partners are e-cigarette bodies.

¹⁹ 25 Member State questionnaires were received, therefore the qualitative terms used correspond to the number of Member States which gave a certain response: 1: one; 2-5: a few; 6-7: around a quarter; 8-9: around a third; 10-11: nearly half; 12-13: around half; 14-15: over half; 16-17: around two thirds; 18-21: most; 22-24: nearly all; 25: all.

semi-quantitatively through descriptive terms²⁰. See Annex 8 for details and additional data analysis for the online surveys of economic operators and CSOs and HEs.

2.3.3 Stakeholder cost data templates

Cost data templates were sent to Member States along with the offline questionnaire, and to economic operators who indicated they were manufacturers and importers of tobacco and related products. Responses to the cost template were received by 20 Member States and eight economic operators. The figures were extracted from the template and aggregated into the following categories: Fees; EU CEG; Compliance costs; Enforcement costs. Where Full-time equivalents were stated, conversion into Euros was conducted using the average full-time-equivalent of each Member State obtained from Eurostat.

2.3.4 Targeted interviews

Semi-structured interviews to inform our evidence base and address gaps were undertaken in June and July 2020. A cross-section of individuals with knowledge and experience of tobacco and related products in Europe were invited to provide a range of views and insights. All stakeholders were identified from the stakeholder surveys, and covered the three main stakeholder groups (CSOs, HEs, and economic operators). Tailored topic guides were developed for each of the groups, based on the stakeholder surveys, and specific questions were asked to interview participants based on their responses to the surveys. In some cases, where responses to the surveys were very comprehensive, the stakeholders were given the option to clarify specific points by email instead of via an interview - this was the case for eight Member States.

A total of 60 stakeholders were contacted to take part in these interviews (27 Member States, 15 CSO and HEs, and 17 economic operators). However, not all stakeholders replied to this invitation. This report captures the responses and clarifications from:

- 12 CSO and HEs (three HEs; two organisations representing consumers; seven CSOs)
- 18 Member States (10 interviews and eight clarifying email exchanges)
- 13 economic operators within the industry for tobacco and related products across the Member States.

2.3.5 Case studies

We undertook four case studies to further support the assessment of the TPD implementation, with the following aims:

- Provide evidence to support the requirements set out in Art. 28 of the TPD regarding regulation of ingredients in terms of the **feasibility, benefits and possible impact of a European system for the regulation of the ingredients used in tobacco products**
- Help fill some of the knowledge gaps around the use of **flavours in electronic cigarettes (e-cigarettes)**, including which EU/EEA Member States have banned the use of flavours in e-cigarettes, and the challenges and impacts of doing so.
- Explore in more detail how Member States **monitor and enforce product compliance**, by conducting a high-level comparative analysis of Art. 23 and related articles (Art. 6, 7, 19 and 20).
- Identify lessons learned from the examples of early adopters of **plain packaging**. This case study is focused on three EU Member States (France, Ireland, and the UK) that have fully implemented plain packaging policies

²⁰ For economic operators, CSOs, HEs, and organisations representing consumers, the qualitative terms used are: 1: one; 2-5: a few; 5-15: several; 15 and higher: many.

over an extended time period as examples of ‘positive deviance’ to be able to draw lessons.

Information from the desk research and other field research tasks were re-considered specifically with the case studies’ aims in mind. Some additional research was also undertaken, for example assessing additional literature and sending clarification questions to key Member States. See Annex 9 for the detailed write-ups of the case studies.

2.3.6 Market surveillance/Mystery Shopping

The main purpose of this mystery shopping exercise was to understand if online retailers from different Member states comply with the provisions of Art. 18 of the TPD. The objective was to determine if there is an age-verification system in place and what form that system takes, when purchasing tobacco and e-cigarettes cross-border online. A set of retailers were selected from 11 Member States and a set of 46 scenarios developed in which the shopper was based in an EU country other than that of the retailer. See Annex 10 for the detailed methodology and results of the mystery shopping exercise.

2.3.7 Stakeholder gap-filling workshops

Two gap-filling stakeholder workshops were carried out in November 2020, one with CSOs and HEs and one with Member State National Competent Authority (NCA) representatives. These workshops sought to explore gaps in the evidence which had been collected up to that point, and also asked a few questions related to the case studies. Discussions occurred in breakout rooms with several study team members in each group, as well as full group discussions. At the end of the workshops two summary questions were asked using the website screen.io to allow everyone to contribute. DG SANTE attended the workshops as an observer.

2.3.8 Stakeholder validation of key findings workshops

Four stakeholder validation workshops took place in March 2021. The purpose of the workshops was to present the key findings of this study, and validate these findings with key stakeholders, ensuring no inaccuracies in the information presented nor pertinent outstanding issues remained.

The stakeholder lists from the previous consultation activities (verification workshop, surveys, and interviews) were reviewed, and one member was selected from most organisations. Due to restraints on participant numbers, not all individual organisations were invited, however all relevant sectors were represented. In addition, all umbrella organisations representing various stakeholders could invite up to two additional representatives. Information on each specific workshop is below:

- **Member States** (17 March): DG SANTE invited all Member State NCAs to attend the workshop, and the workshop was attended by **45 participants from 22 Member States** (BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, NL, PL, PT, RO, SE, SI, SK) and Norway, in addition to key study team members and observers from DG SANTE.
- **CSOs and HEs**: The initial workshop occurred on 17 March, and findings were presented, however there was not high participation in the discussion due to concerns over funding sources of some invitees. A subsequent workshop was organised for 25 March, and this session was open only to those previously invited to the initial workshop. The final list of participants was sent to all participants one day in advance of the meeting. Participants were instructed: *'Please confirm participation by replying to this email and please note that by accepting this invitation, participants in the workshop declare in good faith that neither they nor their respective organisations accept funding from tobacco (and related products) industry or otherwise represent it. According to Part I. Article 1 e/f of the Framework Convention'*

on Tobacco Control: ‘tobacco industry’ means tobacco manufacturers, wholesale distributors and importers of tobacco products.’ The second workshop was attended by **14 participants from seven organisations**, in addition to key study team members and observers from DG SANTE.

- **Economic operators** (18 March): The workshop was attended by **72 participants from 47 organisations**, in addition to key study team members and observers from DG SANTE and five CSOs.

Prior to the workshops, stakeholders were sent a short summary note containing the draft main findings for each of the five assessment areas (Effectiveness, Relevance, Efficiency, Coherence, and EU added value). In the workshops, study experts presented slides outlining these main findings and providing a few key examples, and for each assessment area this was followed by a discussion period for stakeholders to ask clarifying questions and provide feedback on the main issues.

2.3.9 Member States' factual check

In March 2021, DG SANTE conducted a factual check exercise focussing on interpretation of the information provided by Member States in their questionnaire responses submitted as part of this report. DG SANTE extracted information referring to the Member States response to the survey (and subsequent interviews) from Tier 1 of this report and emailed this file to all Member States. **12 Member States** replied with comments and corrections which were taken into account, when possible, while producing this report.

2.4 Tasks 4 and 5: Data analysis and synthesis of findings

The data and information gathered from the desk and field research tasks described above were analysed with the objective of answering the assessment questions presented in the analytical framework (Annex 1). A systematic evidence database was created, with each indicator from the analytical framework mapped to relevant data and information extracted from the identified data sources. An internal workshop was carried out with the core study team to review the consistency and complementarity of the evidence with respect to each indicator and identify key gaps or inconsistencies across the different data sources that may lead to limitations in the overall analysis and synthesis in Task 5. This exercise was repeated with the full study team and experts once the remaining field research tasks were completed.

The desk and field research gathered from Tasks 1-3 and the analysis in Task 4 has been triangulated to construct detailed, robust and traceable findings. The synthesis of findings is presented at two levels, to reflect the two levels of our analytical framework.

- Triangulated information related to each article of the TPD is presented in **Tier 1** (Section 3); this information is generally presented as information which relates to the whole article, followed by in-depth sub-article analysis.
- Information from Tier 1 has been aggregated and triangulated in order to answer the assessment questions for **Tier 2** (Section 4). Section 4 is presented for each of the evaluation questions included in the analytical framework.

2.5 Considerations for interpreting findings

Secondary data and reports were conducted by others, and therefore were not specifically designed to meet the objectives of the current study, and there are some gaps in our present assessment. The academic literature in particular does not provide a systematic in-depth exploration of the implementation of each article and provision of the TPD for each Member State.

Many of the items in the Member State survey asked a closed question, such as 'Has your Member State faced any issues in requiring manufacturers and importers to carry out the comprehensive studies required in Article 6(2)?', followed by closed-ended response options (e.g. 'Yes / No / To some extent'), followed by a prompt to elaborate. Some Member State responses seemed contradictory, for example answering 'No' to the first part, and then in the elaboration describing issues they faced. Within the other stakeholder survey responses, the study team noted that within the samples of Economic stakeholders and CSOs and HEs, there are many collective and 'shared' responses. That is, identical or near-identical open-ended responses to the survey questions. These groups of respondents may have shared responses amongst themselves and therefore their share of voice compared to the rest of the sample may be overrepresented.

A number of Economic stakeholders also chose not to answer all questions with a substantive proportion either selecting 'don't know' or 'prefer not to say'. Thus, views among economic operators are based on only a small number of responses and must therefore be interpreted with care.

Where relevant, views of independent CSOs, views of CSOs with possible links or financial support from the tobacco and related products industry, and views of organisations representing consumers were distinguished. Note that all hyperlinks provided in footnotes are accessible as of 17 May 2021, unless otherwise stated.

Table 4 presents the strengths and limitations of the study approach.

Table 4. Overview of the research tools and the strength of the evidence collected

Research tools	Description	Strength of the collected evidence
• Secondary data collection tools		
Literature and document review	<ul style="list-style-type: none"> • Peer-reviewed literature: 53 • Grey literature: 96 	<ul style="list-style-type: none"> • Strong quality: Most of the literature used was identified through a 'snowball' search, based on the bibliography provided in the Terms of Reference, and documents provided by DG SANTE. This evidence base was further expanded, based on internal discussions with study experts; suggestions from DG SANTE; reference mining using bibliographies of highly relevant studies previously identified; targeted literature searches to fill gaps, and recommendations from the focus groups and stakeholder event participants. • Limitations: The study team only read documents in English and for the most part which were available to access online. Documents produced by the tobacco industry were not included.
Data mapping and analysis	<ul style="list-style-type: none"> • Special Eurobarometer Surveys: 2014, 2017, and 2020 waves • Euromonitor International: 2013-2019 • EU-CEG notification numbers as of January 2021 	<ul style="list-style-type: none"> • Strong quality: Data on the market size of tobacco and related products in retail value and retail volume was provided by Euromonitor International for the years 2013-2019 for 25 EU Member States. Market size data was provided for the following products: cigarettes; cigars; cigarillos; smoking tobacco (pipe tobacco, fine cut tobacco); smokeless tobacco (chewing tobacco, moist snuff); e-cigarettes(open-vaping systems, closed vaping systems); heated tobacco products (HTPs: heated tobacco, tobacco heated devices). Prevalence data was provided for the following: cigarettes; e-vapour products; HTPs. Eurobarometer provided survey data on the prevalence of smoking for tobacco and related products, frequency of use of tobacco and related products, perceptions of harmful effects of e-cigarettes, and attitudes towards tobacco/e-cigarette control policies. EU-CEG information has come directly from DG SANTE and provides an accurate picture of the numbers and types of products being notified. • Limitations: No data was provided on the retail volume of e-cigarettes. Retail volume was also measured using different units for different

Research tools	Description	Strength of the collected evidence
		products, so it was not possible to aggregate the retail volume of the whole market for tobacco and related products.
	<ul style="list-style-type: none"> • Primary data collection tools 	
Stakeholder surveys and cost data templates	<ul style="list-style-type: none"> • Surveys and cost-data templates sent to 487 stakeholders from three key stakeholder groups. 	<ul style="list-style-type: none"> • Mixed quality: Three different surveys were designed and sent to the relevant stakeholders. The Member State Questionnaire (comprised of an offline questionnaire and cost-data template), The Industry Survey and Questionnaire (including an offline article-specific questionnaire and cost-data template for manufacturers and importers) was sent to economic operators, and The CSO and HEs Survey was sent to CSOs, HEs, and organisations representing consumers of tobacco and related products. We received 52 completed responses from the Industry survey (60% response rate), and 43 from the CSO and HEs survey (11% response rate). Where relevant, views of independent CSOs, views of CSOs with possible links or financial support from the tobacco and related products industry, and views of organisations representing consumers were distinguished. We received completed responses from 25 out of 28 Member States, an 89% response rate. • Limitations: In both the Industry and CSO and HEs Survey, we received some identical qualitative responses from respondents from different organisations which limited the scope of the views captured by the surveys. Only 20 Member States and 8 economic operators completed the cost data template.
Targeted interviews	<ul style="list-style-type: none"> • 60 semi-structured interviews with three key stakeholder groups 	<ul style="list-style-type: none"> • Mixed quality: These interviews followed up responses to the online and offline study surveys. Tailored topic guides were developed for each of the stakeholder groups, including a set of questions specific for each type of stakeholder. In addition each interviewee tailored specific questions depending on the responses received. The quality of responses differed across stakeholders and the interviews tried to address these gaps and differences. In some cases where the responses to the online or offline surveys were very complete, interviews were not undertaken and rather emails were sent for minor clarifications.

Research tools	Description	Strength of the collected evidence
		<ul style="list-style-type: none"> Limitations: Not all Member States replied to the invitation to participate in the interviews. This is probably because NCAs were invited during in the summer period (end June- July), a common time for work holidays. In both industry and CSO interviews the responses given were the same as the ones presented in the Survey which again limited the scope of the views captured.
Mystery shopping	<ul style="list-style-type: none"> Multiple researchers acted as shoppers using online retailers of tobacco products and E-cigarettes under a range of different scenarios. A set of retailers were selected from 11 Member States and a set of 46 scenarios developed in which the shopper was based in an EU country other than that of the retailer. 	<ul style="list-style-type: none"> Strong quality: We included 11 Member States which allow cross-border distance sales (CBDS) in this exercise. The exercises were stratified to ensure we covered different scenarios in terms of if a consumer behaved as if they were underage or of legal age, if the product purchased was tobacco or an e-cigarette, and if the product was actually purchased or not. Limitations: This exercise was only an initial exploration of the age verification systems in place. In most Member States, fewer than five exercises were conducted and therefore it does not give a comprehensive view of retailers in that Member State.
Stakeholder workshops	<ul style="list-style-type: none"> Four workshops held with stakeholders 	<ul style="list-style-type: none"> Verification workshops: Mixed quality - Two types of stakeholders were invited to share their views on the overall assessment of the TPD implementation. Given the high-level exchange of views, important insights were gained which allowed for the study team to further explore areas of enquiry, however not all views were supported by evidence and may be biased. Gap-filling workshops: Strong quality - Allowing participants to contribute in smaller group breakout rooms gave all participants an opportunity to share their views, and then discussions in the wider group allowed views to be summarised. Further, asking questions to all participants in written format allowed all participants to input simultaneously. As above, not all views were supported by evidence and may be biased. Validation of key findings workshop: Mixed quality – there was a high-level exchange of views, however some participants did not provide

Research tools	Description	Strength of the collected evidence
		any information, citing a lack of sufficient information which they could validate.

3 Assessment of Implementation of Specific Articles and Provisions

The information used for this section of the report comprises:

- Primary data (field research)
 - Survey of Member States
 - Survey of economic operators
 - Survey of CSOs, HEs, and organisations representing consumers of tobacco and related products
 - Cost data (provided by Member States and Economic operators and which quantify the various costs associated with the implementation of the TPD)
 - Targeted interviews with Member States
 - Targeted interviews with CSOs, HEs, and organisations representing consumers
 - Targeted interviews with economic operators
 - Market surveillance / mystery shopping task
 - Stakeholder gap-filling and validation workshops
 - Member States' factual check
- Secondary data
 - Legal assessment
 - Documentation review and analysis
 - Data mapping and analysis: Special Eurobarometer Surveys (2014, 2017 and 2020 waves); Euromonitor International market data (2013-2019); information on the number of notifications provided in the EU-CEG
 - Verification workshop

The findings in this section are structured with articles grouped together by subject matter. Article-specific sections consider relevant sub-articles of the TPD.

3.1 Definitions

Art. 2 - Definitions

Main findings: A number of issues were identified with the definitions in this article, including some divergent interpretations and implementation across the Member States.

Overall, several definitions have not coped well with market developments. For example, there are a number of issues with the definitions of e-cigarettes. Furthermore, new products have appeared on the market which are difficult to categorise (e.g. uncertain how HTPs should be classified). There is also ambiguity concerning which products may fall out of the scope of the Directive (e.g. devices for HTPs, some nicotine products not containing tobacco, etc.), to which stakeholders still consider requiring an EU harmonised approach regulation. In addition, there is a need for new or revised definitions, including of terms and concepts used in the Directive, for example 'combustion', as these terms risk being interpreted differently across the Member States. Member States called for a definition of HTP, and also requested that devices for HTPs should be clearly defined and regulated.

Secondly, in a few cases the problems do not appear to be related to the definitions themselves but rather how these should be applied in practice, as sometimes the products defined are very similar to each other. This can be for example seen in the difficulties in making a distinction between chewing tobacco / tobacco for oral use, given their similar presentations, which may lead industry to put oral tobacco products in the market labelled as chewing tobacco.

Thirdly, several existing definitions lack clarity or are ambiguous, which has led to different national interpretations in practice, potentially hampering the internal market functioning. There would be scope in further elaborating these to ensure a more consistent interpretation.

3.1.1 Findings per definition

Art. 2(1 and 4) Tobacco and tobacco products

(1) 'tobacco' means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;

(4) 'tobacco products' means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;

Overall, no implementation issues were encountered with the above two definitions. However, one Member State found '**processed parts of a tobacco plant**' unclear, in particular as to whether it meant that nicotine should be considered as a tobacco substance derived from a tobacco plant. The national legislator deemed that this could have an effect on the classification of nicotine products not containing tobacco, as products using nicotine derived from a tobacco plant could then be considered as tobacco, however, the Member State does not regulate products with only nicotine as tobacco products.

Art. 2(5) Smokeless tobacco product

(5) 'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;

Around a quarter of Member States faced challenges with the definition of **smokeless tobacco products** used to classify tobacco products, and in particular with the term 'combustion' in this definition, which is not further defined in the Directive. A few Member States indicated that it was not possible to determine whether smoke was

only produced by heating or whether the heating also involved some degree of combustion. One Member State proposed a different criterion, namely heating (above body temperature) or by type of consumption (inhalation of an aerosol / migration via mucous membranes). A few more Member States suggested that the definition of smokeless should focus on the absence of inhalable emissions.

Art. 2(6 and 8) Chewing tobacco and tobacco for oral use

(6) 'chewing tobacco' means a smokeless tobacco product exclusively intended for the purpose of chewing;

(8) 'tobacco for oral use' means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets;

Nine Member States reportedly faced issues with the definition of **tobacco for oral use**, mostly due to technical difficulties in differentiating it from **chewing tobacco** as a result of its similar presentation (around a third of Member States) which led to enforcement challenges. A few Member States highlighted that producers had circumvented the rules and commercialised tobacco for oral use products as chewing tobacco. This was also observed by CSO stakeholders in a few Member States. For example, in a few Member States products very similar to tobacco for oral use (snus) were presented on the packaging as chewing tobacco. For this reason, a few Member States have additionally prohibited chewing and / or nasal tobacco products in their national laws. A few Member States mentioned there was a lack of technical criteria to differentiate both type of products and one Member State specified there was no recommended laboratory method to determine the type of product. Others were investigating a laboratory method to differentiate the products. To address this situation, a few CSO stakeholders, a few HEs, and Member States called for a reassessment of the definitions of chewing tobacco and tobacco for oral use to prevent these circumvention efforts.

The ECJ ruled in October 2018 that it was for the national courts to determine, on a case-by-case basis taking into account all relevant objective characteristics of the products (including composition, consistency, method of dispensation and actual use where appropriate), whether a product fits under the definition of 'chewing tobacco' or 'tobacco for oral use' as defined in the TPD. It added that when tobacco products could be consumed in the 'proper sense' only by chewing, they should be considered 'chewing tobacco' rather than 'tobacco for oral use', and that the latter did not include tobacco products intended to be chewed- a concept that should be interpreted strictly²¹.

At a 2018 meeting of the DG SANTE Group of Experts on Tobacco Policy, Member States had indeed highlighted that inconsistent approaches to these products could be problematic, with one Member State suggesting that 'chewing tobacco products' may

²¹ JUDGMENT OF THE COURT (Sixth Chamber) 17 October 2011; (Reference for a preliminary ruling — Approximation of laws — Manufacture, presentation and sale of tobacco products — Directive 2014/40/EU — Ban on placing tobacco for oral use on the market — Definitions of 'chewing tobacco' and 'tobacco for oral use' — Paste composed of finely ground tobacco (Thunder Chewing Tobacco) and porous cellulose sachet portions filled with finely ground tobacco (Thunder Frosted Chewing Bags)). Available at: <https://curia.europa.eu/juris/document/document.jsf;jsessionid=74EF209FE5ABC59A506C0EB5B6865AD3?text=&docid=206857&pageIndex=0&doLang=en&mode=lst&dir=&occ=first&part=1&cid=1537740>

be considered as a food item and therefore could to a certain extent be regulated as such under food legislation rather than tobacco legislation²².

Art. 2(11 and 12) Cigar and cigarillo

(11) 'cigar' means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 4(1) of Directive 2011/64/EU²³;

(12) 'cigarillo' means a small type of cigar and is further defined in Article 8(1) Council Directive 2007/74/EC (2)²⁴

Overall, few implementation issues were encountered with the definitions of cigar and cigarillo, although a few Member States noted that economic operators had sought to commercialise products as such those which in reality should fall under cigarettes or roll-your-own tobacco, to circumvent the stricter rules applying to cigarettes and roll-your-own tobacco. For example, at the time of the Member State questionnaire, Belgium provided the image below illustrating products commercialised as cigars or cigarillos, which in fact are intended to be used as roll-your-own tobacco. At the time of the questionnaire, the case was under investigation.

Figure 1. Example of product commercialised as cigar and cigarillos that may fall under roll-your-own tobacco (image provided by Belgium)



Another Member State further considered that part of the definition of cigar as set out in Art.4(1) of Directive 2011/64/EU was vague, as it includes a reference to the 'regular colour of cigar'.

Art. 2(14) 'novel tobacco product' means a tobacco product which:

(a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and

(b) is placed on the market after 19 May 2014;

The definition of novel tobacco products gave rise to several practical implementation issues in the Member States. Nearly half of Member States experienced difficulties with the definition, with five noting that the definition did not account for market and technological developments. A few others faced challenges with the classification of HTPs and their differentiation from other novel tobacco products. Seven Member States reported there was a need to clarify definitions and harmonisation across

²² DG SANTE (2018) 11th Meeting of the group of experts on Tobacco policy: 15 March 2018. Available at:

https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_201803152_sr_en.pdf

²³ Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco (OJ L 176, 5.7.2011, p. 24).

²⁴ Council Directive 2007/74/EC of 20 December 2007 on the exemption from value added tax and excise duty of goods imported by persons travelling from third countries (OJ L 346, 29.12.2007, p. 6).

Member States. One Member State recommended that classification as a 'novel tobacco product' should be transitory for an initial period of time (such as six months or one year), after which the product should be categorised as something else.

However, the main points raised by the Member States did not focus on the definition itself, but rather on the fact that the definition, and thus the scope of the TPD, does not cover a wide range of products, such as nicotine pouches, which had been appearing on the market since the entry into force of the TPD. Further, a few Member States requested that devices for HTPs should be clearly defined and regulated. This is further elaborated under the general observations and in the analysis of Art. 19 below.

Art. 2(15) Herbal product for smoking

(15) 'herbal product for smoking' means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process;

Few implementation issues were encountered. In one Member State, the definition transposed in their national law was modified by adding the criterion of 'possible use by inhalation through the mouth or nose'. A few other Member States found the definition to lack clarity and argued that through Art.2(15), the TPD should explicitly exclude cannabis and hemp that exceeded 0.2% of THC connected to the relevant regulation²⁵. These are further discussed in Art. 21-22 on Herbal products for smoking section below.

Art. 2(16) Electronic cigarette (e-cigarette)

(16) 'electronic cigarette' means a product that can be used for consumption of nicotine-containing vapour via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. E-cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges;

Art. 2(17) Refill Container

(17) 'refill container' means a receptacle that contains a nicotine-containing liquid, which can be used to refill an e-cigarette;

Around half of the Member States faced some challenges with the definitions of **e-cigarettes**, such as with components of e-cigarettes. For example, one Member State decided for the implementation not to consider certain parts as components of e-cigarettes (including plastic mouthpieces, resistive wires, and standard batteries) after several discussions with economic operators. Another Member State mentioned that the definition could be more explicit when the battery forms an integral part of the e-cigarette, as opposed to the rechargeable battery.

A few Member States encountered some issues with the definition of refill container, but these mostly related to its coverage. For example, five Member States mentioned that the definition did not include non-nicotine liquids, and therefore a few argued for their inclusion in the TPD scope. Two Member States mentioned that in their national legislation, the definition had been expanded to also cover non-nicotine liquids.

Art. 2(19) Nicotine

(19) 'nicotine' means nicotinic alkaloids;

Around a quarter of Member States faced challenges with the classification of **nicotine salts** in this definition. For example, a few Member States reported that manufacturers tried to exempt nicotine salts from the requirements of the TPD, based

²⁵ Covered by Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009

on the definition of nicotine. Member States called for a further clarification of the definition, to make it explicit that the latter, for example, includes nicotine salts or liquids, or what forms does not include if any.

Art. 2(24 and 25) Flavouring and characterising flavours

(24) 'flavouring' means an additive that imparts smell and/or taste;

(25) 'characterising flavour' means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;

A few Member States²⁶ considered that the definition of **flavouring** lacked clarity. One Member State found it for example difficult to determine how the concept of 'characterising flavour' was linked to permitted use of 'flavourings'.

Art. 2(28) Substantial change of circumstances

'substantial change of circumstances' means an increase of the sales volumes by product category by at least 10 % in at least five Member States based on sales data transmitted in accordance with Article 5(6) or an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies; in any case, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2,5 % of total sales of tobacco products at Union level;

No implementation issues were identified in relation to this definition. One Member State mentioned that the definition for 'substantial change of circumstances' should be a standalone article, as it contains several norms/standards rather than merely defining the concept. Annex 5 of this report explores substantial change of circumstances for tobacco and related products in the EU using Euromonitor International and Eurobarometer data to calculate the above criteria.

Art. 2(29 and 30) Outside packaging and unit packet

(29) 'outside packaging' means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;

(30) 'unit packet' means the smallest individual packaging of a tobacco or related product that is placed on the market;

Some difficulties were encountered with the implementation of this definition. One Member State, for example, encountered issues with the definition of '**outside packaging**' and '**unit packet**' in products like cigars, herbal products and in refill containers. The approach taken by economic operators differs, mostly in terms of the dimensions of the unit package and the health warnings in the contained parts e.g. plastic bag, tubes. A few Member States mentioned that it was unclear if the unit package of the refill containers containing nicotine concerned the bottle or the package surrounding the bottle. One Member State faced challenges with differing interpretations of unit packet and outside packaging by the e-liquid industry. Moreover, a few Member States recommended that if the refill container were to be considered the unit packet, this should be made clear in the 'refill container' definition.

At a DG SANTE Group of Experts on Tobacco Policy meeting in 2019, for example, one Member State raised concerns relating to Art. 2(30) and the labelling of '**unit packets**' for e-cigarette liquids, despite noted previous discussions of this topic by the

²⁶ Eight Member States identified issues with these definitions.

group, suggesting that clarity of this definition remained an issue in relation to e-cigarettes²⁷.

Art. 2(34) Cross-border distance sale (CBDS)

'cross-border distance sales' means distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in a Member State other than the Member State or the third country where that retail outlet is established; a retail outlet is deemed to be established in a Member State:

(a) in the case of a natural person: if he or she has his or her place of business in that Member State;

(b) in other cases: if the retail outlet has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that Member State;

A few implementation issues were encountered in relation to how CBDS were defined. One Member State suggested that the definition should also include cross-border distance purchases, as they want to also penalise the consumer (buyer). A few Member States asked for clarification on the types of transactions that were legal; for example, between distributors and producers or between producers and consumers. A few more Member States also asked for a more detailed description of the computing system for age verification which unambiguously confirms a consumer's age. The latter is discussed more in detail as part of the analysis of Art. 18 and in Annex 10.

Art. 2(40) Placing on the market

'placing on the market' means to make products, irrespective of their place of manufacture, available to consumers located in the Union, with or without payment, including by means of distance sale; in the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located

A few Member States experienced some difficulties with the definition of 'placing on the market', for example determining to what extent a product found during a warehouse inspection must be considered to be put on the market. There were also issues experienced with the coherence of this definition with other legislations; see Section 0 on Coherence for further information.

3.1.2 General observations on the definitions

Scope of the TPD

A high share of the comments made on the definitions of Art. 2 by Member States, CSOs and HEs concerned the fact that certain elements were not included in the scope of the TPD, and thus not regulated at the EU level. They expressed concerns that their present exclusion could have harmful effects on public health and potentially distort the internal market. One Member State, for example, pointed to new products emerging in the market, such as products without tobacco but with nicotine. They also considered that other products already on the market should be addressed, like waterpipe steam stones and nicotine lozenges. Around a third of Member States commented that the definition should clearly cover devices for the consumption of novel (heated) tobacco products. Some Member States, in the meantime, have adapted their national legislation.

This issue was also discussed at a DG SANTE Group of Experts on Tobacco Policy meeting in 2019, seven Member States indicated products without tobacco but with nicotine were becoming available in their jurisdiction²⁸. DG SANTE acknowledged that

²⁷ DG SANTE. (2019). Meeting of the group of experts on tobacco policy: 21 March 2019.

²⁸ DG SANTE. (2019). Meeting of the group of experts on tobacco policy: 21 March 2019.

these were outside the remit of the TPD given the Art. 2(4) definition clearly specifies that 'tobacco products' must contain tobacco. The potential applicability of other sectoral legislations was discussed, including on human medicines.

In the questionnaires Member States listed for example products containing nicotine, such as nicotine pouches not containing tobacco (identified in at least five²⁹ Member States), products for oral use not containing tobacco but nicotine salts (at least six Member States) and herbal snus with nicotine but without tobacco (at least two Member States). Eight Member States suggested to create a specific definition for nicotine products not containing tobacco to bring these products under the scope of the TPD. Indeed, the European Commission's original proposal for the TPD included a specific article (Art. 18 Nicotine-containing products) which later, following negotiations in the European Parliament and the Council was changed to Art. 20 on e-cigarettes.

Different herbal products not for smoking were identified by several stakeholders too as an element which was currently not regulated in the TPD. In Sweden, where tobacco for oral use products are permitted, 'herbal products for oral use' are now more common than herbal products for smoking as reported by the Member State. A few Member States called for a definition of heated herbal products, products based on plants, herbs or fruit not involving a combustion process.

One CSO suggested that market developments in the heated tobacco industry require HTPs and e-cigarettes to fall under the same treatment as conventional cigarettes, and therefore proposed a revision of the definition of conventional cigarettes to include them³⁰. Around a third of Member States called for a definition of HTP. Linked to this, a few Member States requested that devices for HTPs should be defined and regulated. A few Member States asked for a general definition of devices used for smoking or vaping.

Consistency of implementation

Stakeholder consultation overall showed disagreement with the implementation of Art. 2 being inconsistent across Member States. On the one hand Member States, CSOs and HEs highlighted that inconsistencies were in part the result of divergent interpretations of the definitions provided in this Article. On the other hand, economic stakeholders highlighted that Art. 2 provisions were implemented more consistently across MS than other articles of the Directive.

Clarity of definitions

Two Member States indicated to have faced **issues with the clarity of the definitions in the TPD**, while 14 of the Member States faced issues to some extent. Seven Member States reported to not have experienced any particular difficulties. The most reported issues related to the definitions of: 'chewing tobacco' (Art.2(6)), 'tobacco for oral use' (Art.2(8)), 'novel tobacco products' (Art.2(14)), 'electronic cigarettes' (Art.2(16)), 'nicotine' (Art.2(19)) and 'flavouring' (Art.2(24)), as also discussed above in the assessment of each definition.

Relevance of the definitions

Over half of the Member States found that the definitions as laid out in the TPD had only remained **relevant** to some extent (12 Member States) or were no longer relevant (four Member States) **in view of scientific, technological and market developments**. A minority (five Member States) agreed that the definitions had

²⁹ Note that since this meeting, another Member State has clarified they have also identified such products.

³⁰ ENSP. (2018). ENSP Fact Sheet: On heated tobacco products.

remained relevant. Among the opinion of several CSOs and a few HE stakeholders there was also a strong need to update definitions in the TPD.

On the contrary, economic stakeholders had a (mostly) positive view on the relevance of the TPD definitions in relation to scientific, technological and market developments. Economic stakeholders may not be interested in the TPD to be updated to market developments. Over half of the economic stakeholders reported that the TPD definitions remained relevant in view of scientific, technological and market developments (35%) or relevant to some extent (36%).

Almost half (19/42) of the CSO, HEs and organisations representing consumers of tobacco and related products surveyed in this study found that the definitions in Art.2 have not remained relevant to address current developments in the tobacco and related industries. A majority of CSO did not find the definitions relevant, this was the opposite situation for HEs, two thirds (8/12) found the definitions relevant.

Organisations representing consumers of tobacco and related products were divided in their response (2 vs. 3)

The main definitions identified were, as also discussed in the specific assessment of each definition above, 'novel tobacco products', which was considered to require updating 'e-cigarettes', which required a redefinition of various elements (including the different types, designs, parts and accessories of e-cigarettes, as well as to clearly specify the number of refill containers permitted per device). Each of these issues was mentioned by a few Member States.

Need for new / adapted definitions

Definitions used in the TPD were a key area identified by all stakeholders as not having kept pace with market developments. The TPD definitions for tobacco and related products reflected the market at the time the TPD was adopted in 2014. Since then, several new products have been introduced but the TPD definitions lack the flexibility to cover these new developments (reported by a few Member States). Most Member States reported that the **Directive should include definitions for other products or categories**.

Member States also called for new definitions to be included for terms already used in the Directive. One Member State called for a revision of the term '**cigarette**' to also include herbal products. According to the authorities 'this makes some problems to regulate some products'. In the TPD, it is forbidden to sell unit packets of cigarettes that contain less than 20 cigarettes. Cigarettes are defined as 'rolls of tobacco'. Therefore, since herbal products presented as cigarettes do not contain tobacco, the sale of packages of less than 20 units is not restricted by the TPD. This is a challenge because herbal products become cheaper and more available to young people.

New definitions and revision of definitions already included in the Directive

- **Device** should be clearly defined (reported by five Member States). In one Member State, it is defined as 'any device or component of this device, necessary for the consumption and/or use of a novel tobacco product'
- **Combustion** should be further defined to distinguish it from heating or replaced by another term to differentiate smokeless from smoking.
-

3.2 Ingredients and Emissions

Art.3 Maximum emission levels for tar, nicotine, carbon monoxide (TNCO) and other substances & Art.4 Measurement methods

Main findings: There were no significant implementation issues with Art. 3, and the maximum levels themselves for TNCO were uncontroversial. However, there were some concerns about the currently used *methods* for measurement of TNCO, including the ability of the method to adequately reflect partial coverage of ventilation by a smoker and the independence of the method from the industry. Some stakeholders recommended the European Commission to consider alternative methods for measurement, such as the Canadian Intense (CI) method.

One Member State has made use of the TPD provisions allowing additional measurements, and mandates using International Organization for Standardization (ISO) standards to measure TNCO levels in roll-your-own tobacco. Aside from this, there are no detected cases of Member States mandating additional thresholds or methods. Some Member States have carried out testing for demonstration or experimental purposes: e.g. one Member State has tested cigarettes using the CI method and detected higher TNCO levels, and several Member States have piloted testing of the HTP emissions.

In practice, Member States may not fully apply the provisions on the laboratories required by Art.4, as they lack expertise and resources to have in place approved laboratories which are independent from industry. This means that Member States are not always able to conduct testing within their Member State and have to rely on laboratories in other Member States. Further, as in the 2014 TPD Member States are no longer allowed to approve laboratories owned or controlled by the tobacco industry (which was still legally possible in the 2001 Directive), this has the unintended effect that Member States can no longer monitor directly how industry laboratories test and measure their products.

Overview

Art. 3 Maximum emission levels for TNCO and other substances

Art. 3 (1) set the emission levels from cigarettes placed on the market or manufactured in the Member States ('maximum emission levels'), which shall not be greater than:

- (a) 10 mg of tar per cigarette;
- (b) 1 mg of nicotine per cigarette;
- (c) 10 mg of carbon monoxide per cigarette.

It also foresees (2) that the European Commission can adopt delegated acts in accordance with Art.27 to decrease these maximum emission levels, where necessary, based on internationally agreed standards.

(3) Member States should notify the European Commission of any maximum emission levels they set for cigarettes other than the emissions in paragraph 1, and for emissions from tobacco products other than cigarettes.

(4) The European Commission should adopt delegated acts (in accordance with Art.27) to integrate standards agreed by the parties to the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC) or by the

WHO relating to maximum emission for cigarettes and other tobacco products (if different from paragraph 1) into Union law.

Art. 4 Measurement methods

Art. 4 set the measurement methods (1) for TNCO emissions from cigarettes, which should be measured on the basis of

- *ISO standard 4387 for tar*
- *ISO standard 10315 for nicotine*
- *and ISO standard 8454 for carbon monoxide.*

The accuracy of the measurements should be determined in accordance with ISO standard 8243.

(2) The measurements should be verified by laboratories which are approved and monitored by the competent authorities of the Member States. Those laboratories should not be owned or controlled directly or indirectly by the tobacco industry.

Member States should communicate to the European Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied. They should update the list whenever any change is made. The European Commission should make those lists publicly available.

(3) The European Commission can adopt delegated acts (in accordance with Art.27) to adapt the methods of measurement, where necessary, based on scientific and technical developments or internationally agreed standards.

(4) Member States should notify the European Commission of any measurement methods used for emissions from cigarettes other than the emissions described in paragraph 3 and for emissions from tobacco products other than cigarettes.

(5) The European Commission can adopt delegated acts to integrate standards agreed by the parties to the FCTC or by the WHO for measurement methods into Union law.

(6) Member States may charge manufacturers and importers of tobacco products proportionate fees for the verification of the measurements referred to in paragraph 1 of this article.

3.2.1 General observations

Art.3 and 4 together set out maximum emission levels, as well as how these should be measured. For this reason, they are assessed together. In terms of general feedback, CSOs and HEs were asked in the online survey about clarity of transposition requirements, compliance, and relevance of the articles of interest. For Art.3 and 4, 47% of CSOs and HEs agreed that the provisions were **clear regarding the transposition requirements**.

Around a third (35%) of CSOs and HEs reported that they were **not aware of any non-compliant products** on the market related to these articles; 14% said they were aware of such non-compliant products and 42% said they did not know³¹.

CSOs and HEs were split about the **relevance of these provisions**: 40% responded that the provisions had remained relevant, while 44% responded that they had not remained relevant. Several CSOs expressed that **the current maximum emissions levels and measurement methods for TNCO needed to be reassessed or**

³¹ These responses were provided as part of a close-ended question; any further information about non-compliant products has been included in discussions of the relevant articles.

updated, prioritising research to investigate the public health effects of the measurement methods to minimise potential unintended consequences such as methods producing misleadingly low measurements of compounds. Detailed information about the relevance of these provisions is provided in the article-specific discussions below.

Economic operators reported that Art. 3 and 4 were implemented **consistently across Member States**. See Annex 8 for further information.

3.2.2 Findings by article

Art. 3(1) Maximum emissions for cigarettes & Art.4(1) ISO standards

Art.3(1) sets maximum TNCO emission levels for cigarettes placed on the market or manufactured in Member States. These emission levels are currently measured in yields per cigarette based on the ISO testing regimen. Ten Member States reported that the **provisions on maximum TNCO emissions were relevant in view of scientific and technological developments**. Ten other Member States stated that they were relevant to some extent, and two Member States stated that they were not relevant.

When asked about the maximum levels themselves, a few Member States considered that the **maximum levels of emissions could be reconsidered**. One Member State, for example, suggested that a better way to set maximum emission levels for TNCO and other toxicants would be by 'mandated lowering', whereby limits are set for certain smoke constituents expressed **per mg nicotine** rather than per cigarette. Several years ago, this was proposed by the WHO Study Group on Tobacco Product Regulation (TobReg)³², and a WHO report from 2019 recommended several toxicants for mandated lowering³³. Aside from this, Member States did not appear to disagree with the maximum emission levels themselves.

Roughly half of the Member States found that the provisions on measurement methods were **relevant only to a certain extent** (nine Member States) or no longer relevant (four Member States), in view of scientific and technological developments³⁴. Relatedly, ten Member States reported that there would be **scope for changing the measurement methods for emissions from the ISO method**³⁵. Also some CSO stakeholders expressed **dissatisfaction with the ISO standards** specified in Art.4(1).

The main points raised by stakeholders were concerns about the independence of the ISO method from the industry and concerns about the validity of the current smoking machine regime. Further information is given below. Note that the phrasing of the question asked Member States to give an example of a change which could be made: 'e.g. the Canadian Intense (CI) method', which is another way of measuring TNCO, however not all responses given by Member States were necessarily about the CI method.

³² Burns, D.M., Dybing, E., Gray, N., et al. (2008). Mandated lowering of toxicants in cigarette smoke: a description of the World Health Organization TobReg proposal, *Tobacco Control*: 17, 132-141.

³³ World Health Organisation. (2019). WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: seventh report of a WHO study group. Geneva: World Health Organization; Licence: CC BY-NC-SA 3.0 IGO. See p.111.

³⁴ Nine other Member States stated that provisions on measurement methods were still relevant.

³⁵ Three reported that this would be necessary to some extent, and seven stated there would not be scope for such a change.

- According to the WHO, 'The **industry exerts considerable influence on the adopted ISO testing methods** for tobacco and tobacco products, as they make up by far the largest percentage of national and international technical committees.'³⁶ This has led the WHO to form the WHO Tobacco Laboratory Network (TobLabNet), which is an alternative global network of independent laboratories seeking to develop the methods for testing these products. The influence of the industry on the ISO standard for measuring TNCO was seen by a few Member States as potentially in conflict with Art.5(3) of the FCTC³⁷, which states that Parties shall act to protect public health policies related to tobacco control from 'commercial and other vested interests of the tobacco industry'. A few Member States reported that this industry involvement was questionable or inappropriate, and a few others considered that measurement methods which are developed independently from the industry should be used instead. A request for a preliminary ruling from the Rechtbank Rotterdam (NL) was lodged on 24 March 2020 with the ECJ³⁸. This case questions the **independence and transparency of the ISO method** in Art. 4(1), and questions if it is aligned with Art. 297(1) TFEU (and Regulation (EU) No 216/2013) and with the underlying principle of transparency.
- Six Member States and a few CSOs considered that the ISO-mandated method did not **mimic the behaviour of a smoker**, thus, there were issues with the process itself. The ISO method does not require covering filter ventilation holes, which may lead to underestimates of emissions; this is also questioned in the Rechtbank Rotterdam case³⁹. The CI method uses the **same machines** and auxiliary processes as the ISO method, but the most-discussed difference between the methods was that the CI method covers the **ventilation holes in the filter** (as smokers do with their fingers), and has a more intense protocol for puffing, and is therefore seen by a few Member States as producing results which are **more accurate measurements of emissions**. According to the WHO, the tobacco industry uses ventilation holes in cigarettes intentionally as they are aware that testing these products using the ISO method will lead to underestimates of TNCO levels⁴⁰.

³⁶ World Health Organisation. (2020). Information sheet on WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products. Available at: <https://apps.who.int/iris/rest/bitstreams/1272036/retrieve>

³⁷ World Health Organisation Framework Convention on Tobacco Control. (2003). WHO Framework Convention of Tobacco Control. WHO. Available at:

<https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf?sequence=1>

³⁸ Official Journal of the European Union. (2020). Request for a preliminary ruling from the Rechtbank Rotterdam (Netherlands) lodged on 24 March 2020 — Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport (Case C-160/20). Available at:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=228155&pageIndex=0&document=EN&mode=lst&dir=&occ=first&part=1&cid=5311122>

³⁹ Official Journal of the European Union. (2020). Request for a preliminary ruling from the Rechtbank Rotterdam (Netherlands) lodged on 24 March 2020 — Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport (Case C-160/20). Available at:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=228155&pageIndex=0&document=EN&mode=lst&dir=&occ=first&part=1&cid=5311122>

⁴⁰ World Health Organisation. (2020). Information sheet on WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products. Available at: <https://apps.who.int/iris/rest/bitstreams/1272036/retrieve>

- The WHO's TobLabNet and TobReg have both validated the CI method for generating emissions from cigarettes⁴¹. Also, ISO has adopted the CI method as ISO 20778:2018⁴². In an article from the Dutch National Institute for Public Health and the Environment⁴³, the CI method is described as 'more realistic', in particular for low-tar cigarettes. The Netherlands compared the CI and ISO methods and reported a **systematic difference in measured emissions**: TNCO levels were at least twice as high when measured with the CI method⁴⁴. Note that although the Netherlands conducted this test for demonstration purposes, they still use the ISO method for regulation and have not switched to the CI method. No other Member States reported using methods for emissions for cigarettes other than the three specified in Art.4(1).
- CSOs reflected on these growing worries in Member States about the ISO method, and a few expressed concerns that if Member States started **diverging their methods, there would be disharmony**.
- Some Member States were in support of the currently used ISO methods. For example, one Member State noted that no other method was shown to be better than the current one, whilst acknowledging the general drawbacks of the machine smoking regime. Another found that the assumption about covering the filter holes was incorrect, and it would be useless to change systems. A few CSOs also recommended some caution, as the CI method, and indeed any machine measurement method, would not perfectly mimic a smoker. A few Member States and some CSOs considered that **further scientific investigation** was needed to firmly support a move to a different measurement method. For example, a few CSOs recommended further research about filter ventilation in general.
- A few CSOs questioned the value of a more accurate measurement method for **public health**, as any tobacco use remains dangerous.

In summary, most Member States seemed to find the limits themselves to be satisfactory, but there were some concerns, including from CSOs, about the independence and transparency of using the ISO methods for measurement. Some stakeholders (including a few Member States) recommended considering alternative methods.

Other maximum levels and measurement methods (Art. 3.3 and Art. 4.4)

None of the Member States had **set limits for additional maximum emission levels for cigarettes** in line with Art.3(3). Nearly half of Member States clarified that they were not considering setting these additional limits. Reasons given for not setting additional limits included a lack of scientific rationale or expertise. One Member State aims to end the use of tobacco and related products, therefore regulating maximum emission levels was considered as more of a harm reduction policy than an endgame policy. Similarly, another considered that there were no 'safe' levels of these emissions. A few Member States reported that if additional maximum emissions levels were to be set, this would be most effective at the **EU level** for harmonisation purposes.

⁴¹ World Health Organisation. (2020). Information sheet on WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products. Available at: <https://apps.who.int/iris/rest/bitstreams/1272036/retrieve>

⁴² <https://www.iso.org/standard/69065.html>

⁴³ <https://www.rivm.nl/en/news/rivm-measures-much-higher-levels-of-tar-nicotine-and-carbon-monoxide-in-cigarettes>

⁴⁴ <https://www.rivm.nl/en/news/rivm-measures-much-higher-levels-of-tar-nicotine-and-carbon-monoxide-in-cigarettes>

The Netherlands mandates using ISO 15592-3 to measure TNCO in **roll-your-own** tobacco, in line with Art. 4(4). A few Member States performed measurements of emissions of **other tobacco products**⁴⁵, including emissions of HTPs and e-cigarettes, primarily for experimental purposes.

Art. 4(2) Measurement laboratories

Overall, three Member States faced issues regarding the **appointment and monitoring of laboratories**. Four faced issues to some extent, and 15 did not face such issues. As required by this article, the European Commission published a list of approved laboratories in Member States as of March 2019⁴⁶. Currently, 17 Member States **have at least one approved laboratory** in their country; four use approved laboratories in **other Member States**; and five **do not have such laboratories** for testing. Information is absent for two other Member States.

As not all Member States have sufficient approved laboratories, this represents a potential issue with the implementation of the TPD if **products are not being tested adequately**. A few Member States described particular issues with capacity and expertise for the laboratories. Between the first (2001) TPD and the 2014 iteration, the phrase 'Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry' (Art. 4(2)) was added. This means that while previously Member States had the option to approve and monitor laboratories which were run by economic operators, now they have to identify and approve other laboratories. In practice this means that there is less oversight on the quality of the laboratories being used by economic operators to measure their products. The 2001 TPD mandated the labelling of TNCO levels on products. One CSO noted that another unintended consequence of this was the misrepresentation of health risks in certain brands. However, now that this information has been removed from packaging in the present iteration of the TPD, TNCO levels are only entered into EU-CEG, and are not widely provided to consumers. Therefore, the added value of these laboratories and measurements is only to determine if a product is **above or below** the TNCO limits, with the measurement itself not having as much bearing.

Art. 4(6) Fees for verification of measurement methods

Seven Member States reported to have effectively **charged manufacturers and importers of tobacco products proportionate fees for the verification of these measurement methods**. In one Member State, manufacturers must pay a fee to the independent laboratory if they request measurement. However, they are not obligated to request verification from this laboratory as verification from **other Member States' laboratories is accepted**.

Fourteen Member States⁴⁷ have not (yet) charged manufacturers and importers these fees. Of those who reported not doing so, two Member States clarified that they were not considering doing so in the future. In one Member State, a National action plan for reducing of administrative burdens means that fees are **not applied**. A few Member States have included the fee in other ways, for example through taxation, such as applying a flat-rate annual fee or tax. One Member State would only charge fees if **analysis results are not compliant with the TPD**; but this has not yet happened.

⁴⁵ Most Member States have not used measurement methods for **other tobacco products**, and a few clarified that they were **not considering** doing so. Reported reasons for not using measurement methods for emissions for other tobacco products included that this was not legally required (for example for novel tobacco products), a lack of financing, equipment, and technical capacity.

⁴⁶ https://ec.europa.eu/health/sites/health/files/tobacco/docs/approved_laboratories_en.pdf

⁴⁷ One Member State clarified that if the verification tests were done, the costs will be paid by the manufacturer or importer.

A more detailed description of fees used in Member States is included in the Efficiency section.

Art. 5 Reporting of ingredients and Emissions

Main findings: Art. 5 concerns submitting and processing information on ingredients and emission levels for tobacco products into the EU-CEG system. One of the main problems experienced by Member States related to economic operators submitting information incorrectly into the system. For example, absence of sales data, toxicological information, statements of reasoning, descriptions of additives, research studies on their products; and incorrect language. This hinders the effective use of this information for a public health benefit.

From a technological perspective, users reported various problems with the user interface and usefulness of the EU-CEG system, both when entering information and when extracting and analysing the data. Improvements may be needed to ensure that the information can be submitted correctly, and to ensure that key data can be easily viewed and extracted in a usable format.

Member States are required to publish the information on a public website, but this process has been made difficult as many economic operators declare information as 'trade secret' in an inappropriate manner, which often makes the information impossible to publish.

Data sharing of EU-CEG information among Member States has been made possible through JATC, as part of an agreement signed by 19 Member States and Norway, which received positive feedback.

In some Member States, consumers have been using the publicly available information, for example to check TNCO information. This demonstrates the value of ensuring there is a functioning EU-CEG system, as it allows communication of important information also to the public. There could be benefits to an EU-wide database containing information about tobacco products, including increased communication and reduced workload for Member States.

An overarching issue repeated in all articles where submission of information is requested (also Arts. 6, 19, 20), is that Member States authorities lack resources and technical capacity to properly assess, process and react to the information.

Overview

Art. 5 (1) states that Member States shall require manufacturers and importers of tobacco products to submit the following information to their competent authorities (by brand name and type):

- (a) a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products, in descending order of the weight of each ingredient included in the product;
- (b) the emission levels referred to in Art. 3(1) and (4);
- (c) information on other emissions and their levels.

Manufacturers or importers should also inform the Member States' competent authorities if the composition of a product is modified in a way that affects the information provided. For a new or modified tobacco product the information should be submitted prior to the placing on the market of those products.

5(2) The list of ingredients shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients. The list should also indicate the status of the ingredients, including whether they have been registered (under Regulation (EC) No 1907/2006), and their classification (under Regulation (EC) No 1272/2008).

5(3) The list shall be accompanied by the relevant toxicological data regarding the ingredients in burnt or unburnt form, referring in particular to their effects on the health of consumers. For cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties, should also be submitted. Manufacturers and importers should indicate the methods of measurement of emissions used. Member States can require them to carry out studies in order to assess the effects of ingredients on health.

5(4) Member States shall ensure that the information submitted is made publicly available on a website; they should make sure to protect trade secrets when doing so. Member States should require manufacturers and importers to specify which information constitutes trade secrets.

5(5) The European Commission (through implementing acts) should lay down and, if necessary, update the format for the submission and the making available of information.

5(6) Member States should require manufacturers and importers:

to submit internal and external studies available on market research and preferences of consumer groups, relating to ingredients and emissions, as well as executive summaries of any market surveys carried out when launching new products;

to report their sales volumes per brand and type, reported in sticks or kilograms, and per Member State on a yearly basis starting from 1 January 2015.

5(7) All data and information should be provided in electronic form. Member States shall store the information electronically; they should ensure that the European Commission and other Member States have access to it and that trade secrets and other confidential information are treated in a confidential manner.

5(8) Member States may charge manufacturers and importers proportionate fees for receiving, storing, handling, analysing and publishing the information submitted to them.

3.2.3 General observations

Art. 5 requires manufacturers and importers to submit information on ingredients and emission levels per tobacco product to the NCAs, in a certain format, and Member States to make this information publicly available. All relevant information needs to be reported into the EU-CEG. Similarly, reporting requirements also exist in Art. 6, 19 20 and 22. As of March 2021, there were around 42,000 active TP-IDs in EU-CEG⁴⁸.

Overall, article 5 was considered to have facilitated the smooth functioning of the internal market, and to have been implemented similarly across the Member States. However, a series of practical implementation issues were encountered by Member

⁴⁸ EU-CEG data provided by DG SANTE in March 2021.

States hampering its full application, although it appears that progress is being made to resolve most of the challenges.

To facilitate the implementation of articles relating to ingredients and emissions, DG SANTE formed a specific subgroup of the Group of Experts on Tobacco Policy in 2014. It also commissioned the EUREST study which assisted the implementation of this article with the development of a common format for electronic reporting of ingredients and emissions of tobacco products and electronic cigarettes⁴⁹, in accordance with Art. 5(5) of the TPD. The reporting formats were established by two implementing acts^{50,51}, which outline the minimal set of mandatory information to be provided for tobacco products and electronic cigarettes. These were implemented through data dictionaries, providing further specifications, including for description of ingredients and emissions, as well as several other product specific domains and descriptions⁵².

To further facilitate implementation, the JATC was launched in October 2017. This comprehensive EU funded project aimed to provide support for the implementation of the TPD across the 28 EU Member States. It addressed the issue of tobacco product monitoring at EU wide level through facilitating access of data within EU-CEG, assessing tobacco and e-cigarette products compliance with the TPD, assessing aspects of laboratory harmonisation and evaluating the role of priority additives in tobacco products. In addition, during the 8th Meeting of the subgroup on ingredients, the JATC Work Package (WP5) on EU-CEG data Extraction and Handling was established to provide the framework for the efficient usage of data submitted in the EU-CEG. A few derivable were produced: D5.1 outlining the parameters used to define the level of confidentiality of the data submitted through EU-CEG; D5.2 defining the legal requirements for sharing data between MS within JATC and D5.3 establishing a guideline for requesting, sharing and handling data from the EU-CEG for those Member States participating in JATC.

According to DG SANTE, the technical implementation of the EU-CEG is progressing well. Recent improvements of the Member States Reporting Tool (MSREP) include the introduction of a 'new view' that provides a full history of product information, secure bulk data transfer to Member States via MSREP and possibility to deactivate obsolete non-compliant products. Moreover, the full product information had been extracted for all Member States in December 2018 and made available for download. The system supports data sharing as piloted by 19 Member States in the framework of the JATC⁵³.

⁴⁹ DG SANTE (2014) 1st meeting of the subgroup on ingredients established by the expert group on tobacco policy. 7 November 2014.

DG SANTE. (2015). 2nd Meeting of the Subgroup on Ingredients established by the Expert Group on Tobacco Policy: 1 June 2015.

⁵⁰ European Commission (2016) 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 obligations. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.131.01.0088.01.ENG&toc=OJ:L:2016:131:TOC

⁵¹ European Commission (2015) Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_312_R_0003

⁵² EUREST Consortium. (2015). Study on the development of a EU common reporting format for submission of data on ingredients contained in tobacco and related products, and disclosure of the collected data to the public: Final Report.

⁵³ JATC: Second Meeting Newsletter (2020) Available at: http://jaotc.eu/wp-content/uploads/2020/10/JATC_Newsletter-2.pdf

3.2.4 Findings by provision

Around half of the Member States reported to have faced **issues in requiring manufacturers and importers to submit the information pursuant to Art. 5(1), the statement of reasoning foreseen by Art. 5(2), or the toxicological data (Art. 5(3))⁵⁴**, as elaborated in the following sub-sections.

Art. 5(1) – Submitting the required information

Eight Member States encountered difficulties in getting manufacturers to **properly submit the information required in Art. 5(1)**. The main issues identified concerned **missing information** and the **administrative and technical burden** for NCAs to review the submitted information. One Member State, for example, noted that information was misleading in some cases, e.g. only TNCO emissions were reported, but the data contained strange numbers such as 0.8666666667 and 0. In another Member State, data was not verifiable as it is not required to be supported by laboratory test reports and manufacturers submit the data in different ways.

A few Member States reported a general lack of human resources to review the submitted information in the EU-CEG system. Member States found the reviewing process highly **administrative and technically burdensome**.

11 economic operators (out of 19) reported issues with EU-CEG relating to the submission formats of the information required by this article. On the other hand, a few economic operators considered the EU-CEG system to work effectively. Similarly to Member States, manufacturers and importers thought that a considerable amount of manpower and expensive IT systems were needed to submit the high volume of information required for each product and that the submissions were time consuming. Also, a few economic operators reported there was a lack of feedback from the Member States on the data submitted.

Art. 5(2) Statement of reasoning and Art. 5(3) Toxicological data

A few Member States faced challenges with the provisions in Art. 5(2) and Art 5(3), because the data submitted was either missing or misleading⁵⁵. Similarly, **due to the large amount of data received, checks could not always be carried out** (reported by a few Member States). It seems that a few Member States have not enforced the submission of the statement of reasoning, due to a lack of resources and expertise. This affects the overall control over ingredients.

Art. 5(4) Publicity of Data

More than half of the Member States faced **issues in making the submitted information publicly available on a website**. Eight Member States declared to not face any issues in publishing the data, although these include three Member States who actually do not seem to publish such information, thus not being in compliance with the TPD. One Member State also mentioned that the requirements set out in the General Data Protection Regulation may be of relevance for the publication of such information, however this regulation is outside the scope of the present study.

Issues were faced with the determination of confidential information in EU-CEG (reported by seven Member States), due to a lack of clarity on **what constitutes confidential data / a trade secret**. Member States found that economic operators

⁵⁴ Eight Member States did not face any issues in requiring Manufacturers and importers to submit the information pursuant to Article 5(1), the statement of reasoning foreseen by Article 5(2), or the toxicological data (Article 5(3))

⁵⁵ One Member State mentioned that the statement of reasoning of ingredients was usually missing. The same Member State pointed that manufacturers and importer may not include toxicological data because EU-CEG includes an option of 'data not available'.

marked large amounts of information provided as confidential (reported by a few Member States), which meant that this information cannot be published – going as far as the brand name (reported by a few more Member States). However, reports resulting from the work of JATC provide guidance on how to treat this data, as above explained.

Indeed, a few **economic operators** indicated to have **classified all the information reported as trade secret information**, due to uncertainty as to how ‘confidential’ should be interpreted. A few other economic operators considered data such as ingredients and toxicological information/studies resourced by a third party as confidential. Other information considered to be trade sensitive included: STED files; market research/consumer preference studies and executive summaries of studies performed and resourced to support their commercial strategy. Even emissions values and testing methods or manufacturing details were considered secret by one economic operator, which mentioned that it may identify their key suppliers or reveal their recipe.

Sixteen Member States publish the information required in Art. 5(4): Austria⁵⁶, Czechia⁵⁷, Croatia⁵⁸, Denmark⁵⁹, Estonia⁶⁰, Finland⁶¹, France⁶², Germany⁶³, Italy⁶⁴, Latvia⁶⁵, Lithuania⁶⁶, Slovenia⁶⁷, Spain⁶⁸, Sweden⁶⁹. However, in most cases the information published is not complete. One Member State (FR) has been the first Member State to publish such detailed information about tobacco and vaping products (mostly e-cigarettes) placed on their market⁷⁰. The analysis identified inconsistencies and non-conformities in the information reported, of which the manufacturers were informed to help them take appropriate corrective action⁷¹.

Overall, HEs indicated to be aware of the availability of this information and some had tried to access it. However, nearly all those consulting it said that it was not useful in

⁵⁶ <https://www.ages.at/en/service/tobacco-and-related-products/tabak-infomation/>

⁵⁷ <https://www.szpi.gov.cz/clanek/informaci-povinnost-seznam-tabakovych-vyrobku-a-bylinnych-vyrobku-urcenych-ke-koureni.aspx>

⁵⁸ <https://zdravlje.gov.hr/o-ministarstvu/djelokrug-1297/javnozdravstvena-zastita/duhanski-i-srodnji-proizvodi/popis-duhanskih-proizvoda-prijavljenih-ministarstvu-zdravstva-kroz-eu-ceg-zajednicko-mjesto-elektronickog-ulaza-eu-a/3046>

⁵⁹ <https://www.sik.dk/registre/tobaksregister>

⁶⁰ <https://www.terviseamet.ee/et/kemikaaliohutus-tooteohutus/toodete-kaitlejale/tubakatooted/tubakatooted-teavitamine> and
<https://www.terviseamet.ee/et/kemikaaliohutus-tooteohutus/toodete-kaitlejale/tubakatooted/tubakatooted-koostis-tnco>

⁶¹ <https://tupakkarekisteri.valvira.fi/tuoteilmoitukset>

⁶² <https://www.anses.fr/en/content/tobacco-and-related-products> and
<https://www.anses.fr/en/content/vaping-products>

⁶³ www.bvl.bund.de/tabaklisten

⁶⁴ www.ingredientiprodottideltabacco.it

⁶⁵ http://www.vi.gov.lv/lv/tabakas-izstradajumi/_3457 and <http://www.vi.gov.lv/lv/tabaka>

⁶⁶ <http://ntakd.lrv.lt/uploads/ntakd/documents/files/Licencijavimas/EU-CEG/eu-ceg-tob.pdf>

⁶⁷ www.tobak.si

⁶⁸ https://www.mscbs.gob.es/ciudadanos/proteccionSalud/tabaco/Lista_Productos_Tabaco.htm

⁶⁹ <https://www.folkhalsomyndigheten.se/livsvillkor-levnadsvanor/alkohol-narkotika-dopning-tobak-och-spel-andts/tobak/tobaksreglering/tillverkning-och-import-av-tobaksvavor/offentliggjorda-rapporter/>

⁷⁰ 3.000 (cigarettes, cigars and cigarillos and more than 33.000 vaping products (mostly e-cigarettes). <https://www.anses.fr/en/content/tobacco-and-vaping-products-anses-publishing-unprecedented-overview-products-sold-france>

⁷¹ ANSES (2020) Tobacco and vaping products: ANSES is publishing an unprecedented overview of products sold in France. Accessed on January 4th 2020. Available at:
<https://www.anses.fr/en/content/tobacco-and-vaping-products-anses-publishing-unprecedented-overview-products-sold-france>

its current form, citing problems with regard to large parts being classified as 'trade secret', missing data on emissions and the fact that often too much information is made available, which makes it impossible to analyse it. They also noted that Member States had taken different approaches to publishing the information, which may be related to their capacity and resources⁷².

Art. 5(6) Submission of studies on market research and consumer preferences

Ten Member States experienced issues to some extent **in requiring manufacturers and importers to submit studies required in Art. 5(6) and assessing the provided information**⁷³. Not all Member States have fully enforced this provision: one had not requested the submission of the relevant studies yet; another had only enforced this provision recently due to a lack of capacity; and another indicated that they had not been actively requesting market studies. However, some Member States highlighted difficulties with economic operators **not submitting the required research studies** (reported by around a quarter of Member States) and not responding to the Member States' requests for studies or for follow-up information (reported by a few Member States). One economic operator claimed that this provision meant that studies must only be submitted if they were already available / had already been carried out.

Three Member States noted a **lack of consistency in the data on volume sales** submitted by economic operators. Some importers / manufacturers reported on the volume of production of the factory, while others provided the sale volumes of the national retailers, which meant for example that some economic operators reported zero sales if the product was not marketed yet. France reported that **66% of the expected annual sales volume of products were missing**⁷⁴, when compared with launch date / withdrawal date parameters. Other submitters forgot to provide the data, as reported by one Member State. To solve issues with the differing nature of the information provided (for reported sales and market studies) one Member State **designed mandatory templates**⁷⁵ to guide manufacturers and importers to provide the correct information.

Art. 5(7) Member State and European Commission access to and sharing information submitted under Arts. 5 and 6

One of the purposes of information sharing under Art. 5(7) was to enable Member States to consult data from another Member State. However, eighteen Member States had not used the data or information made available by other Member States. A few Member States would consider using the information available from other Member States if it was needed. A few Member States do not consider using such information at the moment, because of a lack of resources, as they are focusing on analysing national data. Another Member State has not used other Member States' data, however, they found that exchanges with other Member States on how they managed data useful.

Member States reported that not all information that is shared between the Member States and the European Commission is made public (product notifications, and

⁷² Based on discussions during the Gap filling workshop – December 2020

⁷³ Eight Member States did not experience any issues.

⁷⁴ <https://www.anses.fr/en/system/files/PRES2020DPA01EN.pdf>; p15-16

⁷⁵ Ministerio de Sanidad del Gobierno de España (2019) Plantillas para comunicación de ventas y estudios de mercado de productos de tabaco y DSLN del año 2019. Available at: https://www.mscbs.gob.es/ciudadanos/proteccionSalud/tabaco/Plantillas_Estudiosmercado_ProductosTabaco_DSLN.htm

comments by the Commission and Member States). Others were supportive that more information should be made available, such as information on product design.

The JATC WP5 worked on the issue of the interpretation of trade secrets, preparing a guide on what should be considered as public and what may be considered as confidential. For example, the length of the cigarette stick is public information, even though economic operators have sometimes marked it as confidential. Data that may be considered confidential in certain circumstances could be the release date of a product before it goes to market. Hence, data sharing has been facilitated through the work of JATC WP5^{76,77}, which included a multilateral agreement on data sharing amongst Member States. The latter is binding for as long as the JATC is operational⁷⁸. Furthermore, the JATC worked to produce D5.5⁷⁹ where it proposes recommendations for a permanent mechanism for sharing EU-CEG data across Member States following the completion of the JATC project. Five Member States highlighted that the JATC had enabled the sharing of data upon request, with one Member State indicating that information on submitters and products had been shared with other Member States via email. A few more Member States reported to have **used information made available by other Member States**. For example, Member States requested the impressions, experiences and classifications of other Member States in matters related to products of interest.

Some economic operators **indicated to visit the public websites** for different reasons, for example to check whether the products they market are represented properly.

Consumer use of this publicly available information is limited, with only eight Member States being aware of regular consumer usage. A scientific paper was also published in **the Netherlands** on the uses and effects of online information about tobacco additives among Dutch general population. The study found that the website did not change perceptions of tobacco additives or smoking behaviour⁸⁰.

One Member State mentioned to have faced difficulties in sharing data with other Member States through EU-CEG as they had not signed the JATC WP5 agreement on data sharing, which meant that they needed to sign a separate agreement, which at the time of answering to this survey was in progress. One Member State did not sign the JATC data sharing agreement⁸¹ due to uncertainties about data protection.

Art. 5(8) Fees charged to manufacturers and importers

A few economic operators highlighted that fees were not harmonised across the EU as indeed the TPD leaves this to the discretion of the Member States, whilst a few more commented on having to pay a fee for each modification they introduced to the system. One Member State, which requires an annual fee (of €125) encountered

⁷⁶ The work of the Joint Action on Tobacco Control is to provide support for the implementation of the TPD throughout the 28 EU Member States. One of its Work Packages 'JATC Work Package 5' EU-CEG data extraction and handling. Is the key WP for providing access to data. The aim of this working group is to provide the framework for the efficient usage of the data submitted in EU-CEG. Particularly: D5.1 and D.5.3.

⁷⁷ 19 Member States did not encounter any challenges giving access to the information submitted in EU-CEG to other Member States.

⁷⁸ JATC was 36-month project, it ended in December 2020.

⁷⁹ To be Published: Joint Action on Tobacco Control (2021) D5.5 – Proposal for a permanent mechanism to facilitate the sharing of EU-CEG data.

⁸⁰ Reinwand DA, Crutzen R, Kienhuis AS, Talhout R, de Vries H (2017)

Website Use and Effects of Online Information About Tobacco Additives Among the Dutch General Population: A Randomized Controlled Trial J Med Internet Res 2017;19(3):e60 URL: <https://www.jmir.org/2017/3/e60>

⁸¹ However, upon request of another Member State, this Member State can give formal access.

issues in collecting the fees from submitters, indicating that in practice submitters did not pay the required fee. A more detailed description of fees used in Member States is included in the section on Efficiency.

3.2.5 Specific issues concerning the EU-CEG system

The text below discusses general issues encountered with the EU-CEG, which was designed for submission of information on tobacco products and electronic cigarettes. The system also allows for submission of specific information on novel tobacco products (Art. 19), e-cigarettes (Art. 20) and herbal products for smoking (Art. 22). Any specific issues encountered in relation to the EU-CEG system and such products are reported further in this report, under the respective articles.

A few Member States encountered issues related to the functioning of **EU-CEG**. In around half of the Member States the system worked effectively 'to some extent'⁸². However, several Member States noted that progress had been made since its launch in 2016 and acknowledged the work carried out by DG SANTE and JATC WPs 5-7 to improve the use of EU-CEG⁸³. One economic operator would have welcomed more practical information on how to use the system (e.g. how to withdraw or modify products)⁸⁴.

Issues encountered by economic operators related to the system itself, in terms of entering data, while Member States' issues included analysing, extracting, and publishing the information, as summarised below.

Entering information

One Member State considered that the system allowed for too many free text entries, which caused a lot of errors and inconsistencies in the data. Other Member States encountered issues when accessing data on already submitted products, and manufacturers when notifying **data changes**.

Uses of TP-ID

Several economic operators indicated that they usually made **a single product submission** to all Member States, especially if the product would be available in all Member States. One economic operator clarified that using the same TP-ID helped in connecting product presentations sold in various Member States.

As of January 2021, there were 41,519 distinct TP-IDs active for tobacco and related products in EU-CEG, with the largest share for cigars (32%), followed by cigarettes (25%). There were 1,105 distinct TP-IDs for active novel tobacco product notifications⁸⁵. For more detail on product types and Member States notification, check Annex 6 below. Updated information from March 2021 indicated that notifications continued to grow, amounting to around 42,000 active TP-IDs⁸⁶.

A few economic operators made **separate submissions** for the same product. One economic operator considered that a single product submission to all Member States was misleading, if a new product was notified in one Member State, the type 1

⁸² Five Member States found that the EU-CEG system worked well.

⁸³ JATC W5, Derivable 5.6: Report for M1-18 on the potential improvements/alterations identified through Task 3.1. <http://jaotc.eu/wp-content/uploads/2019/09/WP5-D5.6-Report-for-M1-18-on-the-potential-improvementsalterations-identified-through.pdf>

⁸⁴ The nature of the guidance received included documents from Member States and the European Commission regarding the EU-CEG system, information meetings between Member States and economic stakeholders covering the impact of changes in regulations owing to the TPD, and workshops held by the European Commission on ingredient notification.

⁸⁵ EU-CEG data provided by DG SANTE in January 2021.

⁸⁶ EU-CEG data provided by DG SANTE in March 2021.

notification was used, if it was notified in a second Member State, type 3 was used and explained in the national section, even if it's a new product in the second Member State. Similarly, another economic operator reported that for tobacco products they used EU submission type 3 'Addition of product presentation (e.g. national market) to an existing product submission', as this allowed them to connect several product presentations in various Member States to a single ID. Another economic operator reported to make one submission per TP-ID on the basis that they had a different 'product presentation' for each country in which they sold the product.

Analysing the information

Around half of Member States faced **issues when processing and assessing submitted products information**, while a few Member States faced issues 'to some extent'⁸⁷. Problems identified related to the complexity of the data collected and the **lack of qualified personnel (scientific background) and capacity to analyse submissions**. As a consequence, a few Member States indicated to only carry out administrative checks to verify that all sections of the submissions were completed. These Member States also acknowledged to heavily rely on initiatives like the JATC.

Around a quarter of Member States encountered problems with analysing information entered by the industry. These related mostly to **the numerous TP-IDs used by industry to submit information on the same brand** (reported by a few Member States) as identified in the above section. One Member State pointed out that different types of submissions created extensive non-relevant information. For example, every time a product changes, the information is resubmitted, but this does not allow for comparison between old and newer versions. It is not possible to find the exact changes for submissions Type 2,3,4,5 and 7.

Contacting Manufacturers

A few Member States faced issues in contacting manufacturers located outside the EU since full contact information was not provided. However, these submissions are still processed in the system.

Extracting information

Eight Member States experienced issues in extracting information from EU-CEG due to the complexity of the system. A few Member States faced issues downloading a file including the full amount of data submitted, as they were unable to download details on ingredients and emission levels.

In order to help processing the data to make it publicly available a few Member States have been developing internal IT tools to facilitate the treatment of notification data, allowing publication of the information on national websites. However due to interconnectedness issues this has been impossible to accomplish so far in these Member States.

Improvements suggested to the EU-CEG System

As a result of the issues identified in the above sections, several economic operators and a few Member States found that the EU-CEG system was not user friendly enough. Member States and economic operators proposed several **changes to make the EU-CEG system work effectively**, in relation to system functionality, guidance, traceability and data analysis. These are summarised below:

Overall system improvements

⁸⁷ Three Member States did not face any issues.

One economic operator noted that the system could benefit from an update which allows checking for submitted data, another economic operator reported that the system should automatically check for errors in the submissions. A few Member States proposed an **automated recognition of ingredients and additives** and connect them to the Chemical Abstract Services (CAS) number. In addition, six Member States requested a more extensive validation on submitted data (for example the submitter could receive alerts when ingredients are not allowed in the EU, or when they must provide further information). This would include check and controls. For example: if a mandatory field is not completed it will not be possible continue with the submission.

Since the current system architecture is based on one-direction information flow to ensure system security, a few economic operators mentioned that the **system should provide some feedback**, for example inform when information had been received or seen by NCA and confirm whether the information submitted was accurate. A few Member States similarly asked to update the system **so that NCAs can send remarks internally to economic operators**. One economic operator and one Member State considered that it would be beneficial to have a shared view of data with the individual submitter, for example to see what they have uploaded in each submission and provide guidance if needed. Additionally, economic operators should be able to **submit annual data and research data regarding consumer behaviour** per company (suggested one Member State).

Several economic operators made recommendations to improve the functioning of the EU-CEG, and two Members States suggested that changes to the EU-CEG system should focus on **user friendliness**. Hence, an **easier user manual / guideline to use the EU-CEG database would be useful**; two Member States prefer manuals and guidelines to be in **national languages** for Member States and economic operators. In this line, one economic operator pointed that the EU should continue to offer webinars, forums, support desks, and opportunities for technical improvements ideas. This could help EU level **training for data processing**. A few economic operators called for the European Commission to publish and regularly update a list of national interfaces, contact points, and deadlines for submission. Additionally, the data dictionaries need to be updated (reported one economic operator).

EU-CEG administrators should check with the European Chemical Agency the list of chemicals, to have a clear assignment and uniform spelling for economic operators to submit the required information, one Member State recommended.

Entering data

An economic operator stated that the standalone tool used to compile submissions had a slow operating speed when processing multiple notifications, and that the portal could make it easier to track submitted notifications. A Member State pointed out that it was difficult to link new and old versions of product information when changes were made.

One economic operator considered that the system should allow for the automatic submission of data, instead of having to do this manually. Two Member States wished to see submitted data in other Member States to compare.

Submissions should be done by Product ID (recommended by two Member States), and the **mandatory fields** should be (properly) filled-in to allow the submitter to move to the next step/field or complete submission. These should be also used as **check controls** which, for example create '**barriers**' if information is not properly submitted (recommended by five Member States). The system should allow to flag ingredients that are prohibited (two Member States), so the notifier can provide additional data or to communicate that the product is not allowed in the EU market.

The system should also send reminders when data is not completed (three Member States).

A few Member States also requested that possibly **confidential fields indication should be limited** in the system for example the indication of brand names. Additionally, values should also be limited in some areas, for example, ranges when notifying emissions should be kept realistic within realistic values (recommended by a few Member States⁸⁸). A proper differentiation between confidential data should be established (recommended by a few more Member States) in addition to a clarification of trade secret. One Member State notified that this has been addressed in one JATC WP. Additionally, a few Member States recommended that the **brand name should not be allowed to be filled with empty spaces or hyphens** or that the system should include limit values for certain fields (e.g. emissions).

It was suggested that the system should avoid accepting a '**launch date**' earlier than 6 months after 'first submission date' where applicable. One Member State proposed that a longer time period before launch (for example one year) could be given. Also, withdrawal date of inactive products needs to include a date. Inactive or withdrew products should be marked in the system.

A few Member States recommended the **name or the legal person or importer in Europe** as well as the full address, must be compulsory in the notifications. There are situations in which the manufacturer is located outside the EU, in the submission is not specified who is the importer or the legal person in EU.

Finally, it was suggested that the EU-CEG system would automatically show an information block in which Member States have fees before submission.

Analysing data

One Member State recommended that when data is modified it should be clear what data and what part has been changed. Another recommended that Member States should also be able to flag products to be deleted from the national view of the system.

Extracting data

The system could handle the data in a more efficient way for example by being able to extract ready to publish information (recommended by around a third of Member States). One Member State mentioned it is difficult to prepare information using two formats: one for the public and one for regulators. Another suggested that the system should allow to download a complete list of on ingredients or emissions. Such a tool for publish data should be developed by JATC and the European Commission.

Publishing data

When data is validated it should be notified as completed (recommended by a few Member States).

Filtering

Improvements suggested included advanced search with targeted filters (recommended by five Member States) and the possibility to **filter by ID or brand entries** (recommended by five Member States) which would give access to pertinent information for consumers and regulators and make inspections easier. The ingredients search function could be improved as well (recommended by two Member States), and there is not a search tool for emissions for e-cigarette / e-liquids. Other suggestions include that the **EU-CEG system should be organised by product and**

⁸⁸ Note for one Member State, this applies for any numeric value, not solely emissions.

brand and not by date of first notification or date of corrections and that all input fields should be available for search or filter options, as the search functions were only available for TNCO emissions.

Connection to the traceability system

One Member State recommended that the traceability system should be able to connect EU-CEG information with the Unique Identifier (UI), as this could help surveillance. Inspectors could scan using a phone APP and check the available information (recommended by two Member States). IDs should only be given per product and brand. At present, some products have several TP-IDs. One economic operator asked for a better traceability of TP-ID iterations at Member State level and ability to include files at a market specific level.

One Member State suggested that requesting additional mandatory information could facilitate market surveillance, such as for example, adding pictures of the product and the national labels.

The JATC project produced a deliverable to assess⁸⁹ and address⁹⁰ the issues (mirroring the ones presented above) that prevent the efficient use of the EU-CEG system and make recommendations to solve them.

Reacting to incorrect or insufficient submissions

Fifteen Member States **contacted the submitter in case of lack or incorrect or insufficient information or needs clarification**. Of those, five Member States added that they had imposed more severe actions for uncompliant submitters such as product withdrawal or fines. At the time of drafting this study, five Member States had not (yet) take any action.

Five Member States reported to have taken 'severe' actions. Two Member States had the possibility to also **contact prosecuting authorities**, to impose sanctions in case the notification of a product is not uploaded with the correct information. Another Member State reported that in case of detected harmful substances they have informed the Inspectorate of Health, however, details on the action taken or process were not further elaborated. In the case of another Member State, the Health Authority first contacts the submitter via letters. For example, in the process of a market authorisation they contact submitters to solve the issue before informing the Tax Authority. On some occasions, processes of non-compliant manufacturers or importers have been sent to the Inspection Authority. However, this Member State does not provide information about the legal penalties of those infringement processes due to confidentiality reasons.

In France, starting in August 2020, manufacturers received a first notification with a list of discrepancies identified in their submissions⁹¹, and list of such discrepancies are publicly available and updated monthly on their website⁹² to encourage improvement.

One Member State reported as usually contacting submitters via email. If there was no reaction, the product was not authorised to be placed on the market. Another

⁸⁹Joint Action on Tobacco Control (2020) D5.6:Report for M1-18 on the potential improvementsalterations identified through. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP5-D5.6-Report-for-M1-18-on-the-potential-improvementsalterations-identified-through.pdf>

⁹⁰ [Not yet publicly available] Joint Action on Tobacco Control (2020) D5.7: Addressing Potential improvements.

⁹¹ <https://www.anses.fr/en/content/tobacco-and-vaping-products-anses-publishing-unprecedented-overview-products-sold-france>.

⁹² <https://www.anses.fr/en/content/tobacco-and-related-products> and <https://www.anses.fr/en/content/vaping-products>

option was to withdraw products from the market immediately, but this option was rarely used. Another Member State noted that the inspectorate could **give warnings, seize products, give fines**, etc., if information was not corrected or fees were not paid by the notifier. Only compliant products are put in a 'positive list of tobacco products' that can be marketed.

Member States which confirmed to have taken action against manufacturers or importers due to non-compliant reporting of ingredients and emissions, were asked how many times they had taken action since the entry into force of the Directive. Member States reported to only have taken a few actions against manufacturers or importers. The reason behind the low number of actions taken may be the lack of capacity in analysing the submitted information and to follow-up with economic operators. Examples of actions taken included: requests for clarification; product withdrawal; fines and other punitive measures. Seven Member States have not taken any action to date.

Development of a European Union database containing information about tobacco products

Nearly half of Member States reported that an EU database would be **beneficial**, however some disadvantages were also identified. A few Member States reported a single EU data base would help in reducing the workload and increasing efficiency regarding review and analysis of information from the Member States' standpoint. In addition, a few Member States reported it could improve collaboration between Member States and/or industry. One Member State also reported it could also be helpful for research purposes to compare legislation and products in the different Member States.

A few Member States reported that such a database would also increase the ease of implementation and enforcement of the Directive and assisting the surveillance of products in the market. Implementing an EU data base where all the information is available about tobacco products and ingredients, would solve the issues with trade secrets (reported by one Member State).

Disadvantages identified of an EU Database:

On the other hand, one Member State pointed out an obstacle in the establishment of such a database, in that it may be a challenging process due to potential issues with trade secrets of economic operators. Two Member States highlighted that it could also mean a duplication of efforts as national databases would also need to be maintained.

Relevant findings of Case study 1 on a European system for the regulation of ingredients used in tobacco and related products

The current system for the regulation of ingredients operates at the Member State level with EU-level support for certain aspects (e.g. electronic submissions database, data sharing), but not all aspects adequately meet the needs of stakeholders and Member States.

Implementation of an EU-level system incorporating a centralised list of ingredients and database of information from economic operators could have benefits across three broad areas:

- More efficient **submission and publication of data** submitted by economic operators on products and priority additives via a single submission to an EU-wide database that would incur a single fee but cover all relevant Member States;
- Pooling resources and expertise would **improve the analysis and assessment** of submitted data, while also removing the administrative burden and reducing disparities between Member States;

- Provide **simplified access to EU-wide data** for Member States to support collaboration, learning, and enforcement.

However, alterations to the current system would **require in-depth consideration** of:

- How an EU-level system would be co-ordinated and which body/agency would take the lead;
- Resource implications, both in terms of those required for a centralised system and those that may be reduced for Member States through the transfer of tasks to an EU-level system;
- Minimisation of duplication of effort between the European Commission and Member States while also ensuring that individual Member State needs are met;
- Current Member State differences regarding regulation of ingredients and emissions, resources and enforcement responsibilities and how this would be addressed in the creation of an EU-level system.

The full case study can be found in Annex 9.

Art. 6 Priority list of additives and enhanced reporting obligations

Main findings: Art. 6 requires economic operators to establish detailed and accurate scientific information about 15 additives which were selected as 'priority', in order to put a higher reporting burden on these additives. This has not worked in practice, and the data about these additives is not sufficiently conclusive.

There were some non-negligible difficulties with the quality of the reports submitted on priority additives. The reports were often difficult to assess; this was occasionally due to Member State capacity issues, but largely it was due to the poor quality of the reports themselves. There have been very few reports submitted for the additive diacetyl as this does appear not to be a common additive. There were also some challenges with the criteria and definitions set out in Art. 6(2)(a-d). However, work by the JATC was helpful in assessing this information. Thus, based on their experience to date, some Member States considered that a joint EU system could potentially facilitate ingredients regulation and assessment.

The findings imply that reporting obligations are not being respected in full. Notably, although many Member States reported difficulties with the reports, few have actually taken subsequent actions against non-compliant economic operators.

Overview - Priority list of additives and enhanced reporting obligations

Art. 6 establishes that (1) enhanced reporting obligations apply to certain additives contained in cigarettes and roll-your-own tobacco. These additives are included in a priority list, laid down by the European Commission (through implementing acts).

This list shall contain additives:

(a) for which initial indications, research, or regulation in other jurisdictions exist suggesting that they have one of the properties set out in points (a) to (d) of paragraph 2; and

(b) which are amongst the most commonly used additives by weight or number (according to the reporting of ingredients, as established paragraphs 1 and 3 of Art.5).

(2) Member States should require manufacturers and importers of cigarettes and roll-your-own tobacco containing an additive that is included in the priority list, to carry out comprehensive studies, which shall examine for each additive whether it:

- (a) contributes to the toxicity or addictiveness of the products concerned, and whether this has the effect of increasing the toxicity or addictiveness of any of the products concerned to a significant or measurable degree;
- (b) results in a characterising flavour;
- (c) facilitates inhalation or nicotine uptake; or
- (d) leads to the formation of substances that have Carcinogenic, mutagenic or reprotoxic (CMR) properties, the quantities thereof, and whether this has the effect of increasing the CMR properties in any of the products concerned to a significant or measurable degree.

(3) Those studies should:

- consider the intended use of the products concerned and examine in particular the emissions resulting from the combustion process involving the additive concerned.
- examine the interaction of that additive with other ingredients contained in the products concerned.

Manufacturers or importers using the same additive in their tobacco products may carry out a joint study when using an additive in a comparable product composition.

(4) Manufacturers or importers should establish a report on the results of these studies, which should include an executive summary, and a comprehensive overview of the available scientific literature on that additive and summarising internal data on the effects of the additive. They should submit these reports to the European Commission and the competent authorities of the Member States where a tobacco product containing this additive is placed on the market (at the latest 18 months after the additive concerned has been included in the list). The European Commission and the Member States may request supplementary information. The European Commission and the Member States concerned may require these reports to be peer reviewed by an independent scientific body. Manufacturers and importers could be charged proportionate fees for the peer reviews. The information received should help the European Commission and Member States in taking the decisions pursuant to Art.7.

(5) Small and medium-sized enterprises (as defined in Commission Recommendation 2003/361/EC) should be exempted from these obligations, if a report on that additive is prepared by another manufacturer or importer.

3.2.6 General observations

Art. 6 sets out the requirements for a priority list of additives and enhanced reporting obligations. The European Commission's implementing decision 2016/787⁹³ established a list of **additives** contained in cigarettes and roll-your-own tobacco which are subject to **enhanced reporting obligations**. These additives are: Carob bean, Cocoa, Diacetyl, Fenugreek, Fig, Geraniol, Glycerol, Guaiacol, Guar gum, Liquorice, Maltol, Menthol, Propylene glycol, Sorbitol, and Titanium dioxide.

⁹³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0787&from=EN>

There were a few points of ambiguity brought by CSOs and HEs, mostly about the products which these provisions apply to. In the online consultation, around half (54%) of CSOs and HEs agreed that the provisions were **clear regarding the transposition requirements**. 20% found that provisions regarding additives, and ingredients (see Art. 7 below) could be **more clear**, and that both Art. 6 and 7 should provide Member States with the explicit possibility to adopt **stricter national measures**.

A few CSOs recommended that the enhanced reporting obligations **should apply to all tobacco products**, not just cigarettes and roll-your-own tobacco.

Finally, 44% of CSOs and HEs responded that this article remains **relevant** to address current developments in the tobacco and related industries including technological, scientific, or market developments, while 35% responded that it has not remained relevant. See Annex 8 for further information.

3.2.7 Findings by article

Art. 6(2): Comprehensive studies of priority additives

Manufacturers and importers of cigarettes or roll-your-own tobacco containing additives included in the list of priority additives are required by Art. 6(2) to conduct **comprehensive studies** on them (both clinical and non-clinical) due to insufficient evidence on how these additives contribute to addictiveness or facilitate inhalation⁹⁴. The Scientific Committee on Health, Environmental and Emerging Risks (**SCHEER**) produced an opinion on tobacco additives⁹⁵ to provide guidance on the type and criteria for comprehensive studies, and on the most suitable methodologies to be used. This opinion applies to these first 15 tobacco additives, as well as additives on future updated lists.

Three economic operators (out of 19) reported facing issues in the **preparation of the studies and/or the reports required by Art. 6**, while three more reported facing issues to some extent. A few economic operators cited **time constraints**, referring in particular to the SCHEER-recommended tests as being difficult to conduct in the time frame. Seven Member States encountered difficulties in **requiring manufacturers and importers to carry out these comprehensive studies in practice**⁹⁶.

A few Member States reported particular challenges with the **clarity and coherence of Art. 6(2)(a-d)**, which set out what the studies should examine. Further information is given in the box below.

- First, issues were noted with the wording of Art. 6(2)(a), as this provision seems to contain two measurement points: firstly, if an additive **contributes** to the toxicity or addictiveness of a product, and secondly whether this has the effect of **increasing** the toxicity or addictiveness of the product to a measurable degree.

⁹⁴ Simms, L., Clarke, A., Paschke, T. et al. (2019). Assessment of priority tobacco additives per the requirements of the EU Tobacco Products Directive (2014/40/EU): Part 1: Background, approach, and summary of findings. *Regulatory Toxicology and Pharmacology*: 104, 84-97; McEwan, M., et al. (2019). Assessment of priority tobacco additives per the requirements of the EU Tobacco Products Directive (2014/40/EU): Part 3, Smoking behavior and plasma nicotine pharmacokinetics. *Regul Toxicol Pharmacol*, 104: 29-38.

⁹⁵ Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), (2016). Opinion on Additives used in tobacco products (Opinion 2): Tobacco Additives II. European Union. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_001.pdf

⁹⁶ Seven faced issues to some extent, and seven did not face such issues.

This was perceived as being unclear in terms of what outcome should be measured and presented by the industry, and a revision to the phrasing of this point was recommended.

- Relatedly, Art. 7(9) requires regulatory actions by the Member States if the additives 'increase the toxic or addictive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measurable degree'. Therefore, one Member State considered that any regulatory actions from Member States must be based on information which addresses the **second component of Art. 6(2)(a)**. However, the only current experimental approach to assess this aspect of an additive's toxicity is **comparative testing**, which lacks discriminating power in the case of products with an extremely high toxicity such as cigarettes. Therefore, rephrasing Art. 6(2)(a) and 7(9) may make the wording more consistent.
- On the other hand, one economic operator reported that the guidance provided in SCHEER Opinion II on tobacco additives⁹⁷ on the type and criteria for comprehensive studies was not sufficient and partially not in line with the TPD requirements. For example, it **does not endorse comparative testing** for toxicity and CMR properties, while Art. 6(2) and 7(9) of the TPD require comparative testing to measure increases in toxicity and CMR properties. If the tests followed SCHEER's recommendation of not performing the comparative testing, the results would not allow Member States to identify if the additives increase toxicity and CMR properties, which is required by the TPD.

Art. 6(4): Reports on the results of the studies

Art. 6(4) requires manufacturers and importers to **establish reports** on the results of the aforementioned studies. To facilitate this process, **a consortium of 12 tobacco manufacturers was formed to develop joint reports on the priority additives**⁹⁸. The consortium submitted reports containing comprehensive studies on priority additives to the EU-CEG⁹⁹ within the submission deadlines for 14 of the 15 additives. These have also been published by the consortium in peer-reviewed publications¹⁰⁰.

⁹⁷ Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), (2016). Opinion on Additives used in tobacco products (Opinion 2): Tobacco Additives II. European Union. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_001.pdf

⁹⁸ DG SANTE (2019). Meeting of the Group of Experts on Tobacco Policy. 15 October 2019. Available at: https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20191015_sr_en.pdf [Accessed 30 June 2020]

The 12 organisations are: British American Tobacco (Investments) Limited, Continental Tobacco, Imperial Tobacco Limited, JT International SA, Philip Morris Products SA, KT&G Corporation, Joh. Wilh. von Eicken GmbH, Karelia Tobacco Company Inc., Landewyck Tobacco SA, Mac Baren Tobacco Company A/S, Pöschl Tabak GmbH& Co. KG, Scandinavian Tobacco Group A/S.

⁹⁹ JATC. (2019). WP9- D9.2: Inventory of Industry documents: A report on the type of information from the EU-CEG system on enhanced reporting of priority additives. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.2-Inventory-of-Industry-A-report-on-the-type-of-information.pdf>

¹⁰⁰ Simms, L., Clarke, A., Paschke, T., et al. (2019). Assessment of priority tobacco additives per the requirements of the EU Tobacco Products Directive (2014/40/EU): Part 1: Background, approach, and summary of findings. Regulatory Toxicology and Pharmacology: 104, 84-97
Stabbert R., Ghosh, D., Clarke, A., et al. (2019). Assessment of priority tobacco additives per the requirements in the EU Tobacco Products Directive (2014/40/EU): Part 2: Smoke chemistry and in vitro toxicology. Regulatory Toxicology and Pharmacology: 104, 163-199

McEwan, M., Coburn, S., Ghosh, D., et al. (2019). Assessment of priority tobacco additives per the requirements of the EU Tobacco Products Directive (2014/40/EU): Part 3, Smoking behavior and plasma nicotine pharmacokinetics. Regulatory Toxicology and Pharmacology: 104, 29-38.

Some manufacturers **outside of the consortium** have also submitted documents on priority additives¹⁰¹.

As part of WP9¹⁰², **the JATC established an independent review panel**, and provided an assessment and evaluation **framework** in order to 'assist the Commission and Member States to identify missing information that needs to be requested from industry'. In addition, JATC provided a structure by which to assess methodology and conclusions of submitted studies, along with an overview of most relevant risks associated with each of the priority listed additives. Six Member States indicated to have used the results of the JATC, or followed the framework provided by WP9 of the JATC¹⁰³ to assess the reports.

Nearly half of Member States reported **capacity and/or resource constraints, as well as a lack knowledge to assess the reports**, and most therefore saw wider cooperation as beneficial. One Member State, due to the large amount of associated data, said to not have requested the reports yet. Another found it difficult to distinguish the **technical reports required in Art. 5(3)** above from the studies required for Art. 6(2).

In some instances, **no reports appear to have been provided at all**. For example, in one Member State, some manufacturers and importers said they had conducted studies but there was no corresponding information in EU-CEG. Few reports had been submitted for **diacetyl**¹⁰⁴ (no reports received by at least four Member States). This may be because this ingredient is being phased out; a few Member States added that no products containing this additive had been reported in their respective countries. The **consortium** did not conduct studies for diacetyl as reportedly none of the companies in the consortium uses diacetyl in their cigarettes and roll-your-own tobacco¹⁰⁵.

Reports which were produced appear to be **of generally poor quality** (e.g. reported by three Member States), which may have harmful implications for human health protection. One Member State considered that manufacturers provided a high volume of poor-quality reports, despite the guidelines provided in the SCHEER Opinion II on tobacco additives¹⁰⁶. Another Member State reported that incomplete or poor reporting

Chambers, E. & Paschke, T. (2019). Validation of a recommended practice for assessing 'characterizing flavor' to meet requirements of the EU Tobacco Product Directive (2014/40/EU). Journal of Sensory Studies: 34(5).

¹⁰¹ JATC. (2019). WP9- D9.2: Inventory of Industry documents: A report on the type of information from the EU-CEG system on enhanced reporting of priority additives. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.2-Inventory-of-Industry-A-report-on-the-type-of-information.pdf>

¹⁰² Joint Action on Tobacco Control. (2018). WP9- D9.1 Assessment/Evaluation Framework for enhanced reporting of priority additives and guidelines for 'Good Experimental Practicing'. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.1-Assessment-Evaluation-Framework-for-enhanced-reporting-of-priority-additives-and-guidelines-for-%E2%80%98Good-Experimental-Practicing%E2%80%99.pdf>

¹⁰³ Joint Action on Tobacco Control. (2018). WP9- D9.1 Assessment/Evaluation Framework for enhanced reporting of priority additives and guidelines for 'Good Experimental Practicing'. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.1-Assessment-Evaluation-Framework-for-enhanced-reporting-of-priority-additives-and-guidelines-for-%E2%80%98Good-Experimental-Practicing%E2%80%99.pdf>

¹⁰⁴ DG SANTE (2019) Meeting of subgroup on ingredients: 6-7 February 2019.

¹⁰⁵ Commission Implementing Decision 2016/787 states in recital 3 that the additives in the priority list should be among the most commonly used, therefore it is interesting to note that this does not appear to be the case for diacetyl.

¹⁰⁶ Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), (2016). Opinion on Additives used in tobacco products (Opinion 2): Tobacco Additives II. European Union. Available at:

made it difficult to proceed with regulatory activities based on the reports. Four Member States considered that in the future this research and information should come from **independent organisations, rather than the manufacturers themselves, given the potential industry bias.**

A JATC-created inventory of industry documents¹⁰⁷ related to report submissions concluded that documents on priority additives submitted by manufacturers outside of the consortium **did not contain sufficient data about additives**. JATC also noted the following concerning the reports from the industry consortium:

- **Smoke chemistry** and **in vitro toxicity** tests were conducted for all priority additives except titanium dioxide.
- A **human clinical study** was performed for 10 out of 14 additives (i.e. Carob bean extract, cocoa powder, fenugreek extract, fig juice concentrate, glycerol, guaiacol, liquorice extract powder, menthol, propylene glycol).
- **Transfer rates** were only investigated for 9 out of 14 additives (i.e. cocoa powder, geraniol, glycerol, guaiacol, liquorice extract powder, maltol, menthol, propylene glycol and titanium dioxide).
- The **sensory analysis for characterising flavour** was conducted for 9 out of 14 additives (i.e. Carob bean extract, cocoa powder, fenugreek extract, fig juice concentrate, geraniol, guaiacol, liquorice extract powder and menthol).

DG SANTE **prepared a letter requesting additional information**, sending it to manufacturers and importers on behalf of Member States and **provided Member States with a template** to send to manufacturers and importers concerning products containing the ingredient diacetyl¹⁰⁸. On 19 June 2019, the European Commission sent a letter on behalf of Member States to representatives of the 12 tobacco organisations in the consortium¹⁰⁹. This letter added the initial observations of WP 9 of the JATC and requested additional information in line with Art. 6(4). The industry consortium subsequently submitted their comprehensive reply to the request from the European Commission, with the exception of two pending issues raised by the WP9 review panel.

Other observations on Art. 6

Two Member States indicated to **charge manufactures and importers proportionate fees for peer reviews of their reports**¹¹⁰. Eighteen had not charged such fees. Some Member States clarified that they were (one Member State) or were not (three Member States) considering charging such fees. In two Member States, the costs for implementing the article are **covered by more general fees** (e.g. a global fee for each product, an annual fee collected from manufacturers and importers based on their market share). In some Member States, it is **not possible to charge fees for administrative reasons**, including a national action plan for reducing of administrative burdens or current tax law. In one Member State, authorities are in the process of preparing the decree to define and impose fees to manufacturers and

https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_001.pdf

¹⁰⁷ JATC. (2019). WP9- D9.2: Inventory of Industry documents: A report on the type of information from the EU-CEG system on enhanced reporting of priority additives. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.2-Inventory-of-Industry-A-report-on-the-type-of-information.pdf>

¹⁰⁸ DG SANTE. (2019). Meeting of the group of experts on tobacco policy: 21 March 2019.

¹⁰⁹ DG SANTE (2019). Meeting of the Group of Experts on Tobacco Policy. 15 October 2019. Available at:

https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20191015_sr_en.pdf [Accessed 30 June 2020]

¹¹⁰ One Member State clarified this is occurring only until 2021.

importers for the provisions of Art. 4, 5, 6, 7 and 20. A more detailed description of fees used in Member States is included in the section on Efficiency.

Since the publication of the priority list of additives, a few Member States have **taken (regulatory) action on one or more of the ingredients identified**, and a further few reported that this was being considered¹¹¹. Such actions included product modification, product withdrawal, fines, or other punitive measures **against manufacturers or importers due to non-compliant behaviour related to additives or reporting since the Directive came into force**¹¹². The actions which have been taken often concerned diacetyl:

- One Member State initiated a **general enforcement action** for all the priority additives, since the reports did not meet the criteria of this article: letters were sent to the two identified manufacturers and responses were received.
- In another Member State, submitters were required to complete the missing information related to a product, however no administrative sanctions were given related to this.
- A few Member States, prior to taking action, were **awaiting recommendations for further action from the JATC**.
- Two Member States supported action related to ingredients at the EU level.
- In a few others, actions were not yet taken due to a lack of capacity.
- Five Member States would **consider taking action if the need arose**.

Art. 7 Regulation of ingredients

Main findings: Art. 7 regulates the use of ingredients in tobacco products. Overall, it was considered one of the least clear articles by Member States and stakeholders, which likely contributed to some of the transposition issues identified. In the view of CSOs and HEs, the main application issue was a lack of scientific capacity for implementation. The lack of clarity of the text also led to different interpretations across the Member States and in some cases to misinterpretations, which included for example mixing the provisions regarding additives and characterising flavours. However, these two provisions cover two different elements all together.

The implementation challenges of this article mostly related to the overarching issue of Member State having insufficient (scientific) capacity to analyse submitted data and determine if additives produce a characterising flavour other than tobacco. Similarly, a few Member States also encountered difficulties to undertake tests to verify the composition of products. The issues reported by the Member States imply that, in practice, they are not fully applying the provisions of the article. For this reason, the provisions in this article do not necessarily enable Member States in achieving the highest level of public health protection.

Another challenge noted by several Member States was the emergence of products which appear to be developed to circumvent the ban on characterising flavours. Some Member States also referred to economic operators relying on extensive litigation to keep non-compliant products on the market as long as possible. In this respect it is, however, important to bear in mind that when the TPD sets minimum standards or does not

¹¹¹ 15 Member States have not taken such actions.

¹¹² 18 Member States reported not having taken such actions since the Directive came into force.

harmonise certain requirements, it allows Member States for bans of products going beyond what is stated in the Directive, provided these are compatible with the TFEU and do not jeopardise the full application of the Directive, as set out in Art. 24.

Overview

Art. 7 states that (1) Member States shall prohibit the placing on the market of tobacco products with a characterising flavour. They shall not prohibit the use of additives which are essential for the manufacture of tobacco products, if they do not result in a product with a characterising flavour and do not increase to a significant or measurable degree the addictiveness, toxicity or the CMR properties of the product.

(2) The European Commission shall determine (by means of implementing acts) whether a tobacco product falls within the scope of par. (1).

(3) The European Commission shall also lay down uniform rules for the procedures for determining whether a tobacco product falls within the scope of par. 1.

(4) An independent advisory panel shall be established at Union level, which should be consulted before adopting a measure pursuant to par. 1 and 2. The European Commission should lay down the procedures for the establishment and operation of this panel.

(5) Where the content level or concentration of certain additives (or their combination) has resulted in prohibitions pursuant to par. (1) in at least three Member States, the European Commission should adopt delegated acts to set maximum content levels for those additives or combination of additives.

(6) Member States shall prohibit the placing on the market of tobacco products containing the following additives:

(a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;

(b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

(c) additives having colouring properties for emissions;

(d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and

(e) additives that have CMR properties in unburnt form.

Member States shall:

(7) prohibit the placing on the market products containing flavourings in any of their components, or any technical features allowing modification of the smell or taste or their smoke intensity. Filters, papers and capsules shall not contain tobacco or nicotine.

(8) ensure that the provisions and conditions laid down in Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.

(9) prohibit the placing on the market of tobacco products containing additives in quantities that increase the toxic or addictive effect, or the CMR properties at the stage of consumption to a significant or measurable degree.

notify to the European Commission the measures they have taken pursuant to this paragraph.

(10) The European Commission may determine (through implementing acts) whether a tobacco product falls within the scope of par. (9).

(11) Where an additive has been shown to amplify the toxic or addictive effect of a product, and this has resulted in prohibitions pursuant to par. (9) in at least three Member States, the European Commission should set maximum content levels for those additives.

(12) Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in par. (1) and (7).

(13) The Member States and the European Commission may charge proportionate fees to manufacturers and importers for assessing whether: a product has a characterising flavour; prohibited additives or flavourings are used; a product contains additives in quantities that increase the toxic or addictive effect or the CMR properties.

(14) In the case of tobacco products with a characterising flavour whose Union-wide sales volumes represent 3 % or more in a particular product category, the provisions of this Article shall apply from 20 May 2020.

(15) This Article shall not apply to tobacco for oral use.

Art.7(1) Prohibition of products containing characterising flavours

The literature reviewed showed that substantial resources have been invested in developing strategies to support Member States in implementing the legislation relating to the prohibition of products with characterising flavours. Art. 7(4) of the Directive provides that when determining whether a tobacco product has a characterising flavour, EU Member States and the European Commission may consult an Independent Advisory Panel (IAP). This panel was tasked with issuing opinions on whether a tobacco product has characterising flavour. To do so, the IAP prepared a methodology, approved by DG SANTE, on determination of characterising flavours in tobacco products, taking into consideration the input from the Technical Group (Commission Implementing Decision (EU) 2016/786 of 18 of May 2016), and the best available practices in this field¹¹³. The work of the group was preceded by the consortium 'Health Effects Tobacco Composition (HETOC)', **which** helped develop and pilot the underlying methodological concepts¹¹⁴. The chemical analysis of cigarette tobacco, supplementary to the sensory analysis for characterising flavours has proven efficient in discriminating flavoured from non-flavoured products¹¹⁵.

Since the entry in to force of Art. 7 and the related implementing regulations, several brands with characterising flavours have been removed from the market¹¹⁶ and Member States overall reported high compliance with the initial ban on characterising flavours¹¹⁷. One Member State also commented that the media coverage on the TPD

¹¹³ European Commission, Independent Advisory Panel on characterising flavours in tobacco products (IAP) (2021) Methodology for the technical assessment of test products assisting in determining tobacco products with a characterising flavour Application to cigarettes and roll your own products. Available at:

https://ec.europa.eu/health/sites/health/files/tobacco/docs/methodology_technical-assessment_test-products_en.pdf

¹¹⁴ DG SANTE. (2015). 2nd Meeting of the Subgroup on Ingredients established by the Expert Group on Tobacco Policy: 1 June 2015.

¹¹⁵ Wenzl, T. & Zelinkova, Z. (2018). Administrative Arrangement N°34851 between DG SANTE and DG JRC regarding the project Technical support to the implementation of the Tobacco Products Directive. Joint Research Centre: JRC114627.

¹¹⁶ DG SANTE (2016) Meeting on the group of Experts on Tobacco Policy. 2 December 2016.

¹¹⁷ DG SANTE (2017) Meeting of the Group of Experts on Tobacco Policy Summary Record. 9 October 2017.

about the changes coming into force and, more recently, the menthol cigarette ban has probably contributed to more public awareness of harm and reduced smoking rates.

Art. 7(12) introduces exemptions from the characterizing flavours provisions for tobacco product categories other than cigarettes and roll-your-own tobacco. These exemptions shall be withdrawn for a particular product category if there is established a substantial change of circumstances. Some Member States considered that flavours and additives in other tobacco products were already posing a serious risk. For example, they raised concerns about the **growing market for waterpipe tobacco and alternative ways emerging to flavour products, e.g. with menthol capsules/strings**¹¹⁸. Flavoured cigarillos and cigars, among other, are currently exempted from TPD characterizing flavour ban and a few CSO and HE stakeholders reported that this was problematic. Under such circumstances, manufacturers have been able to circumvent stricter regulations applicable to cigarettes and roll-your-own tobacco. One CSO emphasised that there was a need for a significant decrease in the number of permitted flavours and additives as a means to streamline quality control and reduce the appeal to young people. Finally, one Member State suggested that the threshold for other tobacco products to be added to the scope of Art. 7 was too high and insufficiently flexible. Another Member State also considered that Art. 7(12) constituted a major gap in protecting consumers, especially young people. A few Member States **encountered issues with prohibiting the placing on the market of tobacco products with characterising flavours**, and a few others mentioned to have faced issues 'to some extent'¹¹⁹. For example, one Member State found it difficult to determine whether a product represented the required 3% of Union wide sales. Others experienced difficulties to identify characterising flavours, and highlighted a lack of technical capacity.

One challenge experienced by a few Member States was the lengthy process required to determine if a product had a characterising flavour. As a consequence, while awaiting the decision, the same manufacturer could put a new product on the market with a similar flavour. Some economic operators used **litigation to gain time with products in the market**. The courts (almost without exception) prohibited / suspended the product subject of the challenge, but while a certain case was being considered by a court, the economic operator could continue to sell the non-compliant product(s) and gain advantage of the non-compliance. An example included a **court case by initiated by Planta Tabak**^{120,121}.

In addition, as mentioned above, **new tobacco products have emerged in the market with characterising flavours**. This is the case of cigarillos, for instance, which look like cigarettes, but are exempt from the prohibition on characterising flavours. As an example, one CSO stakeholder pointed to a cigarillo launched in recent

¹¹⁸ DG SANTE (2018) 11th Meeting of the group of experts on Tobacco policy: 15 March 2018.

¹¹⁹ Over half of Member States did not face any issues.

¹²⁰ **Planta Tabak** (which manufactures and markets tobacco products, in particular flavoured roll-your-own tobacco) argued that the prohibition **infringed the principles of legal certainty, equal treatment and proportionality, and the free movement of goods**. The Court analysed in depth the issue of flavouring - concluded that since tobacco products having a characterising flavour facilitate initiation of tobacco consumption and affect consumption patterns, that prohibition is liable to make them less attractive and meets objectives of general interest recognised by the EU, by contributing to ensuring a high level of protection of public health and does not go beyond that, especially of young people. It does not infringe the principle of proportionality. The restriction is justified by the balancing of its economic consequences against the requirement to ensure a high level of protection of human health.

¹²¹ C-220/17, Planta Tabak-Manufaktur Dr. Manfred Obermann GmbH & Co. KG v Land Berlin, 30 January 2019, ECLI:EU:C:2019

months which has the same brand name as the flavoured cigarette it replaced. Another CSO also reported product displacement, with menthol increasing in products not covered by the characterising flavour ban, such as cigarillos.

Similarly, a few other CSO stakeholders considered that the provisions regarding ingredients were inconsistent, due to the exemption introduced by Art. 7(12). In this regard, one CSO stakeholder recommended that the European Commission should adopt delegated acts to withdraw the exemption and at the same time consider introducing a ban on accessories designed to circumvent the prohibition, to ensure that Member States could continue to achieve a high level of protection of public health.

Member States also noted the increase of new **flavoured products intended to change the taste of cigarettes and roll-your-own tobacco but sold separately**, such as cigarette paper tubes with characterising flavour, liquid to flavour roll-your-own tobacco, aroma capsules, **menthol sticks** to insert into cigarettes, and flavoured filters or flavoured cards put inside a cigarette packet. Such products are currently not regulated by the TPD and are likely developed by the **industry to circumvent Art. 7**. Member States noted that sales of such products were on the rise too. Member States also noted that e-cigarette liquids have been used by consumers to flavour cigarettes. One Member State considered that menthol as an ingredient should be banned, not just 'menthol cigarettes,' and similarly, another recommended that the characterising flavour prohibition be extended to any type of tobacco product, and to e-cigarette liquids. Another Member State stated that they already had a ban on all products containing menthol in place.

It is worth pointing out, however, that to avoid some of the circumventions by manufacturers outlined above, Art.7(7) already requires Member States to ban products if any of their components (such as filters, papers, packets, capsules, etc.) contain flavours or modify the smell, taste or smoke intensity.

Art. 7(6) Prohibition of products containing specific additives

In terms of implementation, over half of the Member States had national legislation on the prohibition of the general additives as stated in the TPD¹²². One Member State **faced issues with prohibiting the placing on the market of tobacco products with additives listed in Art. 7(6)** and five more faced challenges to some extent¹²³. Four Member States¹²⁴ reported that they did not face issues in implementing this provision. Another Member State indicated that they were planning to perform tests to check this information. They had received notifications from ten economic operators of tobacco products **containing prohibited ingredients** in 2019. These operators were informed and required to modify the composition or withdraw the product.

The most common issues identified related to products found on the market containing certain specific additives, namely caffeine and vitamins (A, C and E). **Tobacco products with coffee and mate flavours containing caffeine** were reported in two Member States , as caffeine is the inevitable 'side' effect of adding such flavours. A few Member States had issues with the **CBD content in tobacco** that came from 'technical cannabis' plants **mixed** with tobacco.. CBD content in tobacco could be banned based on 7(6) as it can create the impression that a tobacco product had a health benefit (reported by a few Member States). Hence, a few Member States proposed hemp and CBD to be included in the list of prohibited additives.

¹²² NCA input during the gap filling workshop.

¹²³ 16 Member States did not face any challenges

¹²⁴ One Member State clarified compliance is assessed based only on the submissions, as it would be difficult to perform a wider analysis of the products.

Member States had different views on possible lists: one Member State pointed out that for broad definition of substances such as vitality and energy, a harmonized **negative and evolving** list of substances (including plant extracts) **could also be set up**. Other substances, such as caffeine or taurine, are easier to control. Another Member State considered that having two lists, one with prohibited additives and products and another one with permitted ones would be helpful. A few other Member States, on the other hand, would prefer a list containing additives which are permitted. Another Member State called for the **clarification of what additives** are to be considered to 'facilitate inhalation or nicotine uptake'. Two Member States reportedly had a list of substances that are not allowed.

Ambiguities were reported with the **identification of ingredients due to the practice of using generic names**, incomprehensible abbreviations for some ingredients and inconsistent CAS N° input by the submitter. With regard to issues with naming conventions, one Member State pointed out that there was no EU-level '**banned names list**'.

Finally, some **terminology issues** were reported regarding the application of Art. 7(6) (which also applies to Art. 20(3)(c)) as it is not clear how proven or approved 'other additives' are identified.

Art.7(9) Prohibition of products with additives that increase the toxicity or addictiveness or the CMR properties

At the time of the questionnaires, not a single Member State in the EU had prohibited any product under this provision. Two Member States reported that this prohibition could be considered after **the results of WP 9 of the Joint Action of Tobacco Control (JATC) are published**. Another Member State was considering the creation of a national negative list based on the results of this WP. Member States noted that to enforce such a prohibition they have to prove that an additive is in the product. However, it was difficult for them to know which additives to target/start with, due to lack of expertise. Some Member States mentioned the need to pool technical expertise on additives in the EU. One Member State suggested splitting/co-ordinating each ingredient focus across Member States. Along the same lines, there was also mention of a lack of resources and laboratories, and time or difficulty to review product data submitted through the system. However, a few Member States stated that a lack of resources and laboratories was not a problem for them.

Another Member State considered **the provision an extreme measure**, therefore if a Member State was considering any bans of products, in order not to distort the internal market, the relevant TRIS¹²⁵ procedure might need to be considered.

Another Member State found that Art. 7(9) did not have much use, as in their view, regulatory actions can only be based on Art. 6(2)(a) regarding increased toxicity, considering that the only current experimental approach to assess toxicity was comparative testing. This testing however lacks discriminatory power in the case of products with an extremely high toxicity such as cigarettes. Hence, the current phrasing of Art.7(9) and 6(2)(a) would require more consistent wording and reflect the limitations of the current scientific methods for the intended purpose.

¹²⁵ The Single Market Transparency Directive (EU) 2015/1535 (<https://eur-lex.europa.eu/eli/dir/2015/1535/oj>) serves to prevent regulatory barriers arising in the internal market for products and information society services. The European Commission, the EU Member States and the other participating countries share information on the notification procedure under the Single Market Transparency Directive using the Technical Regulations Information System (TRIS)

One CSO pointed that the problem is also whether information that is submitted can be used to ban products based on the TPD terms. Another CSO agreed that the terms are hard to prove, such as 'addictiveness,' and 'toxicity,' adding that 'attractiveness' is easiest.

Art.7(14) Transposition for products with characterising flavours representing sales volumes of 3% or more

Products with characterising flavour with a market share above 3% were still permitted on the market until 20 May 2020 as prescribed by Art. 7(14). Member States responded to the study's survey shortly before 20 of May 2020, between one and two weeks before the deadline for the application of this provision. A few Member States indicated that products containing the characterising flavour menthol were still on the market, but only until the deadline.

There was some degree of misinterpretation among few Member States. These noted that inconsistencies between the provisions about 'additives' in Art. 7(6) and 'characterising flavours' in Art. 7(1) and in Art. 7(14) prompted by the 'menthol ban'. In their view this meant that the provisions covered the same element all together. This is however not correct, as Art. 7(6) prohibits additives with certain characteristics, while Art. 7(14) only provides for a longer implementation period for tobacco products banned through Art. 7(1) given their high market share.

Other issues with the application of Art. 7

Two Member States **encountered difficulties in the practical application of the provision of Art. 7**. Seven Member States encountered issues to some extent¹²⁶. The main issues identified concerned a lack of laboratory assessments performed, capacity to check the products, and a need to assess the existence of prohibited characteristics.

Member States reported for example on their lack of capacity to undertake **a follow-up laboratory test** which may be linked to the fact, as explained in Art.4(2) above, that not all Member States have certified laboratories on their territory. One Member State is currently looking how to support their laboratory and institute of public health to achieve this goal, another Member State also mentioned a lack of capacity to carry out the assessments in their own laboratory.

One laboratory in one Member State sought to adapt its methods for determining caffeine and taurine and to apply them to tobacco products. Due to the **lack of technical equipment with high sensitivity and low quantifications, the studies did not provide sufficiently reliable data and were stopped**.

Art. 7(14) states that 'In the case of tobacco products with a characterising flavour whose Union-wide sales volumes represent 3 % or more in a particular product category, the provisions of this Article shall apply from 20 May 2020.' DG SANTE has clarified to Member States that it considered that Article 7(14) TPD is not intended to permit a derogation from all provisions in Art. 7 TPD, but merely those parts of Art. 7 referring to 'characterising flavours'.

Effect of Art. 7 prohibitions on economic operators

Roughly half of the manufacturers (9/19) mentioned that **the portfolio of their organisation has been affected by the implementation of the provisions introduced in Art.7 on characterising flavours**. One manufacturer mentioned having been affected to some extent.

Cigarettes with characterising flavour were discontinued by different manufacturers. Several economic operators reported to have discontinued between 13

¹²⁶ Roughly half of the Member States did not find any issues.

and 196 SKUs (*SKU: Stock-keeping Unit*: The SKU relates to an item that is unique in terms of product, brand, variant or packaging—such as distinct variant packaging options of 20, 22 or 40 sticks¹²⁷). In the majority of cases it was a consequence to the ban on menthol. Three manufacturers (out of 17) reported that **the portfolio of their organisation had been affected by the implementation of the prohibition of tobacco products containing the additives in Art.7(6)** and six additional manufacturers mentioned that the portfolio of their organisation had been affected to some extent. The actions taken to correct their products are summarised in the table below:

Table 5. Corrective action taken (Each row represents a manufacturer)

Aligned portfolio to Art.7(6)	Ceased use of additives	Change brand names	Change packaging	Changed recipes
X				
	X			
		X	X	X
		X		

¹²⁷ Greenland SJ. (2015) Cigarette brand variant portfolio strategy and the use of colour in a darkening market. *Tob Control* 2015;24:e65–e71.

3.3 Labelling and packaging

3.3.1 General observations on Art.8-14

The Directive includes a set of requirements for mandatory health warning labelling and packaging of tobacco products. These requirements include general warnings and information messages (Art. 9) and combined health warnings consisting of a picture and text (Art. 10) for tobacco products for smoking, and specific provisions for these warnings. The TPD (Art. 11) allows for exemptions for certain tobacco products for smoking, and also sets out requirements for labelling smokeless tobacco products (Art. 12). Certain elements of product presentation are prohibited, such as promotional elements or references to taste or smell (Art. 13), and finally the shapes and size of cigarette unit packets and roll-your-own tobacco are prescribed (Art. 14). The study sought to understand how the general provisions on labelling and packaging were being implemented, and any obstacles encountered.

CSOs and HEs considered that the TPD represented a **step forward in tobacco control** due to the labelling and packaging provisions it provides in Art. 8-14. Particularly positive packaging changes brought by the TPD were **increasing the size of health warnings** (several CSOs, prohibiting '**slim' packs** (one CSO), and providing **information on cessation services** (a few HEs). An organisation representing consumers stated that provisions on health warnings '*have contributed to making tobacco 'old-fashioned' to young people'* which has led to decreased consumption.

Further, harmonising rules on labelling and packaging allowed the TPD to facilitate the smooth functioning of the internal market.

CSOs and HEs found the articles related to labelling and packaging to have the clearest **transposition requirements** of any set of articles: more than four in five respondents (82%) agreed that these provisions were clear regarding transposition. 37% of CSO and HE respondents to the online survey were **not aware of any products** on the market which were **not compliant** with these articles; 19% were aware of non-compliant products. Among economic operators, 57% reported that **guidance on packaging was useful** 'to some extent'. Member States, on the other hand, seem to not have experienced many problems¹²⁸. One Member State reported that the regulation of tobacco product packaging is detailed and rather complicated, but nevertheless it is largely complied with by operators.

A consistent theme in economic operator responses related to Art. 8-14 concerned the **costs and effort required to bring their products in line with the Directive**. For example, product portfolios were redesigned, which was reportedly expensive (reported by a few economic operators), and one economic operator indicated that some products with distinctive packaging (e.g. slide packs) were **discontinued**. These changes represent a necessary process as indeed the TPD required product packaging to change, and therefore this does not represent an issue with the implementation of the TPD.

Harmonisation and consistency of labelling and packaging

Stakeholders largely perceived **harmonisation of packaging across Member States**, and this increased uniformity was seen as a **particular strength of the TPD**. Five Member States reported that the standardisation of the labelling requirements in the TPD had provided an element of **consistency** across Member States. Similarly, when asked to consider all labelling and packaging provisions (Art. 8-14), many

¹²⁸ In the gap-filling workshop, there were generally few comments from Member States on their experiences with current rules, suggesting they have not experienced considerable problems.

economic operators reported they were implemented consistently across Member States. The small number of CSO and HE respondents surveyed which operate across more than one Member State were also of this view; e.g. '*Measures could have been initiated by Member States without EU level involvement, but the effectiveness, ambition and coherence would likely have suffered. For example, there would most likely not be harmonised health warnings...*' (HE).

Economic operators which operated in more than one Member State were asked more specifically to reflect on the consistency of labelling, packaging, and product presentation requirements. Detailed information is provided in the relevant articles in Section 3.3.2; however the responses are summarised in the table below. The main source of disharmony noted by a few CSOs and a few of the economic operators above was that only some Member States implemented **plain packaging**. See the analysis of Art. 24(2), as well as the case study in Annex 9 for further information about this optional provision.

Table 6. Number of Economic operators-that reported Member State variation (out of 19)

Variations between Member States in how they had interpreted...	Variations	Variations to some extent	No variations
Labelling requirements	Nine	One	Four
Packaging requirements	Eight	One	Four
Product presentation requirements	Six	One	Five

A few Member States drew attention to potential incoherence with the **Single-Use Plastics (SUP) Directive**. The SUP Directive requires informing consumers of re-usable alternatives, while the TPD may prohibit this as adding information on the use of re-usable alternatives could be considered as tobacco promotion. In one Member State, discussions are ongoing on the implementation of Art. 7 of the SUP Directive and how this interacts with current packaging and labelling requirements of tobacco products with filters according to the TPD. This provision involves marking appropriate waste management options or waste disposal means and information on the presence of plastics in tobacco products with filters and filters marketed for use in combination with tobacco products. Several economic operators reported that the TPD requirements around packaging and labelling were **incoherent** with the requirement to report plastics and recycling information as per the SUP Directive, particularly due to physical space constraints on packaging.

Art. 7(12) of the TPD states that tobacco products other than cigarettes and roll-your-own tobacco are exempted from the prohibition on characterising flavours. However, the European Commission is permitted to adopt delegated acts to withdraw that exemption for a particular product category, if there is a substantial change of circumstances. Several economic operators reported dissatisfaction with the fact that although flavours are allowed for the time being, **packaging is not permitted to include information about flavour**.

Proposed improvements to labelling and packaging requirements

Around half of CSO and HE respondents (49%) considered that the provisions of Art.8-14 had **remained relevant to address current developments** in the tobacco and related industries including technological, scientific, or market developments. However, over a third (37%) responded that the provisions had not remained

relevant. When Member States were asked if there should be stricter/clearer labelling provisions overall or on specific products, nearly half of Member States agreed that there should be. One stated there should be stricter/clearer provisions to some extent, and nine stated there should not be stricter or clearer provisions. The main recommendations stakeholders gave to improve labelling and packaging provisions are the following:

- **Update requirements:** Stakeholders (several CSOs and a few HEs) highlighted that updated provisions are required to better protect public health. For example, many suggested increasing health warnings to **85%** of the surface. One Member State suggested that consideration should be given to packaging of new products and emphasising nicotine concentration and addictiveness on labels.
- **Mandatory plain packaging:** Many CSO and HE stakeholders recommended making plain packaging mandatory in the EU, for instance to align more with FCTC Art. 13. One Member State considered that stricter regulation on labelling and packaging could lead to **easier implementation**, as in this Member State plain packaging has reportedly helped avoid circumvention of the rules by the industry. On the contrary, another Member State expressed its hesitation towards implementing plain packaging. See Art. 24(2) and the case study in Annex 9 for more information about plain packaging.
- **Improved packaging for products other than cigarettes and roll-your-own tobacco:** A few CSO and HE stakeholders recommended extending the provisions for labelling and packaging which apply to cigarettes and roll-your-own tobacco to all tobacco products to close 'loopholes' (presumably in the form of the exemptions made possible by Art. 11). One Member State considered that cigarette papers should be included in provisions related to labelling.
- **Regulate aspects such as edges and seals:** CSOs and HEs remarked that the tobacco industry was finding ways to distinguish packaging through edges and seals. They stated that regulations on this could help to prevent this in the future.
- **Regulate the number of cigarettes per package:** A few Member States stated that there may be scope for also regulating the maximum number of cigarettes allowed per package to avoid different sizes as marketing strategy or perceived price differences. As an example, Hungary has set a maximum number of cigarettes per pack: 25 cigarettes¹²⁹.
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3.3.2 Findings by article

Art. 8 (Labelling and packaging general provisions) and Art. 9 (General warnings and information messages on tobacco products for smoking)

Main findings: Art. 8 and 9 were mostly implemented smoothly, and in the spirit of the Directive, with minor instances of ambiguity.

Most Member States did not experience issues with provisions on general warnings and information messages on tobacco products for smoking. There were a few points of confusion with how and where the warnings were to be published on the package. Economic operators reported being hindered somewhat by the Implementing decisions being published later than they

¹²⁹

<https://net.jogtar.hu/getpdf?docid=a1300039.kor&targetdate=&printTitle=Government+Decree+39/2013+%28II.+14.%29+Korm.&dbnum=62&getdoc=1>

considered desirable; however there was no timeline specified in the TPD and they were adopted well ahead of the TPD applicability date.

Subsection Art. 9(3) was more challenging to implement, with half of Member States facing issues. The main difficulty was that it was confusing to stakeholders if this provision was meant to prohibit 'slim' packets of cigarettes. As a result, there has been some degree of disharmony as some Member States have prohibited them and some not. Some economic operators attempted legal challenges to the prohibition of slim packets.

Overview

Art.8 - General provisions

Art.8 states that each unit packet of a tobacco product and any outside packaging shall carry health warnings which are described in the subsequent articles, and these warnings shall be in the official languages of the relevant Member State (Art.8(1)).

The health warnings should not be commented on in any way (Art.8(2)). Health warnings must also:

- Be irremovably printed, not obstructed by any other stamps or markers, and intact, except for flip-top lids, in which case the warning may be split in a manner which ensures the graphical integrity of the warning (Art.8(3)).
- Not hide or interrupt tax stamps, price marks, tracking and tracing marks, or security features (Art.8(4)).
- Have a black border with a width of 1 mm inside the surface area that is reserved for these warnings, except for health warnings in Art.11 (Art.8(6)).

Health warnings may be adapted in certain cases (Art.9(5), Art.10(3) and Art.12(3)), and in these instances the warnings must be factual, or Member States must have a choice of two warnings, one of which is factual (Art.8(7)).

Art.9 - General warnings and information messages on tobacco products for smoking

Art.9 states that each unit packet and any outside packaging of tobacco products for smoking shall carry one of the following general warnings: 'Smoking kills – quit now' or 'Smoking kills' (Art.9(1)), and the following information message: 'Tobacco smoke contains over 70 substances known to cause cancer.' (Art.9(2)).

Art.9(3) states requirements about these general warnings should be implemented on varied packet types:

- Cigarette packets and roll-your-own tobacco in cuboid packets. Importantly, these health warnings shall have a width of not less than 20 mm.
- Packets in the form of a shoulder box with a hinged lid that result in the lateral surfaces being split into two when the packet is open
- Roll-your-own tobacco marketed in pouches
- Roll-your-own tobacco in *cylindrical packets*

Art.9(3) also requires that both the general warning and the information message shall cover 50 % of the surfaces on which they are printed.

Art.9(4) states other requirements about the general warnings, including font and placement requirements.

The European Commission is empowered to adopt delegated acts to adapt the wording of the information message (Art.9(5)), and implementing acts to determine the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches, taking into account the different shapes of pouches (Art.9(6)). Commission Implementing Decision 2015/1735¹³⁰ was adopted to specify the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches.

One Member State faced issues in implementing the **provisions concerning general warnings and information messages on tobacco products for smoking**, and a few faced issues to some extent¹³¹. A proportionally higher share of economic operators also reported implementation difficulties¹³². The main points raised, as listed below, concerned ambiguities as to how and where the warnings were to be published on the package, and practical problems applying the warnings:

- Member States described several questions and challenges they received. a few Member States, for example, faced some issues with the packaging of **waterpipe tobacco**, but further information was not provided.
- There was no timeline specified in the TPD for publication of the implementing decision, and Commission Implementing Decision 2015/1735¹³³ was published in September 2015. Nevertheless, a few economic operators reported that in their opinion, these decisions were not published in a **timely manner**, which created packaging waste in particular for roll-your-own tobacco.
- Many economic operators reported having to alter packaging to make it compliant with the TPD, and this sometimes led to discontinuing products (e.g. 'soft packaging products'). This was an unavoidable element of the TPD, **consistent with the introduction of the new requirements**.

However, there were some reported instances which were ambiguous or may represent genuine problems with the TPD. The box below provides an overview of the issues reported by a few economic operators, by product type.

- **Roll-your-own tobacco:** The implementing act on lateral health warnings for pouches only covered laminate and paper pouches and standing bags, leaving ambiguity over round and square tins and buckets.
- **Cigarettes:** Uncertainty about the positioning of the 20 mm label, hinge lids and soft packs. Clear implementing acts for combined health warnings, but not for lateral health warnings for cigarettes.
- **Cigars and cigarillos:** High reported costs for SME cigar manufacturers. Art.9 was not made with cigars in mind and claimed that cigar boxes are required to carry more warnings than cigarettes, although this is clearly not the case in the TPD.

¹³⁰ The European Commission. (2015). Commission Implementing Decision (EU) 2015/1735 of 24 September 2015 on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1735&from=EN>

¹³¹ 17 Member States faced no issues.

¹³² 12 /19 economic operators reported issues in implementing the provisions. Four reported issues to some extent, and one reported no issues.

¹³³ The European Commission. (2015). Commission Implementing Decision (EU) 2015/1735 of 24 September 2015 on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1735&from=EN>

Art.9(3) General warnings for cigarettes and roll-your-own tobacco

One CSO cited the **prohibition of slim packets** (cigarette packet with a depth of less than 20 mm) as a main strength of the TPD in improving tobacco control. However, ambiguity and inconsistency in interpretation of Art.9(3) meant that not all Member States are implementing this provision as it was intended, leading to some degree of non-harmonisation across Member States.

11 Member States indicated to have faced issues in implementing the provisions concerning the minimum dimensions of health warnings on the lateral surfaces of cuboid packets such as slim/flat/shoulder-hinged lid-packets, while 10 did not face issues. The main point of unclarity was **whether the provision was meant to explicitly prohibit slim packets or not**; this provision has been interpreted differently across Member States. The European Commission clarified to Member States that in its view slim cuboid packages less than 20 mm deep are not allowed in the EU.

There were also some legal challenges from economic operators, potentially to circumvent the ban of slim packages. The following specific issues were raised:

- Around a quarter of Member States experienced problems with **interpretations of terms such as 'width' and 'lateral surface'**. A few Member States noted that it was not clear if this provision de facto prohibited slim packets:
 - In two Member States, slim packets are **still permitted** because of the uncertainty of the interpretation of this article. Another highlighted that '*In a revision of the TPD this point must become clearer, with a clearer prohibition of slim packets.*'
 - Another Member State was uncertain whether slim packets were permitted, although they considered that the overall attitude of the European Commission suggested the slim packets were prohibited. This Member State is currently revising a provision which at present still allows slim packets on the market. Another Member State declared that slim packets **would be prohibited** from 30 October 2021.
 - Two Member States recommended that Art.9(3) should be clearer regarding the **20 mm width** and **prohibition of slim packets**. In one of these countries, manufacturers want to measure the 20 mm along the height putting the packet in a lying position, not in the natural vertical position.
- Member States have chosen various methods to ensure that the ban on slim packets is enforced. To illustrate the enforcement activities, the following examples can be given: one Member State launched a **targeted effort** to ensure the market was compliant with the requirements of the Directive, and there were no subsequent reports of slim packets. Another issued **fines** for non-compliance.
- In a few Member States which prohibited slim packets, there were legal challenges. In one Member State, national law now clarifies, after an unsuccessful legal challenge, that the thickness of the cigarette pack may not be less than 20 mm. The provisions were also challenged or contested in three other Member States. Another Member State indicated that they received many communications from lawyers representing the industry related to slim packets, and overall found that it was **difficult to implement**. Two Member States considered that slim packets could be more explicitly banned in the Directive, with specifications to manufacturers on how to comply with the requirements.

Art.10 Combined health warnings for tobacco products for smoking

Main findings: Art. 10 is a key article of the TPD, as it introduced combined health warnings for tobacco products for smoking.

There is some evidence from literature that warning labels as specified by Art. 10 have increased awareness of the harmful effects of tobacco products, and combined health warnings as specified in Annex II of the TPD appear to be one of the major routes by which awareness has been achieved.

Art. 10 was overall successfully implemented in the Member States as the Directive intended, with some minor ambiguities. There is a diversity of shapes and sizes of packaging for tobacco products for smoking, and there were some challenges with applying these provisions to non-traditional shapes. There was also ambiguity around what constituted a 'front' of a package.

Overview

Art.10 stipulates that (1) each unit packet and any outside packaging of tobacco products for smoking should carry combined health warnings, which shall (Art.10(1)):

- Contain a text warning, colour photograph, and cessation information
- Cover 65 % of both the external front and back surface of the unit packet and any outside packaging.
- Appear at the top edge of a unit packet and any outside packaging and be positioned in the same direction as any other information appearing on that surface of the packaging (there were some transitional exemptions from these obligations, however this transition period has ended).
- In the case of unit packets of cigarettes, respect the following dimensions: height: not less than 44 mm; width: not less than 52 mm.

(2) The combined health warnings are grouped into sets and should be rotated on an annual basis (Art.10(2)).

(3) The European Commission is empowered to adopt delegated acts to adapt the text warnings and picture library, as well as (4) define the technical specifications for the layout, design and shape of the combined health warnings, considering the different packet shapes. Commission Implementing Decision 2015/1842¹³⁴ was adopted to provide the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking.

Evidence about the effects of this article

Several CSOs cited the size of the combined health warnings as required by Art. 10 as being a key benefit of the TPD, with literature confirming that these provisions have had a positive impact.

In addition to consumers simply noticing the packet changes, **awareness of the harmful effects of tobacco products** appears to have changed since the TPD was

¹³⁴ The European Commission. (2015). Commission Implementing Decision (EU) 2015/1842 of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1842&from=GA>

implemented. Combined health warnings as specified in Art. 10(1) are one of the major routes by which awareness on the effects of tobacco has been achieved. Based on evidence from multiple Member States, these interventions appear to significantly increase knowledge of tobacco-related diseases and associated harms and motivation to quit, and they may even reduce tobacco consumption and youth smoking initiation^{135,136,137,138,139}. Data from 10 European countries (BE, DE, DK, ES, FR, IT, PL, RO, SE and UK) suggests that the effectiveness of pictorial warnings may **decrease over time** but can be mitigated by the periodic inclusion of new pictures, as specified in Art. 10(2) of the TPD¹⁴⁰. A recent study from the EUREST-PLUS consortium¹⁴¹ found that after the introduction of the combined health warnings due to Art. 10, adult smokers in six Member States (DE, EL, HU, PL, RO, ES) reported that these had increased salience, in that they **noticed the warning labels on cigarette packages or roll-your-own tobacco packets more often**. However, there were no clear trends for cognitive reactions (in response to 'To what extent do the warning labels make you think about the health risks of smoking?' and 'To what extent do the warning labels on cigarette packs make you more likely to quit smoking?') or behavioural reactions ('In the last 30 days, have the warning labels stopped you from having a cigarette when you were about to smoke one?'). Another study from the same research group¹⁴² found that among adult smokers and recent quitters in the same six Member States, over half of smokers and around a third of quitters **noticed at least one of five TPD-related packet changes**. Over one-quarter of all respondents noticed changes to health warnings, standardized openings, minimum packet unit size, and the removal of TNCO information on packaging. These results varied across countries and demographics of study participants.

Implementation of this article

One Member State reported issues in implementing the provisions concerning **combined health warnings for tobacco products for smoking, including the minimum dimension of warnings**, and a few reported issues to some extent¹⁴³.

¹³⁵ Mannocci et al (2019). The impact of pictorial health warnings on tobacco products in smokers behaviours and knowledge: the first quasi-experimental field trial after the implementation of the tobacco law in Italy. Ann Ist Super Sanita: 55(2).

¹³⁶ Crosbie E. (2019). Removing the last billboard for the tobacco industry: Tobacco standardized packaging in Ireland. Health Policy, 123(10):932-935.

¹³⁷ Bogdanovica, I. et al. (2017). Awareness of Standardised Tobacco Packaging among Adults and Young People during the Final Phase of Policy Implementation in Great Britain. Int J Environ Res Public Health, 14(8).

¹³⁸ McNeill, A., Gravely, S., Hitchman, S.C., Bauld, L., Hammond, D., & Hartmann-Boyce, J. (2017). Can the use of standardised packaging for tobacco products reduce the use of tobacco? Cochrane Database of Systematic Reviews: 4.

¹³⁹ Hammond, D. (2011). Health warning messages on tobacco products: a review. Tobacco Control: 20.

¹⁴⁰ Woelbert, E. and d'Hombres, B. (2019). Pictorial health warnings and wear-out effects: evidence from a web experiment in 10 European countries. Tob Control, 28: e71-e76

¹⁴¹ Kahnert, S., Driezen, P., Balmford, J., et al on behalf of the EUREST-PLUS consortium. (2020). Effectiveness of tobacco warning labels before and after implementation of the European Tobacco Products Directive—findings from the longitudinal EUREST-PLUS ITC Europe surveys. European Journal of Public Health: 30(Supplement 3).

¹⁴² Kyriakos, C. N., Driezen, P., Girvalaki, C., et al on behalf of the EUREST-PLUS consortium. (2020). Awareness and correlates of noticing changes to cigarette packaging design after implementation of the European Tobacco Products Directive: findings from the EUREST-PLUS ITC Europe Surveys. European Journal of Public Health: 30(Supplement 3).

¹⁴³ 16 Member States reported no issues.

Nine economic operators (out of 19) reported to have faced issues in implementing these provisions¹⁴⁴.

The problems identified are similar to those discussed under Art. 8 and 9 above, and many problems identified by economic operators were 'unavoidable' due to alterations to packaging. However, a few relevant issues mentioned included difficulties to implement the combined health warnings on different types of packets and confusion around the interpretation of certain terms used in the article. Economic operators also reported that variations in national provisions on combined health warnings between Member States created production and implementation issues. More specifically, the following points were raised:

- The **packets** of some tobacco products posed implementation challenges. In one Member State, there was confusion about what constituted the 'front' of a unit packet. One Member State found it difficult to adapting warning size provisions to **cigar and cigarillo** packaging, and this was also reported by an economic operator, however further information was not provided.
- Art.10(1)(c) states that '**cylindrical packets**' shall display two combined health warnings, equidistant from each other, each covering 65% of their respective half of the curved surface'. One Member State considered that a single combined health warning would be more appropriate as it would increase legibility. Similarly, another Member State mentioned issues with the way warnings were printed on cylindrical packets. To avoid misunderstanding, this Member State added in their decree that '*the warnings occupy the entire width of the two surfaces to which they are applied*'.
- Economic operators also highlighted difficulties related to variations between **Member States' national provisions**. One economic operator reported that country-specific packaging meant that orders fell below printers' minimum order quantities. However the elements of packaging which vary by country and cause these issues were not specified.
- A few economic operators considered that the TPD provisions around health warnings for roll-your-own tobacco on non-visible parts of the package **contradicted the TPD provision requiring that health warnings were visible**, at least in the way Member States had chosen to implement these.
- Finally, similarly to Art. 8 and 9, a few economic operators reported difficulties related to the **timeframe** of receiving final clarity about how the health warnings were to be applied.

Around two thirds of Member States received **claims or complaints concerning the content or persons depicted in the picture library of combined health warnings**¹⁴⁵. In nine Member States , the claims or complaints concerned people suggesting that they, or one of their relatives, were depicted on the warnings. The European Commission also reported to have received numerous complaints on this topic, as the copyright holder for the images. One economic operator also reported similar issues with consumers' images. At European level, one such case was brought

¹⁴⁴ Three economic operators reported issues to some extent, and one reported no issues.

¹⁴⁵ Seven had not received such claims or complaints.

by in May 2017¹⁴⁶, and another was brought by an individual in September 2020¹⁴⁷. In both cases the General Court dismissed the actions.

In relation to these claims, one Member State reported that several **legal proceedings had been launched**, at the conclusion of which the Supreme Court clarified that the claim that the deceased person depicted on the pack of cigarettes was a relative of the plaintiff must be substantiated by the plaintiff. In another Member State, the person submitting the complaint was told that everyone in the images had **provided consent**. Another explained the process the European Commission undertook to establish the picture library. In five Member States, complaints were **transferred to the European Commission**, as the copyright holder. A Q&A document published by the European Commission on the combined health warnings¹⁴⁸ clarified that 'all individuals depicted in the pictures were informed that the pictures would be used as part of the EU picture library and signed consents for this purpose...Any similarity to other individuals not having given consent, however unfortunate, is purely coincidental.' A few Member States responded using information **provided by the European Commission**. Spain has published a document of frequently asked questions on the Health Ministry's website¹⁴⁹.

Finally, a few Member States also received complaints that the warning in Figure 2 below encouraged and normalised smoking in young people.

Figure 2. Pictorial warning



Art.11 Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco

Main findings: Around half of Member States implemented exemptions to Art. 9 and 10 allowed through Art. 11, with more Member States exempting products from carrying the information message (Art. 9(2)) than from carrying the combined health warnings (Art. 10). When products were

¹⁴⁶ Order of the General Court of 18 April 2018 — Iordăchescu and Others v Parliament and Others (Case T-298/17). Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62017TB0298&from=CS>

¹⁴⁷ Reports of Cases: Judgment of the General Court (Sixth Chamber) of 23 September 2020 – FF v Commission (Case T-654/19). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62019TJ0654_INF&qid=1608227341583&from=EN

¹⁴⁸ European Commission. (n.d.) Q&A: Combined health warnings on tobacco products.

Available at:

https://ec.europa.eu/health/sites/health/files/tobacco/docs/pictorialwarnings_tpd_en.pdf

¹⁴⁹

https://www.mscbs.gob.es/ciudadanos/proteccionSalud/tabaco/docs/Preguntas_frecuentes_advirtencias_sanitarias.pdf

exempted, there were very few problems with implementing the alternative warnings.

CSOs and some Member States saw the exemptions as being negative for public health. Some Member States may have enacted the exemptions following pressure from the tobacco industry.

Some economic operators reported facing difficulties with implementing the warnings, as Member States adopted different labelling requirements as a result of the exemptions, which are clearly permitted by the Art. 11's 'may' clauses.

Overview

Art. 11(1) states that Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from:

The obligations to carry the information message 'Tobacco smoke contains over 70 substances known to cause cancer' and

The combined health warnings laid down in Art. 10.

If they are exempted, these products shall carry the general warning described in Art. 9(1), one of the text warnings listed in Annex I (e.g. 'Smoking causes 9 out of 10 lung cancers') and shall refer to cessation services.

The general warning shall cover 30 % of the relevant surface of the unit packet and any outside packaging (Art. 11(2)), and the text warning shall cover 40 % of the relevant surface of the unit packet and any outside packaging (Art. 11(3)). These surface area proportions are larger in countries with more than one official language.

Table 7 below shows how many Member States exempted any tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations as permitted in Art. 11.

Table 7. Exemptions for products

Obligation	Status of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco		
	Exempt	Not exempt	No response
Carry the information message 'Tobacco smoke contains over 70 substances known to cause cancer' in Art.9	13	10	5
Carry the combined health warnings laid down in Art.10	14	8	6

Related to the exemption of carrying the information message '**Tobacco smoke contains over 70 substances known to cause cancer**', all 13 Member States had exempted **any tobacco product for smoking** other than cigarettes, roll-your-own tobacco and waterpipe tobacco. Three Member States specified that they were not considering introducing exemptions for carrying the information message 'Tobacco smoke contains over 70 substances known to cause cancer'.

Regarding exempting products from carrying the **combined health warnings**, in most of these 14 Member States, **all eligible products were exempted**. However, in one Member State the exempted products are pipe tobacco, cigars, and cigarillos, in one other Member State cigars are exempted, and in another some cigars are exempted. Two Member States specified that they **were not considering introducing exemptions**.

Some Member States and stakeholders viewed the exemption measures as negative. When considering the Directive overall, a few CSOs reported dissatisfaction with the number of exemptions in the TPD overall for tobacco products other than cigarettes and roll-your-own tobacco. One Member State considered that the exemption constituted a **disadvantage**, as these products may now be perceived as more attractive or less harmful by consumers. Another noted that the exemption in Art. 11 was made because of high pressure from the tobacco industry; there were no health advantages to this decision. One economic operator described how industry had lobbied in Member States to enact the exemption for cigar and cigarillo, as the packaging was reportedly too small to fit the default warnings. One Member State reported exemptions for some large cigars. As these products are not popular among children, this was a compromise between political parties when implementing the TPD.

Member States were also asked whether in case of exempted products, they had faced any issues in **implementing the alternative labels described in Art. 11**. Two Member States confirmed to have faced issues to some extent¹⁵⁰. In one Member State, as cessation information is in black on a yellow background¹⁵¹ for cigarettes, roll-your-own tobacco and waterpipe tobacco, some manufacturers had, in good faith, also put this information with a yellow background on the labels applied to products exempted from the requirements by Art. 11. The Member State legislation did not foresee this development. However, authorities clarified the issue easily.

Six economic operators (out of 19) reported issues in implementing **labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco**¹⁵². One economic operator reported that Art. 11 provisions were **well adapted** for cigars and cigarillos, whilst another reported that it was **not clear where the health warning** should be applied to these products. Another economic operator reported issues with diverse packaging types, for example tube-shaped packaging for cigars and cigarillos. However, variations in the warnings for tobacco products across Member States is clearly permitted by the 'may' clauses in Art. 11.

Art.12 Labelling of smokeless tobacco products

Main findings: This article was implemented in full compliance with the requirements of the Directive, with minor practical difficulties encountered in specific Member States. In a few Member States smokeless tobacco products have not been a regulatory priority therefore there is not much to report (yet) in this area.

Overview

¹⁵⁰ 19 did not face any issues.

¹⁵¹ The Member State response stated 'As the cessation information was in yellow for cigarettes, RYO and waterpipe tobacco, some producers in good faith had also put this information in yellow on these labels.' This was assumed to mean black text on a yellow background, as otherwise it would not be TPD-compliant.

¹⁵² One reported issues to some extent, and six reported no issues.

Art. 12 states that each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning: 'This tobacco product damages your health and is addictive.' (Art.12(1)). The health warning laid down in paragraph 1 shall comply with the requirements specified in Art.9(4). It shall also appear on the two largest surfaces of the unit packet and any outside packaging and cover 30 % of the surfaces of the unit packet and any outside packaging (Art.12(2)).

The European Commission is empowered to adopt delegated acts to adapt the wording of the health warning (Art.12(3)).

A few Member States faced issues to some extent in implementing the provisions concerning **labelling of smokeless tobacco products**¹⁵³. One economic operator (out of 19) faced issues to some extent in implementing these provisions, and five did not face any. The issues encountered were largely unique to the Member State reporting on them. One Member State, for example, noted that smokeless tobacco products had much **more diverse packaging** than classic tobacco products, which could lead to more discussion about how these provisions should be implemented.

In one Member State, authorities mainly focused on the labelling of cigarettes and roll-your-own tobacco so far, and in the coming year they expected **a more targeted effort** for smokeless tobacco. Similarly, another Member State added that all smokeless tobacco products had been banned until now, but there was a need to strengthen smokeless tobacco health warnings.

Art.13 Product presentation

Main findings: In order to cover a range of promotional packaging and products, Art. 13 used broad terms to describe prohibited elements. However, the lack of specific indications about what phrasings should be permitted or prohibited led to problems with interpretation and divergent national approaches. Member States experienced difficulties in determining non-compliance with the requirements of the Directive. There were legal challenges in several Member States. Specific brand and packaging disputes have been settled with varied efficacy.

Overview

Art.13(1) states that the labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that:

- (a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;
- (b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;
- (c) refers to taste, smell, any flavourings or other additives or the absence thereof;
- (d) resembles a food or a cosmetic product;
- (e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.

¹⁵³ 19 did not face any issues.

Unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers (Art13(2).

Around a third of Member States faced issues in **interpreting and implementing the provisions concerning product presentation**, for example on promotional elements. A few faced issues to some extent¹⁵⁴. One Member State gave effect in part to the requirements of Art. 13 in their Standardised Packaging of Tobacco Act 2015 (see later chapter on Art. 24 for more information on plain packaging). Six economic operators (out of 19) reported issues in implementing Art. 13. Five reported issues to some extent, and four reported not facing such issues. Overall, problems encountered related to ambiguities around specific terms and uncertainties as to whether certain packing elements fell within the scope of this article or not. Also, in some Member States, the provisions have been challenged or contested in court.

One Member State found the reference in Art. 13(1)(a) to 'creating an **erroneous impression**' to be ambiguous and recommended that a panel of experts similar to the one put in place for flavourings would be beneficial in this case. In another Member State, it was unclear what constituted a **promotional element**. One economic operator cited conflicts with historic brand rights and cigar formats¹⁵⁵.

Other Member States experienced difficulties in **determining non-compliance with the requirements of the Directive**:

- In one Member State, there have been several disputes about words and graphic elements which could refer to taste, but also to strength and social status. There is an ongoing court case regarding the use of the word '**Royal**' on a tobacco product.
- Disputes in one Member State included when the authorities attempted to prevent the name '**Café crème**'. Following a court decision in another Member State, the manufacturer of this product changed the name to 'Signature'.
- In one Member State, at the beginning, economic operators were reluctant to avoid terms such as '**menthol**', '**green**', '**fresh**', and '**soft**'. However, most problems have been resolved today.
- In another Member State, there were some problems with names of cigars which had invigorating words (e.g. '**Elixir**') and terms which make products seem healthier or natural (e.g. '**organic**' or '**green**').
- In another Member State, there have been several court cases related to the terms '**maxi**', '**mega**', and '**giga**'.
- One Member State considered that Art.13(1)(c) should clearly define what these elements or features are, and economic operators have been using words which resemble flavours (e.g. '**LMN**' for lemon; '**bluemerry**' for blueberry). This Member State also experienced difficulties to decide whether the product **resembles a food or a cosmetic product** (Art. 13(1)(d)) and therefore, the competent authority has not used this provision in practice so far.
- In Finland, it was reported that while some cases of non-compliance related to this article had been easy to enforce, there was a court case in 2016¹⁵⁶ related to three cigarette brands which included filters called 'iceflow+'. The

¹⁵⁴ 11 Member States did not face any issues.

¹⁵⁵ ref ECJ 288/ 17 and 517/11.

¹⁵⁶

<https://www.markkinaoikeus.fi/fi/index/paatokset/markkinaoikeudellisetasiat/markkinaoikeudellisetasiat/1519384870261.html>

court ruled that this phrase referred to taste or smell, therefore the use of 'iceflow' on outside packaging was prohibited.

Overall, it seems that manufacturers may be using descriptive words in an imaginative way which makes it difficult for supervisory authorities to demonstrate non-compliance with these provisions. As one Member State remarked: '*In practice, this means a new court case for every new imaginative word*'.

One Member State issued a **guidance document** regarding the presentation of tobacco products, which seeks to aid economic operators in ensuring compliance with the requirements of the Directive. The effects of this document in terms of improving compliance or reducing problems were not reported. Member States also reported on **actions they had taken** against non-compliant products related to Art. 13. In one Member State, several actions were taken, for example in cases where a unit packet of cigarettes suggested benefits in terms of social status, or when promoting the chance to win an exotic holiday and other prizes. Another Member State reported that implementing plain packaging simplified confusions about product presentation for cigarettes and roll-your-own tobacco, as there was less ambiguity. In France, there was a regulation banning any products which promote tobacco consumption, to avoid diversion of plain packaging legislation and to reduce the attractiveness of packaging of products which do not have plain packaging. However, this regulation was challenged at the High Administrative Court, which then sent a preliminary ruling to the ECJ. The ban was subsequently suspended¹⁵⁷. More information about Member State actions against non-compliance related to labelling and packaging is provided in Table 8 in Section 3.3.3 below.

Art.14 Appearance and content of unit packets

Main findings: 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.

Overview

Art.14(1) states that unit packets of cigarettes shall have a cuboid shape. Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30 g.

Art.14(2) states that a unit packet of cigarettes may consist of carton or soft material and shall not have an opening that can be re- closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid. For packets with a flip-top lid and hinged lid, the lid shall be hinged only at the back of the unit packet.

A few Member States faced issues or faced issues to some extent regarding the **minimum number of sticks per pack or any of the other provisions listed in Art. 14**. Four economic operators (out of 19) reported issues in implementing these provisions, while three reported issues to some extent¹⁵⁸.

¹⁵⁷ <https://www.conseil-etat.fr/actualites/actualites/fabrication-presentation-et-vente-des-produits-du-tabac>

¹⁵⁸ 16 Member States and three economic operators reported no issues.

One Member State considered the 30 g minimum weight for roll-your-own tobacco as a **positive development**. Longitudinal evidence from the UK¹⁵⁹ suggests that there is some link between **packet size** and plain packaging and **smoking behaviour**. When plain packaging and minimum packet sizes of 20 cigarettes or 30 g of roll-your-own tobacco (required by Art. 14 TPD) were introduced, cigarette smokers were more likely to purchase lower-price cigarettes. However, the results of this study may be confounded with the introduction of plain packaging around the same time as the minimum pack size, therefore the effect of pack size cannot be isolated. Surveys associated with this study identified price as the main driver of purchasing. In a previously mentioned study from the EUREST-PLUS consortium¹⁶⁰, over one-quarter of all respondents **noticed changes to minimum packet unit size** due to the TPD, although these results varied across countries and demographics of study participants.

One CSO stated that the exemption of products such as **cigarillos** from minimum pack size requirements was a concern, particularly for youth uptake.

The issues encountered with the implementation of this provision were largely unique to the Member State reporting on them and have overall been resolved:

- There were a few instances of early non-compliance in two Member States, whereby some slim packets had fewer than 20 cigarettes per pack or some roll-your-own tobacco packets were not compliant, although these have since been resolved.
- A Member State found it unclear if there was a ban on selling **single sticks**, and therefore added in its legislation that each product must have an outside packaging. This was needed in addition to the 20-stick minimum provision to prohibit sales of individual sticks effectively.
- Art. 14(2) states that 'A unit packet of cigarettes...shall not have an opening that can be re- closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid'. In one Member State, the Market Court considered a case in which a unit packet of cigarettes had a thick sheet of foil inside a flip-top lid **which 'glued' onto the opening** of the packet, when the lid was closed. The court concluded that the mechanism was compliant with the requirements of the Directive, as it was part of the flip-top lid.

There were reported implications on a few economic operators' portfolios due to the minimum pack size for cigarettes and roll-your-own tobacco.

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Recital 28 - Bevelled edges

Main findings: This guiding recital has been consulted and implemented successfully by Member States. Some Member States have implemented enforcement checks to ensure packets are in alignment with the recital, and Member States have also issued clarifications, such as specifying that bevelled edges must be small enough to avoid the creation of another visible surface. A few Member States made recommendations about incorporating provisions on bevelled edges into the Directive's text, or banning packs with bevelled edges completely.

¹⁵⁹ Breton, M.O., Britton, J., & Bogdanovica, I. (2020). Effect of UK plain tobacco packaging and minimum pack size legislation on tobacco and nicotine product switching behaviour. *Addiction*.

¹⁶⁰ Kyriakos, C. N., Driezen, P., Girvalaki, C., et al on behalf of the EUREST-PLUS consortium. (2020). Awareness and correlates of noticing changes to cigarette packaging design after implementation of the European Tobacco Products Directive: findings from the EUREST-PLUS ITC Europe Surveys. *European Journal of Public Health*: 30(Supplement 3).

Overview

The recitals of the TPD interpret the articles which are to be implemented; they help policy makers to implement the requirements of the relevant article. They are not implemented in the same way as an article.

Recital 28 of the TPD states that when prescribing a cuboid shape for a unit packet, rounded or bevelled edges should be considered acceptable, provided the health warning covers a surface area that is equivalent to that on a unit packet without such edges.

It also states that Member States apply different rules on the minimum number of cigarettes per unit packet. Those rules should be aligned in order to ensure free circulation of the products concerned.

Most Member States reported they ensured that the **provisions for combined health warnings were properly implemented on packages with bevelled edges**. One Member State reported they had ensured this to some extent. A few reported that they had not ensured this. Across Member States there seemed to be instances of non-alignment with the recital, and economic operators have been reprimanded and adjusted their packaging accordingly. There was also some confusion about how bevelled edges should be considered in area calculations¹⁶¹.

Some Member States considered that the recital was not clear enough. Two Member States considered that it would make sense to incorporate the regulation **into the text of the TPD** and to explain that the minimum width only refers to the flat surface and not to the bevelled edges. DG SANTE clarified to Member States how bevelled or rounded edges should be considered in area calculations and that the warning should not be printed on the round or bevelled edges. A few Member States commented that the European Commission's non-paper provided to the Group of Experts on Tobacco Policy had been helpful in clarifying the recital, however it was not legally binding. In another Member State, discussions are ongoing with tobacco manufacturers regarding health warnings on these packets, and how these edges should be included in area calculations: '*More clarity can be given to this topic by including images explaining which dimensions need to be measured and used for calculating the areas.*'

Member States also described the actions **taken to prevent or respond to non-alignment** with the recital:

- In one Member State, the Ministry of Health instructed the Competent Authority to verify the status of the packets with bevelled edges. The Agency wrote to manufacturers and importers of those products asking to modify packets which were not aligned with the recital.
- In another Member State, the enforcement authority issued four fines for violations relating to health warning on packets with bevelled edges which were not aligned with the recital, and therefore the manufacturer developed new aligned packets.
- Another Member State introduced packaging checks as part of the TNCO testing contract. Therefore, the provider now checks for various labelling and packaging issues as part of their regular reporting, and discrepancies are addressed with individual suppliers.
- In a further Member State, it is specified that bevelled edges must be small enough to **avoid the creation of another visible surface**, which would result in an octagonal shape. The Member State also suggested that **bevelled edges should not be allowed**.

¹⁶¹ Bevelled edges were confirmed as often being problematic by Member States during a workshop in December 2020.

- In Belgium, the industry was informed that warnings **cannot be printed on bevelled edges**. Due to this, some packs have been removed from the market, and warnings have been sent to some manufacturers. Manufacturers have modified the packs as requested by the Belgian government. An example given by Belgium can be found in Figure 3 below.

Figure 3. Example of a bevelled edges adjustment in Belgium



3.3.3 Member State actions with regard to non-compliance

Table 8 below provides an overview of the **actions** taken by Member States **against manufacturers or importers due to non-compliance** related to labelling and packaging. This information was in some cases not detailed or complete, however all received information has been presented here. Two Member States reported enacting product withdrawals, two others reported implementing fines, and seven reported implementing a combination of the two or other unspecified actions. In one Member State, before any tobacco brand is commercialised, sketches and information about packaging must be sent to the Finance Ministry beforehand for review. Therefore, there are very few cases of non-compliance on the market.

Table 8. Actions taken by Member States for non-compliance with these provisions: each row indicates one Member State.

Actions taken
Product withdrawal
3: non-compliance in labelling which cannot be corrected (2017)
When non-compliance is detected, a correction is requested from the manufacturer or the product is withdrawn from the market. In the event of repeated non-compliances, the manufacturer or the distributor is penalized.
Fines
A few cases: regarding presentation of cigarette packets in retail outlets without being covered by 'price shields', or slim packets or bevelled edges. Some of these cases are still ongoing and the final decisions of the Supreme Administrative Court are still pending.

Actions taken
106 : violation of the labelling provisions for cigarettes and roll-your-own tobacco. Most violations concern the correct placement and size of the health warnings. (Up until 2018)
Other or unspecified actions
130 fines and withdrawals for infringements to the labelling provisions of tobacco products in tobacco wholesale, importers and manufacturers (May 2017 – May 2020)
20 non-compliant samples of tobacco products identified. Mostly due to insufficient labelling (missing combined health warning; the labelling not in the appropriate language, etc).
4 national actions taken (potentially other actions taken at municipality level)
2 actions:
1 : product non-compliant with combined health warnings on packets with bevelled edges. Agency wrote to manufacturers and importers of those products asking to modify packets.
1 : Chewing tobacco products sold in pouches.
4 actions in 2016.
A few cases were notified to the Inspection Authority (The Food Safety and Economic Activities Authority).
Approximately once a year since 2017: Market inspectorate takes action regarding labelling and packaging.

Note: Member States often did not provide detailed information about their actions - all information collected is presented in the table.

Other difficulties encountered

There were several points brought by CSOs and HEs which demonstrate reduced effectiveness of labelling and packaging provisions. Firstly, a few CSOs reported that in several Member States, the **sales displays of tobacco products** have been devised to minimise the visibility of health warnings, for example by displaying packets lying down. While product display is beyond the remit of the TPD, it is important to note tactics such as this which reduce the efficacy of the provisions on labelling and packaging. Secondly, a few CSOs and one HE stated that CBDS instantly reduce the efficacy of the warnings, as health warnings and cessation service information is likely in another language. Further, a few CSOs and one HE stated that the tobacco industry had invested in **innovative methods to make packaging more appealing**. Some of these methods include the introduction of bevelled or rounded edges on cigarette packets, seals, multipack outers, hand rolled tobacco accessories, cigars, and pipe tobacco.

Considering all responses, there were a few final difficulties with the practical application of the provisions of the chapter. Snus is prohibited in the EU everywhere except Sweden¹⁶². Snus may not legally be sold in Member States other than Sweden, however one Member State noted that snus packages without combined health warnings are more attractive to young people than cigarette

¹⁶² Recital 20 TPD states that 'the responsibility for regulating the ingredients of tobacco for oral use...should...remain with Sweden, where the sale of this product is permitted pursuant to Article 151 of the Act of Accession of Austria, Finland and Sweden.' In Sweden provisions on packaging do not apply to snus.

packets, which carry the required warnings. Finally, economic stakeholders remarked on some incompatibilities between the **traceability and security features** provisions and the provisions on combined health warnings. See the following chapter for the analysis of this issue.

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3.4 Traceability and security features

3.4.1 General observations on Art. 15 and 16

Art. 15 and 16 stipulate the requirements for systems on tobacco traceability and security features to be put in place by the Member States. However, most stakeholders commented on the subsequent implementing and delegated acts adopted by the European Commission rather than on the articles themselves¹⁶³.

The online consultations held as part of this study, provided information from CSOs, HEs and economic operators. As an overall finding, 49% of CSOs and HEs surveyed agreed that the provisions in the TPD were clear regarding the transposition requirements for Art. 15 and 16. 40% of respondents disagreed that the traceability and security features systems operated without interruptions, while 24% stated that it was too early to tell. 46% of respondents disagreed that the traceability system allows for integration with other supply chain systems, and almost a third (32%) disagreed that the system allows for reporting at various packaging levels (see Annex 8).

A few CSOs consulted found that while the tracking and tracing system was based on a common set of rules and on the principle of interoperability, it offered a wide range of implementation choices to the Member States and put a significant amount of responsibilities in the hands of the manufacturers, which, in their view, raised some concerns as to the overall independence of the system. Official data is, however, not yet available to draw any definitive conclusions.

Art. 15 Traceability

Main findings: A few Member States, in particular in the first phases of implementation of the provisions, faced issues with implementing the traceability system, with the main difficulties relating to the novelty of the system to be implemented, the short timing available to put the system in place, caused by relatively late publication of the secondary legislation, and the complexity of the system which requires the participation of many stakeholders and operators.

Nevertheless, all Member States have put ID issuers in place, and the majority of those consulted did not encounter any issues with the maintenance of record of transactions and the provision of necessary equipment from manufacturers to other operators.

There were some concerns at the national level and from CSOs as to whether the appointment and monitoring of ID issuers, the independence requirements for providers of repository services and providers of anti-tampering devices, provided for a sufficient level of overall independence from the tobacco industry. However, the World Bank's publication lists a series of measures protecting the system from undue influence. In addition, some Member States have opted for periodic controls to verify the independence of such parties, an approach which could be adopted at the EU level.

¹⁶³ Relevant European Commission acts: *Commission Implementing Regulation (EU) 2018/574 on technical standards for the establishment and operation of a traceability system for tobacco products; Commission Delegated Regulation (EU) 2018/573 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products; Commission Implementing Decision (EU) 2018/576 on technical standards for security features applied to tobacco products.*

Other difficulties relate to the supervision of the traceability system: given that the responsibility for supervision at the national level is shared between several authorities, there is a risk that no authority has an overall picture on the compliance to the rules by the economic operators.

Economic operators drew attention to a lack of harmonisation among the Member States with regard to technical standards for UIs and to the high costs for implementing the new requirements.

Overview

Art. 15 states that (1) Member States should ensure that all unit packets of tobacco products are marked with a unique identifier (UI), which should be always visible. For tobacco products manufactured outside of the Union, the obligations apply only to those that are destined for, or placed on, the Union market.

(2) The information to be determined on the basis of the UI is listed (e.g. date and place of manufacturing; manufacturing facility; the machine used to manufacture the tobacco products; product description; the intended market of retail sale; the intended shipment route; where applicable, the importer into the Union; etc.).

The article also requires Member States to ensure that:

(5) all economic operators involved in the trade of tobacco products, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession;

(6) all natural and legal persons engaged in the supply chain of tobacco products maintain complete and accurate records of all relevant transactions;

(7) the manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled;

(8) manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant data.

The suitability of the third party shall be approved by the European Commission. The external auditor shall submit an annual report to the competent authorities and to the European Commission, assessing in particular any irregularities in relation to access. Member States shall ensure that the European Commission, the competent authorities of the Member States, and the external auditor have full access to the data storage facilities.

(11)The European Commission shall, by means of implementing acts, determine the technical standards for the establishment and the operation of the tracking and tracing system and for ensuring that the systems used for the UI and the related functions are fully compatible with each other across the Union.

(13) The provisions in this article shall apply to cigarettes and roll-your-own tobacco as from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco as from 20 May 2024.

The systems of traceability and security features for cigarettes and roll-your-own tobacco were due to be in place by 20 May 2019, whereas for all other tobacco products the timeline is 20 May 2024 (Art. 15(13) and 16(3)).

A chapter in a report from the World Bank stated that the EU systems of traceability and security features would help public authorities detect fraud inside and outside the

legal supply chain, such as, related to duplicated UIs or abnormal fluctuations in products being stored or delivered to retail outlets¹⁶⁴. Globally in 2019, 78 countries reported 22,045 tobacco products trafficking cases, representing a 10.5% increase from 2018, as well as a 98.9% increase in the number of seizures of other tobacco products and cigars and e-cigarettes¹⁶⁵. According to an older EU Report, seizure volumes of illicit tobacco products, after having been in decline since 2011, increased from 3.1 billion in 2013 to 3.8 billion in 2015¹⁶⁶, but more recent data is not available. A 2016 survey from the Irish government reported that over 20 million cigarette packets were traded illicitly every year. Nonetheless, prosecutions resulting from illicit tobacco trade and smuggling are extremely rare in Ireland¹⁶⁷.

The chapter in the World Bank report stated that smuggling of genuine products in large-scale seizures has decreased in the past years but does still remain a problem EU-wide. For example, there has been a recent increase in the prevalence of cheap whites, which dominate large-scale seizures reported by Member States to the European Anti-Fraud Office¹⁶⁸. Data on illicit trade at EU level is scarce and difficult to access, with industry often being the main source.

3.4.2 General observations on the implementation of the traceability system

At the time of this study's survey, eleven Member States stated that it **was too early to assess the effect of the implementation of the traceability system** (Art. 15); this would be feasible only after May 2020, as there were still products (cigarettes and roll-your-own tobacco) without ID code due to the transitional period. All tobacco products will be covered by traceability and security features after May 2024, after which the system could be evaluated in its entirety.

A few Member States stated that the obligation to place a **UI** (Art. 15) should **strongly limit the possibility of introducing illicit products** in the EU market. Two Member States added that the traceability system was a powerful tool for national authorities in charge of investigating smuggling and other offenses. A Member State found that the traceability system was helping to some extent, due to better databases in place.

Nevertheless, not all respondents viewed the traceability system as being useful in reducing illicit trade. A few Member States **had not yet identified substantial**

¹⁶⁴ Borkowski, F., & Twomey, C. (2019). European Union: Confronting Illicit Tobacco Trace: An Update on EU Policies. In: Confronting Illicit Tobacco Trade : a Global Review of Country Experiences. WBG Global Tobacco Control Program Washington, D.C. : World Bank Group. Available at: <http://documents.worldbank.org/curated/en/677451548260528135/Confronting-Illicit-Tobacco-Trade-a-Global-Review-of-Country-Experiences>

¹⁶⁵ World Customs Organisation, illicit trade report 2019

¹⁶⁶ European Commission, Progress report on the implementation of the Commission Communication, Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products - a comprehensive EU strategy, COM(2017) 235, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2017%3A235%3AFIN>

¹⁶⁷ Houghton, F., O' Doherty, D., McInerney, D., and Duncan, B. (2019). Response to Tobacco Free Ireland 2025: SimSmoke prediction for the endgame. *Tobacco Prevention & Cessation*, 5(January), 1. <https://doi.org/10.18332/tpc/102277>

¹⁶⁸ Borkowski, F., & Twomey, C. (2019). European Union: Confronting Illicit Tobacco Trace: An Update on EU Policies. In: Confronting Illicit Tobacco Trade : a Global Review of Country Experiences. WBG Global Tobacco Control Program Washington, D.C. : World Bank Group. Available at: <http://documents.worldbank.org/curated/en/677451548260528135/Confronting-Illicit-Tobacco-Trade-a-Global-Review-of-Country-Experiences>; European Commission, Progress report on the implementation of the Commission Communication, Stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products - a comprehensive EU strategy, COM(2017) 235, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2017%3A235%3AFIN>

benefits of the traceability system (Art. 15) **in the fight against the illicit trade of tobacco products** for the time being, as the system started being operational only in May 2019. Two other Member States reported that to fully counteract illegal products being brought into the EU, further ratifications of the ITP Protocol are needed. Another Member State highlighted that problems with illicit trade persisted with **bordering (non-EU) countries**, which are home of large producers of cigarettes for the EU's illegal market. Another Member State highlighted that illegal factories established in the EU territory using raw tobacco and machinery, represented the main source of illicit trade. If raw tobacco and machinery were traced, this would help combat illegal trade in tobacco products.

When asked about the extent to which the provisions were helping to **fight the illicit trade of tobacco products**, many respondents, Member States and economic operators alike, said it was too early to tell. Broadly, respondents were split between those who found the system useful, largely due to it limiting the introduction of illicit products, and those who found it less useful, as further elaborated below.

Five Member States **issues with implementing the traceability system** and issues 'to some extent' have been experienced in seven other Member States. 10 Member States did not face any issues. Among the 19 **economic operator** respondents, 14 stated that they had encountered issues in implementing the traceability system.

The main difficulties identified by both Member States and industry related to the **complexity of the system, the short timing** available to put it in place, and the **lack of clarity** of a few provisions, **technical issues** and **high costs** for implementation, as further detailed below. Some Member States indicated that the complexity of the system made its practical implementation difficult and required a strong commitment from public authorities.

Complexity

The system was found to be **complex**, as it involves the participation of different administrations and economic operators (reported by two Member States). One industry member found that the fact that UIs for the products placed on national markets were issued by ID issuers in that Member State made the manufacturing process more complex, as it meant that industry has to deal with many different ID issuers.

Timing

Eight Member States faced issues in meeting the implementation deadlines introduced in the Directive. Three Member States faced calendar difficulties in the **appointment of an ID issuer** in their Member State.

Several economic operators mentioned that the **secondary legislation as well as the technical specifications for UIs and Repositories were issued relatively late**, which meant that **implementation time was short**, as the entire system had to be set up from scratch. It should however be pointed out that, while the EU legislative procedures caused delays in the adoption of the implementing acts, all Member States (expect for one, which had a few months delay) managed to appoint ID issuers on time¹⁶⁹.

Lack of clarity of provisions

Four Member States noted that **some of the provisions were difficult to understand and required specific expertise**. For instance, two Member States

¹⁶⁹ Interviews with the European Commission.

highlighted that the implementing regulation¹⁷⁰ had not well determined some aspects which had to be clarified with the European Commission (for example, how certain services fall within or outside the services given by the secondary repository provider). Another Member State stated that clarifications issues were still ongoing (e.g. over data quality; control possibilities for the competent authorities). A further Member State also found a number of aspects unclear and their implementation was still being discussed in the relevant expert group; they stressed that this created difficulties to the competent authorities of the Member States and the economic operators.

Technical issues

The European Commission pointed out that Member States were encouraged to dedicate adequate resources to the implementation of the traceability system¹⁷¹. Nevertheless, it appears that most of the problems identified were the result of a lack appropriate resources put in place at national level to implement Art. 15, giving rise to technical difficulties, although some issues of a purely technical nature were also identified.

For instance, the range of controls and inspections – beyond data control - available to the authorities regarding the verified operability of anti-tampering devices were limited, given Member States' **lack of knowledge and limited experience in this area**. Some Member States also reported on **resourcing and supervision issues**. One Member State pointed out that given that the **responsibility for supervision was shared** between several national authorities, the roles were not clear enough and in practice **no authority had an overall picture how well economic operators were following the rules**. Two Member States reported that traceability and security features regulation required substantial resources and expertise, and that the **distribution chain was struggling somewhat**.

Certain markets and operators also appeared to face particular issues, largely due to **a lack of capacity**. One Member State stated that the **main difficulties came from minor markets**, such as diplomatic offices, international organisations, and duty-free products sellers. The meetings of the expert sub-group on traceability have helped sharing information and standardising solutions.

The gradual roll-out of the system required several changes and updates to the technical specifications in the first implementation phases of the system¹⁷². One Member State highlighted that this generated a **cost increases for tobacco trade economic operators** and a strong commitment from the supervisory authorities to provide support to those involved. Also, according to this Member State, the system does not seem to anticipate the very different specificities of the tobacco markets in European countries.

Economic operators highlighted that the **technical architecture of the system, with two layers of repositories**, made the communication flow between the systems complex, giving rise to delays and mistakes. **A few economic operators** pointed out that the **mandatory marking of export products**¹⁷³, disregarding the existence of traceability and security features systems in the country of destination, has **created a burden** resulting from the coexistence of multiple systems. The

¹⁷⁰ Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products; C/2017/8429 ; OJ L 96, 16.4.2018, p. 7–55.

¹⁷¹ Interviews with the European Commission.

¹⁷² Interviews with the European Commission.

¹⁷³ Art. 8, Protocol to Eliminate Illicit Trade in Tobacco Products, WHO Framework Convention on Tobacco Control, <https://www.who.int/fctc/protocol/en/> .

implementation of the Dentsu 1.4 validation rules¹⁷⁴ – which were missing and ultimately introduced in April 2020 – also caused many issues for Member States and economic operators, some of them still present at the time of this study's survey, such as in the data transmission from the Primary to the Secondary Repository.

Costs

One Member State highlighted that, to their knowledge, big producers or importers were able to cope with the legal requirements and to fulfil the obligations and bear the traceability costs. However, **some smaller companies** that had been importing tobacco products earlier **were not able to afford the price for a data storage contract with any of the primary repository providers** and had to give up this part of the business. They expect this issue to occur again in 2024 when all tobacco products will be tracked and traced, and all small importers will have to pay for and use a primary repository.

A few **economic operators** referred to having incurred **high costs** for the implementation of Art. 15 due to the one-off (start-up) and ongoing expenses for several service providers (primary and secondary repository, connectivity modules, EU and third countries with different traceability and security features systems). One economic operator highlighted that **Art. 15 and 16 were primarily designed for cigarette production** and thus the systems will require a **big investment** to adapt the production lines for manufacturers of **other tobacco products**. In particular (small) **cigar manufacturers** that have wide product portfolios with major variations in product shapes and boutique volumes, considered that the costs of traceability and security features were disproportionate. Finally, one industry member highlighted that Art. 15 was **insufficiently flexible** and forced manufacturers into a degree of standardisation which **restricted the ability of manufacturers to gain any competitive advantages** through seeking efficiencies and optimisation of their supply chain operating models.

3.4.3 Implementation of specific provisions

Art. 15(6) Maintenance of records of all relevant transactions and Art. 15(7) provision of equipment from manufacturers

The implementation of Art. 15(6) and 15(7) went smoothly for a small majority of Member States, whilst four Member States encountered issues with the implementation, and another four Member States faced issues to some extent. The main points raised related to the **unclarities of the provisions**, and **short timing** for implementation. Others were of a technical nature, relating to the system itself. It should be highlighted that the implementing acts adopted by the European Commission did not cover Art. 15(6) and 15(7), as these were considered as less of a priority for the functioning of the core elements of the traceability system¹⁷⁵.

One Member State reported that the **implementation** of Art. 15(6) and 15(7) was **still in progress** and that, due to the shared responsibilities between authorities, they **did not have a clear picture of the situation so far**. Another Member State also indicated that the implementation of Art.15(6) was still ongoing. A third Member State added that adequate data was missing at the moment as efforts were halted due to

¹⁷⁴ Validation rules are a part of the IT requirements aiming at ensuring that the traceability systems operates in line with the regulatory requirements; Expert Group on Tobacco Control, meeting of the Subgroup on traceability and security features, Summary record, 7 November 2019, CCAB, European Commission.

In December 2018, the European Commission appointed 'Dentsu Aegis Network Switzerland AG' as provider to operate the secondary repository,
https://ec.europa.eu/health/tobacco/tracking_tracing_system_en.

¹⁷⁵ Interviews with the European Commission.

COVID-19 emergency. Two other Member States stated that the provision regarding the **maintenance of the records of the financial transactions had to be clarified** during the implementation process, and that the provision in Art. 15(7) should be clearer in specifying the way in which manufacturers provide economic operators with the necessary equipment for recording the UIs (referring not only to equipment, but also to software, software updates, etc.).

With regard to technical issues, Member States were concerned that **problems could emerge with the future support of software upgrades**. A Member State found that adequate data on whether all relevant transactions were being recorded correctly was missing and anticipated that COVID-19 could be a negative factor.

In one Member State, the provision requiring manufacturers of tobacco products to provide all economic operators with the necessary equipment to record all tobacco products transactions (Art.15(7)), was challenged by the tobacco industry in the National Courts.

Appointment and monitoring procedures for ID issuers, providers of repository services and anti-tampering devices¹⁷⁶

A policy brief and blog by the Framework Convention Alliance on the EU's tobacco track and trace system¹⁷⁷ suggested that the system may have been undermined by the delegation of certain responsibilities to industry and associated third parties. While the traceability and security features systems were promoted as independent, the paper claimed that it was actually a way to promote industry's objectives and increase their control over the system. The paper also pointed at the need for the European Commission and Member States to guarantee the independence of the EU's tobacco track and trace system from possible industry interference and to ensure compliance with the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products (ITP). Conversely, a chapter in a paper of the World Bank¹⁷⁸ published in 2019 listed a series of measures **protecting the system from vested interests**. Also, the European Commission in its response to the policy briefing, insisted that the TPD fully respected and even went beyond the ITP, by introducing the **concept of independence** and required **public authorities to supervise** the traceability system to ensure its independence¹⁷⁹.

Over half of Member States reported that the **procedures governing the appointment and monitoring of ID issuers**, the independence requirements for providers of repository services and providers of anti-tampering devices ensured a **sufficient level of overall independence from the tobacco industry**. Two Member States noted that regulations in place allowed for full independence, including the implementation of Article 5.3 of FCTC and several levels of control by the Member States and the European Commission. One of these Member States further highlighted

¹⁷⁶ As stated by Commission Implementing Regulation (EU) 2018/574, on technical standards for the establishment and operation of a traceability system for tobacco products.

¹⁷⁷ Framework Convention Alliance, Policy Briefing, Why the EU tracking and tracing system works only for the EU, https://www.fctc.org/wp-content/uploads/2019/07/FCA-Policy-Briefing_Why-the-EU-tracking-and-tracing-systems-works-only-for-the-EU.pdf .

¹⁷⁸ Borkowski, F., & Twomey, C. (2019). European Union: Confronting Illicit Tobacco Trace: An Update on EU Policies. In: Confronting Illicit Tobacco Trade : a Global Review of Country Experiences. WBG Global Tobacco Control Program Washington, D.C. : World Bank Group. Available at: <http://documents.worldbank.org/curated/en/677451548260528135/Confronting-Illicit-Tobacco-Trade-a-Global-Review-of-Country-Experiences>

¹⁷⁹ Letter from the European Commission (2019/6240287) , in response to FCA concerns over the regarding the compatibility of specific components of the European Tracking and Tracing system with the Protocol to Eliminate Illicit Trade in Tobacco Products (ITP), <https://www.fctc.org/update-re-fcas-policy-brief-why-the-eu-tracking-and-tracing-system-works-only-for-the-eu/>.

that their ID issuer was fully independent from the tobacco industry, however due to industry responsibility at several stages, it was important to ensure periodic controls of compliance with the criteria of independence of third parties. Two other Member States stated that no issues with independence have been reported, however as the system has been running for less than one year, it is too early to make a conclusive judgement.

However, a few Member States highlighted some concerns about independence in the appointment of the ID issuer or primary repositories chosen by producers. One Member State for example found that in practice it was nearly impossible to set up a 'no previous contact' rule for IT providers, because the number of companies with the required technical expertise and knowledge was relatively small in their Member State; however, the overall rules on independence were deemed adequate.

Four Member States and some economic operators reported **technical problems with the electronic system** encountered both by the competent authorities and by the economic operators, although **many of these were solved as the system's implementation progressed**. One Member State reported some initial technical **issues relating to the validation of data**, as a lot of data was not complete or had been entered into the system in the wrong dispatch-arrival sequence. Another Member State reported that the requirements for the address format of Economic Operators and Facilities initially did not allow for the accurate identification of shipment routes¹⁸⁰ of tobacco products. The manner of the introduction of more granular data requirements and stricter validation rules led to additional work for industry and the authorities, and to concerns regarding potential disruption to tobacco supply chains.

Eight economic operators (out of 19) reported on **variations in the way in which Member States had applied the discretionary elements of Art. 15¹⁸¹**. For instance, several economic operators mentioned a **difference between the Member States on the price of the UIs charged by different ID issuers**; one economic operator cited a differential reaching a ratio from 1 to 35. This may be due to variations in the company running the system in each Member State. One economic operator stated that there had been significant variations **in the structure and length of the UIs**, with some Member States trying to integrate standards from GS1, while others took guidance from standards of the Eurodata Council, and others setting their own standards¹⁸². This made it more complicated to integrate the different systems into the manufacturing process.

Another economic operator stated that differences in UIs between the **Member States led to technical complexities**, especially related to integration with other supply chain systems. This economic operator also found that Member States had different levels of involvement in the implementation, with some of them being very proactive even before full adoption of the implementing regulations, while others took late decisions, for example regarding UI issuers appointment. It was not specified if these late decisions meant that the deadline was missed or not.

Art. 16 Security feature

Main findings: The vast majority of Member States did not encounter any issues in implementing the tamper-proof security feature. A few Member

¹⁸⁰ Now the more granular data and stricter validation ensures that accurate data is provided.

¹⁸¹ Two reported variations to some extent, and two reported no variations.

¹⁸² Commission Implementing Regulation (EU) 2018/574 relies on ISO/IEC 15459, for which both GS1 and Eurodata Council serve as the issuing agencies,
https://www.aimglobal.org/uploads/1/2/4/5/124501539/register-iac-def_2019.pdf.

States encountered practical issues related to the short time available for implementation and perceived inconsistencies with other provisions in the TPD (e.g. with Art. 8-10), and some economic operators found that the combination of the security feature and other requirements made it impossible to maintain certain pack formats.

Economic operators did not experience any major difficulties in the implementation, but also drew attention to differences in interpretation and practical application in the Member States. Implementation was more complex in countries where the tax stamps or similar markings were not present before.

Many Member States found that it was too early to tell if Art. 16 contributed to the reduction of illicit trade of tobacco products, whilst several economic operators considered the article as not effective.

Art. 16

(1) In addition to the UI referred to in Art. 15, Member States shall require that all unit packets of tobacco products, which are placed on the market, carry a tamper proof security feature, composed of visible and invisible elements. The security feature shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps and price marks, or other elements imposed by legislation.

Member States requiring tax stamps or national identification marks used for fiscal purposes may allow that they are used for the security feature provided that the tax stamps or national identification marks fulfil all of the technical standards and functions required under this Article.

(2) The European Commission shall, by means of implementing acts, define the technical standards for the security feature and their possible rotation and adapt them to scientific, market and technical developments.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Art. 25(2).

(3) Paragraph 1 shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

3.4.4 Overall observations on the effects of implementation

With regard to assessing the effect of the **implementation of** security features (Art. 16), five Member States and a few economic operators stated that **no data are available** yet to respond or that is too soon to tell.

Around half of Member States considered that the use of security features, and in particular the use of excise duty stamps, limited the possibility of **introduction of illicit products**, as it helped identify them easily. One Member State highlighted that the security features system was, together with traceability system, a useful tool in this regard as it enables NCAs to determine if a product is illicit or genuine.

Several economic operators considered that the security features were **not effective** for a variety of reasons. One respondent stated that the security features do not help fighting the illicit trade of tobacco products at all; and another stated that governments were already able to fight illicit trade of tobacco. A few economic operators considered that the security features were **redundant** alongside UIs, generating avoidable complexities.

With regard to cigars and cigarillos, a few economic operators considered that, as their products represented a very limited risk and magnitude of cross-border illicit trade, it was difficult to see how the adopted security features would be successful in fighting illicit trade.

3.4.5 Specific issues

One Member State faced issues to some extent in implementing the security features system required by Art. 16. Nearly all Member States have not faced any issues in this area. Twelve economic operators (out of 19) reported facing issues with implementing security features, and only one economic operator reported no issues.

The main points raised, as summarised below, included the short time available for implementation, perceived inconsistencies with other provisions in the TPD, differences in interpretation of the article across Member States, implementation difficulties due to the presence / absence of tax stamps, and some specific issues with products such as duty-free products.

One Member State reported that the article allowed for **varied interpretations** by Member States, **which caused complaints and pressure from the economic operators**. One economic operator argued the implementation of Art. 16 and the related implementing acts¹⁸³ had an unexpected side effect on other provisions, such as Art. 8-10 of the Directive, as it meant that certain packet formats could de facto no longer be produced. Similarly, another economic operator reported that the lack of a harmonised EU standard made the implementation costly and time consuming.

Two economic operators (out of 19) reported that implementing the security features in the Member States where **tax stamps were already in use** was fairly straightforward. However, some difficulties arose due to repositioning of stamps due to the health warnings placement requirements, in which case guidance about size and placement were sometimes provided late. In Member States which **did not have tax stamps**, there were more difficulties in implementing the security features (reported by a few economic operators), for example due to the short timeline and a lack of a common EU standard. However, one economic operator stated that several non-tax stamp Member States coordinated their specifications which allowed to design and develop very similar security features across those markets in an efficient and timely, manner.

There were some issues **specific to Member States or products**. One economic operator reported that implementation of the security feature in one Member State led to an increase of size of the tax stamp for this Member State, which required new machinery. A few economic operators reported that it was physically not possible to fit the combined health warning, UI, and security feature on the packaging of certain products.

A few economic operators also highlighted some issues with **duty free** products; one stating that they would welcome a common security feature for Duty Free products.

3.5 Tobacco for oral use

Main findings: Issues regarding the practical implementation of this article mainly related to the difficulties in differentiating tobacco for oral use and chewing tobacco (See also Art.2(6-8) above).

Member States reported that allowing tobacco for oral use in one Member State (Sweden) is giving rise to illicit trade issues in particular with bordering

¹⁸³ Commission Implementing Decision (EU) 2018/576 of 15 December 2017 on technical standards for security features applied to tobacco products (notified under document C(2017) 8435) , C/2017/8435 , OJ L 96, 16.4.2018, p. 57-63.

countries. In addition, industry has sought to circumvent the ban on oral tobacco by marketing it as chewing tobacco. This may put consumers at risk, especially young people amongst whom this product is popular. On the other hand, some CSO stakeholders consider that tobacco for oral use could mitigate the proportionally more harmful effects of smoking and therefore question the ban.

Art. 17 Tobacco for oral use

Overview

Art. 17 prohibits the placing on the market of tobacco for oral use (without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden).

Overall, CSO and HE stakeholders considered that the prohibition of tobacco for oral use (Art. 17) was comparatively better implemented in comparison to other articles across Member States.

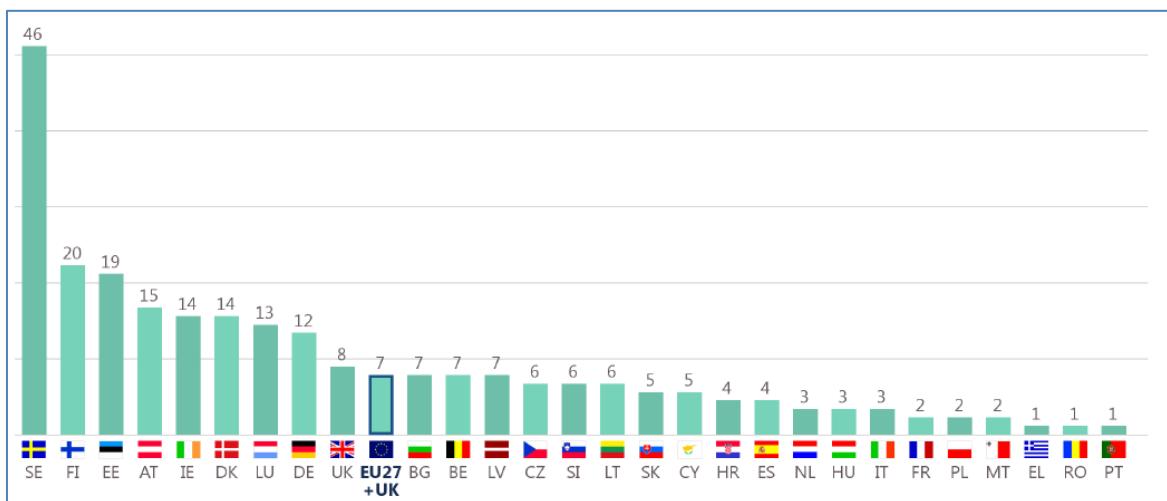
As a general point, a few CSOs (one of which with a potential conflict of interest) and organisations representing consumers questioned the ban introduced in Art. 17, in the interest of the TPD's health protection objective. They underlined that in countries where tobacco for oral use was popular, the prevalence of smoking and incidence of lung cancer was low. They added that in their opinion oral tobacco was likely to have a harm reduction effect when compared to smoking tobacco and could be the reason for the lower lung cancer rates in **Scandinavian countries**.

In the most recent Eurobarometer survey¹⁸⁴, the analysis highlights a large number of those surveyed confirmed to have never tried oral tobacco (snus) and chewing or nasal tobacco (snuff). For those respondents that did so, there has been a two-percentage point increase in those respondents that have tried oral, chewing or nasal tobacco (7%), compared to the proportions in March 2017 (5%). Despite these percentage increases, there is very low proportion of respondents that have used oral chewing and nasal tobacco in the EU, and those who report having used these products say that they do so infrequently. Country differences are shown in Figure 4, presenting few changes have been reported over time in the country level proportions of those who have used these products. Experience of oral, chewing, or nasal tobacco has increased since March 2017, particularly in Ireland (+13pp) and Estonia (+8 pp). By age group, those respondents aged 25-30 represent the highest proportion of users of oral, chewing or nasal tobacco products (10%), compared to 7% in March 2017. The percentages have also slightly increased for the other age groups since the previous Eurobarometer survey in 2017. See Annex 3 for further Eurobarometer information¹⁸⁵.

¹⁸⁴ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

¹⁸⁵ An important methodological note: The Eurobarometer survey grouped all three products (Tobacco for oral use (banned), chewing or nasal tobacco (permitted)) in their questions.

Figure 4. QC6.2 Have you ever used or tried any of the following products? Oral tobacco (snus), chewing or nasal tobacco (snuff) (% - TOTAL 'YES')



Base: All respondents, N = 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.48

3.5.1 Difficulties in implementing the ban on tobacco for oral use

- Seven Member States **encountered some difficulties in implementing the ban on tobacco for oral use** and one more Member State had encountered difficulties to some extent in the implementation of this provision, related to the growing illegal market and problems in differentiating between oral and chewing tobacco¹⁸⁶.

Growing illegal market of tobacco for oral use

With oral tobacco being still permitted in Sweden, in other Member States the illegal market for the product has been growing. One Member State reported that retailers in Sweden illegally market tobacco for oral use to consumer from their website. The Health Authority further noted that it was possible for consumers located in their Member State to buy tobacco for oral use in Sweden and have it shipped to their Member State.

Another Member State pointed out that while there were no official sales of these products in the Member State, the prevalence of oral tobacco was increasing (especially amongst young men in the north of the country), as consumers could purchase tobacco for oral use at retailers located in the Swedish bordering regions with this Member State. The import of tobacco for oral use from Sweden to this Member State as well as illegal sale of tobacco for oral use was in particular growing among young people, including the involvement of organised crime. In both Member States mentioned here, tobacco for oral use products are marketed in social media, online and physical retailers.

One of these Member States sought to restrict tobacco for oral use in their market, for example by imposing a maximum of 1 kg that a person is allowed to carry for personal use when traveling to the country, per 24 hours period. In addition, they prohibited both nasal tobacco and chewing tobacco from their market¹⁸⁷. As further discussed in

¹⁸⁶ Twelve Member States did not face any issues in the implementation of this provision.

¹⁸⁷ EU Commission (2016) Commission Implementing decision of 26.7.2016 C(2016) 4592 final.

Art. 24(3) below, similar action was taken in other Member States, including banning chewing tobacco in three Member States.

Finally, as a side effect of the prohibition of sale of tobacco for oral use, in one Member State, **chewing tobacco has become popular among young people**.

Practical differentiation between chewing tobacco and tobacco for oral use

Over half of Member States **reported to be aware of efforts by industry to circumvent the ban of tobacco for oral use**, usually by **placing on the market products which are commercialised as for chewing which, in reality, are intended for oral use**. A few CSO stakeholders added that such issues had been reported at least in two Member States, where 'snus-like' products have been placed on the market, marketed as 'tobacco for chewing'. In another Member State it was also found that the tobacco industry promoted 'snus-like' products calling it chewing tobacco. To address this, a few CSO stakeholders and a few HEs called for a reassessment of the definitions of chewing tobacco and tobacco for oral use to prevent these circumvention efforts. This is also analysed in detail under Art. 2 above.

The main issues identified by Member States related to difficulties **with the technical differentiation between chewing tobacco and oral tobacco**. One Member State reported not having the right tools to classify products as oral or chewing tobacco and noted that it was very difficult to distinguish them. Another Member State highlighted the need to analyse the composition of tobacco for oral use and chewing tobacco products due to the similarity to tobacco for oral use. One Member State reported to have analysed the composition of one of these products; however, since there were no accredited tests to differentiate between the two product types they were in doubt whether they could justify a possible ban of the product, but no further action was taken to date. In one Member State manufacturers attempted to rename existing tobacco for oral use as chewing tobacco. Another Member State noted that as both products were presented in sachet portions or porous sachets, the rules were circumvented because of the unclear definition and the similarities between the products.

A recent study, carried out in the United Kingdom, found that smokeless tobacco products, whose consumption behaviours suggest they are intended for oral use, are being sold as nasal tobacco in the same Member State¹⁸⁸. Additionally, the study found that some of these products were smuggled via illicit routes or manufactured nationally. Moreover, these products did not respect statutory regulations.

Member States also considered that the definitions in Art. 2(6) and 2(8) were not clear and in practice, and two Member States de facto depended on how producers decided to commercialise their products. As a result, they suspected to have several products on the market that were labelled as chewing tobacco, but which may be for oral use. Another Member State mentioned having issues in identifying the products and therefore enforcing the ban of oral tobacco. It argued for an accredited method, such as laboratory analysis to help determine the intended purpose or use of these products. In one Member State, court decisions are still pending regarding whether chewing tobacco products sold on their market are chewing tobacco or tobacco for oral use products. As already mentioned under Art. 2(6 and 8) above, the ECJ case C-425/17, provides guidance on such interpretation issues¹⁸⁹.

¹⁸⁸Siddiqui, F., Khan, T., Readshaw, A., Croucher, R., Dockrell, M., Jackson, C., Kanaan, M., McCambridge, J., McNeill, A., Parrott, S., Sheikh, A., & Siddiqi, K. (2021). Smokeless tobacco products, supply chain and retailers' practices in England: a multimethods study to inform policy. *Tobacco control*, tobaccocontrol-2020-055830. Advance online publication.

<https://doi.org/10.1136/tobaccocontrol-2020-055830>

¹⁸⁹ EU Commission (2018) Judgement of the Court (Sixth Chamber) Case C-425/17. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62017CJ0425>

Similar products on the market

Similar products to tobacco for oral use have been placed in the EU market, containing nicotine and no tobacco (reported by five Member States) therefore not in the scope of the TPD. Some countries reported having identified these products and tried to address the issue. One Member State reported herbal snus products with nicotine. In another Member State the Ministry of Health is planning to prohibit nicotine containing products (nicotine pouches) and other tobacco substitutes, which are not regulated by the TPD. Two other Member States suggested that tobacco-free nicotine containing products such as nicotine pouches should be regulated at EU level. Six Member States suggested including relevant provisions to regulate nicotine and its derivates/substitutes.

3.6 Cross-border distance sales

Art. 18 CBDS of tobacco products

Main findings: Nineteen Member States prohibited CBDS and nine allow such sales. Of the nine Member States allowing CBDS, two do not publish lists of registered retailers.

Enforcement and monitoring of the provisions in this article seems challenging and cooperation among Member States has not prevented CBDS where these are banned, as Member States found it difficult to monitor and control CBDS, in particular when these are based outside the EU. Nine Member States have acted against non-compliant retailers, and some Member States found non-compliant products in their market (e.g. tobacco for oral use) as addressed above in Art. 17. There is no conclusive evidence as to whether the pattern of CBDS has changed since the introduction of the Directive. In some cases, CBDS increased and in others have been reduced, however, these impacts may have not been connected to the Directive itself.

Actions for non-compliant retailers have differed from seizure of products, warnings, or closure of websites, especially for retailers located in third countries. After such closure, in some Member States retailers opened a new website under a different name.

In general, age-verification systems are in place in most Member States. However, the mystery shopping exercise carried out as part of this study suggests that many retailers across different MS use relatively 'weak' checks that can be easily circumvented by under-age shoppers to complete purchases: 80% of retailers reviewed use self-reporting as age verification, and did not verify age at the point of delivery.

Some statements presented in this part of the Report are refer to CBDS of electronic cigarettes as well. See section on Art. 20(6) for further information.

Art. 18

(1) Member States may prohibit CBDS of tobacco products to consumers; they should cooperate to prevent such sales. Retail outlets engaging in CBDS may not supply such products to consumers in Member States where such sales have been prohibited. Member States which do not prohibit such sales should require retail outlets intending to engage in CBDS to register with the MS competent authorities, where the retail outlet is established, and in the MS where the actual or potential consumers are

located. Retail outlets established outside the Union should be required to register in the MS where the actual or potential consumers are located. All these retail outlets should submit at least the following information when registering:

- (a) name or corporate name and permanent address of the place of activity;
 - (b) the starting date of the activity of offering tobacco products for CBDS to consumers by means of Information Society services;
 - (c) the address of the website or websites used for that purpose and relevant information necessary to identify the website.
- (2) The MS competent authorities should ensure that consumers have access to the list of all retail outlets registered with them. Retail outlets may only start placing products on the market via CBDS when they have received confirmation of their registration.
- (3) Member States of destination of products may require that the retail outlet nominates a natural person to be responsible for verifying — before the tobacco products reach the consumer — that they comply with the national provisions, if such verification is necessary to ensure compliance and facilitate enforcement.
- (4) Retail outlets should operate an age verification system, which verifies, at the time of sale, that the purchasing consumer complies with minimum age requirements provided for under the national law of the Member State of destination. The retail outlet or natural person nominated should provide to the MS competent authorities a description of the details and functioning of the age verification system.
- (5) Retail outlets shall only process personal data of the consumer in accordance with Directive 95/46/EC and those data shall not be disclosed to the manufacturer. Personal data shall not be used or transferred for purposes other than the actual purchase

3.6.1 Findings by provision

Art. 18(1) Prohibition of CBDS

Nineteen Member States prohibited the sale of tobacco products to consumers across borders in their Member States. In addition to the prohibition of CBDS, five Member States have additionally prohibited **domestic distance sales**. Nine Member States allowed CBDS of such products. Due to the prohibition of CBDS of tobacco products being an option for Member States, and not an obligation, related provisions have resulted in the implementation of varying mechanisms across Member States, a few CSO stakeholders reported.

Four Member States which allow CBDS were **not considering prohibiting them when they answered to this survey**. However, one Member State is currently carrying out a study on how to reduce the number of points of sale, the results of these studies should provide new policy options regarding further regulation of the points of sale.

Several CSOs considered that CBDS undermine the functioning of the internal market, public health and fiscal policies in Europe and that CBDS should be banned at EU level. Art. 18(1) requires that **Member States which do not prohibit CBDS shall require retail outlets intending to engage in CBDS to register with competent authorities**. Four Member States have registered retail outlets located **outside the EU** selling to consumers in their Member States: the highest number was seen in the UK (42 retailers).

Art. 18(2) List of retail outlets

Most Member States allowing CBDS **published lists of the retailers registered in their country**. For those Member States that do provide list, these are **published on each Member State's competent authority's website** (IE: Health Services Executive¹⁹⁰, HR: Ministry of Health¹⁹¹, NL: Ministry of Agriculture, Nature and Food Quality¹⁹², DK: Danish Safety Technology Authority¹⁹³, UK: Public Health England (via central government website¹⁹⁴). Czechia uses two different websites for tobacco product retailers (Agriculture and Food Inspection Authority¹⁹⁵) and for retailers of e-cigarettes and refill containers (Ministry of Health¹⁹⁶).

Five Member States reported **monitoring unregistered retailers' activity in their country**. One Member State, for example, has a TPD inspection programme in place which identifies retailers and websites engaged in CBDS and distance sales. They also acted on queries and complaints which may alert them to unregistered retail outlets. Given resource limitations, focus is exclusively placed on the monitoring of retailers based in this Member State. Two other Member States monitored internet and other channels of illegal distribution.

Two out of the five MS that monitored unregistered retailers' activity have identified unregistered retail outlets operating (selling tobacco products) in their Member States and the difficulties in contacting them and enforcing. One Member State noted the difficulties in monitoring non-compliant retailers: '*After an unregistered retailer is identified these websites are closed. Usually the servers of the unregistered retailers operating in their country are located outside of the EU which makes it difficult to enforce. Moreover, shortly after new websites re-open under a different address. However, private buyers can later be identified and sanctioned*'. Another Member State **confirmed to be aware of CBDS** inside their territory despite not having a formal monitoring system in place. The other two Member States **were not aware of cross border distance sales** happening in their country despite having monitoring mechanisms in place. Two Member States had contacted other Member States authorities when an outlet sold its products to a national consumer. In one Member State the contact was made to remind about the prohibition on CBDS in their Member State. Finally, two Member States mentioned the application of the mutual duty of assistance for Member States for the enforcement of banning distance sales is extremely difficult.

Art. 18(4) Age verification system

The literature review carried out for this study identified that, during the 4th meeting of the Group of Experts on Tobacco Policy, a number of Member States (countries not specified) reported challenges with regard to age-verification, particularly for products that are sold by retailers from other EU Member States or from third countries.

¹⁹⁰ <https://www.hse.ie/eng/about/who/tobaccocontrol/tobaccoproductdirective/cross-border-distance-sales-of-tobacco-products.pdf>

¹⁹¹ <https://zdravlje.gov.hr/popis-maloprodajnih-mjesta-koja-sudjeluju-u-prekograničnoj-prodaji-na-daljinu-elektronickih-cigareta-spremnika-za-ponovno-punjjenje-ulozaka-za-jednokratnu-uporabu-koja-su-registrirana-pri-ministarstvu/5154>

¹⁹² <https://www.nvwa.nl/onderwerpen/roken-en-tabak/grensoverschrijdende-verkoop>

¹⁹³ www.sik.dk

¹⁹⁴ https://www.gov.uk/government/publications/tobacco-products-and-e-cigarette-cross-border-sales-registration?utm_source=4b9b0375-57ec-4cc2-98d6-28e30ead3db1&utm_medium=email&utm_campaign=govuk-notifications&utm_content=weekly

¹⁹⁵ <https://www.szpi.gov.cz/clanek/seznam-zaregistrovanych-maloobchodnich-prodejcu-tabakovych-vyrobku-formou-preshranicniho-prodeje-na-dalku.aspx>

¹⁹⁶ http://www.mzcr.cz/Verejne/dokumenty/zaregistrovani-maloobchodni-prodejci-podle-13c-odst4-a-5-zakona-c110/1997-_14082_3478_5.html

Challenges were also reported when enforcing cross-border bans on the sale of cigarettes¹⁹⁷. To address these challenges, one Member State intended to make it mandatory for delivery firms to check the age of the final consumer¹⁹⁸.

The Member State survey, conducted as part of this study, concluded that the **approach to age verification varied among Member States**. The age verification systems in place in four Member States depend on self-reporting, as they ask consumers if they meet the minimum required age or ask to provide their date of birth. In another Member State, economic operators request clients to provide their national ID number and to send the scanned ID document for verification. They also claimed to require age-verification at purchase and signature and ID verification at delivery.

Of the nine Member States allowing CBDS, two indicated that **age verification system did not work**. Currently in one Member State, a retailer is registered once they provide the appropriate information. However, there is no requirement to be in compliance with the Directive regarding the sale of products on the website as a condition of registration. As a result, websites that are not in compliance can be registered. Two Member States reported that the systems work only to some extent. In another Member State, no analysis is currently available regarding the use of age verification systems due to their relative novelty. However, initial results suggest that the age verification system does not work properly, and also does not work when selling tobacco products online to domestic consumers. In another Member State, the age verification systems of retailers registering for cross-borders distance sales or distance sales have been routinely checked. In two other Member States, the systems were reported as working. However, one Member State has not monitored age verification systems yet. Other Member States did not elaborate on whether these systems worked or not.

To check on age verification procedures, inspectorates in two Member States carried out mystery shopping activities to **monitor non-compliant websites**. Furthermore, in another Member State, it is possible to report non-compliant websites via the Competent Authority's website.

The present study included a **mystery shopping exercise** to determine if there the sales channel had an age-verification system in place and what form that system took, when purchasing tobacco and e-cigarettes cross-border online. The main results of the exercise are given in the box below, and the detailed methodology and results are presented in Annex 10.

Objective: To determine whether age-verification systems are in place, and what form they take, when purchasing tobacco and e-cigarettes cross-border online.

Approach: 46 mystery shopping experiences were undertaken using online retailers based in 11 Member States (Croatia, Czechia, Denmark, Germany, Greece, Ireland, Malta, Netherlands, Slovakia, Sweden and the UK). Researchers posed as shoppers based in Members States other than that of the retailer. In half of the experiences, researchers posed as customers under the legal age for purchasing tobacco or e-cigarette products. For a subset ($n = 19$) of the shopping experiences, purchase of selected products was attempted.

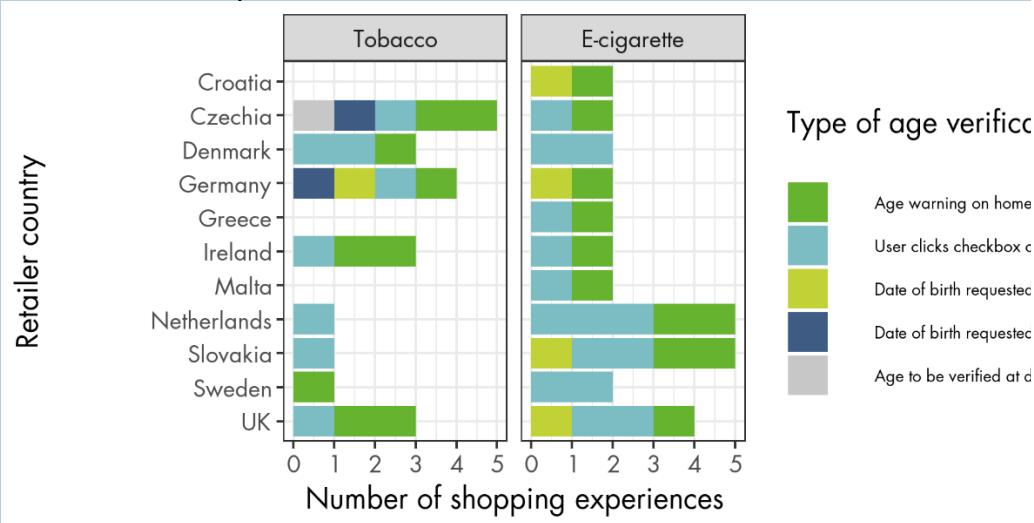
Key findings:

- There was some form of **age verification system in place for 76% of online retailers**. The figure below presents the types of age verification

¹⁹⁷ DG SANTE (2015) 4th meeting of the group of experts on tobacco policy. 15 October 2015.

¹⁹⁸ DG SANTE (2015) 4th meeting of the group of experts on tobacco policy. 15 October 2015.

checks across the retailer locations analysed, by type of product purchased (note that retailers may have employed more than one type of age verification check):



Source: RAND Europe analysis

- The majority of retailers with age verification systems in place (**80%**) **only used self-reported age verification**, which relies on shoppers being honest about their age.
- **Shopper date of birth was only requested and verified by 4% of the online retailers included.**
- No purchases were refused due to age restrictions, and **age verification did not occur at the point of delivery for any of the completed purchases**, including 3 purchases completed by researchers posing as under-age shoppers.

Conclusions: The findings from this research cannot be generalised to all online retailers across the EU or within a particular country, but they demonstrate that many retailers use relatively ineffective age verification systems that can be easily circumvented by under-age shoppers to complete purchases. This lends support to the suggestions made by some Member States for enhanced cross-border age verification systems.

Four Member States called for **improved age verification systems**. Two proposed general strengthening of online age checks. Another proposed a common electronic system for age verification aimed at unification and international application, and another recommended a precise definition of the electronic systems used for age verification would be needed so it could be internationally applicable and unified.

3.6.2 Action taken with regard to non-compliant CBDS retailers

Ten Member States indicated to have acted against non-compliant CBDS retailers. One Member State, for example, rejected licences of new retailers, or banned their registration. In another Member State, e-cigarette retail **websites have been regularly shut down**. Another has **reminded non-compliant retailers** about their national law, which has been sufficient to stop their CBDS activity without having to exert punitive measures.

3.6.3 Other observations on Art. 18

Eight Member States reported that **the pattern of CBDS** in their Member States **had not change since the TPD was introduced**. Around a quarter of Member States mentioned that there was a **lack of historical data** to draw any conclusions the

effect of the article. One Member State suggested that CBDS have increased, based on the number of registrations of retailers following the introduction of the TPD. Another considered that it may have led to a **reduction of CBDS** as the explicit possibility to ban such sales had been introduced with the entry into force of the Directive. Since two Member States prohibited CBDS **before the TPD came into force**, there was no attributable change in CBDS.

Proposed actions to regulate CBDS

Around a quarter of Member States considered that further action was needed to regulate CBDS. For two Member States, further action was needed 'to some extent'¹⁹⁹. The main points raised related to companies engaged in CBDS not being in compliance with national and EU legislation, for example:

- One Member State highlighted that the TPD does not include any requirement for retailers engaged in CBDS to be compliant regarding the sale of products as a condition to be registered as a website. The Member State proposed a centralised database for CBDS retailers.
- One CSO and one HE stakeholder pointed out that there were cases of oral tobacco products smuggling through cross-border distant sales and self-imports. This is the case of 'white snus' is sold in the inter to other to consumers in other Member States.
- **Display of advertisements** are forbidden at the point of sale in the National tobacco legislation of a Member State. However, websites have been reported to display pictures of their products infringing **national tobacco legislation**. In another Member State, in order to avoid discrepancies, similar measures for CBDS were adopted for domestic distance sales.

A few Member States reported on issues with how the prohibition of CBDS was phrased. For example, one Member State pointed out that the current definition only affected retailers, who are liable for placing products in countries where CBDS are prohibited, and not the buyers/consumers in those countries. Hence, the Member State suggested that the definition of cross border distance sales should also include cross-border distance purchase. '*Besides fines on importers, it needs to be clear if there is a penalty imposed on buyers as well. It is not clear if ban applies to both importers and buyers*'. Another Member State called for a **clearer definition in the TPD** differentiating between **cross border distance sales and online sales** and specifying for whom it is legal/illegal to engage in these activities.

Regarding **enforcement**, eight Member States found that **controlling CBDS** was currently difficult. One CSO stakeholder found that enforcement needs to be addressed at regional/EU level. For example, one Member State responded: '*Cross-border distance selling, it is difficult to control, in terms of trade within the European Union. As a matter of fact, a tobacco product can reach [Member State] from a country outside the European Union, through a Member State that allows cross-border distance selling of tobacco products, in particular e-cigarettes.*'. In another Member State, there are difficulties in eliminating e-cigarette retailers as new websites open after others have been closed down. Four Member States said there were **control issues over CBDS** due to dependency on other Member States for notification of breaches. In one Member State, potentially dangerous products, such as pure nicotine, are being purchased by national consumers through CBDS. Another Member State also commented on the difficulty to apply the implementation of the mutual duty of assistance of Member States for the enforcement of banning distance sales. Hence, **Member States that allow cross border distance sales should control whether**

¹⁹⁹ Seven Member States did not consider any further action needed.

their retailers are selling to consumers in Member States where this activity is forbidden. More customs control of intercommunity traffic and inspections was also reported as being needed.

In relation to the above, two Member States called for the regular sharing of information between Member States, for example in the form of **shared best practices** in market surveillance of CBDS. Another Member State called for collaboration between Member States which permit distance sales and those which do not, as they had positive experiences with this.

3.7 Novel tobacco products

Art. 19 Notification of novel tobacco products

Main findings: The effective regulation of novel tobacco products is challenging due to the wide variety of products that may be introduced as novel tobacco products.

The definition of novel tobacco products is, on the one hand, very broad as it aimed to capture a wide group of tobacco products. This means that the products falling within the scope of Art. 19 are highly diverse and that certain provisions are not sufficiently specific to address these unique products. While the TPD covers novel tobacco products, it does not clearly regulate devices and leaves out some emerging tobacco-free products (see also the analysis of Art. 2).

Member States also differed in whether they classified novel tobacco products as for smoking or smokeless, e.g. HTPs, and only a few Member States implemented the voluntary provisions (Art. 19(3)).

Art. 19

(1) Member states shall require manufacturers and importers of novel tobacco products to submit an electronic notification to the competent authority of the Member States they intend to place the product in their market. The notification must be submitted at least six months before the launch date. The notification must be accompanied of a detailed description, instructions for its use and information on ingredients and emissions - the latter in accordance with Art.5.

Submitters shall also provide the competent authorities with:

- a) Available scientific studies on toxicity, addictiveness, and attractiveness of the novel tobacco product's ingredients and emissions.
- b) Available studies, executive summaries, and market research on the preferences of various consumer groups including young people and current smokers.
- c) Other relevant information, risk/benefit analysis, expected effects on cessation tobacco consumption and expected effects on initiation on tobacco consumption.

(2) Manufacturers shall update any information referred in paragraph 1 (a-c). And Member States may require manufacturers or importers of novel tobacco products to carry out additional tests or to provide additional information. This information must be made available to the European Commission.

(3) Member States may introduce authorisation systems and charge fees for the authorisation of novel tobacco products.

(4) Novel tobacco products placed on the market shall respect the requirements of this Directive. Member States shall decide if the provisions applying to these products are the same as smokeless/smoking tobacco products.

3.7.1 General findings

Nine Member States reported that the TPD provisions concerning novel tobacco products had not accounted for new market developments, while another seven Member States found that the provisions had accounted for new market developments only to some extent. Three economic operators (out of 19) mentioned that Art. 19 accounted for new market developments, in the sense of covering all new types of

tobacco products. Several CSO stakeholders described variation and confusion between provisions in different Member States. Some stakeholders described a 'lack of proper rules' for novel tobacco products (), which most () consider to be due to the fact that such products were very new at the time of the adoption of the TPD, and there have been many products adopted since. For example, devices used in the consumption of the novel tobacco product, but that are not connected to tobacco itself, are not clearly regulated, and Member States considered this a loophole in current EU legislation. Nonetheless, the TPD does not prevent Member States from regulating the devices at national level.

Interestingly, in a parallel ongoing study²⁰⁰ being carried out by ICF for the European Commission, similar issues were reported related to the **advertising** of heated tobacco products and their devices: a few Member States reported that their bans for heated tobacco products do not include devices. For example, a few Member States clarified that there is a full ban in place for the tobacco component of a heated tobacco product, but there is no ban at all for the corresponding device. Several Member States reported **intending to include** devices in the advertising bans in the future. The same issue was also raised by CSOs in the context of the present report.

The **main points** raised relating to the relevance of this provision related to **its scope**, namely that the **article was too restrictive in its focus on new tobacco products rather than any new smokeless / for smoking product**. This is analysed in detail under Art. 2 above. Member States also listed other issues which should be considered for novel tobacco products: regulating new products resembling tobacco products, setting further labelling requirements, applying combined health warnings, defining nicotine limits for these products, and banning CBDS.

Several CSOs also argued that the Art. 19 should explicitly grant Member States the flexibility to adopt **stricter measures or ban novel tobacco products or ban flavours** (). A few CSOs from the same Member State reported that they attempted to convince the government to **prohibit** novel tobacco products, however this was not possible.

One of the key issues highlighted by stakeholders was the need to **update TPD definitions** to take into account the diversity of novel tobacco products, in order to close legislative gaps (several CSOs, several HEs, and one organisation representing consumers).

Some stakeholders raised the need to more carefully consider the **health effects** of novel tobacco products. One CSO stated that novel tobacco products are an '*open door for tobacco industry to offer a new very addictive way to induce rapid nicotine addiction*'. Another expressed worries about novel tobacco products being an entry point for youth uptake of tobacco consumption. Three Member States considered that there was a need for a **framework** to evaluate the health impact of novel tobacco products. This is in line with another Member State's suggestion to pool experts' resources of Member States dealing with the same products. Relatedly, one CSO stated that care should be taken to ensure that the available scientific studies on toxicity, addictiveness and attractiveness of novel tobacco products are unsubsidised and independent from the Tobacco Industry.

²⁰⁰ Study on smoke-free environments and advertising of tobacco and related products; ongoing

3.7.2 Findings by provision

Art. 19(1) Notification of novel tobacco products.

Two Member States **faced issues with manufacturers and importers when they submitted notifications about novel tobacco products**, and two faced issues to some extent. This included handling submissions which were **not compliant** with the legal requirements because important documents were missing (reported by three Member States). In one Member State, there were some misunderstandings of the provisions, for example, one economic operator encountered issues with the meaning of '**placed on the market**'.

Another economic operator faced issues to some extent with implementing the notification requirement for novel tobacco products as indicated in Art. 19(1), referring to **unclear guidance**. Perhaps relatedly, one CSO stated that the requirement to submit information 'on the preferences of various consumer groups, including young people...' should more clearly define 'young people', as well as including other characteristics related to target groups, such as gender.

Most Member States reported not facing any issues with manufacturers and importers when they submitted these notifications. However, it is unclear if the Member States not reporting issues have **received notifications** of novel tobacco products or not.

Notification of available studies

Two Member States faced issues with manufacturers and importers **submitting the accompanying information** required under Art. 19(1)(a-c) when notifying a novel tobacco product, and two additional Member States faced issues to some extent²⁰¹. For example, in one Member State, notifications often did not include emissions measurements for the products themselves, but rather included this information for test products used for research. Further, another Member State wondered in the case of risk/benefit analysis what 'benefits' could be expected from any tobacco product but found an analysis of just the risks helpful. Additionally, in the case of an HTP, a Member State pointed out that toxicology or preference studies must be submitted only if they are available. In another Member State, authorities rejected a product notification as a novel tobacco product, and the supplier subsequently modified and re-notified the product as an e-cigarette. One Member State reported to not be able to assess the notified information due to a lack of expertise on these fast-evolving products. Another stated that it was very difficult to assess the submitted data, particularly when comparing studies, due to the **difference in the approach** between submitters and the **lack of guidance** on how they should be assessed, for example for toxicity studies.

- *Requirement to submit notification 6 month before placing the product in the market*

Member States were asked if they had **confirmed or authorised products sooner than six months before they were placed on the market**. Two Member States **have a mechanism** allowing placing on the market of products **faster than six months after the first submission**. Most Member States did not confirm or authorise products before the end of this period, although in a few cases this was because they had not yet received any notifications of novel tobacco products to date²⁰².

²⁰¹ Sixteen Member States did not face any issues.

²⁰² Some Member States reported to not to have Novel tobacco products in the market but in previous questions they mention HTP and tobacco sticks.

Member States were not entirely in agreement about the duration of the **6-month notification period**²⁰³, with a few suggesting it could be shortened to three or four months, a few others seeing the full six months as necessary or even too short and a few not committed either way. Two Member States found that the period should be shorter for minor modifications to existing products that had already been notified, although this would require a definition of 'minor'. The amount of data to be processed and checked was seen as challenging, requiring a lot of resources and expertise (reported by four Member States). More collaboration across Member States would be sensible as not all had the same resources or expertise, plus it would avoid Member States ending up with divergent results (reported by three Member States). Two Member States also commented that the notification process did not explicitly provide an option of not allowing a product on the market if Art. 19 requirements are not fulfilled.

Art. 19(2) Submission of additional information and studies of novel tobacco products

Seven Member States **required manufacturers and importers of novel tobacco products to carry out additional tests or submit additional/updated information**²⁰⁴. A few economic operators confirmed that they had been **requested to submit additional information by at least one NCA**, and information was mainly requested for HTPs.

Three Member States demanded **emission tests**, and another requested a manufacturer to provide an update on the studies on **cessation and initiation**. One economic operator received three requests for additional information or clarification on submissions in accordance with Art .19(2): one request was related to the effect of the electronically heated **aerosol of HTPs** on metabolism of medicinal products, and two requests concerning additional information on aerosol chemistry.

Five Member States **introduced other specific requirements related to novel tobacco products in addition to the requirements of this article**²⁰⁵. Member States introducing these requirements differed in their approach except for the assessment of toxicity which is a common specific requirement. The following approaches were described:

- In one Member State, additional requirements included an **evidence-based approach** by which manufacturers are asked to submit scientific data substantiating any information to consumers about the level of risk of the novel tobacco products **compared to the traditional products for smoking** (e.g. cigarettes). These include toxicity, consumer behaviour, attractiveness, dependency, adverse effects, health effects, among others.
- The same Member State required that **pre-clinical and clinical** studies are performed in accordance with the Good Laboratory Practice and the Good Clinical Practice.
- In another Member State, manufacturers must send to the NCA a **specimen** of the product.

Some Member States described other requests or options in the submission process, which are not strictly requirements:

- A Member State on occasion has requested further data on emissions. These requests included for manufacturers/importers to submit emission data on

²⁰³ Discussions during a Member State workshop in December 2020.

²⁰⁴ Fifteen Member States did not require such additional information.

²⁰⁵ Sixteen Member States did not.

39 priority substances, (according to 2018 WHO Priority list of toxic contents and emissions of tobacco products).

- In another Member State, manufacturers can plead **harm reduction risk** for their products versus traditional products for smoking such as cigarettes or other tobacco products for smoking. They must provide proof of the benefits to the health of the population, including consumers and non-consumers, paying particular attention to young people.

Art. 19(3) Authorisation system for novel tobacco products

Six Member States **introduced an authorisation system for Novel tobacco products in their respective Member States**, as permitted by Art. 19(3). One such Member State reported that they use the same system as for tobacco products, however they did not provide further details. Three others indicated to have put in place a **specific system for novel tobacco products**.

In Portugal, for example, the authorisation process²⁰⁶ requires the manufacturer to submit a request to the Director-General of Economic Activities (DGAE). This authority evaluates the submission and sends the request to the Directorate General of Health (DGS) within 10 days. The DGS gives an opinion within 4 months at the latest. DGS can request more information to the submitter, but this 4-month period will be suspended by the DGS under their request, this can only be done once. After receiving the answer from DGS, the DGAE must decide about the placing on the market within 30 days. The product must respect the minimum six months requirement to be authorised.

Economic operators reported on their interactions with some of these authorisation systems. A few economic operators mentioned that the existing authorisation systems for novel tobacco products **facilitated dialogue** and enabled Member States to ask for any new or updated information on the studies and updates on scientific developments. However, another economic operator mentioned that an authorisation system and requirements for placement on the market, should be grounded on **independent expert** assessment, internationally recognised standards and based on the local needs to tackle the evolution of the local novel tobacco products' market. One economic operator mentioned that in those Member States which had put in place an authorisation system and respective procedure, **the requirements were generally harmonised**. Further, the same economic operator mentioned that the **management of post-authorisation updates was complex**, and the **rules were not always clearly defined**.

Around two thirds of Member States **do not have an authorisation system in place**, as they considered that sufficient oversight was available for novel tobacco products (one Member State), the introduction of such a system would lead to a high administrative burden and costs (two Member States), they lacked expertise (one Member State) or that having such a system in place could create a false impression of safeness (two Member States). One Member State also considered that an authorisation system would make it very difficult to withdraw a product, once authorised, from the market, if they showed effects on health which were not anticipated based on the information submitted.

Member States were also asked if they had **prevented any submitted product to enter the market based on Art. 19**. Only one Member State had done so; as stated above, the NCA rejected authorisation of a novel tobacco product which was modified

²⁰⁶ Regulated by a legal ordinance - Portaria 284/2018, October 23:
<https://dre.pt/application/conteudo/116747966>

and re-notified as an e-cigarette. Similarly, another Member State noted that an e-cigarette had sought to enter the Member State's market using the 'novel tobacco product' category, arguing that the e-liquids contain an aromatic tobacco extract. By doing so, they intended to keep their 60 mg/ml nicotine concentration and produce the mandatory studies for novel tobacco products, rather than lowering the nicotine level to 20mg/mL required for e-liquids. This Member State, in cooperation with other Member States, refused to let them to do so.

Most Member States reported not to have prevented any submissions from entering the market, but this may in part be due to them not having received the respective notifications.

Regulation of Heated Tobacco Products

Evidence from the UK suggests that there is a lack of certainty around how the HTP market will evolve, and respondents to a consultation highlighted the need for flexibility in the definition when enacting legislation on novel tobacco products²⁰⁷. The main issues found in these provisions are summarised below, largely mirroring the responses given above concerning the definitions.

Member States requested that **HTPs should be properly addressed in the TPD** (three Member States), in particular emissions.

Additionally, the topic of **devices used for novel tobacco products**, including HTPs, was controversial. A few Member States reported that the promotion of products has focused on **devices**. Nine Member States stated devices should be explicitly subject to regulation. One Member State's court considered devices as novel tobacco products²⁰⁸, whereas another's court did not (as reported by the relevant Member State). A Member State suggested that the approval of devices should be done in connection with tobacco products and meet specific requirements, similar to e-cigarettes (e.g. notification in EU-CEG, national advertising bans, mail order bans). Another Member State proposed specific regulations regarding these devices, which include a notification to the competent authority, and certain regulatory requirements, such as a ban on device advertising and combined health warnings.

In addition, one Member State highlighted that **hybrid products** are not properly addressed in the TPD; presumably about products which are a hybrid of HTPs and e-cigarettes.

More than half CSOs reported that the TPD did not address new developments related to HTPs (62%). Annex 8 provides a more detailed overview of the responses to this question.

A few CSOs highlighted that HTPs should be treated as a distinct category of tobacco products with a sufficiently strict regulation. A few Member States found that the lack of specific regulation on packaging and composition for HTPs and their respective devices, needs to be addressed in TPD updates.

More information on market developments, health effects and perception of HTPs can be found in Annex 11.

Authorisation fees for novel tobacco products

At the time of the questionnaire, seven Member States charged fees for analysis and verifications. For more information consult the section on efficiency.

²⁰⁷ HM Treasury. (2018). Tax treatment of heated tobacco products: response to the consultation.

²⁰⁸ In the Gap filling workshop this Member State noted to have fined the manufacturer of a HTP for not respecting the rules applicable to tobacco products.

Art. 19(4) Provisions applicable to novel tobacco products: for smoking or smokeless

Art. 19(4) clarifies that the provisions of the TPD apply to novel tobacco products differently depending on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking. The implications of this classification include labelling and packaging provisions; see Art. 8-14 for a discussion of labelling and packaging provisions for tobacco products.

Novel tobacco products are currently represented mainly by HTPs. As discussed under Art. 2, Member States reported problems with the definitions relevant to this article, in particular in relation to HTPs classification, which was due to interpretation of ambiguous term '**combustion process**'.

Ten Member States²⁰⁹ reported applying the provisions of **smokeless tobacco products** to novel tobacco products currently on the market. On the other hand, three Member States **applied the provisions of tobacco products for smoking** and eight Member States applied a **combination of both types of provisions**. For example, one Member State uses a combination of both if a product is a hybrid of e-cigarette liquid and tobacco leaf combined. A few CSO stakeholders stated that the lack of common standard for classifying novel tobacco products as one or the other has created issues and confusion, as well as '*obstacles to the functioning of the internal market, different levels of public health protection across the EU and a lack of legal certainty*'.

Non-compliance relating to Art. 19

Three Member States have **acted against manufacturers or importers due to non-compliance related to notification of novel tobacco products**. Most Member States have not taken such actions to date. All three Member States reported that this had only happened once.

²⁰⁹ One Member State clarified that this was because so far only HTPs had been proposed by manufacturers.

3.8 E-cigarettes

Art. 20: E-cigarettes

Main findings: This article is broadly considered by stakeholders as one of the least clear articles, mostly because of its length and complexity. As the market for e-cigarettes grew, Art. 20 has not remained fully relevant.

Submissions of notifications for e-cigarettes posed several specific challenges, e.g. high volume of notifications submitted, submissions which were incorrect and/or not compliant with the article. Further guidance on submissions of notifications is needed.

Quality and safety violations related to e-cigarettes were noted in some Member States. Provisions on packaging, leaflets, and combined health warnings have mainly been implemented smoothly, but there were some issues with absent leaflets and challenges regarding coherency with the Classification, Labelling and Packaging (CLP) Regulation.

Member States faced difficulties in enforcing the provisions on commercial communications and promotion of e-cigarettes, e.g. social media, where consumers can be reached in any country.

CBDS of e-cigarettes are allowed in 12 Member States and prohibited in 16. Information on systems for reporting adverse effects on human health of e-cigarettes is very limited. Many economic operators have not been submitting the required market data in Art. 20(7) by the required time period.

Member States and CSOs recommended that non-nicotine containing e-cigarettes should also regulated (already in practice in roughly a third of Member States).

Overview

Art. 20 states that (1) the Member States should ensure that e-cigarettes and refill containers are only placed on the market if they comply with the Directive and with all other relevant Union legislation.

The Directive does not apply to e-cigarettes and refill containers that are subject to an authorisation requirement under Directive 2001/83/EC or to the requirements set out in Directive 93/42/EEC.

(2) Manufacturers and importers should submit a notification to the Member States competent authorities if they intend to place such products on the market. The notification should be submitted in electronic form six months before the intended placing on the market. A new notification shall be submitted for each substantial modification of the product.

The notification shall, depending on whether the product is an e-cigarette or a refill container, contain the following information:

- (a) manufacturer's name and contact details, a responsible legal or natural person within the Union, and, if applicable, the importer into the Union;
- (b) a list of all ingredients contained, and emissions resulting from the use of the product;
- (c) toxicological data regarding the ingredients and emissions, including when heated;

- (d) information on the nicotine doses and uptake when consumed;
- (e) a description of the components of the product;
- (f) a description of the production process, and a declaration that the production process ensures conformity with the requirements of this article;
- (g) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product.

Where Member States consider that the information submitted is incomplete, they can request additional information. They may charge manufacturers and importers proportionate fees for receiving, storing, handling and analysing the information submitted.

(3) The article also specifies the nicotine levels in the liquids, the volume of the liquids, the quality of ingredients. The respect of these measures should be ensured by the Member States.

(4) Art. 20 also establishes that (a) leaflets have to be included in unit packets of e-cigarettes and should include certain information (e.g. instructions for use and storage of the product; contra-indications; possible adverse effects; etc.). (b) Unit packets and any outside packaging of e-cigarettes and refill containers should (i) include a list of all ingredients; an indication of the nicotine content; the batch number and a recommendation to keep the product out of reach of children; (iii) carry a health warning; (c) health warnings should comply with Art. 12(2).

(5) Member States shall ensure that: (a) commercial communications in Information Society services, in the press and other printed publications, or on the radio (b), with the aim of promoting e-cigarettes and refill containers are prohibited, except for publications intended exclusively for professionals; (d) any form of public or private contribution with the same aim and involving or taking place in several Member States or having cross-border effects is prohibited; (e) audio-visual commercial communications to which Directive 2010/13/EU applies, are prohibited for e-cigarettes and refill containers.

(6) Art. 18 shall apply to CBDS of e-cigarettes and refill containers.

(7) Member States shall require manufacturers and importers of e-cigarettes and refill containers to submit, annually, to the competent authorities: (i) comprehensive data on sales volumes, by brand name and type of the product; (ii) information on the preferences of consumer groups; (iii) the mode of sale of the products; and (iv) executive summaries of any market surveys carried out in this regard.

Member States should monitor the market developments concerning e-cigarettes and refill containers. (8) Member States shall ensure that the information received pursuant to par. 2 is made publicly available on a website. They should make sure to take trade secrets duly into account when making that information publicly available.

(9) Member States should require manufacturers, importers and distributors to establish and maintain a system for collecting information about suspected adverse effects on human health. Should any economic operator have reason to believe that a product is not safe or not of good quality or not in conformity with this Directive, they should immediately take the corrective action, or withdraw it. Member States may also request additional information.

(10) The European Commission should submit a report to the European Parliament and the Council on the potential risks to public health associated with the use of refillable e-cigarettes by 20 May 2016 and whenever appropriate thereafter.

(11) Where a competent authority ascertains or has reasonable grounds to believe that specific products could present a serious risk to human health, it may take appropriate provisional measures. It should immediately inform the European Commission and the competent authorities of other Member States and communicate any supporting data. The European Commission should determine whether the provisional measure is justified and inform the Member State concerned of its conclusions, to enable the Member State to take appropriate measures.

(12) The European Commission can adopt delegated acts in accordance with Art. 27 to adapt the wording of the health warning in par. 4(b) of this article. (13) The European Commission should also lay down a common format for the notification provided for in par. 2 and technical standards for the refill mechanism provided for in paragraph 3(g).

Art. 20 regulates all aspects related to nicotine-containing e-cigarettes. In the first sub-section we present general findings about this article and e-cigarettes more broadly in the EU, including the prevalence of e-cigarette use, the relevance of this article to the market, and the potential impacts on health of e-cigarettes. The second subsection considers key sub sections of Art. 20 and how these have been implemented in the Member States.

3.8.1 General findings

Note that in the offline survey conducted as part of this study, many of the responding economic operators were not involved in e-cigarettes and refill containers, therefore only five economic operators responded to questions about Art. 20. Their characteristics are provided in Table 9 below; all five had more than 1000 employees and operated in nearly all Member States. Four of these operators commercialise cigarettes and roll-your-own tobacco as well, therefore their main area of business is likely to be tobacco products. No economic operators independent of the large tobacco companies were involved, which is a limitation of the available data as their experience, aims, and views are likely to differ from those of bigger organisations. Please note that there were more respondents which were involved in e-cigarettes and refill containers to the **online** part of the survey than the **offline** part of the survey, and therefore throughout this section results of the online survey often include more than five participant responses.

Table 9. Art. 20 item survey respondents' characteristics

Category	Number of economic operator survey respondents²¹⁰
Organisation type	
Other upstream supplier	1
Manufacturer	5
Importer	3
Products organisation concerns (only for products relevant to Art. 20)	
Electronic cigarettes (devices)	5

²¹⁰ Note that the respondents were able to select more than one response to each item, for example an organisation may be both a manufacturer and an importer.

E-liquids: cartridges and pods	5
E-liquids: refill bottles	3
E-cigarette parts in contact with e-liquids	2
E-cigarette parts not in contact with e-liquids	3
Size of organisation	
> 1000 employees	5

Overall, the online consultations held with CSOs, HEs and economic operators showed that 47% of CSOs and HEs agreed that the provisions in the TPD were clear regarding the **transposition requirements** for Art. 20. The desk review indicated that there has been EU-level guidance from the DG SANTE sub-group on e-cigarettes on how the TPD applies to e-cigarettes, in particular around the rapidly developing e-cigarette market and how this intersects with the transposition and enforcement of Art. 20 of the TPD. For example, in a 2019 DG SANTE meeting of the sub-group on e-cigarettes, it was reported that there would be a checklist to support e-cigarette compliance with the TPD, covering areas, such as labelling, packaging, combined health warnings, unit packets and ingredients. Member States that participated in this meeting also exchanged views on emerging market trends around e-cigarettes, including trends around the use of cannabidiol and cannabinoid liquids, e-liquids without nicotine and enforcement of e-cigarette measures with respect to internet sales²¹¹. Many (64%) economic operators in the online survey responded that the **guidance received** on e-cigarettes was clear and useful ‘to some extent’.

The inclusion of e-cigarettes in the TPD has been contested. For example, there was an **initiative** (funded by the tobacco industry) to repeal Art. 20 and create bespoke legislation to regulate e-cigarettes, claiming they are not designed as nicotine delivery systems²¹². However, this initiative did not reach the required threshold of signatures. Art. 20 was also contested in **UK courts**²¹³, where its validity was brought into question with respect to the restrictions on e-cigarettes as a distinct category from traditional cigarettes. Similarly, some **stakeholders** (one CSO, one HE, a few organisations representing consumers) disagreed with the inclusion of e-cigarettes in the TPD, as they opined that the Directive was meant to regulate tobacco products only. A few HEs stated that including e-cigarettes in the TPD failed to acknowledge the **important differences** between tobacco products and e-cigarettes; and combining them could cause confusion between HTPs and e-cigarettes, despite them being very different products.

Despite these viewpoints, European level experts agreed that the measures in Art. 20 of the TPD made sense for all nicotine-containing e-cigarettes, which was agreed towards the beginning of implementation of the TPD in 2015²¹⁴. In the UK court case,

²¹¹ DG SANTE. (2019). Meeting of the Subgroup on Electronic Cigarettes established by the Group of Experts on Tobacco Policy. 7 May 2019. Brussels.

²¹² The European Citizens' Initiative. (2019). Let's demand smarter vaping regulation!. The European Citizens' Initiative: Official register.

DG SANTE. (2019). Meeting of the group of experts on tobacco policy: 21 March 2019.

²¹³ Pillbox 38 (UK) Limited, trading as Totally Wicked v Secretary of State for Health. (2016).

Case C-477/14, Judgment of the Court (Second Chamber) of 4 May 2016, ECLI:EU:C:2016:324. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62014CJ0477>

²¹⁴ DG SANTE (2015) 1st MEETING of the SUBGROUP ON ELECTRONIC CIGARETTES. 29 May 2015.

the court ruled that Art. 20 was valid, highlighting that the article has imposed restrictions proportionate to the risk of e-cigarettes as compared to traditional cigarettes by creating a set of distinct regulations for this category of products²¹⁵. Conversely, one CSO indicated that treating e-cigarettes separately from the stricter provisions applying to tobacco products provided economic operators the opportunity to advocate for **looser controls**.

Coherence and inconsistencies / incompatibilities

HEs and CSOs found Art. 20 to be one of the less clear provisions (47% of respondents disagreed with a statement about its clarity). Similarly, Member States reported that **unclear categorisations and definitions** had led to different regulations on e-cigarettes across Member States. These ambiguities have also caused some problems in the interpretation and consequently delays in the transposition into the national legislation. Two Member States initially thought that e-cigarettes could be categorised and regulated as medicinal products, however, they both now regulate these products as per the TPD.

As an instance of **internal inconsistency**, Member States and economic operators noted the different treatment of cigarettes and roll-your-own tobacco, e-cigarettes and HTPs in terms of **characterising flavours**. Several CSOs and HEs stated that there was ambiguity on whether a **ban on flavoured e-liquids would be permitted**. On this point, recital 47 states that the TPD does not harmonise all aspects of electronic cigarettes or refill containers and that the responsibility for adopting rules on flavours remains with the Member States. At present, Finland, Estonia and Hungary have fully implemented bans on e-cigarette flavours, and additional Member States are considering or implementing bans. One CSO urged a drastic reduction in the number of permitted flavours and additives in e-cigarettes in order to better protect public health, especially to reduce youth use. Another recommended prohibiting flavours in all e-cigarette liquids across the EU. Several CSO and HE stakeholders reported a lack of clarity regarding whether Member States can regulate e-cigarette **ingredients other than flavours**, such as nicotine salts.

Relevant findings of Case study 2 on E-cigarette flavours

To date, only 3 EU Member States, Finland, Estonia and Hungary, have fully implemented bans on e-cigarette flavours. As Hungary only implemented a ban recently, there is limited evidence available from this Member State; consequently this case study focuses primarily on Estonia and Finland. The impact of EU flavour bans on use of e-cigarettes is currently unclear, as only Finland has had a ban in place for an extended time period, and because there has also been concomitant legislation around e-cigarettes in the countries where e-liquids flavours have been banned. However, despite this lack of conclusive evidence, some sources have attributed Finland's success in lowering smoking rates, while also keeping e-cigarette use to just 1% of the population, to their strict e-cigarette flavour ban.

There are indications of significant public support for e-cigarette flavour bans, and also potentially for an EU-wide e-cigarette flavour ban, with additional Member States considering or implementing bans. In particular, Denmark is currently in the process of implementing a ban, while legislation including a ban is due to be considered in Lithuania during 2021, and the Netherlands has opened a consultation for potential legislation around e-cigarette flavours. However, Member States that have

²¹⁵ Pillbox 38 (UK) Limited, trading as Totally Wicked v Secretary of State for Health. (2016). Case C-477/14, Judgment of the Court (Second Chamber) of 4 May 2016, ECLI:EU:C:2016:324. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62014CJ0477>

implemented e-cigarette flavour bans have faced substantial challenges, particularly around companies selling liquids that can be used in e-cigarettes at times circumventing bans by portraying them as foodstuff. Additionally, Member States have limited capacity to keep up with the large number of e-cigarettes that are notified to them. An EU-wide e-cigarette flavour ban would potentially help address some of these challenges.

Member States, HEs, and CSOs have all expressed concerns that having separate rules around flavours for cigarettes, roll-your-own tobacco and other tobacco products, and e-cigarettes will simply lead to a shift in consumption towards products where flavours are allowed, rather than a decrease in the overall consumption of tobacco and related products. They have also expressed concerns around e-cigarette flavours attracting users (especially young people). Both of these concerns have likely fuelled an appetite for greater regulation around e-cigarette flavours.

Evidence for the role that flavours play in making e-cigarettes appealing to potential users is still emerging, but research to date suggests:

- E-cigarette flavours attract users, particularly adolescents and young adults, and may encourage initiation of use. Sweet and fruity flavours are perceived as less harmful than tobacco flavour, and play an important role in e-cigarette appeal to younger users, but appear to be less appealing to older users.
- There is some evidence that e-cigarette flavours are important in adult users switching from smoking combustible tobacco to e-cigarettes, but the SCHEER scientific opinion on electronic cigarettes found some evidence that for young people e-cigarettes are a gateway to smoking, and strong evidence that flavours contribute to the attractiveness and thus initiation of e-cigarette use.
- 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.

The full case study can be found in Annex 9.

In terms of consistency with **other EU legislation**, a few CSO and HE respondents reported that e-cigarette manufacturers need to comply with both the TPD and **REACH regulation** when labelling products, which are not aligned with one another. One Member State reported inconsistencies with the **CLP regulation** related to whether labelling needs to be in the official language(s) of each Member State. See the chapter on Coherence for more information.

Prevalence of e-cigarette use

E-cigarettes were introduced to Europe in 2006 and the consumer preference and perception study²¹⁶ survey data showed that most respondents over the age of 30 had begun using e-cigarettes around 5 or 6 years before. The most recent (2020)

²¹⁶ LSE, Open Evidence, BDI Research, & ICO (2020). Consumer preference and perception of specific categories of tobacco and related products Request for Service Chafea/2017/Health/34 under Framework Contract Chafea/2015/CP/01. European Commission Directorate-General for Health and Food Safety

Eurobarometer survey²¹⁷ provides some indication of the prevalence and use of e-cigarettes:

- **14%** of respondents had at least tried e-cigarettes, which represents a 1% reduction since the 2017 wave.
- Regarding the frequency of use, nearly one in ten (9%) say they have tried them only once or twice, while 3% used to use them but have stopped. A small proportion (2%) say they currently use them. There are no significant changes in the results compared to March 2017.
- Among those who currently use e-cigarettes, country-level differences are minimal. The country-level analysis shows that more than 70% respondents in all EU countries+ UK have never used e-cigarettes. In all countries, less than one in twenty are current e-cigarette users. See Annex 3 for detailed information, including by Member State.
- Around half (49%) of e-cigarette users are **everyday** users, and 16% use them every week. Compared to the previous survey in 2017, there has been a 12 percentage points decrease in daily e-cigarette users. Kantar analysis highlights that as the question was asked differently in 2017 results are not directly comparable, and also that a country-level analysis on the results of this question is not possible due to low sample sizes.
- The **socio-demographic** analysis reveals that the younger the respondents, the more likely they are to have at least tried e-cigarettes. For instance, 25% of young people (aged 15-24) have at least tried e-cigarettes, compared with 8% of the oldest respondents (aged 55 or over), or 14% of those aged (40-54). In comparison to 2017 figures, the proportion of younger respondents that use e-cigarettes has remained the same for those aged 15-24, has slightly increased for those aged 25-39 (+1pp), and also for adults+55 (+2 pp). Finally, the use has slightly decreased for adults aged 40-54 (-1pp). More than 60% of those aged 40 or more use e-cigarettes daily, compared with around four in ten (41%) of the youngest users (aged 15-24).
- One in ten (10%) of respondents who are e-cigarette users use **e-cigarettes without nicotine** every day, and the same proportion use them every week.
- In terms of types of e-cigarettes, more than 72% of current and former e-cigarette users say they use or had used a **refillable** device which contains a tank that is refilled with an e-liquid from a separate container. A little less than 23% use a pod-system, while a much smaller proportion (8%) use a disposable device which is thrown away after use.
- Of respondents who use e-cigarettes at least on a monthly basis, most users prefer **fruit** (49%) or **tobacco** (36%) flavour liquid variants²¹⁸.

The box below presents additional information gathered about the use and harms of e-cigarettes. This information does not directly relate to Art. 20, but this discussion is linked to the TPD and its public health aims.

²¹⁷ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

²¹⁸ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

Supplementary insights: Use and harms of e-cigarettes

While the harms of tobacco products for smoking have largely been studied and understood, a more controversial topic which relates to public health concerns the effects of e-cigarettes. The text below discusses evidence on the use and harms of such products.

Experts have recommended that e-cigarettes should be **more closely studied** in terms of their use and adverse health effects, potential role as a gateway to smoking (particularly for younger people), and role in smoking cessation²¹⁹. A review from the Cochrane organisation did not detect clear evidence of harm from nicotine e-cigarettes, but the longest follow-up was two years and the overall number of studies was small²²⁰. The WHO has concluded that e-cigarettes are '**undoubtedly harmful**' and it is safest to consume neither tobacco products nor e-cigarettes²²¹. Various stakeholders and sources (e.g. WHO²²²; SCHEER²²³) have made it clear that further research is needed in this area, particularly on long-term effects.

In a 2016 report to the European Parliament by the European Commission that was mandated through Art. 20, the main health risks of refillable e-cigarettes that were identified were: **poisoning** from ingestion of e-liquids containing nicotine, **skin reactions** due to contact with e-liquids, risks associated with **home blending** of e-liquids and risks associated with **untested combinations** of e-liquids, devices, and the customisation of e-cigarette hardware. Considering these risks, the European Commission concluded that the TPD measures around e-cigarettes, secondary legislation around e-cigarettes and national legislation were adequate in terms of mitigating against the public health risks²²⁴. This European Commission report had been informed by meetings of experts in tobacco policy, who had raised the issue of potential risks around e-cigarettes in a series of meetings²²⁵.

The European Commission has tasked the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) to study²²⁶ the health effects of e-cigarette use, and their role in encouraging people to start or quit smoking to understand better the health effects and the public health dimension of electronic cigarettes. For users of e-cigarettes, the SCHEER has concluded that there is moderate weight of evidence for risks of local irritative damage to the respiratory

²¹⁹ European Commission. (n.d). Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) Request for a scientific Opinion on Electronic cigarettes.

²²⁰ Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Butler AR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub4. Accessed 08 February 2021.

²²¹ WHO. (2020). E-cigarettes are harmful to health. Available at: <https://www.who.int/news-room/detail/05-02-2020-e-cigarettes-are-harmful-to-health>

²²² WHO. (2020). E-cigarettes are harmful to health. Available at: <https://www.who.int/news-room/detail/05-02-2020-e-cigarettes-are-harmful-to-health>

²²³ SCHEER. 2021. Opinion on electronic cigarettes. Available at: https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_10_en

²²⁴ European Commission. (2016). Report from the Commission to the European Parliament and the Council: On the potential risks to public health associated with the use of refillable electronic cigarettes. Brussels: European Commission.

²²⁵ DG SANTE. (2016). Meeting on the Group of Experts on Tobacco Policy. Summary Record: 2 December 2016

²²⁶ SCHEER. 2021. Opinion on electronic cigarettes. Available at: https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_10_en

tract and moderate, but a growing level of evidence from human data suggesting that electronic cigarettes have harmful health effects, especially but not limited to the cardiovascular system. More so, the SCHEER has concluded that there is weak to moderate weight of evidence for risks of carcinogenicity of the respiratory tract due to long-term, cumulative exposure to nitrosamines and due to exposure to acetaldehyde and formaldehyde and that weight of evidence for risk of poisoning and injuries due to burns and explosion is strong. The SCHEER has also concluded that there is weak to moderate weight of evidence for several risks related to second-hand exposure. Overall, there is moderate evidence that electronic cigarettes are a gateway to smoking for young people and strong evidence that flavours have a relevant contribution for attractiveness of use of electronic cigarette and initiation. On the other hand, there is weak evidence for the support of electronic cigarettes' effectiveness in helping smokers to quit while the evidence on smoking reduction is assessed as weak to moderate.

In the present study, CSO stakeholders reported that e-cigarettes are being used to **inhale cannabis oil**, which carries risks, and there have been reported increases in sales of CBD cannabidiol liquids in cannabis shops, which is of potential concern to public health. In response to the 2019 death of a Belgian young man after using an e-cigarette device to consume a cannabis derivative that had been sold on the black market²²⁷, the European Commission highlighted their coordination with Member States to support European monitoring of potentially harmful e-liquid ingredients that are prohibited under Art. 20 of the TPD²²⁸. E-liquids adapted to contain THC and Vitamin E acetate have led to a string of deaths in the US recently, which has raised awareness around the harms associated with black market e-cigarettes and e-liquid²²⁹.

Use of e-cigarettes as a cessation aid

There is a **lack of consensus** on the role of e-cigarettes in public health and no medicinal licenses have been provided for e-cigarettes. A **systematic review from the Cochrane organisation** found 'moderate-certainty' evidence that e-cigarettes with nicotine increase quit rates compared to e-cigarettes without nicotine and compared to nicotine replacement therapy. E-cigarettes with nicotine may also be more effective than usual care or no treatment, but this is less certain. More studies are needed to confirm the degree of effect, particularly when using modern e-cigarettes; there was only a small number of randomised controlled trials on this topic, but more were being conducted²³⁰. SCHEER²³¹ and the European Respiratory Society²³² are opposed to the use of e-cigarettes for cessation and have argued there is weak or inconclusive evidence for e-cigarettes as a cessation aid. Further, in

²²⁷ Ries, F. (2019). Priority question for written answer to the Commission: Rule 138: First death in Belgium attributed to the toxic mixture in an e-cigarette European Parliament.

Available at: http://www.europarl.europa.eu/doceo/document/P-9-2019-003949_EN.html

²²⁸ Kyriakides. (2020). Answer given by Ms Kyriakides on behalf of the European Commission: Question reference: P-003949/2019. European Parliament.

²²⁹ Centres for Disease Control and Prevention (2020) Outbreak of Lung Injury Associated with the Use of E-cigarette, or Vaping, Products. 25 February 2020.

²³⁰ Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Butler AR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub4.

²³¹ SCHEER. 2021. Opinion on electronic cigarettes. Available at: https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_10_en

²³² The ERS Tobacco Control Committee. (2019). ERS Position Paper on Tobacco Harm Reduction. European Respiratory Society.

the recent Eurobarometer survey²³³, only a small percentage of tobacco smokers who had quit smoking or have attempted to quit smoking had used e-cigarettes or similar devices (13%). More than three quarters (76%) say they gave up smoking – or attempted to give up smoking – without using any cessation aid. Despite the lack of conclusive evidence, **smoking cessation is an increasingly common reason reported for using e-cigarettes** in Europe²³⁴. In the Eurobarometer survey²³⁵, the most common reason for starting use of e-cigarettes was to stop or reduce tobacco consumption (58% of those who use or used e-cigarettes), although this fell by 3 percentage between 2017 and 2020. Focus group participants in the consumer preference and perception study²³⁶ identified e-cigarettes as an aid to reduce or quit another tobacco product, and current and former users, responding to the study's survey, often cited stopping or reducing consumption of another tobacco product as a reason for starting to use e-cigarettes. By Member State, the recent EUREST-PLUS study showed that e-cigarettes were the **most widely used smoking cessation aid** in England (51.7% of respondents who reported making a quit attempt in previous 12 months), Greece (26.3%) and Germany (15.0%)²³⁷. In the UK, national guidance around smoking cessation states that e-cigarettes are substantially less harmful to health than smoking, although they are not without risk entirely²³⁸.

However, the Eurobarometer 2020 survey observes **that large majorities of e-cigarette and heated tobacco product users are 'dual users'**, i.e. their use of these products comes on top of their traditional tobacco product consumption.

The box below presents a more detailed discussion from the evidence base concerning consumers' awareness of the harmful effects of e-cigarettes.

Supplementary insights: Awareness of harmful effects of e-cigarettes

Research on consumers' perceptions of harmfulness of **e-cigarettes** has indicated that consumers increasingly view e-cigarettes as **harmful**:

- A 2016 study found that the perceived harms of **e-cigarettes** changed after TPD implementation, with an increase in the percentage of people who believe they are 'less harmful' or 'more or equally harmful' compared

²³³ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

²³⁴ Filippidis, F.T., Laverty, A.A., Mons, U., et al. (2019). Changes in smoking cessation assistance in the European Union between 2012 and 2017: pharmacotherapy versus counselling versus e-cigarettes. *Tobacco Control*: 28, 95-100.

²³⁵ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

²³⁶ LSE, Open Evidence, BDI Research, & ICO (2020). Consumer preference and perception of specific categories of tobacco and related products Request for Service Chafea/2017/Health/34 under Framework Contract Chafea/2015/CP/01. European Commission Directorate-General for Health and Food Safety

²³⁷ Papadakis, S., Katsaounou, P., Kyriakos, C.N., et al. (2020). Quitting behaviours and cessation methods used in eight European Countries in 2018: findings from the EUREST-PLUS ITC Europe Surveys. *European Journal of Public Health*, 30(Issue Supplement 3): iii26-iii33. <https://doi.org/10.1093/eurpub/ckaa082>

²³⁸ Borkowski, F., & Twomey, C. (2019). European Union: Confronting Illicit Tobacco Trade: An Update on EU Policies. In: *Confronting Illicit Tobacco Trade : a Global Review of Country Experiences*. WBG Global Tobacco Control Program Washington, D.C. : World Bank Group. Available at: <http://documents.worldbank.org/curated/en/677451548260528135/Confronting-Illicit-Tobacco-Trade-a-Global-Review-of-Country-Experiences>

to tobacco cigarettes, but a decrease in those who perceive them as “a lot less harmful”²³⁹.

- In a recent study from the EUREST-PLUS consortium²⁴⁰ in six Member States (DE, EL, HU, PL, RO, ES), the majority of respondents (who were all adult smokers) perceived e-cigarettes to be **equally or more harmful** than combustible cigarettes, both prior to the implementation of the TPD in 2016 (58.5%) and after in 2018 (61.8%). This may thus make it less likely that they would consider using e-cigarettes as a cessation device.
- In the most recent Eurobarometer survey²⁴¹, more than 65% of respondents considered that e-cigarettes are harmful to the health of those who use them. Compared to 2017, this proportion has **increased ten percentage points** (55% in 2017). By age group, the increase ranges from +6pp in those aged 15-24, to +13pp on those aged +55. However, note that the percentage of those that do not know have increased for all age stakeholder groups.
- Also in the Eurobarometer survey²⁴², seven in ten (70% of those who only tried or never used e-cigarettes or HTPs) think that e-cigarettes should be **regulated as strictly as cigarettes**.
- Some research suggests that TPD e-cigarette health warning messages may dissuade people from using e-cigarettes as an alternative to conventional tobacco products²⁴³.

However, the evidence is somewhat mixed, for example perceptions of e-cigarettes as harmful appear to **not be shared by e-cigarettes users**. In the Eurobarometer survey²⁴⁴, the most common reason cited for starting use of e-cigarettes was to stop or reduce tobacco consumption, followed by respondents believing that their use was less harmful than using tobacco. This has risen by 5 percentage points since 2017²⁴⁵. A Dutch study examining the impact of TPD Art. 20(4) regarding information on the perceived addictiveness and toxicity of e-cigarettes found that awareness was limited amongst both e-cigarette users and cigarettes users²⁴⁶. One

²³⁹ Anthopoulou, E. (2016). Regulating Electronic Cigarettes: Not Tobacco and Not (Yet) Therapy. *Pharmaceutical Medicine*: 30(4), 203-211

²⁴⁰ Gravely, A., Driezen, P., Kyriakos, C.N. et al on behalf of the EUREST-PLUS consortium. (2020). European adult smokers' perceptions of the harmfulness of e-cigarettes relative to combustible cigarettes: cohort findings from the 2016 and 2018 EUREST-PLUS ITC Europe Surveys. *European Journal of Public Health*: 30(Supplement 3).

²⁴¹ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

²⁴² DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

²⁴³ Cox, S., Frings, D., Ahmed, R. & Dawkins, L. (2018). Messages matter: The Tobacco Products Directive nicotine addiction health warning versus an alternative relative risk message on smokers' willingness to use and purchase an electronic cigarette. *Addictive Behaviours Reports*: 8, 136-139

²⁴⁴ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

²⁴⁵ Ibid.

²⁴⁶ Van Mourik, D.A., Nagelhout, G.E., van den Putte B., Hummel K., Willemsen M.C., de Vries H. (2019) Did e-cigarette users notice the new European Union's e-cigarette legislation? Findings from the 2015-2017 International Tobacco Control (ITC) Netherlands Survey. *Int. J. Environ. Res. Public Health* 16(16): 2917.

recent study²⁴⁷ compared several measures in England following the introduction of TPD-mandated e-cigarette warning labels and leaflets with Canada, the US and Australia, where no warnings and leaflets were mandated. The study found that introduction of the mandatory warnings and leaflets in England was associated with small increases in **noticing** mandatory warnings and leaflets but not with changes in concerns about e-cigarette use.

Furthermore, perceptions that e-cigarettes are less harmful than conventional tobacco products may contribute to the increased number of people reporting the use of e-cigarettes as a smoking cessation aid in Member States, particularly young people^{248,249,250,251}.

In a EUREST-PLUS study it was shown that public attitudes about e-cigarette policy may be influenced by how e-cigarettes are regulated by the country in which they live. For example, countries such as Poland, Hungary and Greece have higher levels of support for more restrictive e-cigarette policies, which reflects their governments' positions on e-cigarette use: these countries have often gone beyond the provisions of the TPD. This differs from England, where the government promoted a harm-reduction approach of using e-cigarettes for smoking cessation; in England there is lower public support for restrictive e-cigarette policies as compared to England, where there is governmental support for e-cigarettes as a harm reduction approach²⁵².

Note that for e-cigarettes in particular, researchers have argued that the way in which the comparative risks of e-cigarettes and conventional combustible tobacco are communicated needs further review, particularly in regard to the wording of warnings on nicotine^{253,254}.

²⁴⁷ Taylor, E.V., East, K.A., McNeill, A., et al. (2020). Changes in responses to nicotine vaping product warnings and leaflets in England compared with Canada, the US and Australia: findings from the 2016–2018 ITC Four Country Smoking and Vaping Surveys. *Tobacco Control*: Published Online, doi: 10.1136/tobaccocontrol-2020-055739

²⁴⁸ IFF Research. (2016). Understanding the Online E-cigarette market. HM Revenue and Customs.

²⁴⁹ Anthopoulou, E. (2016). Regulating Electronic Cigarettes: Not Tobacco and Not (Yet) Therapy. *Pharmaceutical Medicine*, 30(4): 203-211.

²⁵⁰ Filippidis, F.T., Laverty, A.A., Mons, U., et al. (2019). Changes in smoking cessation assistance in the European Union between 2012 and 2017: pharmacotherapy versus counselling versus e-cigarettes. *Tobacco Control*: 28, 95-100.

²⁵¹ Hummel, K., Nagelhout, G. E., Fong, G. T. et al. on behalf of the EUREST-PLUS consortium. (2018). Quitting activity and use of cessation assistance reported by smokers in eight European countries: Findings from the EUREST-PLUS ITC Europe Surveys. *Tobacco Induced Diseases*: 16(2), 6.

²⁵² Chung-Hall, J., Font, G.T., Meng, G., et al. (2020). Support for e-cigarette policies among smokers in seven European countries: longitudinal findings from the 2016–18 EUREST-PLUS ITC Europe Surveys. *European Journal of Public Health*, 30(Issue Supplement 3):iii68-iii77. <https://doi.org/10.1093/eurpub/ckaa085>.

²⁵³ McNeill, A., Brose, L.S., Calder, R., Bauld, L., Robson, D. (2018). Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England. London: Public Health England.

²⁵⁴ Smets, J., et al. (2019). When Less is More: Vaping Low-Nicotine vs. High-Nicotine E-Liquid is Compensated by Increased Wattage and Higher Liquid Consumption. *Int J Environ Res Public Health*, 16(5).

Relevance of Art.20 to the market

To track market developments, DG GROW of the European Commission has conducted market surveillance of e-cigarette products, and has invited inputs from Member States with respect to potentially dangerous products that become available in their respective countries²⁵⁵. Both DG SANTE and individual Member States have provided updates on market developments around e-cigarettes in regular meetings of the Group of Experts on Tobacco Policy²⁵⁶ and the subgroup on e-cigarettes²⁵⁷. The rapidly evolving nature of the European e-cigarette market was also highlighted in SCHEER scientific opinion provided to the European Commission on e-cigarettes²⁵⁸, which may have implications on how Art. 20 is enacted in practice.

Data from the Euromonitor International indicates that the market size for 'e-vapour products' (the Euromonitor International definition of which matches 'e-cigarettes'; see Annex 4 for further information²⁵⁹) was approximately €5.58 billion in 25 EU Member States²⁶⁰ (hereinafter EU 25) in 2019. Over the period 2013-19 the size of the market for such products increased by a total of 237% in terms of retail value, following a consistent upward year-on-year upward trend before starting to flatten off in 2019²⁶¹. One reason for the flattening of the growth of e-vapour products is that they have been salient in the EU market for a longer period than HTPs²⁶², and thus the market has had time to stabilise.

²⁵⁵ DG SANTE. (2019). Meeting of the group of experts on tobacco policy: 21 March 2019.

²⁵⁶ DG SANTE (2018) Meeting of the Group of Experts on tobacco Policy : 26 November 2018.; DG SANTE (2017) Meeting of the Group of Experts on Tobacco Policy Summary Record. 9 October 2017.;

DG SANTE. (2017). 9th Meeting on the Group of Experts on Tobacco Policy: March 30, 2017.

²⁵⁷ DG SANTE (2020) Meeting of the Subgroup on Electronic Cigarettes Established by the Group of Experts on Tobacco Policy: Summary Record. 16 January 2020.

²⁵⁸ SCHEER. 2021. Opinion on electronic cigarettes. Available at:
https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scheer_consultation_10_en

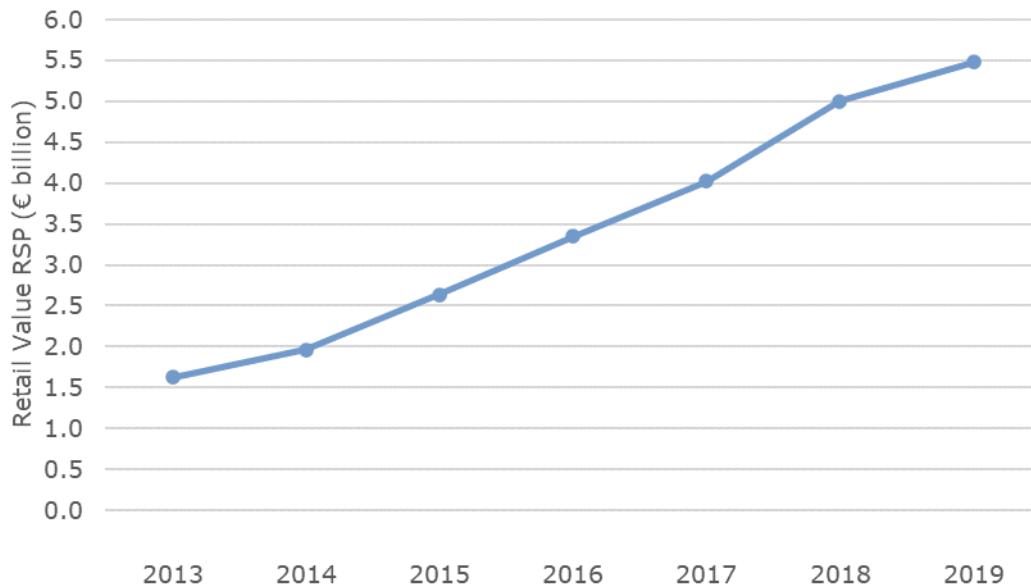
²⁵⁹ Euromonitor International confirmed that HTPs are treated in the category "Heated tobacco products" and are not included in the E-vapour category as defined in their data used for this study.

²⁶⁰ In the Euromonitor International data collection, information was collected in the 27 Member States and the UK, except for Malta, Luxembourg, and Cyprus. These Member States were omitted due to their small size.

²⁶¹ There is no retail volume data available for E-vapour products. Therefore, it is not possible in this case to make inferences about whether prices or volumes are driving the increase in retail value RSP.

²⁶² Euromonitor International data suggests that until 2016, sales of HTPs were only reported in three Member States (AT, FR, IT), indicating that they were not widely available in the EU market until 2016, whereas the data shows that e-cigarettes were available in all EU Member States from as early as 2013.

Figure 5. Evolution of market size of e-vapour products



Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

The UK was the main driver of the market for e-vapour products across the EU 25, accounting for almost €2.5 billion worth of the total retail value of the market in 2019. Other prominent Member States included France and Germany, who respectively contributed sales of approximately €800 million and €700 million in 2019. Between 2013-19, the countries that experienced the highest rates of growth in the size of the e-cigarette market were Croatia (1912%, increase of approximately €33 million), Latvia (1875%, increase of €8 million), and Sweden (1025%, increase of €29 million).

The growing **popularity of e-cigarettes** also can be considered a disruption of the European market²⁶³. The market for e-cigarettes is rapidly evolving, with some indications in the literature that consumer preference is moving from smaller, pen-like e-cigarettes to larger 'tank' style devices with longer battery lives, larger e-liquid reservoirs and a higher level of vapour²⁶⁴. Of Eurobarometer respondents who use e-cigarettes or used them in the past, **refillable devices are the most preferred type** of e-cigarette (72%). Less than a quarter (23%) used a pod-system device²⁶⁵.

Over time, high wattage devices have also become more common in Europe, which means that lower concentrations of nicotine are more frequently used. However, using low-concentration nicotine e-liquid is also associated with the consumption of more

²⁶³ European Commission. (n.d). Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) Request for a scientific Opinion on Electronic cigarettes.; Laverty, A.A., Filippidis, F.T., & Vardavas, C. (2018). Patterns, trends and determinants of e-cigarette use in 28 European Union Member States 2014-2017. Journal of Preventive Medicine: 116, 13-18.;

Girvalaki, C., Tzatzarakis, M., Vardavas, A., Kyriakos, C., Nikitara, K., Stivaktakis, P., Tsatsakis, A. & Vardavas, C. (2020). Discrepancies in reported versus measured nicotine content of e-cigarette refill liquids across 9 European Countries before and after the implementation of the EU Tobacco Products Directive. European Respiratory Journal. 55(2):pii:1900941;

ENSP. (2019f). ENSP Fact Sheet: Series #3/2019: Emerging and Novel Tobacco Products. ENSP.

²⁶⁴ IFF Research. (2016). Understanding the Online E-cigarette market. HM Revenue and Customs.

²⁶⁵ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

liquid, resulting in the same amount of nicotine being consumed but alongside higher amounts of any potentially harmful constituents²⁶⁶. Furthermore, there is evidence that the use of nicotine salts in certain products increases nicotine delivery²⁶⁷. Although this study was done in the USA with higher concentrations of e-liquid than would be allowed in the EU, it demonstrates that nicotine salt e-liquid leads to higher nicotine delivery than standard free base nicotine.

In the consultation activities for the present study, stakeholders were asked about the relevance of Art.20 to the market. A few Member States responded that the TPD provisions **sufficiently covered all aspects of emerging e-cigarette products**. Over half of Member States responded that the TPD covered these emerging trends to some extent, and a few responded that the TPD did not cover these trends, largely because the market was **growing very quickly in general**, and there were new types of products being created that were not covered by the TPD. Over one third of CSOs and HEs (35%) responded that the TPD did 'not at all' address new developments in e-cigarettes. In the online survey, around a quarter (21%) of economic operators responded that the TPD sufficiently addresses new developments in relation to e-cigarettes. One economic operator (out of 5) reported that Art. 20 sufficiently accounted for new market developments in the sense that it could be used to cover all types of nicotine-containing e-cigarettes. Two economic operators reported that it sufficiently accounted for developments to some extent, and one reported that Art. 20 did not account for such developments.

Examples of emerging products, which were considered to not be sufficiently covered by the TPD, are given below²⁶⁸:

- Customisable products such as those with modifiable tank size (one Member State);
- Single use and pod products (three Member States²⁶⁹);
- CBD vaping products (five Member States);
- Products which use nicotine salts (six Member States);
- Mix-it-yourself (two Member States) and nicotine booster products which can be mixed with non-nicotine containing liquid (five Member States), due to the 20mg/ml requirement for nicotine;
- Hybrid devices combining liquids and tobacco or herbal products (one Member State);
- Products with more than one tank (one Member State);
- Nicotine and non-nicotine gels which can be vaporised (one Member State);
- Modifiable products, for example with the addition of coils (one Member State);
- Products with features such as clocks and games (one Member State); and

Due to the changing market, some stakeholders (one CSO and one HE) recommended a revision of Art. 20.

Assessment of impact of Art.20

In terms of the impact of Art. 20 on e-cigarette use, a longitudinal study from the UK showed that awareness of the changes implemented through the TPD was low, but

²⁶⁶ Smets, J., et al. (2019). When Less is More: Vaping Low-Nicotine vs. High-Nicotine E-Liquid is Compensated by Increased Wattage and Higher Liquid Consumption. *Int J Environ Res Public Health*, 16(5).

²⁶⁷ Goniewicz, M.L., Boykan, R., Messina, C.R., et al. (2018). High exposure to nicotine among adolescents who use Juul and other vape pod systems ('pods'). *Tobacco Control*: 28, 676-677.

²⁶⁸ Note that detailed information was not provided, and products were generally presented in a list format

²⁶⁹ For one Member State, this concern was particularly related to the ease of use by children.

compliance was high²⁷⁰. In a study in the Netherlands, only a third of e-cigarettes users²⁷¹ reported that they noticed text warnings and leaflets that are required in Art. 20(4)(a), (4)(b) and (4)(c), and study authors concluded that they should therefore be made more noticeable²⁷².

The EUREST-PLUS study also provided information on the impact of Art. 20 of the TPD across six European countries (DE, EL, HU, PL, RO, ES)²⁷³. The study found that from 2016 (before TPD implementation) to 2018 (after TPD implementation) there was a significant increase in respondents that noticed and read health and product safety information on leaflets inside e-cigarette packets from 8.39% to 11.62%. However, there was no increase in respondents noticing warning labels printed on e-cigarette packets and vials, which may potentially be due to users discarding external packaging without reading them. Over this time period, there was no significant change in the proportion of respondents who used e-cigarettes daily or weekly.

One recent study²⁷⁴ compared several measures in England following the introduction of TPD-mandated e-cigarette warning labels and leaflets with Canada, the US and Australia, where no warnings and leaflets were mandated. The study found that introduction of the mandatory warnings and leaflets in England was associated with small increases in **noticing them** but not with changes in concerns about e-cigarette use.

There is some evidence about the TPD's **impact on the market for e-cigarettes** in the EU. Respondents to a consultation of companies in the tobacco industry regarding the impacts of the TPD on e-cigarette and HTPs anticipated that the TPD would make production costs higher for e-cigarettes, driving out smaller players in the market with potentially inferior products, and consolidating the market²⁷⁵. There is some evidence that market consolidation has occurred since implementing the TPD, although it is unclear whether this is due to the TPD or whether it would have happened regardless. For example, in 2016-2017, large tobacco companies acquired smaller e-cigarette companies, and launched new lines of products related to e-cigarettes with target markets in EU countries including the United Kingdom, Poland, Spain and the Netherlands²⁷⁶.

²⁷⁰ Lee, H. S., Wilson, S., Partos, T., McNeill, A., Brose, L. S. (2019). Awareness of Changes in E-cigarette Regulations and Behaviour Before and After Implementation: A Longitudinal Survey of Smokers, Ex-smokers, and Vapers in the United Kingdom. *Nicotine & Tobacco Research*: 10(10). Note that this survey found that use of TPD-compliant e-cigarette devices was not predictive of subsequent smoking

²⁷¹ Defined as respondents who used e-cigarettes at least monthly.

²⁷² Van Mourik, et al. (2019). Did E-Cigarette Users Notice the New European Union's E-Cigarette Legislation? Findings from the 2015–2017 International Tobacco Control (ITC) Netherlands Survey. *Int. J. Environ. Res. Public Health* 2019, 16(16), 2917; <https://doi.org/10.3390/ijerph16162917>

²⁷³ Nikitara, K., Girvalaki, C., Kyriakos, C.N., et al. (2020). Changes in electronic cigarette use and label awareness among smokers before and after the European Tobacco Products Directive implementation in six European countries: findings from the EUREST-PLUS ITC Europe Surveys. *European Journal of Public Health*, 30(Issue Supplement 3): iii62-iii67. <https://doi.org/10.1093/eurpub/ckaa081>

²⁷⁴ Taylor, E.V., East, K.A., McNeill, A., et al. (2020). Changes in responses to nicotine vaping product warnings and leaflets in England compared with Canada, the US and Australia: findings from the 2016–2018 ITC Four Country Smoking and Vaping Surveys. *Tobacco Control*: Published Online, doi: 10.1136/tobaccocontrol-2020-055739

²⁷⁵ IFF Research. (2016). Understanding the Online E-cigarette market. HM Revenue and Customs.

²⁷⁶ Mathers, A., Hawkins, B., & Lee, K. (2019). Transnational Tobacco Companies and New Nicotine Delivery Systems. *American Journal of Public Health*: 109(2).

3.8.2 Findings per provision

Art.20(2): Notifications about e-cigarettes and refill containers

As of January 2021, there were 270,997 active distinct EC-IDs in EU-CEG, which far exceeds the number of IDs for tobacco products and herbal products for smoking (41,519 distinct TP-IDs total across 12 product categories²⁷⁷). Information about the types of products notified and the distribution across Member States as of January 2021 is included in the table and graph below; also see Annex 6. As of March 2021, these figures had slightly risen to around 303,000 active submissions²⁷⁸.

Table 10. Active e-cigarette notifications by product type (total: 270,997 distinct EC-IDs)

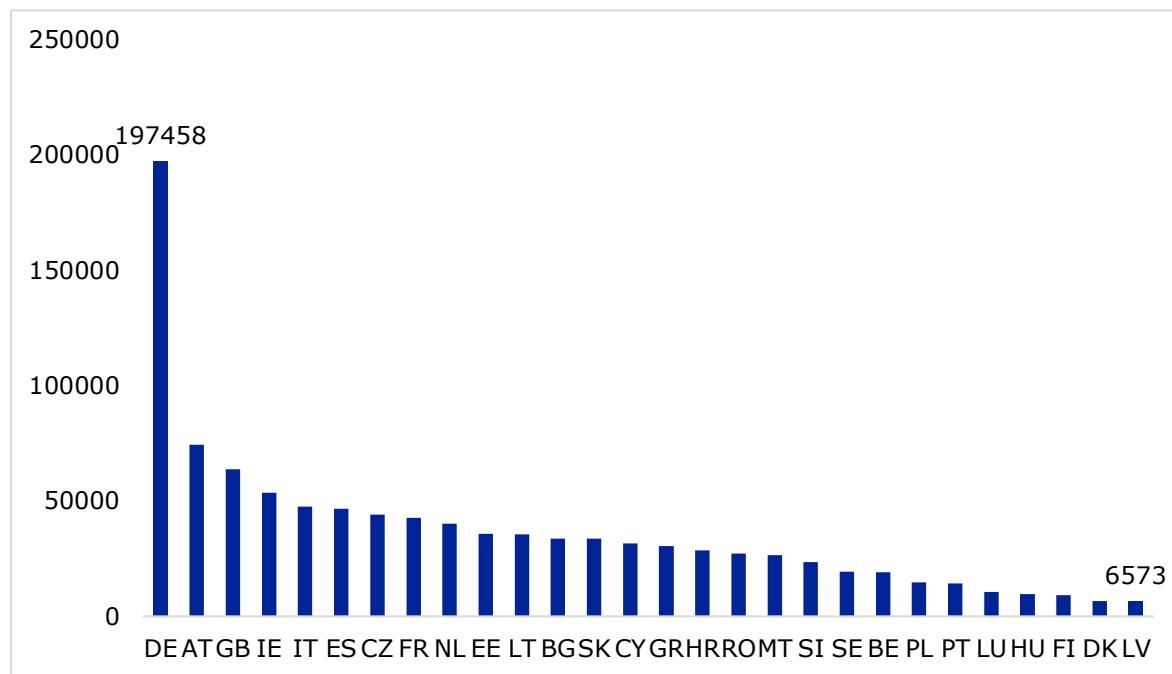
Product Type	Count distinct EC-IDs
Refill container/cartridge containing e-liquid.	143141
Other	64102
Individual part of electronic cigarette capable of containing e-liquid.	20933
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge.	17592
Electronic cigarette – Refillable, device only.	16701
Electronic cigarette – Rechargeable, device only Any rechargeable which can also be used as a refillable should be reported under the refillable category.	4880
Electronic cigarette – Disposable.	3041
Electronic cigarette – Refillable, placed on the market with one type of e-liquid (fixed combination).	822
Electronic cigarette – Rechargeable, placed on the market with one type of e-liquid (fixed combination). Any rechargeable which can also be used as a refillable should be reported under the refillable category	302

Source: EU-CEG data provided by DG SANTE in January 2021.

²⁷⁷ Categories: Chewing tobacco; Cigar; Cigarette; Cigarillo; Herbal product for smoking; Nasal tobacco; Novel tobacco product; Oral tobacco; Other; Pipe tobacco; Roll your own tobacco; Waterpipe tobacco. See Annex 6 for further information.

²⁷⁸ EU-CEG data provided by DG SANTE in March 2021.

Figure 6. Active e-cigarette notifications by Member State (total: 270,997 distinct EC-IDs)



Source: EU-CEG data provided by DG SANTE in January 2021.

Submitting the notifications

Nearly half of Member States faced issues with **manufacturers and importers submitting notifications about e-cigarettes and refill containers** and another seven had faced issues to some extent²⁷⁹. Out of five economic operators, two reported issues to some extent with **collecting the information required for notifications** about e-cigarettes and refill containers²⁸⁰, and three economic operators reported issues to some extent with the **process of submitting notifications about e-cigarettes and refill containers**, which is done through the EU-CEG²⁸¹. The main points raised were related to technical problems with EU-CEG, inconsistencies between information recorded on the system and made available on the market and reported inconsistencies between Member States²⁸².

In addition to the issues analysed as part of Art. 5 above, there were difficulties identifying e-cigarette products by name (reported by three Member States), and EU-CEG was also not seen as **flexible** enough to accommodate notification for different combinations of products. Some **inconsistencies** were also noted between the recorded notifications and the actual market. In one Member State, products were notified on EU-CEG without ever being placed on the market. In reverse, two Member States reported that products have also been placed on the market without being notified to EU-CEG. One economic operator reported being aware of thousands of products being placed on the market by organisations in third countries, without these being notified. A few Member States found there was an overwhelming **number of**

²⁷⁹ Five Member States did not face issues.

²⁸⁰ Three reported not facing such issues.

²⁸¹ Two reported not facing such issues.

²⁸² For example, economic operators noted variations between Member States in terms of notification fees which, although allowed, according to one economic operator varied significantly despite TPD requirements for the fees to be 'proportionate'.

notified products, and many questions received from organisations making the submissions.

Incorrect submissions

There is some evidence from the **document review** that submissions are not always in compliance with the requirements of the Directive. One assessment found that the presentation of data in EU-CEG for liquids for e-cigarettes was not always compliant with data quality requirements, and data entered by different data providers were found to be **inconsistent**²⁸³. Specific issues included that **declarations** were missing from the database and that a **common format was lacking** when reporting ingredients and emission levels²⁸⁴. For example, an analysis of liquids for e-cigarettes found that declarations were either missing or wrong for several products purchased from the market; not all data providers declared the **toxicity** of all ingredients (e.g. nicotine, Group 3 substances benzyl acetate, coumarin, eugenol and d-limonene), which are required to report on as per Art. 5(3). At least one of the four International Agency for Research on Cancer (IARC) Group 3 substances were present in a substantial number of analysed e-liquids without being declared in EU-CEG²⁸⁵. There seems to be more consistency in the use of CAS numbers, which is the standardised format to report chemicals that is used in the EU-CEG.

Around half of Member States had **requested the completion of notification information following incorrect submission by manufacturers and importers**, and one Member State had requested this to some extent. In two Member States, this is under consideration, and six did not request such information. Three Member States found that information provided was often incomplete or insufficient, for example omitting toxicological data. One Member State said up to 20 percent of notifications required some corrective action before publication. Few Member States provided more information on how they dealt with incorrect submissions of e-cigarettes. Requests were sent by both letters and emails in two Member States. In one of these Member States, if there is no correction made, the product is not allowed on the market and can be seized by an inspection team. As discussed in the section on Art. 5, France stated that starting in August 2020, manufacturers received a first notification with a list of discrepancies identified in their submissions²⁸⁶, and list of such discrepancies are publicly available and updated monthly on their website²⁸⁷ to encourage improvement.

Common issues with **gaps in notifications** included: the declaration of responsibility, information on refill mechanisms, toxicological information, manufacturers incorrectly categorising themselves, and missing information about the composition of products.

Technical information submitted

Around half of Member States have encountered issues with **objectively assessing technical information submitted on the various product characteristics**

²⁸³ Wenzl, T. & Zelinkova, Z. (2018). Administrative Arrangement N°34851 between DG SANTE and DG JRC regarding the project Technical support to the implementation of the Tobacco Products Directive. Joint Research Centre: JRC114627.

²⁸⁴ Wenzl, T. & Zelinkova, Z. (2018). Administrative Arrangement N°34851 between DG SANTE and DG JRC regarding the project Technical support to the implementation of the Tobacco Products Directive. Joint Research Centre: JRC114627.

²⁸⁵ Wenzl, T. & Zelinkova, Z. (2018). Administrative Arrangement N°34851 between DG SANTE and DG JRC regarding the project Technical support to the implementation of the Tobacco Products Directive. Joint Research Centre: JRC114627.

²⁸⁶ <https://www.anses.fr/en/content/tobacco-and-vaping-products-anses-publishing-unprecedented-overview-products-sold-france>.

²⁸⁷ <https://www.anses.fr/en/content/tobacco-and-related-products> and <https://www.anses.fr/en/content/vaping-products>

required in Art. 20(2). One Member State has faced issues to some extent, and nine have not experienced any issues. The main points raised concerned:

- A lack of consistent standards for requirements, for example in regard to nicotine doses (six Member States)
- A lack of resources or technical expertise to adequately assess the product characteristics (two Member States)
- Child-proofing provisions (two Member States)
- Carry-over ingredients (one Member State)
- Typos and variation in terms for ingredients (one Member State)
- Unrealistic values and lack of market share data (one Member State)

Requirement to submit notification 6 month before placing the product in the market

Manufacturers and importers must submit their notifications at least six months before they intend to place a product on the market. This allows the Member States time to review the application. Five Member States **have a mechanism in place allowing placing on the market of products faster than six months** after the first submission. 16 Member States did not confirm products before the end of this window.

An economic operator said that the process of allowing a product to be launched before the end of the six-month window should be broadened across Member States. A Member State stated that differences in how the six-month window was used may distort competition. As described in the section on Art. 19, Member States were not entirely in agreement about the duration of the 6-month notification period, with some suggesting it could be shortened to three or four months, others seeing the full six months as necessary and some not committed either way. Some found that the period should be shorter for minor modifications to existing products that had already been notified, although this would require a definition of 'minor'. Four Member States reported the amount of data to be processed and checked was challenging, requiring a lot of resources and expertise. More collaboration across Member States would be sensible as not all had the same resources or expertise, plus it would avoid Member States ending up with divergent results (reported by two Member States).

Submitted products prevented from being placed on the market

Nine Member States had **prevented submitted products from being placed on the market** by refusing the application or asking submitters to withdraw it. 13 Member States have not prevented products to be launched. In one Member State, around 650 products have been removed from the market after publication of the product notifications and nearly 1500 products have been refused publication. Across Member States, the **frequency** of prevention varies by Member State from 37 products in total, since the entry into force of the Directive, to almost daily prevention actions.

Products prevented from entering the market include e-cigarettes which can be activated by drawing (draw-activated), products with a tank capacity more than 2 ml, products with more than 20mg/ml of nicotine, and particular bundle kits.

Art.20(3): Quality and safety requirements

A 2019 study on compliance with the e-cigarette **packaging and labelling** requirements specified in the TPD compared products sold before and after TPD implementation in nine Member States (FR, PO, DE, NL, UK, ES, RO, HU and EL)²⁸⁸. The study found that compliance with child-resistant packaging and tamper-proof

²⁸⁸ Girvalaki C., Vardavas A., Tzatzarakis M., et al. (2019). Compliance of e-cigarette refill liquids with regulations on labelling, packaging and technical design characteristics in nine European member states. *Tobacco Control*, Published Online First: 13 September 2019.

vials, as required by Art. 20 (3)(g), had improved, with 100.0% and 86.9% of products (respectively) in compliance after TPD implementation as compared to 93.3% and 58.9% of products pre-implementation. 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.

Six Member States faced issues with the **quality/safety requirements set out in Art. 20(3)**, while five faced issues to some extent²⁸⁹. Two economic operators (out of 5) reported issues to some extent with the **requirements for nicotine-containing liquid** in Art. 20(3), and three reported not facing such issues. The main points raised, summarised below, include instances of non-compliance with TPD requirements (and related actions taken), and a reported need for harmonising technical standards:

- **Quality and safety violations** included e-liquids containing vitamin E, tanks with volumes over 2ml, products which include tubes or gaskets which can expand the tank size over 2ml, products with information in other European languages, non-disposable e-cigarettes that do not fall under regulations and nicotine shots. Overall, CSO and HE stakeholders emphasised that nicotine was often sold separately and then mixed with the base, through self-mixing of e-liquids and e-liquid shots.
- Three Member States are not strictly applying **the 2ml maximum tank size requirement** (Art. 20(3)(a)). For one of these, the translation is vague, so tanks bigger than 2ml are being tolerated. One has tanks larger than 9ml being sold online as spare parts. In addition to such points raised, another Member State also reported finding e-cigarettes with tank volumes greater than 2ml, and adaptor kits which can modify tank sizes.
- One Member State also reported that this caused some issues as many of these products were sold in their Member State from a neighbouring Member State. There is some discussion at the EU level, but currently the resolution is unclear.
- A few Member States explicitly referred to **removing some products from the markets**, and often have notified them to **Safety Gate**. These products include refill containers with a volume of 100ml, products labelled as 'vitamin vaporizers', and products without adequate child-proofing, containing prohibited substances, containing Vitamin E, containing Vitamin C, or containing CMR property 2.
- One Member State stated that more **extensive validation** of submitted information would be desirable. One HE recommended improvements in quality-control mechanisms for the nicotine content of e-cigarette refill vials.

There were also several points stakeholders said need to be clarified, including:

- Child-proofing requirements (three Member States, one economic operator);
- Ingredients that are considered not to be of 'high purity' and substances in 'trace levels' that are technically unavoidable during manufacture (three Member States); and
- Ingredients that pose a risk to human health in particular when consumed via inhalation (one Member State).

Stakeholders also reflected on the value of some of these quality and safety requirements; and made the following recommendations:

²⁸⁹ Ten Member States had not faced such issues.

- **Remove the 10 ml capacity limit for refill bottles** (Art. 20(3)(a)) for ecological reasons, as this reportedly creates **high plastic waste** (one CSO with a potential conflict of interest, one HE, a few organisations representing consumers)
- **Remove the 2 ml volume limit** for cartridges and tanks (Art. 20(3)(a)); this limit is not applied in one Member State where, in contrast to the opinions of some stated above, this limit reportedly does not create difficulties (one CSO with a potential conflict of interest, one organisation representing consumers).
- **Raise the nicotine concentration limit of 20 mg / ml**, (Art. 20(3)(b)); as this is reportedly not effective for heavy smokers (one CSO with a potential conflict of interest, one organisation representing consumers). One economic operator said the **maximum allowable concentration** of nicotine in e-liquids is lower than for cigarettes, which may put e-cigarettes at a disadvantage for consumers if these products deliver less nicotine per puff. Guidance from the expert subgroup on e-cigarettes was seen as potentially being useful in this area.
-

Art.20(4): Packaging, leaflets and health warnings

The aforementioned study on **packaging and labelling compliance**²⁹⁰ found that alignment with text-only health warnings on unit-packs of e-cigarettes and refill liquid, as required by Art. 20(4)(b)(iii) and (4)(c), had increased from being included on 32.7% of products pre-implementation to 86.0% of products post-implementation. However, there was relatively low alignment with the inclusion of a leaflet in product packaging, as required by Art. 20 (4)(a), which was included in just over half (53.3%) of products after implementation as compared with just over a quarter (26.2%) of products pre-implementation. Low compliance was also found with the requirement in Art. 20 (4)(b)(i) for manufacturers of e-liquid to include the nicotine content on products.

A recent study from the EUREST-PLUS consortium²⁹¹ found that adult smokers in six Member States (DE, EL, HU, PL, RO, ES) reported noticing and reading leaflets included in the packaging of e-cigarettes **significantly more than before the introduction of the TPD**. However, there was no significant change in reported noticing and reading of warning labels.

A few Member States faced issues and a few more faced issues to some extent in implementing the provisions concerning **leaflets in unit packets of e-cigarettes**²⁹². Two economic operators (out of 5) reported issues to some extent with these provisions, and three reported not facing such issues. The main points, as summarised below, related to leaflets not being included, leaflets not complying with the Directive's requirements, a lack of clarity as to what information the leaflets should include, how leaflets should be inserted, leaflets being made available in the wrong language,

²⁹⁰ Girvalaki C., Vardavas A., Tzatzarakis M., et al. (2019). Compliance of e-cigarette refill liquids with regulations on labelling, packaging and technical design characteristics in nine European member states. *Tobacco Control*, Published Online First: 13 September 2019.

²⁹¹ Nikitara, K., Girvalaki, C., Kyriakos, C.N., et al. on behalf of the EUREST-PLUS consortium. (2020). Changes in electronic cigarette use and label awareness among smokers before and after the European Tobacco Products Directive implementation in six European countries: findings from the EURESTPLUS ITC Europe Surveys. *European Journal of Public Health*: 30(Supplement 3).

²⁹² 11 have not faced such issues.

otherwise being illegible or not including the required information, and differences between Member States preventing harmonisation.

Six Member States faced issues in implementing the provisions concerning **unit packets and outside packaging of e-cigarettes, including ingredients and combined health warnings**. Four Member States faced issues to some extent, and nine did not face such issues. Three economic operators (out of 5) reported issues to some extent with these provisions, and two reported not facing such issues.

The main points, as summarised below, related to violations of the provisions reported and points of ambiguity or inconsistency reported by economic operators:

- Violations included information on outside packaging not referring to ingredients of liquids, nicotine content and dose, recommendation to keep products away from children, health warnings, batch number, and nicotine toxicity. One Member State with several national languages encountered issues with including information in **all languages**, for example with recommendations to keep out of reach of children and lists of ingredients. **Advertising** statements were also found on product packaging, as well as references to foods, fruits, and candies, and claims about products being organic or therapeutic. As with leaflets, one economic operator reported issues fitting all the **required information**.
- There were also some issues around the **ingredient lists**. One economic operator responded that a requirement to list all ingredients would violate **trade secrets**. Another cited issue (from an economic operator) with ingredients is that Art 20 (4)(b)(i) requires a list of ingredients on packets, but the lack of de minimis threshold has led to some Member States allowing a **0.1% cut off** and allowing flavouring ingredients to be abbreviated as 'flavourings'. In one Member State, it was unclear if 'aroma' was a sufficient reference in an ingredient list. There were also ambiguities in the same Member State around the definition of 'nicotine per dose', as with many products this is variable based on settings.
- Six Member States also noted ambiguities and points of confusion in relation to the information requirements, for example there are varying interpretations of what **unit packaging versus outside packaging** meant, and more specifically whether a refill container was a unit packet.
- Stakeholders reported that the TPD contradicted the **CLP Regulation**²⁹³: several economic operators who responded to the online survey reported that e-cigarette manufacturers need to comply with both the TPD and CLP regulation when labelling products, which are not aligned with one another. One economic operator cited variation in the implementation of CLP warnings between and within Member States. Variations were also noted in terms of labelling requirements for e-cigarette components and the physical space on bottles. Four Member States reported variation in requirements whether e-liquid refill containers needed to be labelled as hazardous, and whether this was dependent on the nicotine concentration. Economic operators reported that some Member States required CLP warnings to be applied to the cartridges themselves, but that this causes problems as the products must be small as mandated by the TPD, and it is not always possible to fit the warning due to technical limitations. One economic operator suggested the CLP warnings should be on the exterior packaging rather than the product itself.

²⁹³ The CLP Regulation for (Classification, Labelling and Packaging)

A few organisations representing consumers reported that packaging and warning requirements were unfounded as e-cigarettes did not pose as much damage to health as tobacco products. Conversely, one CSO stated that attractive packaging of e-cigarettes could be misleading for young people and, therefore, **there is a need for stricter restrictions on labelling**. Similarly, a Member State recommended certain **additions** to these requirements, including warnings for certain allergens and minimum expiration dates. In December 2020, amendments to the Act on tobacco products and the Act on electronic cigarettes were adopted in Denmark²⁹⁴, which included introducing **plain packaging** for electronic cigarettes.

Art.20(5): commercial communications and promotion

According to data from the most recent Eurobarometer, 7% of respondents had often **seen advertisements or promotions for e-cigarettes, liquids or refill cartridges** in the past 12 months, while 16% had exposure from time to time²⁹⁵. These numbers were similar to those observed in 2017, when 7% had often seen advertisements, and 20% had seen them from time to time²⁹⁶, however note the phrasing of the item was slightly different²⁹⁷. 57% of respondents did not have any exposure to such advertising, compared to 53% in 2017. Member States with the highest level of exposure were the UK (23% of respondents reported no exposure), Ireland (28%) and Germany (52%) while exposure was the lowest in Hungary (87% reported no exposure)²⁹⁸. A study from the EUREST-PLUS consortium²⁹⁹ found that among adult smokers in six Member States (DE, EL, HU, PL, RO, ES), **self-reported exposure to advertising, promotion, and sponsorship of e-cigarettes** varied across countries. The study found that exposure declined in some channels regulated by the TPD (TV and radio), but increased in some channels under Member State competence, including at the point of sale. Exposure to advertising exposure on social media or the internet was also generally high in this study.

Ongoing study on smoke-free environments and advertising of tobacco and related products

A parallel ongoing study³⁰⁰ being carried out by ICF for the European Commission has examined advertising, promotion, and sponsorship of tobacco and related products in the EU, including e-cigarettes. In terms of the rules Member States have

²⁹⁴ <https://www.retsinformation.dk/eli/lt/2020/2071>

²⁹⁵ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

²⁹⁶ DG SANTE. (2017). Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/ResultDoc/download/DocumentKey/79002>

²⁹⁷ 2017: 'In the past 12 months, have you seen advertisements or promotions for electronic cigarettes or any similar devices (e.g. e-shisha, e-pipe) in (OUR COUNTRY)?'

2020: 'In the past 12 months, have you seen advertisements or promotions for the following products in (OUR COUNTRY)?...E-cigarettes, liquids or refill cartridges'

²⁹⁸ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

²⁹⁹ Kahnert, S., Driezen, P., Balmford, et al. on behalf of the EUREST-PLUS consortium. (2020). Impact of the Tobacco Products Directive on self-reported exposure to e-cigarette advertising, promotion and sponsorship in smokers—findings from the EUREST-PLUS ITC Europe Surveys. European Journal of Public Health: 30(Supplement 3).

³⁰⁰ Study on smoke-free environments and advertising of tobacco and related products; ongoing

in place, for most environments, the **coverage of rules** on advertising, promotion, and sponsorship for e-cigarettes was good or very good³⁰¹. Coverage was moderate for products visible on display in shops, supermarkets and other retail outlets, and low for print advertising in the trade press. Note that some environments examined are regulated by the TPD and other advertising directives, while others are not.

Stakeholders (including Member States, CSOs, and HEs) reported several **challenges** specific to advertising, promotion, and sponsorship of e-cigarettes, including the following:

- The regulations may be **out of date** or have not caught up with the changing landscape related to e-cigarettes. The definitions in legislations could be updated and broadened accordingly, and not all Member States have always enacted strong legislative responses related to e-cigarettes.
- The fact that the TPD only covers **nicotine-containing e-cigarettes** has reportedly enabled economic operators to advertise non-nicotine containing versions of products, with a small footnote disclaimer.
- There may be higher exposure to e-cigarette marketing in places where non-smokers and **adolescents** could be exposed (e.g. billboards, stores that sell tobacco, social media and the internet), therefore warranting more comprehensive regulation and effective enforcement in order to prevent initiation of e-cigarette use among these groups. An HE interviewee therefore advocated for a framework in which e-cigarettes may only be promoted in adult settings, and only as a cessation aid (therefore targeted at current smokers only).
- The introduction of e-cigarettes into the market has created increased advertising '**spill over**' for **tobacco products** for smoking. For example, imagery used for e-cigarettes is reportedly the same as that used for tobacco products for smoking, thereby indirectly promoting tobacco products for smoking. In addition, concerns were raised that advertising of e-cigarettes which are linked to tobacco brands promotes these brands in a form of brand stretching.

A few Member States faced issues in **interpreting and implementing provisions of Art. 20(5), which prohibits commercial communications and promotion of e-cigarettes**. Around a quarter faced issues to some extent³⁰². Two economic operators (out of 5) reported issues with the **prohibitions on commercial communications about e-cigarettes**. Overall, difficulties identified by these stakeholders related to the practical implementation and compliance with the requirements of the Directive,

³⁰¹ Rules in the following environments were 'good': Advertising outside the home; Cinema advertising; Competitions or prize draws linked to tobacco and related products; Advertising at point of sale in shops, supermarkets and other retail outlets; International print advertising for the general public; Online sales by specialist retailers of tobacco and related products for smoking; Wider sales channels; Non-retailer websites, social media, appstore or apps downloaded from appstores for mobile devices; Corporate Social Responsibility actions by tobacco companies; Brand stretching and imitation products; Corporate promotion and other public relations tactics.

Rules in the following environments were 'very good': Free samples, free gifts and promotional items; National or local print advertising for the general public; National or local TV advertising; International TV advertising; National or local radio advertising; International radio advertising; Product placement; Sponsorship.

³⁰² Ten Member States did not face such issues. One economic operator reported issues to some extent, and another reported not facing such issues.

and this seems to be related to variations and ambiguities of national law in Member States. More specifically:

- With regard to the **implementation** of the provision, in one Member State, the Supreme Administrative Court³⁰³ ruled that 'advertising is a subset of commercial communications and the Act on the Regulation of Advertising does not prohibit commercial communications for electronic cigarettes.', opening the way for the industry to advertise e-cigarettes.
- An economic operator said that it should be allowed to communicate any evidence-based **benefits** of e-cigarettes relative to smoking to consumers, with regulatory oversight. As stated previously, the document review undertaken as part of this study did not reveal conclusive evidence about these so-called benefits.
- Member States cited **challenges** with e-cigarette advertising on billboards (two Member States), websites (three Member States), buses (two Member States), and social media (two Member States). One Member State added that online and social media content was overall difficult to detect, due to the sheer size of the platforms and the marketing methods used (e.g. with private persons, such as influencers, saying positive things about a product or using it without receiving monetary compensation). One economic operator said that there has been an issue with **inappropriate marketing techniques** both on and off packs, such as including toys, fictional characters, celebrities, athletes, sports, music, animals, games, or media.
- One Member State stated that **fines for non-compliance** with the requirements of the Directive had not been effective in preventing economic operators from repeating the infringement. In another Member State, there were issues with the industry understanding that advertising a product may not be allowed even if selling the product itself is legal.
- There have been reported instances of non-compliance related to **online** advertising and sponsorship of e-cigarettes, including the use of social media (one CSO), such as influencers on Instagram (another CSO). One HE noted that marketing of e-cigarettes to youth using social media has risen significantly recently. One CSO recommended that provisions on 'commercial communication' should be updated with digital methods of communication. A HE also noted that **Corporate Social Responsibility** tactics, improves public perceptions of the industry and may comprise a type of promotion.

Art.20(6): Cross border distance sales (CBDS)

CBDS of e-cigarettes are allowed in 12 Member States and prohibited in 16 Member States. Around a quarter of Member States faced issues in implementing **provisions concerning CBDS specifically related to e-cigarettes**. A few faced issues to some extent, and around a third did not face such issues.

A few CSOs reported that in one Member State, although CBDS are prohibited, some e-cigarettes are sold into the country. Violations of the provision have been found with products being sold cross-border through online retailers (two Member States) or elsewhere on the **internet** (two Member States). **Enforcement** of this article has been difficult. For example: '*It is difficult for front line enforcement officers to identify e-cigarettes, parts which fall under this article and which do not, what is prohibited and what is not, what should be seized and what should not.*' (Member State). Two Member States stated it was difficult to monitor and track these sales as the domain and IP was often different for the manufacturer, importer, and seller of a product.

³⁰³ Decision of Senate of the Supreme Administrative Court of 16 April 2020, 10 As 413/2019-49.

That the TPD allows Member States to choose if they want to prohibit CBDS has made it harder to regulate (one Member State). Some organisations representing consumers claimed that allowing Member States to prohibit CBDS of e-cigarettes was detrimental to health.

There have been some problems in Member States which **allow** CBDS as well, for example with retailers in other countries selling products which were **not compliant** with the requirements of the Directive into the country (two Member States). Some CSOs and HEs considered that cross-border sales and especially online sales of e-cigarettes should be banned at the EU level.

Art.20(7): Submission of market data

Seven Member States faced issues in **requiring manufacturers and importers to submit the market data required** in Art. 20(7), and a few faced issues to some extent³⁰⁴. Many or most manufacturers and importers **have not been submitting** the required information by the required time period (reported by nine Member States), or did not understand the requirements of the submission. In one Member State, around one third of sales data had been provided, although there were no cases of levying the €45,000 fine for not providing the information. Member States provided very little information about their follow up for incorrect or incomplete information. One Member State reported they did not react to incorrect or insufficient submissions. There have also been some actions taken by Member States to **improve** the process of submission and verification of market data; one Member State reported it will soon begin verifying the information more stringently to improve the quality of the data. Spain has made a report format for the industry, which has been published online³⁰⁵. In another Member State this has not been actively enforced due to lack of capacity.

Eight Member States confirmed that they were **monitoring market developments concerning e-cigarettes and refill containers**. A few monitor this to some extent, and a few do not monitor such developments. Some Member States track and record information about consumption patterns in **general** (DK³⁰⁶, FR³⁰⁷, IT³⁰⁸, LU³⁰⁹, ES³¹⁰, IE³¹¹) and in **young people** (FR³¹², CZ³¹³, IE³¹⁴), e-cigarettes as a **gateway** (IT³¹⁵,

³⁰⁴ Eight did not face such issues.

³⁰⁵

https://www.mscbs.gob.es/ciudadanos/proteccionSalud/tabcaco/Plantillas_Estudiosmercado_ProductosTabaco_DSLN.htm;

³⁰⁶ 'The survey on smoking prevalence in Denmark' (Danskernes Rygevaneundersøgelse).

³⁰⁷ 18-75 years health survey (Barometre Santé)

³⁰⁸ <http://www.iss.it/documents/20126/0/PACIFICI-31-maggio-2019.pdf/c5c9a560-86dd-3240-65e4-3ed6aa2b17?t=1576338071234>

³⁰⁹ <https://statistiques.public.lu/fr/actualites/conditions-sociales/sante-secu/2017/02/20170224/20170224.pdf>

³¹⁰ ESTUDES and Barometro Sanitario

³¹¹ Annual Healthy Ireland survey (<https://www.gov.ie/en/collection/231c02-healthy-ireland-survey-wave/>); Health Service Executive quarterly tracker survey

³¹² Youth drugs use survey (Enclass).

³¹³ http://www.szu.cz/uploads/documents/szu/aktual/uzivani_tabaku_alkoholu_cr_2018.pdf; <http://www.szu.cz/tema/podpora-zdravi/studie-gyts-2016>; <https://www.drogy-info.cz/publikace/vyrocní-zpravy/vyrocní-zprava-o-stavu-ve-vecech-drog-v-ceske-republice-v-roce-2018/>

³¹⁴ ESPAD Ireland 2019; HBSC: <http://www.nuigalway.ie/hbsc/publications/nationalreports/>

³¹⁵ <http://www.iss.it/documents/20126/0/PACIFICI-31-maggio-2019.pdf/c5c9a560-86dd-3240-65e4-3ed6aa2b17?t=1576338071234>

SE³¹⁶), and general developments in **products** (IT³¹⁷, NL³¹⁸, SI³¹⁹). In at least one Member State, there were not enough resources to conduct these studies.

Art.20(8): Publication of information on a website

Art. 20(8) states that Member States shall ensure that the information received is made publicly available on a website, except for trade secrets. Some Member States provided links to their publicly available databases of submitted information (BE³²⁰, DK³²¹, FI³²², SE³²³, ES³²⁴, HR³²⁵, CZ³²⁶, FR³²⁷, IT³²⁸, LT³²⁹, SI³³⁰). A few reported publishing general information without detailed product information. In one Member State, information is not published but can be requested via email. Seven Member States faced issues in **making submitted information publicly available on a website**. Three faced issues to some extent, and ten did not face such issues. Four Member States reported there were issues with ambiguities over what could be considered a '**trade secret**', as on EU-CEG every piece of information can be declared a secret.

Three economic operators (out of 5) had requested that information submitted, such as product composition, **would not be published on a public website, due to trade secrets**. One economic operator reported that they had requested this to some extent. Most responses did not clarify what information was declared a trade secret, although one economic operator said they marked product composition as a secret. Three Member States mentioned the publication of **JATC deliverable 5.1** 'Report on the principles to distinguish what data is public or confidential'. This report had not been published at the time of the consultation activities, but has now been published and outlines the parameters to be used to define the level of confidentiality of the data submitted through EU-CEG taking into account the available legislation and international evidence³³¹. Three Member States reported not publishing this information at the present time.

³¹⁶ Literature survey; results to be published in June 2020 (SWEDISH AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT AND ASSESSMENT OF SOCIAL SERVICES).

³¹⁷ <http://www.iss.it/documents/20126/0/PACIFICI-31-maggio-2019.pdf/c5c9a560-86dd-3240-65e4-3ed6aa2b17?t=1576338071234>

³¹⁸ <https://publichealth.jmir.org/2018/2/e55/>

³¹⁹ National Institute of Public Health in Slovenia is monitoring market developments.

³²⁰ <https://www.health.belgium.be/fr/notification-des-produits-de-la-e-cigarette-0>

³²¹ https://www.sik.dk/registre/register_over_e_cigaretter

³²² <https://tupakkarekisteri.valvira.fi/tuoteilmoitukset>

³²³ <https://www.folkhalsomyndigheten.se/livsvillkor-levnadsvanor/andts/regler-for-tillverkning-handel-och-hantering/elektroniska-cigarettter-och-pafyllningsbehallare/offentliggjorda-produktanmalningar/>

³²⁴

https://www.mscbs.gob.es/ciudadanos/proteccionSalud/tabaco/docs/Lista_positivos_DSLN.pdf; https://www.mscbs.gob.es/ciudadanos/proteccionSalud/tabaco/docs/Dispositivos_Susceptibles_Liberacion_Nicotina.pdf

³²⁵ <https://zdravlje.gov.hr/popis-e-cigareta-i-spremnika-za-ponovno-punjjenje-prijavljene-ministarstvu-zdravstva-kroz-eu-ceg-zajednicko-mjesto-elektronickog-ulaza-eu-a/3047>

³²⁶ http://www.mzcr.cz/Verejne/dokumenty/bylinne-vyrobky-urcene-ke-kourenielektronice-cigarety-a-nahradni-naprne-do-ni_14514_3478_5.html

³²⁷ <https://www.anses.fr/en/content/vaping-products>

³²⁸ www.ingredientiprodottideltabacco.it

³²⁹ <http://ntakd.lrv.lt/uploads/ntakd/documents/files/Licencijavimas/EU-CEG/eu-ceg-elcig.pdf>

³³⁰ www.tobak.si

³³¹ <https://jaotc.eu/wp-content/uploads/2021/02/WP5-D5.1-Report-on-what-data-is-public-and-non-confidential-in-EU-CEG.pdf>

Art.20(9): Systems for reporting adverse effects

One Member State faced issues in requiring manufacturers, importers and distributors of e-cigarettes and refill containers to **establish and maintain a system for collecting information about all suspected adverse effects on human health** of these products. A few Member States reported issues to some extent, while around half did not face such issues. Some Member States said the economic operators experienced issues **using the system** or have not submitted the information. In one Member State, a reporting system has not been enforced due to a lack of capacity. A few Member States said it would be useful to have a **joint, potentially EU-wide system** for collecting and reviewing this information.

Economic operators described their **systems or procedures to detect and report on adverse effects** to competent authorities, described in the box below:

- A few economic operators use an **internal customer service-based** resource, which involves consumers communicating with customer service staff. For one economic operator, consumers are then sent a questionnaire, and complaints are assigned a risk score.
- One economic operator has engaged a **Contract Research Organisation** to process adverse events reported through different channels (e.g. literature screening, monitoring the economic operator's customer care pages on social media and websites, call centres, local market surveys and campaigns, market research studies). Cases which include at least one serious adverse event are medically reviewed by a physician in the safety database. The other economic operators may have systems with this level of intricacy, but in the present questionnaire may have only reported their systems as applicable to the TPD. One economic operator reported that they **monitor Safety Gate** (previously RAPEX) for potential issues with their products.
- One economic operator reported informing National Competent Authorities when a relevant adverse effect is detected, although details were not provided. A few others reported that adverse effect information is stored and submitted to **regulatory authorities** upon request, which appears in breach of the relevant provision. However, more guidance on post-marketing surveillance would be appreciated.

In order to **report on adverse effects**, five Member States have used Safety Gate (formerly RAPEX), and one Member State has used the Information and Communication System on Market Surveillance (ICSMS), an IT platform to facilitate communication between market surveillance bodies in the EU and in EFTA countries. Four Member States have used both. Nine have used neither. In one Member State, thousands of products were found to be not compliant with the requirements of the Directive, making it impractical to report them all, as well as their adverse effects, on ICSMS. Two Member States have only been monitoring information from other Member States in Safety Gate.

Seven Member States had instances of **economic operators withdrawing or recalling products which were unsafe or not compliant with the requirements of the Directive** or taking corrective action to bring the product into conformity with the Directive. Over half of Member States have not had such withdrawals or recalls. Member State responses were not clear about if this concerned products already on the market or products intended to be placed on the market. One Member State clarified that a number of these have met the criteria for a notification submitted on the grounds Art. 12 of the General Product Safety Directive to be made to the Safety Gate which have then been disseminated as Alerts by the European Commission to

other Member States. In some Member States this had only happened very infrequently.

Art.20(11): Additional serious risks to human health

A few Member States have taken provisional measures against manufacturers/importers of e-cigarettes or refill containers that **comply with the requirements of Art. 20 but could present a serious risk to human health**. Around two thirds have not done so to date. For example, in one Member State controls to identify potential risks to human health are routinely performed by Ministry of Health, National Institute of Health, and Police for Health, and if there is reasonable reason to believe that certain products are at risk, they are **removed from the market** and not authorised for sale. In another Member State, they are working to prioritize chemical substances, the first step of a **risk assessment process** which may lead to those provisional measures. The results will be available in 2021.

One Member State **prohibited e-liquid products** containing additives in quantities that increase the toxic or addictive effect, or the CMR properties at the stage of consumption to a significant or measurable degree, as in Art. 7(9). Another Member State is considering such a prohibition.

Non-nicotine-containing products

Some stakeholders were concerned about the omission of **nicotine-free e-liquids from the scope of the TPD** (one Member State, several CSOs, one HE, a few organisations representing consumers, and one economic operator). Some have reported that not regulating them has provided a means for **circumvention** of restrictions. Some stakeholders reported that the lack of inclusion of these products '*has led to a market in non-nicotine products expressly intended for mixing with nicotine*' (economic operator); these 'shake and vape' products comprised of nicotine-free flavoured e-liquid together with nicotine solutions, with the intention of the two being mixed (reported by a few CSOs).

Many of these stakeholders recommended **regulating these products in the same way as those containing nicotine**; four Member States said it would be valuable to have similar regulations or provisions at the EU level. Ten Member States confirmed to have applied similar provisions for **non-nicotine containing e-liquids** as for nicotine containing e-cigarettes. A few have applied similar provisions to some extent, and nine have not done so. In a few Member States all or almost all provisions are applied similarly (for example all provisions except those relating specifically to nicotine). In other Member States, specific provisions which have been applied similarly included smoke-free environments (four Member States; note however this is not within the provisions of the TPD), sales to minors (two Member States), planned restrictions on flavourings (one Member State), and CBDS (one Member State). In three Member States they are planning on implementing provisions to bring non-nicotine containing e-liquids under provisions on e-cigarettes.

A few economic operators dealing with e-cigarette products mentioned that requirements in the TPD could restrict innovation in the e-cigarette category and impose additional burden on manufacturers, namely through delays for placing products in the market due to bureaucratic procedures and nicotine limits. One stakeholder from an e-cigarette company viewed these restrictions as not proving a level playing field and suggested they were used to protect the tobacco industry.

In terms of packaging for these products, one economic operator stated: '*There is lack of clarity provided by Member States on labelling and requirements that conflict with other regulations. For example, the warning text on the packaging, when it comes to nicotine containing liquids it is clear, however many Member States want to put it on the tank- even when those tanks do not contain nicotine*'.

Non-compliance with Art.20 and actions taken in response

In the online consultations held with CSOs and HEs, 30% responded that they were aware of **non-compliant** products on the market related to Art.20³³².

When asked about non-compliance with TPD provisions in general, around a third of Member States cited Art. 20 as a key area with low compliance. Instances of non-compliance related to specific sub-articles are discussed in the preceding sections.

The 2019 study of compliance with e-cigarette **packaging and labelling** requirements specified by the TPD³³³ found there was broad compliance with most measures around e-cigarettes in the TPD, including the previously discussed patterns for Art. 20 (3) and (4). Studies of the **content of e-liquids** have reported mixed findings regarding compliance with TPD requirements set out in Art. 20(3) and Art. 20(4). In a study investigating the content of the most popular brands of e-cigarette refill liquids in 9 Member States (FR, PL, DE, NL, UK, ES, RO, HU, EL), purchased before and after the implementation of the TPD (2016 and 2018), over half the products were found to have a discrepancy in nicotine concentration that was over 10% of that indicated by the product label (a threshold set by the European Commission's Joint Research Centre). Whether the products were purchased before or after TPD implementation did not appear to be associated with the level of discrepancy between the measured and reported nicotine content; 53.7% of products were above the threshold of 10% discrepancy after the TPD had been implemented, compared to 57.6% of products before the TPD³³⁴. However, only one product from the post-TPD samples was found to have a nicotine concentration exceeding the 20mg/ml legislated limit, compared to eight of the pre-TPD implementation samples. Another study focused on e-cigarette refills available in Belgium from 2013 to 2018 found that labelling discrepancies regarding nicotine content have decreased over the period of TPD implementation, as has the number of products containing high-risk volatile organic compounds, caffeine, and the flavourings diacetyl and acetyl propionyl³³⁵. In the present study, a HE reported that potentially hazardous substances have been found in e-cigarettes, and several stakeholders (one CSO and one HE) urged **stronger monitoring of e-cigarette additives**.

There was significant variation in how many times a Member State reported **taking actions** (such as product modification, product withdrawal, fines, or other punitive measures) against manufacturers or importers due to non-compliance related to e-cigarettes and refill containers since the Directive came into force. Six Member States reported enacting **product withdrawals**, five Member States reported implementing **fines**³³⁶, and nine Member States reported implementing a combination, or other or unspecified actions. See Table 11 for further information, including reasons for these punitive actions.

³³² 28% were not aware of such non-compliant products, and the remaining respondents preferred not to say or responded 'don't know'.

³³³ Girvalaki C., Vardavas A., Tzatzarakis M., et al. (2019). Compliance of e-cigarette refill liquids with regulations on labelling, packaging and technical design characteristics in nine European member states. *Tobacco Control*, Published Online First: 13 September 2019.

³³⁴ Girvalaki, C., Tzatzarakis, M., Vardavas, A., Kyriakos, C., Nikitara, K., Stivaktakis, P., Tsatsakis, A. & Vardavas, C. (2020). Discrepancies in reported versus measured nicotine content of e-cigarette refill liquids across 9 European Countries before and after the implementation of the EU Tobacco Products Directive. *European Respiratory Journal*. 55(2):pii:1900941

³³⁵ Barhdadi S, Moens G, Canfyn M, Vanhee C, Desmedt B, Courseselle P, et al. (2020) Impact of the Revised European Tobacco Product Directive on the Quality of E-cigarette Refill Liquids in Belgium. *Nicotine Tob Res*. 1–8 (advance online publication).

³³⁶ Another Member State clarified that they also could implement fines.

Table 11. Actions taken by Member States for non-compliance with Art.20: each row indicates one Member State

Actions taken
Product withdrawal: numbers indicate the number of cases.
Nicotine-containing liquid had contained nicotine in excess of 20 mg/ml
1: incorrect data on manufacture
2: incorrect notification
1: disposable e-cigarettes containing healthy substances and vitamins
12: high concentrations and volume of refill containers
3: product after expiration
3: missing notification
12: missing leaflet
Withdrawals and seizures have been enacted.
49% of products with non-compliances that do not pose a health risk are identified on the market, which are instructed to eliminate the identified non-compliances within the specified time period. Among them, distribution of 32% of products (45 out of 138) is temporarily stopped until the non-compliance is corrected.
Withdrawals have been enacted some times.
20: product ban, withdrawal from the market, withdrawal or modification of applications, withdrawal of the products from the resellers.
Fines
For cross border distance sale to the country where this kind of sale is banned
Missing notification in the EU-CEG database + missing components
For the sale of products with a higher concentration of nicotine and a higher volume
Lack of cooperation in checking
Fines have been enacted.
Fines have been enacted several times.
Other or unspecified actions: numbers indicate the number of cases.
Fines, product withdrawals or both:
219: non-compliance related to the labelling of e-cigarettes and/or refill containers.
26: non-compliance related to the composition of e-cigarettes and/or refill containers.
130: e-cigarettes and/or refill containers were not notified.
General non-compliance related to e-cigarettes and refill containers.

Actions taken
Product withdrawal: numbers indicate the number of cases.
3: Re-labelling of nicotine content in the dose
2: Addition of the batch number
2: Filling in the list of ingredients
3: Missing and late notifications in the EU-CEG
2: Addition of information about the manufacturer
4: Missing leaflet
1: Missing labelling in the appropriate language
1: Fraudulently labelled products - as an importer was listed company, which did not import or sell products
5: Admonition
220
Fewer than 10 times
6: Compliance Notices
15: invoked certain legislative powers
The use of these combined legislative powers has resulted in the removal of in excess of 3544 non-compliant products from the market.
4: non-specific actions
Actions taken almost daily.
Over 650: removed from publication for non-compliance.

3.9 Herbal products for smoking

Art. 21 Herbal products for smoking & Art. 22 Reporting of ingredients of herbal products for smoking

Main findings: Herbal products for smoking have been notified to EU-CEG less than other products discussed in this report. . The provisions in Art. 21 concerning health warnings for herbal products have been implemented successfully across the EU, although there were some instances of packaging being non-compliant. Sometimes products which are very similar, are marketed in different ways, which may be due to novelty in the market. It will be important to ensure consistency in classification and packaging of these products in the future.

Art. 22 has overall been implemented effectively across the EU, with issues reported in only few Member States. There have been some instances of economic operators not complying with the requirements of the Directive, for example by not classifying products as conceivable for smoking or by not reporting ingredients to EU-CEG.

Member States indicated which herbal products have been reported in their countries; common products were herbal cigarettes, hemp products, and CBD products. Issues with illegal products are not within the remit of the TPD, and rather fall under illicit drug laws.

Overall, it seems that herbal products have not been a regulatory priority, and the market appears to be new and changing.

Art. 21(1) requires that each unit packet and any outside packaging of herbal products for smoking should carry the following health warning: 'Smoking this product damages your health.'

(2) The health warning shall be printed on the front and back external surface of the unit packet and on any outside packaging.

(3) The health warning shall comply with the requirements set out in Art.9(4). It shall cover 30 % of the area of the corresponding surface of the unit packet and of any outside packaging.

(4) Unit packets and any outside packaging of herbal products for smoking should not include any of the elements or features set out in Art.13(1)(a), (b) and (d) and should not state that the product is free of additives or flavourings.

Art. 22

(1) Member States should require manufacturers and importers of herbal products for smoking to submit to their competent authorities a list of all ingredients, and quantities used in the manufacture of such products, by brand name and type. Manufacturers or importers should also inform the MS competent authorities when the composition is modified in a way that affects the information submitted. The information required under this article shall be submitted prior to the placing on the market.

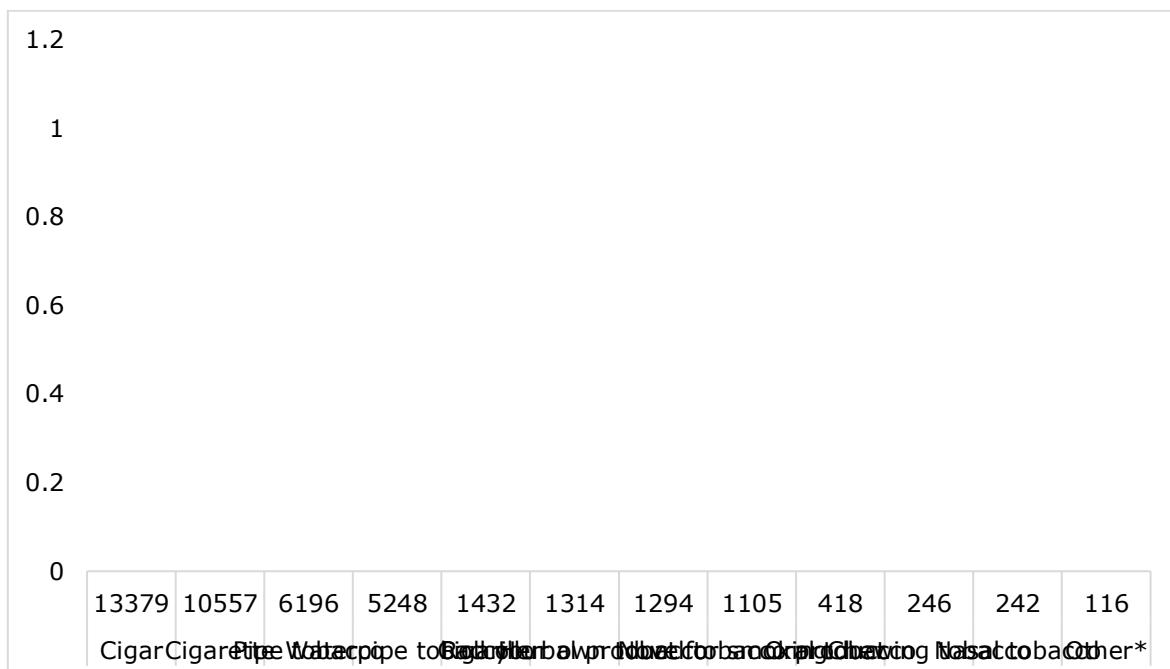
(2) Member States shall ensure that the information submitted is made publicly available on a website. They should make sure to protect trade secrets when making that information publicly available. Economic operators should specify exactly which information they consider to constitute a trade secret.

Art. 21 and 22 refer to herbal products for smoking, which are not tobacco products and are therefore not covered by tobacco products' provisions. The online consultations provided the opinions of CSOs and HEs about these provisions: 44% of

CSOs and HEs agreed that the provisions in Art. 21-22 are **clear regarding the transposition requirements**. Only 5% disagreed³³⁷.

As of January 2021, there were 1294 active distinct TP-IDs in EU-CEG for herbal products for smoking, which is a relatively small number of notifications compared to other product types; see Figure 7 below. By Member State, there were relatively high numbers of notifications for herbal products in Austria (475), Belgium (465), and Luxembourg (280). See Annex 6 for further information.

Figure 7. Active tobacco and related product notifications by product type (total: 41,519 distinct TP-IDs)



Source: EU-CEG data provided by DG SANTE in January 2021.

There is some indication that the market for herbal products is changing and the TPD may not be fully relevant in this regard. Around a third (28%) of CSOs and HEs responded that **provisions on herbal products for smoking have remained relevant** to address current developments in the tobacco and related industries including technological, scientific, or market developments (42% said they did not know). In a related question, around a fifth (19%) of CSO and HE respondents said the TPD 'somewhat' sufficiently addresses **new developments related to herbal products**, although a large percentage (44%) said they did not know. Economic operators who responded to the online survey were largely split about the TPD's ability to address new developments in this area: around 10% of them said 'a great deal', 'somewhat', 'a little', and 'not at all' to this item, and over half of them (56%) said they did not know. Some stakeholders (a few CSOs and one HE) recommended that as the market was changing quickly the TPD may need to adapt to these newer products, such as CBD products. For example, regarding CBD products, one Member State suggested that it should be allowed to ask for a proof of the THC percentage.

Overall, CSOs and HEs stated that herbal products were a complex topic on which too little data was currently available. Not many countries reported problems in relation to Art. 21-22, but it could be due to a lack of prioritisation or focus. There is no tracking and tracing like for tobacco cigarettes and there is no data on the number of users and how the products are being used. The lack of data is a big problem in the view of CSOs and HEs because it makes it hard to determine the scale of the issue.

³³⁷ The remainder of respondents did not know or preferred not to say.

CSOs and HEs also stressed that products which combine cannabis with tobacco cause several problems because of the absence of warnings, individual sales, and access to children. These issues are also reported about herbal products in general. CBD and cannabis products, nicotine-free cigarettes, and herbal mixes for waterpipes are being used increasingly in some countries, thus it is a growing issue, and there have been some individual cases of untested and unregulated herbal products being released onto the market. Some countries do not allow herbal products to be sold, but consumers buy them online from other countries.

CSOs and HEs also stated that any herbal product that imitates smoking tobacco is problematic because it could act as a gateway to tobacco use and could normalise tobacco use. Protection of young people and prevention should thus be emphasised. CSOs and HEs recommended warnings about contents and side-effects, similar to those applied to e-cigarettes.

Art. 21 Herbal products for smoking

Four Member States have faced **issues in placing health warnings on packets for herbal products for smoking**³³⁸. The issues encountered mostly related to differences in packaging and a lack of compliance with the requirements of the Directive.

One Member State noted when they started controlling herbal products for smoking, plant-based products continued to be put on the market without combined health warnings. Following several complaints to manufacturers, compliance with these requirements has improved. However, three Member States considered that there were still products on the market without combined health warnings, as well as noting differences in how economic operators implemented the combined health warnings and differences in packaging.

Another Member State found that similar products available on the market were registered differently. For example, herbal wraps were marketed as cigarette papers (not covered by health warnings); identical products from other brands were marketed as 'herbal wraps smoking' (covered by health warnings). Belgium pointed out that these labelling issues were due to the novelty of the market and economic operators not wanting to comply with the rules. They also added an example of the different ways in which herbal products are packaged.

Figure 8. Herbal products for smoking – differences in packaging as reported by Belgium.



Another Member State reported that **guidance from the European Commission** on products that would fall within the definition of herbal products for smoking would be appreciated; this may be related to earlier comments on the definition of herbal products in Art. 2(15) (see the earlier section on Art. 2 - Definitions), which includes reference to a combustion process. A different Member State reported that Art. 21(4) does not include the provisions of Art. 13(1)(e) which prohibit the labelling or

³³⁸ Sixteen Member States did not face any issues in implementing this.

packaging of tobacco products suggesting that a certain tobacco product has improved biodegradability or other environmental advantages.

Art. 22(1): Reporting information of herbal products for smoking

Five Member States **faced issues requiring manufacturers and importers to report the ingredients of herbal products for smoking**, while two Member States faced issues to some extent. Over half of Member States did not encounter any issues. A Member State stated that there were general compliance issues with reporting product ingredients for herbal products for smoking.

- **Manufacturers and importers initially did not classify their products as herbal products for smoking** accordingly (two Member States). For example, CBD products or hemp buds were initially classified as room scents and not herbal products for smoking (one Member State).
- Manufacturers and importers of herbal products for smoking did **not report the ingredients in the EU-CEG** (three Member States). According to two of these Member States, this may in part be due to a lack of awareness amongst manufacturers of the regulations concerning these products. In one Member State, they noted that EU-CEG does not require information about THC content, which can make it difficult to monitor herbal hemp products containing THC.
- There were **difficulties in detecting products which would fall within the scope of Art. 22**, as the market is very small; a few Member States found it difficult to check whether all relevant products were being reported on.

Art. 22(2) Publication of information of herbal products for smoking

Member States have published the submitted information in EU-CEG on a **public website**: Belgium³³⁹, Croatia³⁴⁰, Czechia³⁴¹, France³⁴² Sweden³⁴³, Spain³⁴⁴, UK³⁴⁵ and Finland³⁴⁶ provided a list of publicly available products. In Finland, this list includes only limited information such as the product name.

Another Member State published information about herbal products in the same list/website as other registered tobacco products. One Member State reported that the data from EU-CEG was **substantial and complex, often including errors**. One Member State had not yet published this information, but this was being considered.

The Netherlands provided a public list³⁴⁷ with data from 2015 before EU-CEG was in place.

The TPD requires that such a list should be published. However, four Member States encountered **issues in making the submitted information publicly available** on a

³³⁹ <https://www.health.belgium.be/fr/liste-positive-des-produits-fumer-base-de-plantes>

³⁴⁰ <https://zdravlje.gov.hr/o-ministarstvu/djelokrug-1297/javnozdravstvena-zastita/duhanski-i-srodnji-proizvodi/popis-duhanskih-proizvoda-prijavljenih-ministarstvu-zdravstva-kroz-eu-ceg-zajednicko-mjesto-elektronickog-ulaza-eu-a/3046>

³⁴¹ http://www.mzcr.cz/Verejne/dokumenty/bylinne-vyrobky-urcene-ke-kourenie/elektronicke-cigarety-a-nahradni-naplne-do-ni_14514_3478_5.html

³⁴² <https://www.anses.fr/en/content/tobacco-and-related-products>

³⁴³ <https://www.folkhalsomyndigheten.se/livsvillkor-levnadsvanor/andts/regler-for-tillverkning-handel-och-hantering/ortprodukter-for-rokning/>

³⁴⁴

https://www.msCBS.gob.es/ciudadanos/proteccionSalud/tabaco/docs/Lista_positivos_Hierbas.pdf

³⁴⁵ <https://www.gov.uk/government/publications/notification-of-tobacco-or-herbal-products-for-smoking>

³⁴⁶ <https://tupakkarekisteri.valvira.fi/tuoteilmoitukset>

³⁴⁷ <https://www.rivm.nl/toevoegingtabaksproducten/products.html>

website (Art. 22(2)). Four others faced issues to some extent³⁴⁸. Most difficulties related to the type and content of the information to be published. Three Member States were not clear on what information should be considered as confidential or as a **trade secret**, as stated by economic operators on a few occasions. Similarly, another Member State indicated that this list was not published because the data submitted by manufacturers contains information that can be considered confidential, such as the submitter name, the date of submission, the brand name of the product, the type of product, and the ID number. Another Member State also noted that some of the relevant information has been incorrectly marked confidential by the notifiers. Finally, another Member State reported that they had used JATC **WP5 – D5.1 Report on what data is public and non-confidential in EU-CEG**³⁴⁹ and found it very useful.

Type of products notified per Member State

The table below provides an overview of the herbal products reported in the Member States, which shows that the vast majority of notified concern cannabis (hemp) products.

Table 12. Types of herbal products for smoking (each row represents a Member State)

Types of products
Hemp flowers: leaves, flowers and fruits of a Malverceae, probably Althaea (Marshmallow)
The majority are cannabis products
Hemp products
Not yet on the market, however there was a notification for heated herbal sticks
Mostly herbal cigarettes ; further information not provided.
Waterpipe herbal tobacco (without tobacco)
Herbal cigarettes
Plant -based, Herbal -based, or Fruit -based not contain tobacco and that can be consumed through a combustion process are considered plant-based smoking products.
Herbal Cigarettes, Loose leaf, Hemp, Molasses, Steam stones/crystals
Hemp products
Shisha products
Herbal blends for smoking
CBD products
Herbal mixtures for smoking (just notified)
CBD Herbal products with <0,3% THC w/w containing no tobacco.
Several products, including products for use in waterpipes .
Herbal blends for smoking

³⁴⁸ Twelve Member States did not face issues.

³⁴⁹ <https://jaotc.eu/wp-content/uploads/2021/02/WP5-D5.1-Report-on-what-data-is-public-and-non-confidential-in-EU-CEG.pdf>

Types of products

Tea leaf products.

Hemp cigarettes³⁵⁰

Manufactured: **Cut stems** unspecified (less than 30% is identifiable to one leaf type).

Molasses

Herbal mixtures for consumption in **water pipes** (no tobacco contain)

Cigarettes (no tobacco)

Blunt wraps (no tobacco)

Waterpipe (no tobacco)

Hemp products

Cigarette alternatives

Herbal blends for smoking

Two Member States faced issues with the **classification of recently reported herbal products**, for example **heated herbal sticks**, since there is no combustion nor use of tobacco.

Another Member State noted that Art. 22 does not allow Member States to charge manufacturers and importers of herbal products for smoking **proportionate fees** for receiving, storing, handling, and publishing the information submitted to them pursuant to this article. A more detailed description of fees used in Member States is included in the section on Efficiency.

Cannabis or marijuana

Six Member States **apply TPD provisions for herbal smoking products which contain cannabis or marijuana**.

- Products with a **THC content of less than 0.3%** (for example, hemp flowers) are considered as herbal products in two Member States. One of these Member States requires in addition a laboratory certificate stating that the amount of cannabis plant used did not exceed the limit. Products with **THC levels under 0.2% are legal** in two other Member States.
- **Medical cannabis or marijuana is allowed** in two Member States (in one: under the approval of the Medicines Agency; in the other: products with THC and products with CBD are regulated as narcotic).
- CBD is not controlled in another Member State, but THC is. Therefore, any CBD in this Member State must be completely THC-free. Another Member State clarified that they have zero tolerance for THC content.

Issues with **cannabis or marijuana were reported** in three Member States. One had doubts about if these products placed legally on the market should be considered herbal product for smoking or a special product with its own rules and legislation. Two others reported a lack of clarity in how TPD provisions around herbal products for smoking relate to **drug legislation in the EU**.

³⁵⁰ Not clear if they are legal. This question was sent to Inspection Authority.

Non-compliance with Art. 21 and 22 and actions taken in response

In the online consultation as part of this study, over half (53%) of CSOs and HEs were **aware of products on the market** which were not compliant with these articles; only 9% said they were not aware of such non-compliant products³⁵¹.

Six Member States reported to **have taken actions against importers, wholesale companies or manufacturers** for non-compliance related to herbal products for smoking. Since January 2019, one Member State has acted against eight economic operators. Another reported only one action, but no further information was provided. A third Member State reported that one product had been **prohibited from being placed on the market** on a number of occasions pending notification.

Two Member States described how the authorities had carried out controls in shops, resulting in **illegal herbal products being seized. Administrative fines** were reportedly imposed in one Member State when a **THC value higher than 0.3%** was detected in herbal products. However, illegal products such as these are regulated by illicit drug laws rather than the TPD.

3.10 Cooperation and enforcement

Art. 23 Co-operation and enforcement

Main findings: Some Member States encountered difficulties in monitoring and enforcing the obligations for manufacturers and importers to provide the European Commission and Member States with complete, correct, and timely information.

The levels of enforcement differ across Member States. The majority of Member States have put in place national legislation providing for legal action and penalties. However, not all Member States have the capacity and resources to detect and penalise non-compliant producers and prevent non-compliant products from being placed on the market. They in particular struggle to analyse and assess the information contained in the high number of notifications and are not always able to undertake suitable technical assessment, provide support and take follow-up actions. These enforcement constraints may affect compliance with the TPD and ultimately hamper the Directive's effectiveness.

Almost all stakeholders reported on positive experiences with regard to past collaboration with other Member States and with the European Commission. The Group of Experts on Tobacco Policy allowed for a very good co-operation between Member States and the European Commission, and between different Member States. Member States overall appeared in favour of enhanced cooperation at EU level, for example through the establishment of a network or a platform where they could exchange experiences. This may also support the implementation and enforcement of the TPD provisions in a more uniform manner.

Art. 23

(1) Member States shall ensure that manufacturers and importers of tobacco and related products provide the European Commission and the competent authorities of the Member States with complete and correct information requested pursuant to this Directive and within the time limits set out herein. The obligation to provide the requested information shall lie primarily with the manufacturer, if the manufacturer is established in the Union. The obligation to provide the requested information shall lie primarily with the importer, if the manufacturer is established outside the Union

³⁵¹ The remaining respondents did not know or would prefer not to say.

and the importer is established inside the Union. The obligation to provide the requested information shall lie jointly with the manufacturer and the importer if both are established outside the Union.

(2) Member States shall ensure that tobacco and related products which do not comply with this Directive, including the implementing and delegated acts provided for therein, are not placed on the market. Member States shall ensure that tobacco and related products are not placed on the market if the reporting obligations set out in this Directive are not complied with.

(3) Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures that are necessary to ensure that these penalties are enforced. The penalties provided for shall be effective, proportionate and dissuasive. Any financial administrative penalty that may be imposed as a result of an intentional infringement may be such as to offset the economic advantage sought through the infringement.

(4) The competent authorities of the Member States shall cooperate with each other and with the European Commission to ensure the correct application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive in a uniform manner.

Art. 23(1) - Ensuring that manufacturers and importers provide the European Commission and MSs with complete, correct and timely information

Two Member States faced **difficulties in ensuring that manufacturers and importers provide the European Commission and Member States with complete, correct and timely information**, as required by the Directive; nine Member States faced difficulties to some extent³⁵². These included manufacturers not reporting the necessary information, operators providing incomplete or incorrect information, operators not being aware of the necessary information to report or otherwise not complying with the reporting requirements. One Member State indicated that importers were not necessarily aware of other importers' notifications of the same product, which led to overlapping notifications.

Others highlighted problems in communicating with companies outside the EU. One Member State mentioned that it was usually not possible to identify the EU importer of a foreign manufacturer. They had suggested that foreign manufacturers include the name of the importer as an affiliated company, but this was not well understood by these manufacturers.

Art. 23(2) - Products not complying with the Directive

Four **Member States** stated that they faced **issues in preventing non-compliant tobacco and related products from being placed on the market** (Art. 23(2)), and five stated that they faced issues to some extent³⁵³. Two Member States noted that it was difficult to enforce the requirements of the TPD for online retailers, especially those not located in the EU.

Difficulties were also encountered in analysing all the information contained in the **high number of notifications** of tobacco and related products submitted via EU-CEG, which made it impossible to identify all possible incompliant products. The **lack of resources** and **variety of sanctions** was also problematic. One country mentioned that the **extremely wide range of non-compliant products in herbal smoking products** was a problem, as national authorities could only take a limited number of samples during controls or market surveillance measures.

³⁵² Ten Member States had not faced any difficulties.

³⁵³ 12 Member States did not face issues.

Overall experience with the enforcement of the Directive and dedicated staff

Around a third of Member States experienced a **lack of human resources to carry out the inspections and analyse the data**; in some cases, **technical support** was also **lacking**³⁵⁴.

One Member State indicated that some of the requirements set out in the TPD (e.g. to publish data) came 'on top of' the imperative to review notifications so as to ensure that such products do not give rise to a public health risk, and created an enormous administrative and technical burden on regulatory agencies, given the vast number of notifications received through the EU-CEG. Without adequate resourcing, support, and technical solutions, the functioning of the regulatory agencies could be negatively impacted. They also highlighted that tobacco control authorities could learn from those dealing with food safety in terms of sharing regulatory infrastructure between countries.

Another Member State noted that one of the main challenges for policy makers and enforcement bodies were industry's developments of products not covered by the TPD, e.g. devices to heat tobacco and herbal products with nicotine for oral use.

Several Member States³⁵⁵ highlighted difficulties in enforcing regulations with manufacturers located outside the EU, in particular for e-cigarettes.

Capacity and resources issues were also mentioned, as well as tobacco policy not always being a priority at national level. One Member State found that cooperation was important for smaller countries, which have fewer resources for the enforcement of the Directive.

CSOs and HEs considered the Directive as a very good example of cooperation on public health, however, a need for improved knowledge, training, and more capacity was highlighted, in particular within smaller Member States³⁵⁶.

Economic operators were also asked about their experience with the enforcement of the Directive. A few noted that sometimes there was some degree of legal uncertainty, for example due to the complexity of the Directive and a lack of clarity on how certain articles should be interpreted - for instance, labelling and packaging provisions - which resulted in unintended non-compliance for some products. Others referred to the different enforcement mechanisms put in place by the Member States with regard to e-cigarettes, leading to uncertainty, lengthy procedures and different remedies.

Enforcement of penalties for infringements

Around two thirds of Member States declared to have **used administrative and/or criminal penalties as part of enforcement**³⁵⁷. Other measures introduced included inspections, monitoring of websites, setting up a mechanism to allow reporting by the public and monitoring of the information provided into the EU-CEG database. Specific actions taken by Member States for non-compliance are further described under the specific articles discussed above.

Court cases related to the enforcement of the Directive

Thirteen Member States reported national **litigation related to the enforcement of the Directive**³⁵⁸. The cases, listed below, concerned bans and prohibitions of sales

³⁵⁴ Seven Member States reported having no particular issues with the enforcement of the Directive and adequate staff for enforcement activities.

³⁵⁵ Discussed during a workshop with Member State competent authorities in December 2020.

³⁵⁶ Discussed during a workshop with Member State competent authorities in December 2020.

³⁵⁷ One Member State indicated that it had not yet taken any action. Four Member States did not provide any information.

³⁵⁸ Ten Member States said there was none.

including distance sales, incompliant labelling, and incompliant advertising and sponsorship activities.

- Two court cases regarding nicotine-containing e-liquids.
- A case where the producer of chewing tobacco whose products were banned, sued the government.
- Cases relating to the **methods used to measure the size of health warnings**, and to ISO-standards for TNCO emissions related to cigarette filters.
- Three cases related to the **prohibition to sell cigarettes with capsules**, and one on the prohibition of referring to characterising flavour in cigarettes' marketing.
- A case related to the labelling of the cigarettes with not allowed features and one regarding the **package leaflet for e-cigarettes**.
- A request for constitutional review has been filed against the ban on **distance sales and cross border distance sales** of e-cigarettes and refill containers.
- Several cases, e.g. on the ban of chewing tobacco, on **selling e-cigarettes outside of tobacco shops**, on the **ban of e-cigarettes mail orders** and on images on packaging.
- A number of cases related to **advertising and sponsorship**.
- Manufacturers criticized provisions such as the notification procedure, notification rights, the prohibition of promotional brands, as well as packaging in more than 60 court cases.

Circumventing the obligations of the Directive

The literature reviewed suggests that tobacco companies have continuously **innovated and marketed their products by focusing on exemptions to the Directive** (e.g. in relation to filters, packaging edges, seals, multipack outers, roll-your-own tobacco accessories, cigars and pipe tobacco) and **rebranding them** (e.g. calling products cigarillos whilst in reality should fall under cigarettes or roll-your-own tobacco). This has allowed manufacturers to continue to market their products to retailers and customers whilst benefiting from the lower regulatory requirements.

For example, under the TPD, cigars and pipe tobacco may not be subject to the same packaging restrictions as other tobacco products. Therefore, such products may become a growth opportunity for the tobacco industry. Standardised packaging has also prompted adaptation by industry. For example, in the UK, following standardised packaging legislation tobacco companies have adapted marketing strategies and products, allowing for continued brand differentiation³⁵⁹. The changes of flavour names (banned by Art. 13 of the Directive) to colour names is one example, a strategy that has been pointed out as being misleading in the communication of relative harms of tobacco products. In addition, tobacco companies have leveraged the 1-year sell-through to advertise brand name changes and prompt retailers to buy large volumes of branded packs through financial incentives.

Art. 23(4) Experience in cooperating with other Member States

Most Member States reported having had positive experiences when **collaborating with other Member States and with the European Commission**. In particular, it was highlighted that the **Group of Experts on Tobacco Policy** allowed for a very good co-operation both between Member States and the European Commission, and between different Member States. Informal cooperation and information exchanges were also mentioned.

³⁵⁹ Evans-Reeves K.A., et al. (2019). Prospective longitudinal study of tobacco company adaptation to standardised packaging in the UK: identifying circumventions and closing loopholes. BMJ Open: 9(9), e028506.

One Member State also pointed out that organising regular EU-level workshops on TPD application (as the one organised in 2018) would contribute to improvements in the quality of implementation of the Directive, both at the EU and national level. Another Member State suggested to build an enforcement network/secure platform for competent authorities to be able to implement and enforce the provisions and application of TPD in a uniform manner. The building of relationships between competent authorities through such enforcement networks would allow for the discussion of open cases/issues with manufacturers and importers.

Consistent application of the Directive across Member States

Eight Member States found that the **Directive was implemented in a consistent way across Member States**³⁶⁰; nine national authorities considered that it was not. Examples of differences in implementation mentioned are:

- Member States are implementing certain provisions differently, e.g.: the verification of the data in the notification dossiers; the control of TNCO measures; ban on slim packets of cigarettes; as for the size of the tank in e-cigarettes, not all MS apply the 2 ml maximum size. Also, Art. 13 provisions are subject to significant variations in interpretation which affects consistent implementation.
- Differences regarding TNCO emissions, which are not verified in all Member States; variety in regulating ingredients based on Art. 7; in procedures of approval/evaluation of novel tobacco products; and enforcement of EU CEG obligations.

One Member State pointed out that further clarifications on the definitions would help to ensure a more uniform interpretation and implementation. Another stated that a Regulation would have been preferable to a Directive, as this would have avoided differences between the Member States (and also in transposition periods). A third Member State mentioned that 'identical rules would be beneficial', highlighting that the different additional national rules for related products not covered by the Directive were also creating greater disharmony overall and argued for an expansion of the scope of the Directive to make it easier to monitor and control industry.

Art. 24 - Free movement

Main findings: Overall, no specific implementation issues were identified in relation to Art. 24.

Eight Member States implemented plain packaging. This led to strong opposition from industry, with economic operators in some countries challenging the national authorities in court and attempting to prolong the transitional period for implementation. Studies suggest that plain packaging reduces the appeal of packs, increases awareness of health-warning labels (which depict tobacco harms and diseases) and the motivation to quit, and also helps contribute to a reduction of smoking prevalence. Most plain packaging legislation was adopted too recently to allow for a conclusive analysis of its impact. However, there are some indications that it has decreased youth smoking rates to some degree in two Member States. HEs and CSOs consider that plain packaging was a great success of the Directive (albeit not being required by the Directive) and a number of CSOs suggested that plain packaging should be made mandatory in all Member States.

As for the prohibition of certain product categories, five MS have prohibited additional categories of tobacco products.

³⁶⁰ Two Member States that the Directive was implemented in a consistent way to some extent.

Art. 24

(1) Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.

(2) This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the European Commission together with the grounds for maintaining or introducing them.

(3) A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the European Commission together with the grounds for introducing them. The European Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection of human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the European Commission within the period of six months, the national provisions shall be deemed to be approved.

Overall, no specific implementation issues were identified in relation to Art. 24. The online consultations as part of this study showed that overall, CSOs and HEs surveyed agreed that the provisions in the TPD were clear regarding the requirements for Art. 24. However, concerns have been voiced by some CSOs that the provisions might be an obstacle for Member States willing to ban additional categories of products on public health grounds, and they called for a further clarification of Art.24(3).

Art. 24(2) Implementation of plain or standardised packaging

To date, eight EU countries³⁶¹ have introduced plain packaging (laws adopted or provisions applicable): Belgium (introduction at manufacturer level: 1 January 2020)^{362,363}; Denmark (1 July 2021 for tobacco products and 1 October 2021 for e-

³⁶¹ The UK was counted as an EU Member State for the purpose of this study as the UK was governed by EU regulations for a substantial proportion of the time from implementation of the TPD until the commencement of this study.

³⁶² Sante Publique, Sécurité de la Chaine Alimentaire et Environnement (2019) Arrêté royal relatif au paquet standardisé des cigarettes, du tabac à rouler et du tabac à pipe à eau. As of 23 April 2021:

<http://www.ejustice.just.fgov.be/eli/arrete/2019/04/13/2019012059/justel#LNK0012>

³⁶³ Service public fédéral sante publique, sécurité de la chaine alimentaire et environnement (2019). Arrêté royal relatif au paquet standardisé des cigarettes, du tabac à rouler et du tabac à pipe à eau. As of 31 March 2021: https://www.etaamb.be/fr/arrete-royal-du-13-avril-2019_n2019012059.html

cigarettes)^{364,365}; France (20 May 2016)³⁶⁶; Hungary (currently applicable at retailer level for some products; full applicability from 1 January 2022)^{367,368}; Ireland (30 September 2017)³⁶⁹; The Netherlands (1 October 2020 for cigarettes and roll-your-own,)³⁷⁰; Slovenia (1 January 2020)³⁷¹; and the UK (21 May 2016)³⁷². At the time of writing, an additional Member State (Finland) is considering proposals for plain packaging. To date, 18 EU Member States have no proposals in place regarding introducing plain packaging for tobacco products (Austria, Bulgaria, Croatia, Czechia, Estonia, Germany, Greece, Italy, Latvia, Luxembourg, Malta, Poland, Portugal, Republic of Cyprus, Romania, Slovakia, Spain, and Sweden).

HEs and CSOs consider that plain packaging was a great success of the Directive (albeit not being required by the Directive), and that there is scope for an EU obligation to introduce standardised packaging. They also consider that providing technical guidance at EU level on standardise packaging would be very helpful. In the most recent Eurobarometer survey³⁷³, almost **half of respondents** (47%) are in favour of **introducing plain packaging** for cigarettes (vs 36% who are against). The share of respondents in favour of introducing plain packaging for cigarettes has remained broadly stable (+1 pp). By age group, we can see that those respondents aged 25-54 have the highest proportion of respondents in favour of introducing plain packaging (49%), however there are not significant differences across age groups.

Several CSOs consulted stated that plain packaging should be made mandatory for all Member States in order to better protect young people against tobacco uptake and improve the functioning of the internal market. One CSO highlighted that making plain packaging compulsory for all Member States would allow to finally meet the implementation guidelines of articles 11 and 13 of the FCTC. A study from 2020³⁷⁴ suggests that standardised plain packaging reduces the appeal of packs and increases the relevance of health warning labels; the study also provides evidence and support for incorporating standardised packaging into the Directive. Another study suggests that the implementation of plain packaging 'reduces smoking prevalence, increases thoughts about quitting and calls to quit lines, reduces brand awareness,

³⁶⁴ Lov om ændring af lov om forbud mod tobaksreklame m.v., lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v. og forskellige andre love (2020) As of 23 April 2021: <https://www.retsinformation.dk/eli/ita/2020/2071>.

³⁶⁵ von Eyben (2020). Denmark: a new era for tobacco control.

<https://blogs.bmj.com/tc/2020/01/24/denmark-a-new-era-for-tobacco-control/>

³⁶⁶ Vardavas et al., (2017). Plain packaging of tobacco products in the European Union: an EU success story? European Respiratory Journal, 50: 1701232;

³⁶⁷ ENSP. (n.d.). ENSP and ERS congratulate Hungary on the finalisation of plain packaging requirements. As of 31 March 2021: <http://ensp.network/policies/resources/plain-packaging/ensp-and-ers-congratulate-hungary-on-the-finalisation-of-plain-packaging-requirements/>

³⁶⁸ Direct communication between DG SANTE and the NCA for Hungary.

³⁶⁹ Vardavas et al., (2017). Plain packaging of tobacco products in the European Union: an EU success story? European Respiratory Journal, 50: 1701232;

³⁷⁰ Netherlands Enterprise Agency, RVO (n.d.) Plain packaging for cigarettes and rolling tobacco. As of 6 May 2021: <https://business.gov.nl/amendment/plain-packaging-cigarettes-and-rolling-tobacco/>

³⁷¹ INT6

³⁷² Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

³⁷³ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

³⁷⁴ Evaluating the impact of introducing standardized packaging with larger health-warning labels in England: findings from adult smokers within the EUREST-PLUS ITC Europe Surveys, European Journal of Public Health, 1 Jul 2020.

attractiveness and appeal of the package, and increases the salience and effectiveness of health warnings among adolescents' ³⁷⁵. Furthermore, two studies carried out in Australia showed that the proportion of people who used tobacco after the introduction of standardised packaging dropped slightly (by half a percentage point compared to before), and that standardised packaging reduced how appealing people found the packs compared with branded packs³⁷⁶.

One case, relevant to plain packaging, was brought in front of the ECJ ³⁷⁷; the Court established that Art. 24(2) 'must be interpreted as permitting Member States to maintain or introduce further requirements in relation to aspects of the packaging of tobacco products which are not harmonised by that directive' (Par. 84).

For further information about the experiences of specific Member States, as well as barriers, facilitators and challenges for plain packaging implementation, see case study 4 (Annex 9).

Relevant findings of case study 4 on plain packaging

- To date, eight EU Member States have introduced plain packaging: Belgium, Denmark, France, Hungary, Ireland, the Netherlands, Slovenia and the UK³⁷⁸. Proposals for plain packaging are currently under government consideration by an additional Member State (Finland).
- Based on the information summarised in this case study from Member States that have had plain packaging in place for a number of years (France, Ireland, and the UK), there appear to be a range of potential benefits:
 - Reduction in perceived attractiveness of cigarette packets and smoking, which was observed in all three Member States.
 - An increase in the perception of the harmfulness of smoking, as identified in France and the UK, and providing a motivating factor to stimulate smoking cessation, as found in Ireland and the UK.
 - A decrease in smoking prevalence, as found in France and Ireland, and a decline in cigarette sales, as found in the UK.
- The major impediment to introducing plain packaging highlighted by Member States that have not yet introduced plain packaging was the threat of legal action by tobacco companies and the resources this would require.
- Most countries are in support of EU-level legislation for plain packaging, which they felt would represent an important facilitator to help overcome some of the impediments to introducing plain packaging at national level, and help to harmonise regulations across the EU, which are currently fragmented.
- Key lessons for countries considering introducing plain packaging include:

³⁷⁵ Vardavas et al. (2017) Plain packaging of tobacco products in the European Union: an EU success story? European Respiratory Journal, 2017 50: 1701232
<https://erj.ersjournals.com/content/50/5/1701232>.

³⁷⁶ McNeill, A., Gravely, S., Hitchman, S. C., Bauld, L., Hammond, D., & Hartmann-Boyce, J. (2017). Tobacco packaging design for reducing tobacco use. The Cochrane database of systematic reviews, 4(4), CD011244. <https://doi.org/10.1002/14651858.CD011244.pub2>

³⁷⁷ C-547/14 Philip Morris Brands SARL and Others v Secretary of State for Health.

³⁷⁸ The UK was counted as an EU Member State for the purpose of this study as the UK was governed by EU regulations for a substantial proportion of the time from implementation of the TPD until the commencement of this study.

- EU-level policy on plain packaging would be considered of added value and would represent an important facilitator to introduce plain packaging at a national level. Public health advocacy combined with strong political support can help to reject tobacco industry arguments and prioritise plain packaging as a public health issue.
- A 'whole systems' approach (e.g. combining complimentary policies such as marketing controls and pricing policies alongside plain packaging legislation) is likely to be more effective than any single measure alone.
- Scientific evidence from countries that have already implemented plain packaging, such as Australia, France and the UK, provide a strong basis for introducing plain packaging in other countries.
- The full case study can be found in Annex 9.

Art. 24(3) - Prohibition of certain categories of tobacco or related products

Five Member States stated to have **prohibited additional categories of tobacco or related products** while fourteen had not.

The following examples of prohibited products were provided:

- Nasal tobacco and chewing tobacco.
- All smokeless tobacco products.

In this regard, the European Commission issued three decisions, on the basis of the notifications submitted under Article 24(3):

- Chewing and nasal tobacco, in Greece (February 2020)
- Certain categories of smokeless tobacco products, in Finland (July 2016)
- Chewing tobacco, in Austria (December 2016)³⁷⁹.
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4 Overall assessment of the Directive

The following section summarises the research and provides an overall assessment of the Directive against five evaluation criteria (effectiveness, relevance, efficiency, coherence and EU added value), as outlined in the analytical framework.

Research informed both the article-specific assessment in the Tier 1 section (Section 3) and this overall assessment, thus there are some overlapping findings with the previous section.

4.1 Effectiveness

Main findings: The structures and procedural arrangements of the TPD facilitated the transposition of the TPD. Member States found guidance clear and were able to fulfil the obligations to transpose the TPD, albeit with some difficulties. Member States have also largely fulfilled their obligations to apply the TPD in practice, with several problems and discrepancies and a number of enforcement issues. Generally, economic stakeholders have complied with the rules and provisions set by the Directive, although non-compliance with a few provisions, such as those in Art. 6 and Art. 18, impaired effectiveness.

The current application of the TPD facilitated the internal market, particularly in respect of labelling and packaging, although there were some difficulties with CBDS.

³⁷⁹ https://ec.europa.eu/health/tobacco/products/notifications_en

It is too early to draw conclusions on the extent to which the TPD has improved public health and contributed to the downward trend in tobacco use in the EU. However, there is some evidence of increased awareness of the harmful effects of tobacco, and the overall prevalence of smoking has decreased. It was not possible to determine the extent to which decreases can be attributed specifically to the TPD.

In terms of the outputs and outcomes of the TPD, regulations of tobacco and related products have mostly been harmonised across Member States. At the same time, Member States have made use of opportunities to implement additional public health-oriented measures, which have (generally) not created obstacles to the successful implementation and harmonisation of TPD standards. It may be too early to draw conclusions on whether the TPD has established effective systems to reduce illicit trade.

4.1.1 E.Q1: To what extent are the structures and procedural arrangements of the TPD clear about how to transpose the TPD?

This evaluation question explores the extent to which structures and procedural arrangements were deemed to be clear and supporting full transposition of the TPD. It also explores the level of transposition and subsequent enforcement across the Member States, and the level of compliance reached by all relevant economic stakeholders.

4.1.1.1 Clarity of transposition guidance

Member States have found the transposition guidance for the TPD clear.

All Member States found the guidance received from the European Commission clear and useful in ensuring correct transposition. In particular, guidance received in the meetings of the Group of Experts on Tobacco Policy and Subgroups with Member States was considered very useful (e.g. guidance on bevelled and rounded edges, menthol capsules, and slim packages were highlighted as very helpful³⁸⁰).

Potential areas for improvement in the guidance received were reported as part of this assessment study. Member States would like **more focus on the practical enforcement of the TPD**, for example more activities like the meeting organised in Copenhagen in 2019 with national enforcement officials, which was mentioned as a good example of communication and collaboration³⁸¹. Member States would also have liked **more guidance documents** related to issues discussed during Expert Groups, as well as **regular updates on problematic issues** (e.g. regulation of non-nicotine e-cigarettes or nicotine pouches in different Member States)³⁸². In this respect Art. 23(4) specifies that the competent authorities of the Member States are responsible for cooperating with each other and with the European Commission to ensure the correct application and due enforcement of the TPD.

Most economic operators found the transposition guidance for the TPD clear.

Nearly all economic stakeholders (92%) received at least some level of guidance on implementing the TPD from Member States or the European Commission³⁸³. There

³⁸⁰ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

³⁸¹ Gap-filling workshops, November 2020.

³⁸² ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

³⁸³ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

were some differences in the level of guidance received, with **larger** organisations³⁸⁴ and organisations related to **tobacco products**³⁸⁵ more likely to report receiving guidance. Guidance to economic operators included documents about the EU-CEG system, information meetings on the impact of changes in regulations owing to the TPD, and workshops held by the European Commission on ingredient notification, traceability and security features systems. Of those who did receive guidance, **83% of respondents found it was useful to some extent**³⁸⁶. Those who did not find it useful (10%) felt the guidance was too theoretical and lacked technical support, or was limited in scope and did not cover all critical areas relevant to economic stakeholders. One economic operator stated, in reference to the EU-CEG, that despite the guidance providing good technical consultation, information was lacking on how to use the system in practice (e.g. how to withdraw or modify products)³⁸⁷.

4.1.1.2 Transposition in Member States

Member States encountered some problems in transposing the TPD, however this did not impede fulfilment of obligations to transpose the TPD.

By March 2018, all EU Member States had notified their transposition measures³⁸⁸, and all late transposition infringement cases were closed. Nevertheless, during the consultation activities held as part of this assessment study, more than half of the Member States highlighted several issues encountered during transposition (particularly concerning Art. 15, 16, 18 and 20³⁸⁹), while CSOs and HEs considered Art. 7 and Art. 19 the least clear for transposition and application³⁹⁰. For example, there were some misinterpretations in some Member States about perceived inconsistencies between the provisions on 'additives' in Art. 7(6) and 'characterising flavours' in Art. 7(1)³⁹¹. Ambiguities related to Art. 20 caused some problems in interpretation, with consequent delays in transposition into the national legislation.

Member States have largely fulfilled obligations to apply the TPD, with a few problems and enforcement issues encountered.

Most of the 24 articles studied in the present assessment study were **implemented smoothly**, with some problems or enforcement issues encountered. For example, Art. 3, 12, and 14 had very few reported issues (see related sections in Tier 1 for further information). However, more issues were experienced in relation to other articles, in particular, Art. 4, 5, 6, 7, 17, and 20.

There were variations in the practical implementation of certain elements of the Directive, and varying compliance by economic operators such as product manufacturers and retailers of products. The present study included **an in-depth**

³⁸⁴ Over one-third (36%) of large organisations responded 'yes' to this question. This compares to 14% of small organisations (less than 50 employees), and 11% of mid-sized organisations (between 251 and 1000 employees).

³⁸⁵ Almost one-quarter (24%) responded 'yes' to this question. In comparison, only 12% of organisations related to e-cigarettes answered 'yes' to this question, with the same figure being reported for smokeless tobacco products.

³⁸⁶ Organisations related to tobacco products for smoking were most likely to have received useful guidance, with almost one-quarter (24%) answering 'yes' to this question. Organisations related to packaging and other paraphernalia for use of tobacco products were most likely to have received guidance that was not clear or useful (17%). A breakdown of the responses to this question by organisation products is presented in Annex 8.

³⁸⁷ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

³⁸⁸ DG SANTE (2018). 11th Meeting of the group of experts on Tobacco policy: 15 March 2018

³⁸⁹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

³⁹⁰ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

³⁹¹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

case study to explore in detail how Member States monitor and enforce product compliance, which was the most challenging area. The main results of the case study are given in the box below, and the detailed methodology and results are presented in **Annex 9**.

Relevant findings of case study 3 on monitoring and enforcement

A recurring theme was the **lack of capacity and/or technical expertise** that meant Member States were hindered from fully applying the TPD articles:

- **A lack of capacity for effective enforcement:** For example, there were overarching issues related to product submissions and reporting through the EU-CEG system (Art. 5). This was partially related to Member State authorities lacking capacity to properly assess, process, and react to the large volume of submissions, which also hindered the application of Art. 6, 19 and 20. However, improvements could be made to the technological system itself, and an EU-wide database containing information about products could potentially increase communication and reduce workload among NCAs. Another example is that Member States may not have fully applied the provisions on TNCO laboratories, as they lacked resources to approve labs that would be independent from industry (Art. 4).
- **A lack of expertise and technical knowledge for effective monitoring and enforcement:** Similarly, the provisions of Art. 7 (characterising flavours) were not fully applied, largely due to a lack of Member States' technical capacity to properly identify, assess and process non-compliant products, or to perform tests to verify the composition of tobacco products. Analysis of the reports on priority additives (Art. 6) was hindered by a lack of expertise, as well as insufficient quality of the documentation submitted by the industry.

Denmark, Italy and the Netherlands were selected as **examples of good practice in monitoring and enforcement**, based on the evidence gathered as part of the study³⁹².

- **Denmark:** The main success factor of the Danish approach is strong market surveillance efforts (including targeted operations to detect non-compliant menthol products and slim packages of cigarettes) linked to a dynamic case handling system that organises information and updates submitted in EU-CEG. Denmark has also implemented a new comprehensive Tobacco Act, demonstrating its broader focus and dedication to tobacco control.
- **Italy:** Italy's main success factors include making use of the optional mechanisms in the Directive, which allow them to apply the most diligent approach set out in the TPD to strengthen their overall monitoring and enforcement approach; closely studying the information on EU-CEG to identify and anticipate possible incompliance; and monitoring the market continuously. When Italy implemented the TPD, it simultaneously introduced provisions banning smoking in certain hospital areas and in certain situations in private cars, and increased fines for selling tobacco products to minors. These provisions demonstrate Italy's focus and dedication to tobacco control.
- **The Netherlands:** The Netherlands found success through conducting in-depth technical assessments for **product emissions**, which are not required

³⁹² These Member States are not necessarily the only countries to enact strong measures, and their inclusion is intended only to illustrate some interesting initiatives related to the enforcement and monitoring of the TPD.

by the TPD³⁹³; using a risk-based approach to ensure provisions with low compliance and high risk are prioritised for enforcement; and efficiently screening cigarettes and roll-your-own tobacco products for TNCO levels every three years.

The full case study can be found in Annex 9.

Art. 7 on ingredients and characterising flavours appeared particularly difficult to apply. At a 2015 meeting of the Group of Experts on Tobacco Policy, the practical application of a transitional period granted by Art. 7(14)³⁹⁴ was discussed. While all members agreed that Art. 7(6) applied from 20 May 2016, there was debate on the extent to which the transitional period applied to provisions not directly linked to the presence of certain characterising flavours. For example, some favoured full application of such requirements from May 2016, while others were unsure whether this would be in line with the legal text. DG SANTE clarified to Member States that, in its view, Article 7(14) TPD was not intended to permit a derogation from all provisions in Art. 7 TPD, but merely those parts of Art. 7 referring to 'characterising flavours'.

During this study's consultation activities³⁹⁵, this article was **considered one of the least clear** articles by stakeholders, with the lack of clarity often resulting in deferred implementation by Member States.

Member States also struggled with prohibiting a product on the basis of additives. Some stakeholders felt it would be beneficial to have lists of allowed or prohibited substances instead of the categories presented in Art. 7(6)³⁹⁶.

There were some additional difficulties related to the **classification of products**:

- Classifying some **smokeless tobacco products** (Art. 17) was difficult, as products were marketed as 'chewing tobacco' while in reality being products that should be prohibited by the TPD's ban on tobacco for oral use³⁹⁷. Such products are banned in all Member States except Sweden. Inconsistent approaches to this issue could create problems³⁹⁸.
- **HTPs** were the main type of novel tobacco product (Art. 19) notified, and they caused some confusion in terms of classification as a smokeless tobacco product or tobacco product for smoking³⁹⁹.

Art. 20 was generally considered one of the **least clear articles**, mainly because of its length and complexity. There was confusion about health warnings and

³⁹³ For example, the Netherlands mandates the use of ISO standards to measure TNCO levels in roll-your-own tobacco, and has also tested cigarettes using the Canadian Intense (CI) method for demonstration purposes.

³⁹⁴ DG SANTE. (2015). 4th Meeting of the Group of Experts on Tobacco Policy. 15 October 2015.

³⁹⁵ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020.

³⁹⁶ Gap-filling workshops, November 2020.

³⁹⁷ DG SANTE (2015). 4th Meeting of the Group of Experts on Tobacco Policy. 15 October 2015.; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

³⁹⁸ DG SANTE (2018). 11th Meeting of the Group of Experts on Tobacco Policy: 15 March 2018.

³⁹⁹ DG SANTE (2015). 4th Meeting of the Group of Experts on Tobacco Policy. 15 October 2015; DG SANTE (2018). Meeting of the Expert Group on Tobacco Policy: 18 December 2015; DG SANTE (2016). Meeting of the Expert Group on Tobacco Policy: 23 February 2016; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020; Gap-filling workshops, November 2020.

packaging⁴⁰⁰, advertising, enforcement, age-verification and cross-border sales from other Member States or third countries⁴⁰¹. Member States would also benefit from improved guidance on technical standards within Art. 20, such as child-proofing requirements.

Other specific points of the TPD that were difficult to apply in practice are described in later effectiveness sections, for example E.Q4 on harmonisation across Member States describes instances where Member States applied provisions differently.

4.1.1.3 Compliance with rules and provisions by all economic stakeholders

Generally, economic stakeholders complied with the rules and provisions set by the Directive, however non-compliance of a number of provisions, such as those in Art. 5, 6 and 18, impaired effectiveness.

For most of the 24 articles examined here, instances of non-compliance were uncommon, or were quickly addressed through NCA involvement⁴⁰². Detailed information about compliance with each article is presented in the Tier 1 section of the present report. However, some instances of non-compliance had a greater impact on the general effectiveness of the TPD, as discussed below.

Compliance seems to have differed between various parts of the sector. In general, Member States felt that **bigger tobacco economic operators were more compliant than smaller operators**⁴⁰³. This difference in compliance could be due to larger economic operators having increased (legal) resources and knowledge, or having a more prominent reputation to uphold.

Reporting on ingredients and emissions of tobacco products as required by the TPD does not appear to have been achieved to a consistently satisfactory quality level. Often, data provided by economic operators are not consistent and information on ingredients and emission levels is not presented in a standardised way, with declarations sometimes missing from the database entirely⁴⁰⁴. This non-compliance by economic operators hindered effective use of the information.

Art. 6 of the TPD, which sought to ensure that economic operators established detailed and accurate **scientific information about 15 additives**, has not achieved its objectives in practice⁴⁰⁵. Economic operators submitted extensive but low-quality reports. Although many Member States reported difficulties with the reports, few have actually taken action to address deficiencies in those reports.

⁴⁰⁰ DG SANTE (2015). 1st Meeting of the Subgroup on Electronic Cigarettes: 29 May 2015; DG SANTE (2018). Meeting of the Expert Group on Tobacco Policy: 18 December 2015.

⁴⁰¹ DG SANTE (2015). 4th Meeting of the Group of Experts on Tobacco Policy. 15 October 2015.

⁴⁰² Non-compliance of economic stakeholders can only be detected through proper enforcement by Member States. In Member States that invested little in enforcement, some incompliance issues may have gone undetected.

⁴⁰³ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁰⁴ DG SANTE (2019). Meeting of the Group of Experts on Tobacco Policy: 21 March 2019; Wenzl, T. & Zelinkova, Z. (2018). Administrative Arrangement №34851 between DG SANTE and DG JRC regarding the project Technical support to the implementation of the Tobacco Products Directive. Joint Research Centre: JRC114627.; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020.

⁴⁰⁵ DG SANTE (2019). Meeting of the Group of Experts on Tobacco Policy: 21 March 2019; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020

The mystery shopping exercise undertaken as part of this assessment revealed that the age verification systems in place for **CBDS** (required by Art. 18(4)) are of poor quality and very easy to circumvent. Such systems are often in place but **do not prevent minors** from accessing products, which directly contradicts the definition of the age verification system in Art. 2(36), as 'a computing system that unambiguously confirms the consumer's age electronically in accordance with national requirements'. Overall CBDS have been difficult to monitor and control, and Member States have acted against some cases of non-compliance. However, closing non-compliant retailer websites has not been effective, as new websites rapidly emerge. Several Member States considered that further action was needed to regulate CBDS (see related section in Tier 1 and **Annex 10** for more information).

Obstructions or circumvention

There have been cases of economic operators acting in ways that, although not strictly non-compliant, were clearly not in the spirit of the Directive:

- Some economic operators launched **legal challenges** to obtain a more favourable interpretation⁴⁰⁶. In particular, economic operators have used litigation on national laws transposing Art. 7 on characterising flavours as a way to keep non-compliant products on the market while the litigation is in process. In one Member State, almost the entire suite of transposition measures has been challenged at the High Court, with more than 60 cases on notification procedures, notification rights, the prohibition of promotional brands, and packaging. Other examples include cases in another Member State relating to the methods used to measure the size of health warnings, and in yet another Member State, on the ban of chewing tobacco, the ban on CBDS for e-cigarettes, and images on packaging.
- The EU-CEG system encountered issues with economic operators declaring many fields on the system **confidential 'trade secrets'**⁴⁰⁷, which hinders Member States' ability to publish the information submitted in a timely way and impacts the effectiveness of Art. 5, 20 (for notifications of e-cigarettes), 21 and 22 (notifications of herbal products for smoking).
- Difficulties encountered with the recent ban on **menthol characterising flavours** included manufacturers selling products for consumers to add menthol flavouring to cigarettes and increases in the presence and marketing of other menthol 'replacement' products that are not banned (e.g. cigarillos)⁴⁰⁸.

4.1.2 E.Q2. To what extent has the current application of the TPD contributed to the facilitation of the internal market?

The TPD recitals cited several areas of discrepancy between Member States that had limited the functioning of the internal market prior to the introduction of the revised TPD in 2014 and which the current Directive aimed to resolve. This included the manufacture, presentation and sale of products (Recitals 4 and 5), as well as regulating ingredients (Recital 15). A high level of cross-border trade meant that stronger action was needed from the EU to facilitate the smooth functioning of the internal market (Recital 6). This evaluation question explores the degree to which the TPD has improved the functioning of the internal market, particularly in relation to

⁴⁰⁶ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020.

⁴⁰⁷ Gap-filling workshops, November 2020.

⁴⁰⁸ Gap-filling workshops, November 2020.

packaging and labelling, maximum TNCO emission levels, and cross-border distance sales.

From the evidence collected for the present study, it seems the TPD has **largely accomplished this goal**. Most Member States, as well as a few CSOs and HEs operating across several Member States, agreed that the TPD had improved the functioning of the internal market, at least to some extent⁴⁰⁹. Key examples of facilitating that functioning included the harmonisation of rules on packaging (Art. 8-14), larger combined health warnings (Art. 8-14), reporting and regulation of ingredients, EU-CEG common reporting system (Art. 5), and novel tobacco products (Art. 19). Fewer economic operators than Member States agreed that the TPD had improved the functioning of the internal market, at least to some extent. Some economic operators felt it was too early to make a proper assessment of this⁴¹⁰.

The inability to directly control tobacco at the EU-level prevents the EU from enabling an internal market where tobacco products can move freely across EU Member States. Each Member State has its own tobacco legislation that is transposed from EU-level directives. More importantly, **ambiguity in the interpretation and application** of provisions within the TPD by individual Member States may inhibit the smooth functioning of the internal market⁴¹¹. Some challenging areas were identified, which could threaten the functioning of the internal market (see relevant sections in Tier 1 for more information):

- **Art. 2:** Several existing definitions lack clarity or are ambiguous, for example the meaning of 'combustion' in the definition of 'smokeless tobacco product', 'tobacco for oral use', 'novel tobacco product', and 'electronic cigarette'. This has led to different national interpretations in practice, potentially hampering the internal market functioning. A high share of the comments on the definitions of Art. 2 by Member States, CSOs and HEs related to the fact that certain elements were not included in the scope of the TPD and are thus not regulated at EU level. They expressed concern that their exclusion could have harmful effects on public health and potentially distort the internal market. Stakeholders felt there would be scope to further elaborate these to ensure a more consistent interpretation (e.g. including a nicotine product category)⁴¹².
- **Art. 15 & 16:** There is a perceived lack of harmonisation from the internal market perspective, including varied technical implementations of the identification standard and non-fully harmonised security features measures⁴¹³.

⁴⁰⁹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴¹⁰ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴¹¹ Delhomme, V. (2018). Between Market Integration and Public Health: The Paradoxical EU Competence to Regulate Tobacco Consumption. College of Europe European Legal studies. Bruges; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴¹² ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020.

⁴¹³ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020.

- **Art. 19:** A lack of a common standard for classifying novel tobacco products as ‘for smoking’ or ‘smokeless’ has created some obstacles to the functioning of the internal market.
- **Standardised packaging:** Some Member States and CSOs recommended that mandatory plain packaging could create smoother functioning in the internal market, as variations between Member States create disharmony.
- The sub-sections below discuss other key areas of the internal market, and how effectively the TPD has addressed them.
-

4.1.2.1 Regulation of packaging and labelling

The TPD established clear guidance and regulations on labelling and packaging, with a few minor points of unclarity.

A justification for the TPD was that disparities in the labelling of tobacco products were a barrier to the internal market (Recitals 22 & 23). Harmonising labelling and packaging rules were a key success of the TPD, largely because it standardised packaging across the internal market. There were few issues related to Art. 8, 10, and 11, with some minor confusion resolved early on.

There were some other issues, however. For example, Art. 9(3) was ambiguous about whether or not it was meant to prohibit ‘slim’ packets of cigarettes in light of the minimal warning size requirements, and as a result, there has been some degree of **disharmony**, with some Member States prohibiting them and others not. Similarly, at the 2015 meeting of the Group of Experts on Tobacco Policy⁴¹⁴, clarity was sought by Member States on how health warnings should be printed on cigarette packaging with **bevelled or rounded edges** (related to Recital 28), with Group members agreeing that warnings should not be printed across bevelled or rounded edges. DG SANTE clarified to Member States how bevelled or rounded edges should be considered in area calculations and that the warning should not be printed on those edges. Due to its importance and the difficulties caused, it may be beneficial to clarify this point within the main body of the Directive, rather than in the recitals (see Tier 1 section on Art. 8-14 for further information).

4.1.2.2 Regulation of maximum TNCO emission levels

The TPD established clear guidance and regulations on setting maximum emission levels in accordance with relevant scientific research and data. Only a small number of Member States have acted beyond the provisions of the TPD.

The maximum TNCO levels themselves were uncontroversial, but there were some concerns about the independence of the ISO methods from the industry, and the ability of machine-based methods to adequately reflect smokers’ individual behaviour, e.g. partial coverage of filter ventilation holes. Some stakeholders recommended that the European Commission consider alternative methods for measurement, such as the **CI method**⁴¹⁵. However, Member States’ use of the TPD provisions allowing additional measurements methods and thresholds (including for products other than cigarettes) was rare. The Netherlands mandates using ISO 15592-3 to measure TNCO in **roll-your-own** tobacco, in line with Art. 4(4). A few Member States performed measurements of emissions of **other tobacco products**, e.g. emissions of HTPs and e-cigarettes, primarily for experimental purposes (see Tier 1 section on Art. 4 for further information).

⁴¹⁴ DG SANTE (2015). 4th Meeting of the Group of Experts on Tobacco Policy. 15 October 2015.

⁴¹⁵ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

4.1.2.3 Regulation of CBDS

There have been difficulties with cross-border distance sales, which threatens the effectiveness of the TPD.

The TPD permits Member States to prohibit **CBDS**: for tobacco products, 19 Member States prohibit them and nine allow them, while for e-cigarettes, 16 Member States prohibit them and 12 allow them. Several CSO stakeholders considered that CBDS undermine the functioning of the internal market, public health and fiscal policies in Europe, and should therefore be banned at EU level⁴¹⁶ (see Tier 1 section on Art. 18 for further information).

4.1.3 E.Q3. To what extent has the TPD contributed to improving public health? Have there been any trends observed in the prevalence of tobacco use, particularly among young people?

TPD Recital 8 cites the need for a high level of health protection as the primary basis for the Directive. This evaluation question explores the TPD's effectiveness in contributing to public health, in terms of awareness of the harmful effects of tobacco, prevalence of smoking and use of tobacco-related products, and consumer appeal of products.

4.1.3.1 The TPD's response to its objectives for improving public health

It is still too early to draw conclusions on the overall effect of the TPD on public health, especially as some provisions such as traceability and security features were introduced very recently. Nor is it possible to conclude the extent to which the TPD is the cause of any changing trends in prevalence of use of tobacco and related products. However, nearly all Member States, CSOs and HEs agreed that the TPD had improved public health, at least to some extent⁴¹⁷. Key examples are given below:

- **Labelling and packaging** provisions, which increase awareness of the harmful effects of tobacco products^{418,419,420,421,422};
- **Prohibition of CMR ingredients** (for reproduction, stimulants and other substances);
- **Prohibition of characterising flavours** in cigarettes, including media coverage around the menthol ban; and

⁴¹⁶ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴¹⁷ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴¹⁸ Mannocci et al. (2019). The impact of pictorial health warnings on tobacco products on smokers' behaviours and knowledge: the first quasi-experimental field trial after the implementation of the tobacco law in Italy. Ann Ist Super Sanita, 55(2).

⁴¹⁹ Crosbie E. (2019). Removing the last billboard for the tobacco industry: Tobacco standardised packaging in Ireland. Health Policy, 123(10), 932-935.

⁴²⁰ Bogdanovica, I. et al. (2017). Awareness of Standardised Tobacco Packaging among Adults and Young People during the Final Phase of Policy Implementation in Great Britain. Int J Environ Res Public Health, 14(8).

⁴²¹ McNeill, A., Gravely, S., Hitchman, S.C., Bauld, L., Hammond, D., & Hartmann-Boyce, J. (2017). Can the use of standardised packaging for tobacco products reduce the use of tobacco? Cochrane Database of Systematic Reviews, 4.

⁴²² Hammond, D. (2011). Health warning messages on tobacco products: a review. Tobacco Control, 20.

- For e-cigarettes - the limits of recharges, tanks and nicotine concentration, the prohibition of additives including vitamins, caffeine, and additives with CMR properties in e-liquids and child-proof tampering regulations.

Although progress has been made to achieve public health objectives, some Member States noted a need for further strengthening of the Directive, especially for tobacco-related products, novel tobacco products and emerging nicotine products in order to address challenges related to increased consumption of those emerging products.

There was no consensus among economic stakeholders on whether the TPD has been effective in improving public health. Several were of the view that as the TPD was only introduced in 2014 and implemented from 2016, many of the systems were **too nascent** to be able to quantify their influence on public health⁴²³.

There is some evidence that awareness of harmful effects of tobacco has increased (overall and among young people).

One of the greatest successes of the TPD has been to **create better awareness and understanding of the various product categories and their overall harmfulness**. Colour picture libraries, bigger health warnings, warning messages and information on ingredients have all contributed to increased awareness among smokers and especially young people. This was expressed by Member States⁴²⁴ and illustrated in the evidence below.

Table 13 presents the perceived harmfulness of tobacco and related products by age, as found in the 2020 consumer preference and perception study. The results show that **waterpipe tobacco is considered the least harmful** to users' health for both age groups, scoring 53 out of 100 for the 18-25 age group and 47 for the 26+ age group. The other products perceived as less harmful included **e-cigarettes and HTPs**, again for both groups. Interestingly, young people perceive HTPs as more harmful than those aged 26+.

Table 13. Perceived harmfulness of tobacco and related products to users by age (average scores, out of 100)⁴²⁵

	18-25 age group	26+ age group
Cigarettes, except slim	82	82
Small cigarillos	67	61
Slim cigarettes	66	60
HTPs	58	51
E-cigarettes	55	52
Waterpipe tobacco	53	47

Source: ICF based on consumer preference and perception of specific categories of tobacco and related products, DG SANTE, February 2020

⁴²³ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴²⁴ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴²⁵ Consumer preference and perception of specific categories of tobacco and related products, DG SANTE (2020) provides a description of the methodology (p.56): Respondents were asked to score the products in terms of harmfulness; the scores given by respondents in the sample were averaged and ranked in the figures in the table. The study applied 'swing methodology' for assessing relative harmfulness of the products in the table. The figures represent an average score of harm to the use that ranges between 0 and 100, the higher the score, the greater perceived harmfulness of a product.

Respondents were first asked 'Which of the six tobacco products listed below do you think is likely to be most damaging to the health of users?' and subsequently 'You have chosen (the product they chose) as likely to be the most damaging to the health of users. We will give (the product they chose) 100 points on a scale of 0-100 for damaging users' health. Please assess the other products' damage on a scale of 0 to 100. If you think a product is about half as damaging to the health of users, you would give that product 50 points. If you think another product is just as damaging as (the product they chose), you would give it 100 points'.

In the most recent Eurobarometer⁴²⁶, over half of respondents believed that **HTPs** were harmful to the health of those who use them. This item was not asked in previous years, so it is not possible to compare trends. There were no meaningful differences between age groups for this item, however the age group more likely to have at least tried HTPs (age group 15-24) also had a higher proportion of respondents thinking that they are harmful. Respondents who had never used, or only tried, e-cigarettes or HTPs were asked if they thought that these products should be regulated as strictly as cigarettes. The majority of respondents (72%) were in favour of stricter regulation for HTPs, with only one in five thinking that HTPs should be regulated as strictly as cigarettes.

Awareness of the harmful effects of tobacco products appears to have changed during the time since the TPD was implemented. **Combined health warnings, as specified in Art. 10(1) of the TPD, combined with standardised packaging** are one of the major routes by which this has been achieved. Based on evidence from multiple Member States, these interventions appear to significantly increase knowledge of tobacco related-diseases and associated harms, and motivation to quit, and to reduce tobacco consumption and youth smoking initiation^{427,428,429,430,431}. Data from 10 European countries (Belgium, Germany, Denmark, Spain, France, Italy, Poland, Romania, Sweden and the UK) indicates that the effectiveness of pictorial warnings may decrease over time, but can be mitigated by the periodic inclusion of new photographs, as specified in Art. 10(2) of the TPD⁴³².

There has been some mixed research findings on consumers' perceptions of harmfulness of **e-cigarettes** (see Tier 1 section on Art. 20 for further information).

Prevalence of smoking and use of tobacco-related products decreased overall, but these changes cannot be attributed solely to the TPD.

This section describes the evidence on prevalence and incidence of using and smoking tobacco and related products for the general population (for information related to this topic for **young people**, see EQ.5 in Relevance).

⁴²⁶ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

⁴²⁷ Mannocci et al. (2019). The impact of pictorial health warnings on tobacco products on smokers' behaviours and knowledge: the first quasi-experimental field trial after the implementation of the tobacco law in Italy. Ann Ist Super Sanita, 55(2).

⁴²⁸ Crosbie E. (2019). Removing the last billboard for the tobacco industry: Tobacco standardised packaging in Ireland. Health Policy, 123(10), 932-935.

⁴²⁹ Bogdanovica, I. et al. (2017). Awareness of Standardised Tobacco Packaging among Adults and Young People during the Final Phase of Policy Implementation in Great Britain. Int J Environ Res Public Health, 14(8).

⁴³⁰ McNeill, A., Gravely, S., Hitchman, S.C., Bauld, L., Hammond, D., & Hartmann-Boyce, J. (2017). Can the use of standardised packaging for tobacco products reduce the use of tobacco? Cochrane Database of Systematic Reviews, 4.

⁴³¹ Hammond, D. (2011). Health warning messages on tobacco products: a review. Tobacco Control, 20.

⁴³² Woelbert, E. and d'Hombres, B. (2019). Pictorial health warnings and wear-out effects: evidence from a web experiment in 10 European countries. Tob Control, 28: e71-e76.

According to a 2020 Eurobarometer⁴³³, the prevalence of smoking at EU level remained stable between 2014 and 2017 (26% in both years), but the **proportion of smokers has decreased by three percentage points (pp) since 2017**⁴³⁴. A detailed analysis can be found in Annex 3.

In most EU countries (all but seven), at least one in five are smokers. However, **significant differences can be observed between countries** in respect of smoking prevalence. In 2020, the highest smoking prevalence was in Greece, where the smoking rate had increased by 4pp (to 42%), followed by Bulgaria and Croatia (28%). Slightly more than half of Member States (15) experienced a downward trend in the proportion of smokers between 2017 and 2020. This trend was most pronounced in France (-8pp), the Netherlands (-7pp) and Portugal, Estonia, Finland, and the UK (-5pp). Countries with the highest increase in the prevalence of smoking were Greece (+5pp), Bulgaria, Romania, Luxembourg and Belgium (all +2pp). Respondents to the Eurobarometer survey were asked about the **type of tobacco products** they used and how frequently they used them. Less than one-quarter (23%) were current smokers of cigarettes, cigars, cigarillos or pipe, a decline of 3pp compared to 2017. More than half of respondents (55%) had never smoked, and more than one in five (22%) used to be smokers but had stopped.

In the recent Eurobarometer⁴³⁵, **boxed cigarettes** were the most popular product among smokers in 2020: among smokers, almost eight in 10 (78%) were regular users (at least monthly) of boxed cigarettes and almost seven in 10 (69%) smoked boxed cigarettes at least once a day. The proportion of those smoking boxed cigarettes daily had decreased slightly from 2017 to 2020 (-1%), and over the longer-term, from 76% in December 2014. The average **number of cigarettes** current cigarette smokers used was 14.2 per day. The average daily consumption increased by 0.5 since 2017, when it was 13.7.

Other product-specific results from the 2020 Eurobarometer data⁴³⁶ included:

- **Hand-rolled cigarettes** were consumed by 28% of tobacco users and more than one in five (22%) consumed hand-rolled cigarettes daily. The proportion of daily users of hand-rolled cigarettes decreased slightly compared to 2017 (-1pp).
- A very small proportion of all survey respondents used **cigarillos** (4%), **cigars** (3%), or **pipes** (2%). Only 2% or less smoked cigarillos, cigars or pipes on a daily basis. These tobacco products were more likely to be smoked on an occasional basis or tried only once or twice. Following a decline between 2014 and 2017, the proportion of those occasionally smoking cigarillos, cigars, or pipes increased again between 2017 and 2020. All survey respondents were also asked if they had tried **water pipes** (shisha, hookah): 18% had tried a water pipe, which represents an increase from 13% in 2017. There was a 2pp increase in respondents that had tried oral, chewing or nasal tobacco (7%), compared to 2017 (5%). The largest increases occurred in Ireland (+13pp) and Estonia (+8pp). As the only country where tobacco for oral use is legal, Sweden unsurprisingly had much higher rates of having tried oral, chewing, or nasal tobacco than other Member States (46%). However, this share had dropped by 4pp since 2017 (50%).

⁴³³ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>.

⁴³⁴ EU-27+ UK 23% / EU-27 25%.

⁴³⁵ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>

⁴³⁶ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>.

- All survey participants were asked for the first time⁴³⁷ if they had tried **HTPs** and how often they used such products. Around 6% of respondents had tried HTPs and 93% had never used these products.
- More than one in 10 (14%) of all survey participants had tried **e-cigarettes**. Nearly one in 10 (9%) said they had tried them only once or twice, while 3% used to use them but then stopped. A small proportion (2%) used them currently. There are no significant changes in these results compared to March 2017. Compared with 2017, the proportions of all survey participants who had tried e-cigarettes at least once or twice substantially increased in two countries: Ireland (+16pp) and Luxembourg (+9pp). Conversely, other countries observed a decrease in those who have tried e-cigarettes at least once or twice: Poland (-7pp), Cyprus (-6pp), and Malta and the Netherlands (-5pp). No substantial changes can be observed in the proportions of current e-cigarette users compared to 2017, except a 5pp increase in Ireland.

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.

A recent study⁴³⁸ assessed **consumer preference and perceptions** of specific categories of tobacco and related products (including e-cigarettes) in 600 users of tobacco and related products (including those who quit in the last 12 months), aged 26 years and above, and 600 young people aged 18-25 (including users and non-users). Online surveys and focus groups of these participants revealed common associations people make with products, as described in the box below.

- **Common associations with each product type**⁴³⁹
- **Waterpipe tobacco** was associated with relaxation, pleasure, and nice flavours. More negative associations ('complicated', 'unhealthy' and 'addictive') were mainly cited by never users.
- **Slim cigarettes** were associated with femininity, wealth, elegance and hedonism/pleasure.
- **Small cigarillos** were associated with cosiness, special occasions and high class; however, they were also viewed by some as 'disgusting' due to the strong taste and smell.
- **HTPs** were seen to be unhealthy, modern and technological, and also costly.
- The overall sample viewed **e-cigarettes** in a rather more negative than positive light, but this varied by level of use of the product (current users of the product were much more likely to view the product in a favourable light than never users). E-cigarettes were seen as unhealthy, addictive and modern/technological.

⁴³⁷ This question was not included in the 2017 Eurobarometer survey.

⁴³⁸ LSE, Open Evidence, BDI Research, & ICO (2020). Consumer preference and perception of specific categories of tobacco and related products Request for Service Chafea/2017/Health/34 under Framework Contract Chafea/2015/CP/01. European Commission Directorate-General for Health and Food Safety.

⁴³⁹ LSE, Open Evidence, BDI Research, & ICO (2020). Consumer preference and perception of specific categories of tobacco and related products Request for Service Chafea/2017/Health/34 under Framework Contract Chafea/2015/CP/01. European Commission Directorate-General for Health and Food Safety.

In the same study, participants sometimes falsely assumed that **slim cigarettes** were less harmful than traditional cigarettes, although the 26+ age group were more aware of the harmful effects associated with slim cigarettes than the 18-25 age group.

Fewer than one in 10 (7%) of Eurobarometer respondents who had tried e-cigarettes once or twice or never used e-cigarettes found them **appealing**⁴⁴⁰.

None of these sources allow for a comparison over time, thus it is unclear if the TPD has contributed to any changes in perception.

4.1.4 E.Q4. What outputs and outcomes have been achieved as a result of the TPD and have they contributed to the objectives of the TPD?

This evaluation question explores the key outputs and outcomes of the TPD: a harmonised and coordinated approach across Member States, whether Member States have implemented additional requirements, a reduction in illicit trade in tobacco products, and its effectiveness in meeting the requirements of the WHO FCTC.

Overall, the TPD has achieved its intended objectives and has created minimum standards in previously problematic areas, such as emissions levels, ingredients, packaging and labelling, flavouring, and traceability and security features. The TPD has made strong gains in public health. Specific outputs and outcomes are discussed below.

4.1.4.1 To what extent has there been a harmonised and coordinated approach across Member States to implementing the TPD?

Regulations of tobacco and related products have been largely harmonised across Member States, with a few problem areas identified.

As described in **E.Q2**, the TPD has created consistency in areas that were not previously harmonised, despite a few persisting areas of disharmony that have impacted the internal market. In addition to the points discussed in E.Q2 (disharmony in definitions, traceability and security features systems, classifying novel tobacco products, plain packaging, labelling and packaging, TNCO emission levels, and cross-border distance sales), some other minor areas of disharmony were also noted (see related sections in Tier 1 for further information):

- **Art. 13** uses broad terms to cover a range of promotional packaging and products; however, the lack of specific indications about the phrasing that should be permitted or prohibited led to difficulties with application, divergent national approaches, and legal challenges in several Member States⁴⁴¹. Providing more clarity on this article, such as defining the terms and phrases prohibited, could provide clarity on prohibited products and increase harmonisation.
- **Art. 17:** Although tobacco for oral use is prohibited by this article, this product is allowed in Sweden through the *Act of Accession of Austria, Finland and Sweden* (Art. 151). This discrepancy between rules across Member States has led to some illicit trade, especially with bordering countries.

⁴⁴⁰ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

⁴⁴¹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020.

- **Art. 19:** Member States differed on whether they classified certain novel tobacco products as 'for smoking' or 'smokeless', which has implications for the packaging requirements applied, leading to disharmony.
- **Art. 20(3)(a)** limits the size of e-cigarette cartridges and tanks to 2 ml. However, a few Member States are not consistently applying this rule. There has been some discussion at EU level⁴⁴².

The TPD leaves certain provisions to Member State discretion. While this could be beneficial to public health by allowing Member States to go beyond the TPD requirements, it does create instances of disharmony. For example, **Art. 11** permits Member States to exempt certain tobacco products from labelling requirements. This has created inconsistent packaging across Member States, and harmonisation would be improved if there were no such opportunities for exemptions. Some Member States suggested that these exemptions were the result of political compromise rather than public health motivations.

4.1.4.2 To what extent have Member States implemented additional requirements more restrictive than the TPD?

Member States made use of opportunities to implement additional requirements, which in most cases did not create obstacles to the successful implementation and harmonisation of TPD standards.

As discussed in the previous EQ, there were a few instances where Member States implemented additional requirements, either where they were explicitly permitted by the TPD or, in some cases, where requirements were not specifically described by the TPD. Case studies on two key examples of this - prohibiting flavours in e-cigarettes and implementing plain packaging – are briefly described below, with detailed information in **Annex 9**.

Relevant findings of case study 2 on e-cigarette flavours

To date, only three Member States (Finland, Estonia, Hungary) have fully implemented bans on e-cigarette flavours.

There are indications of significant public support for e-cigarette flavour bans, and also potentially for an EU-wide e-cigarette flavour ban, with additional Member States considering or implementing such bans. More specifically, Denmark is currently in the process of implementing a ban, legislation including a ban is due to be considered in Lithuania during 2021, and the Netherlands has opened consultation for potential legislation around e-cigarette flavours.

Member States, HEs, and CSOs have all expressed concerns that having separate rules around flavours for cigarettes, roll-your-own tobacco and other tobacco products, and e-cigarettes will simply lead to a shift in consumption towards products where flavours are allowed, rather than a decrease in the overall consumption of tobacco and related products. They have also expressed concerns around e-cigarette flavours attracting users (especially young people). Both of these concerns have likely fuelled an appetite for greater regulation around e-cigarette flavours.

The full case study can be found in Annex 9.

Relevant findings of case study 4 on plain packaging

⁴⁴² Gap-filling workshops, November 2020.

- To date, eight EU Member States have introduced plain packaging policies: Belgium, Denmark, France, Hungary, Ireland, the Netherlands, Slovenia and the UK⁴⁴³. Proposals for plain packaging are currently under government consideration by an additional Member State (Finland).
- Most countries support the idea of EU-level legislation for plain packaging, which they feel would be an important facilitator in helping to overcome some of the barriers to introducing plain packaging at national level. It would also help to harmonise fragmented regulations across the EU.
- Key lessons for countries considering introducing plain packaging include:
 - EU-level policy on plain packaging would be considered of added value and would represent an important facilitator in introducing plain packaging at national level.
 - Public health advocacy, combined with strong political support, can help to reject tobacco industry arguments and prioritise plain packaging as a public health issue.
 - A 'whole systems' approach (e.g. combining complimentary policies such as marketing controls and pricing policies alongside plain packaging legislation) is likely to be more effective than any single measure alone.
 - The full case study can be found in Annex 9.

The 2020 Eurobarometer survey⁴⁴⁴ found a large proportion of respondents in favour of banning flavours in e-cigarettes and introducing plain packaging:

- 47% were in favour of **banning flavours in e-cigarettes** (vs 35% against). The proportion of respondents in favour of banning flavours in e-cigarettes had increased by 7pp since 2017. The older the respondents, the more likely they were to be in favour of banning flavours in e-cigarettes.
- Almost half of the respondents (47%) were in favour of introducing '**plain packaging**' for cigarettes, i.e. standardised packaging (vs 36% against). The share of respondents in favour of introducing 'plain packaging' for cigarettes remained broadly stable since 2017 (+1pp).

Finally, one CSO highlighted that making plain packaging compulsory for all Member States would allow the TPD to meet the implementation guidelines for Art. 11 and 13 of the FCTC.

Other minor points where Member States have gone beyond the TPD include:

- **Art. 14(1)** sets the minimum number of cigarettes per pack at 20. Some Member States have gone beyond this and set a maximum number of cigarettes per pack, e.g. 25 cigarettes in Hungary⁴⁴⁵.
- **Art. 19(3)** allows but does not require Member States to introduce a system for the authorisation of novel tobacco products. Only a few Member States have done so.

⁴⁴³ The UK was counted as an EU Member State for the purposes of this study, as it was governed by EU regulations for a substantial proportion of the time between implementation of the TPD and commencement of this study.

⁴⁴⁴ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

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<https://net.jogtar.hu/getpdf?docid=a1300039.kor&targetdate=&printTitle=Government+Decree+39/2013+28II.+14.%29+Korm.&dbnum=62&getdoc=1>

- **Art. 20:** Roughly one-third of Member States have applied similar provisions for non-nicotine containing e-liquids, and many stakeholders recommended they be regulated through inclusion in future tobacco legislation.
- **Art. 24(3)** permits Member States to prohibit certain categories of tobacco or related products and a few have done so for nasal and chewing tobacco products.

4.1.4.3 What role has the TPD played in reducing illicit trade/smuggling of tobacco products?

It may be too early to draw conclusions on whether the TPD has established effective systems to tackle illicit trade.

At this time, only limited evidence is available in respect of the effectiveness of the TPD in tackling illicit trade. The literature indicates that although cigarette manufacturers have collaborated with the EU to implement initiatives to reduce illicit sales, the approaches have been criticised for inadequate penalties, alleged lack of full alignment with the WHO's FCTC Article 5(3), lack of transparency, and overly close alignment with tobacco company interests^{446,447} (see EQ.11 in Coherence for further discussion of the FCTC).

As provisions on traceability and security features (Art. 15 and 16) have been implemented recently, it remains too early to draw conclusions about their contribution to the fight against illicit trade. Although likely **relevant to tackling illicit trade (see E.C5 below)**, **it may be too soon to tell if they are effective in doing so.**

Illicit trade/smuggling has declined since the implementation of the TPD, however there is insufficient evidence to attribute such a trend to the implementation of the TPD and its effects.

In terms of the impact of the TPD on the illicit market, cigarettes remain the most-seized tobacco product at EU level, and this has **not substantially altered** over the past decade⁴⁴⁸. There is insufficient evidence attributing any change in the illicit market to developments arising from TPD implementation.

There is some additional research on this area, although all pre-dating the implementation of the TPD and thus not evidence of the effectiveness of the TPD. A prospective study found that the measures would **likely decrease** illicit tobacco consumption⁴⁴⁹. A European Commission impact assessment conducted in 2017 estimated that the traceability and security features introduced by Art. 15 and 16 of the TPD would result in **€3.8 billion in social and economic benefits** per year. This included an estimated €2 billion per year in taxes collected from increased legal sales

⁴⁴⁶ Joossens, L., Gilmore, A.B., Stoklosa, M. and Ross, H. (2016). Assessment of the European Union's illicit trade agreements with the four major Transnational Tobacco Companies. *Tob Control*. 2016, 25(3), 254–260. doi:10.1136/tobaccocontrol-2014-052218.

⁴⁴⁷ Gallagher, A. W. A., Gilmore, A. B. & Eads, M. (2019). Tracking and tracing the tobacco industry: potential tobacco industry influence over the EU's system for tobacco traceability and security features. *Tobacco Control*.

⁴⁴⁸ Borkowski, F. & Twomey, C. (2019). European Union: Confronting Illicit Tobacco Trace: An Update on EU Policies. In: *Confronting Illicit Tobacco Trade: a Global Review of Country Experiences*. WBG Global Tobacco Control Program Washington, D.C.: World Bank Group. Available at: <http://documents.worldbank.org/curated/en/677451548260528135/Confronting-Illicit-Tobacco-Trade-a-Global-Review-of-Country-Experiences>.

⁴⁴⁹ European Commission, Everis, & NTT Data Company (2018). Implementation analysis regarding the technical specifications and other key elements for a future EU system for traceability and security features in the field of tobacco products: Final Report. Brussels.

of tobacco products⁴⁵⁰. As a whole, the impact assessment found that the estimated benefits would outweigh the estimated costs more than 20 times⁴⁵¹.

⁴⁵⁰ European Commission (2017). Commission Staff Working Document: Impact Assessment: Accompanying the document: COMMISSION IMPLEMENTING REGULATION (EU) .../... on technical standards for the establishment and operation of a traceability system for tobacco products and Commission Implementing Decision on technical standards for security features applied to tobacco products. Brussels: European Commission.

⁴⁵¹ Ibid.

4.2 Relevance

Main findings: The TPD has made significant gains in addressing identified needs related to the regulation of tobacco and related products, but in some areas has not remained relevant due to the rapid development and diversification of the market.

In terms of addressing identified needs:

- The need to address the availability of illicit tobacco and related products in the EU has been accomplished via the implementation of the traceability and security features systems. However, these systems have not been in place long enough to evaluate their effectiveness. Additionally, cross-border flows of non-compliant products, between EU countries and bordering non-EU countries and between bordering EU countries, have continued under the TPD.
- The TPD has demonstrated relevance to Member State harmonisation by effectively setting a minimum standard for health warning labels, packaging formats, maximum emission levels, characterising flavours for cigarettes and roll-your-own tobacco, certain ingredients and additives, traceability and security features. The flexibility the TPD in permitting Member States to go beyond some of the regulations maintains its relevance. Where Member States have used this flexibility, they provide an example that others can follow, resulting in other Member States implementing new policies.
- The need to address the use of tobacco products by young people has been addressed by the TPD, but has not been as relevant in relation to e-cigarettes and other novel tobacco products, with greater uptake of these products among those aged under 25 years since the implementation of the TPD. Additionally, as CBDS are still permitted under the TPD but the method of age-verification is not strictly regulated, this remains an access route to these products for those under the legal age in each Member State.

In terms of relevance to the current market and future developments:

- The pace and breadth of market developments since the entry into force of the TPD has made it challenging for all aspects of the Directive to remain relevant to the current market. Although it forms a strong basis for the regulation of tobacco and related products, stakeholders viewed it as outpaced by novel and innovative tobacco and related products, packaging and labelling, marketing and sales methods.
- Although the current size of the market for e-cigarettes, HTPs and smokeless tobacco is small in relative terms, it has quadrupled since the current TPD came into force and accounts for over half of the growth in the retail value of the total market for tobacco and related products. Strengthening and adapting regulation of these products is key to ensuring that the TPD remains relevant to future market developments.

4.2.1 E.Q5 To what extent have the specific objectives underlying the TPD proven to be appropriate for addressing the problems/ identified needs?

This evaluation question explores whether the objectives and measures within the TPD are relevant to identified problems and needs in the EU around the availability and use of tobacco and related products.

4.2.1.1 Availability of illicit tobacco products and variations in tobacco and related products across Member States

The TPD, for the most part, adequately addresses the availability of illicit tobacco products in the EU.

The TPD has remained generally relevant in addressing the problem of illicit tobacco products, although limited evidence is available on its effectiveness (see E.Q4 above). Art. 15 of the TPD includes measures on traceability of tobacco products, and Art. 16 includes measures on security features, which several Member States stated would strongly limit the possibility of introducing illicit products⁴⁵². A chapter in a World Bank review indicated that the traceability and security features systems introduced through the TPD have the potential to detect fraud inside and outside legal supply chains⁴⁵³. However, as mentioned in the Tier 1 section of this report (discussing Art. 15 and 16 in detail), it is still too early to assess the exact impact of the traceability system and security features on illicit tobacco in the EU, as they have been in place for too short a time to permit effective evaluation of their impact.

There are some concerns that certain aspects of the traceability system may not be optimal for combating illicit trade in the EU. For example, some Member States highlighted that the shared responsibility for the traceability system between multiple administrative bodies within a Member State may mean that no single body has sufficient oversight, expertise and knowledge to address the issue of illicit tobacco products. Both economic operators and Member States commented that the complexity of the traceability system (e.g. the technical architecture of the system and repository, the multiple private and public sector bodies involved), as well as the capacity and resources required to comply with the system, constrained its ability to address the problem of illicit trade.

Issues persist with illicit trade in the EU from cross-border flows that the TPD does not address sufficiently. For instance, representatives from Member States with non-EU bordering countries mentioned that tobacco products from non-EU countries remain an issue. There are also minor issues caused by the allowance of CBDS in the TPD and the exemption of Sweden from prohibitions on tobacco for oral use in Art. 17, whereby oral tobacco products from Sweden have entered neighbouring EU countries that prohibit their sale and distribution.

The TPD has made substantial progress in addressing the variations in tobacco and related products across Member States, although variations remain in some areas, such as e-cigarette flavours and plain packaging.

The TPD has remained relevant in reducing the variability between Member States in terms of the tobacco and related products available on the market. More specifically, the TPD effectively set a minimum standard that Member States must meet in regulating health warning labels, packaging formats, maximum emission levels,

⁴⁵² ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁵³ Borkowski, F. & Twomey, C. (2019). European Union: Confronting Illicit Tobacco Trace: An Update on EU Policies. In: Confronting Illicit Tobacco Trade: a Global Review of Country Experiences. WBG Global Tobacco Control Program Washington, D.C.: World Bank Group. Available at: <http://documents.worldbank.org/curated/en/677451548260528135/Confronting-Illicit-Tobacco-Trade-a-Global-Review-of-Country-Experiences>

characterising flavours for cigarettes and roll-your-own tobacco, certain ingredients and additives, traceability and security features (among others).

However, Member States vary in terms of how tobacco and related products are regulated. In part, this is due to the ability of Member States to enact national legislation that can go further than that required in the TPD. For example, Finland, Estonia and Hungary have fully implemented bans on e-cigarette flavours (currently the TPD only bans characterising flavours in cigarettes and roll-your-own tobacco), which was explored in an in-depth case study (see box below for key findings and Annex 9). Finland's ban includes 'smell or taste other than one of tobacco' in nicotine and non-nicotine e-liquids intended for vaporisation⁴⁵⁴, while Estonia's ban includes 'flavourings, except for the taste and smell of tobacco,'⁴⁵⁵ which was later revised to allow for menthol flavouring⁴⁵⁶. Case study interviewees noted that Member States can use the experience and research evidence of countries that are the first to introduce these changes to support and justify their own adoption of similar legislation.

This effect was also identified in the case study on Member States that had implemented plain packaging (see Annex 9), which is not required in the TPD. In presenting evidence to support potential policy changes around plain packaging, Member States drew on evidence from other Member States (and other non-EU countries, such as Australia) that had already implemented plain packaging (e.g. UK, Ireland and France) to demonstrate the expected impacts of this type of regulation⁴⁵⁷.

Relevant findings of case study 2 on e-cigarette flavours

To date, only three Member States (Finland, Estonia, Hungary) have fully implemented bans on e-cigarette flavours. There are indications of significant public support for e-cigarette flavour bans, and also potentially for an EU-wide e-cigarette flavour ban, with additional Member States considering or implementing bans. More specifically, Denmark is currently in the process of implementing a ban, legislation including a ban is due to be considered in Lithuania during 2021, and the Netherlands has opened consultation on potential legislation around e-cigarette flavours. However, Member States that have implemented e-cigarette flavour bans have faced substantial challenges, particularly with companies selling liquids that can be used in e-cigarettes at times circumventing bans by portraying them as foodstuffs. Additionally, Member States have limited capacity to keep up with the large number of e-cigarettes notified to them. An EU-wide e-cigarette flavour ban would potentially help to address some of these challenges.

The full case study can be found in Annex 9.

4.2.1.2 Problem of smoking in the EU and for specific vulnerable populations

The TPD has partially addressed the problem of smoking in the EU and for vulnerable populations (in particular young people), but there are concerns about its relevance for e-cigarettes, and novel tobacco products, including HTPs.

The TPD remains largely relevant in addressing the problem of smoking in the EU. In particular, the health warning labels and other labelling and packaging measures introduced through **Art. 8-14** of the TPD were identified as relevant to changing perceptions and use of tobacco products, especially among young people. Many of the

⁴⁵⁴ Ministry of Social Affairs and Health (2016). Tobacco Act 549/2016 (Tupakkalaki 29.6.2016/549). Helsinki. Available:

<https://www.finlex.fi/en/laki/kaannokset/2016/en20160549>.

⁴⁵⁵ Riigi Teataja (2019). Tobacco Act. Available:

<https://www.riigiteataja.ee/en/eli/ee/523052019008/consolide>.

⁴⁵⁶ Riigi Teataja (2020). Act Amending the Tobacco Act and the Alcohol, Tobacco, Fuel and Electricity Excise Duty Act.

⁴⁵⁷ Case study on plain packaging (see Annex 9 for more details).

CSOs and HEs that responded to the survey and participated in interviews identified the increased size of health warnings, prohibition of slim packets and inclusion of information on cessation services as particularly relevant to changing perceptions among young people and other vulnerable populations.

However, there are **several areas in which the TPD could become more relevant to addressing the problem of smoking in the EU**, particularly among young people. CSOs and HEs that responded to the survey and were interviewed for this study were particularly concerned about **the use of e-cigarettes, HTPs and other novel tobacco products, which is increasing among young people**⁴⁵⁸. The Eurobarometer survey⁴⁵⁹ found that smoking among young people (15-24 years) decreased from 29% in 2017 to 20% in 2020 (Table 14). However, younger people were more likely than other age groups to report that they had ever used e-cigarettes and HTPs. Younger people were also – albeit to a lesser extent – more likely to report currently using these products (Table 14 and Table 15). These trends point to the need to carefully monitor the use of such products among young people in the EU.

Table 14. Smoking for the overall population in the EU and for young people, at three time points

	2014	2017	2020
Overall	26%	26%	23%
Youth	25%	29%	20%

Source: Eurobarometer 2014, 2017 and 2020, Note: Youth in the Eurobarometer data represents those between 15 and 24 years of age

Table 15. Thinking about the following products, which of the following applies to you? HTPs (%) (2020)

Age	You currently use it	You used to use it, but you have stopped	You have tried only once or twice	You have never used it
15-24	2	2	7	88
25-39	2	2	6	89
40-54	1	1	4	93
55+	1	0	2	96

Base: All respondents, N= 28,300

Source: ICF, based on Eurobarometer 2017 and 2020

Table 16. Table 1: Thinking about the following products, which of the following applies to you? E-cigarettes (%) (2020)

Age	You currently use it	You used to use it, but you have stopped	You have tried only once or twice	You have never used it
15-24	2	2	7	88
25-39	2	2	6	89
40-54	1	1	4	93
55+	1	0	2	96

⁴⁵⁸ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁵⁹ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

15-24	4	3	18	74
25-39	3	6	13	78
40-54	2	4	8	85
55+	2	2	4	91

Base: All respondents, N= 28,300

Considering the trends in e-cigarettes, HTP and other novel tobacco product use among young people in the EU, there is some **concern that the current scope of the TPD may be inappropriate for products other than cigarettes and roll-your-own tobacco** (e.g. packaging and labelling requirements, characterising flavours). For instance, there is some evidence that e-cigarette flavours are important for attracting users^{460,461,462}, and limited evidence that they might also be important in switching from combustible tobacco products to e-cigarettes^{463,464,465}. More evidence in this area will be needed to inform how the TPD can remain relevant to addressing the issue of smoking in the EU, particularly among young people and specific vulnerable populations, and in relation to e-cigarettes, HTPs and novel tobacco products.

There are potential issues with the **TPD's ability to safeguard young people accessing tobacco and related products** when they are under the legal age. The mystery shopping exercise undertaken as part of this study (see Annex 10) revealed that there are often insufficient age verification processes for tobacco and related products bought online through CBDS - 80% of the retailers reviewed used self-reported age verification, and age was not verified at the point of delivery. This highlights an important gap in tobacco control where young people could be better protected from the harms associated with tobacco and related products.

4.2.2 E.Q.6: To what extent have the TPD provisions remained relevant to tackle today's reality? How have they responded to scientific, economic or technological developments and new products?

This evaluation question seeks to understand the extent to which the TPD and its objectives are still relevant and meeting needs, in light of scientific, technical and epidemiological developments. It examines whether the TPD is flexible and has the capacity to evolve to withstand developments in the sector.

⁴⁶⁰ LSE and Partners Consortium (2020). Consumer preferences and perception of specific categories of tobacco and related products. Report for CHAFEA

⁴⁶¹ Zare, S., Nemati, M. and Zheng, Y. (2018). A systematic review of consumer preference for e-cigarette attributes: flavor, nicotine strength, and type. PLoS One, 13(3), e0194145.

⁴⁶² Meernik, C., Baker, H.M., Kowitt, S.D., Ranney, L.M. & Goldstein, A.O. (2019). Impact of nonmenthol flavours in e-cigarettes on perceptions and use: an updated systematic review. BMJ Open, 9(10), e031598. doi:10.1136/bmjopen-2019-031598.

⁴⁶³ Friedman, A.S. and Zu, S. (2020). Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation. HAMA Netw Open, 3(6), e203826. doi: 10.1001/jamanetworkopen.2020.3826.

⁴⁶⁴ Gravely, S., Cummings, K.M., Hammond, D., et al. (2020). The Association of E-cigarette Flavors With Satisfaction, Enjoyment, and Trying to Quit or Stay Abstinent From Smoking Among Regular Adult Vapers From Canada and the United States: Findings From the 2018 ITC Four Country Smoking and Vaping Survey. Nicotine and Tobacco Research. Ntaa095. <https://doi.org/10.1093/ntr/ntaa095>.

⁴⁶⁵ Pacek, L.R., Rass, O., Sweitzer, M.M., et al. (2019). Young adult dual combusted cigarette and e-cigarette users' anticipated responses to hypothetical e-cigarette market restrictions. Substance Use and Misuse, 55(6), 108458. <https://doi.org/10.1080/10826084.2019.1626435>.

4.2.2.1 The main implications of new sector developments

Several TPD provisions have not remained relevant in light of new and emerging sector developments, which affects the relevance of the TPD.

The TPD entered into force in April 2014 (with a transposition deadline of 20 May 2016) and the market has evolved rapidly since that time. It is very challenging for a directive to remain relevant in this context. Overall, the evidence suggests that the **TPD forms a strong basis for the regulation of tobacco products** and has remained broadly relevant to addressing new market developments. However, there are some key areas in which market developments are beyond the current scope of the TPD.

Provisions across seven articles (Art. 2, 4, 5, 7, 19, 20 and 21) were perceived as not remaining relevant in light of scientific and technological developments from the tobacco industry on novel and innovative products, packaging and labelling, marketing and sales methods. In particular, the Directive has faced challenges in keeping pace with the rapidly evolving market and the wide variety of products that are difficult to categorise and/or which fall outside its scope:

- **Art. 2** sets out key definitions to support uniformity in implementation of the TPD by Member States. This is a key area identified by all stakeholders as not having kept pace with market developments. In terms of products currently within the scope of the TPD, definitions relating to e-cigarettes and HTPs were viewed as most challenging in remaining relevant. Additionally, challenges were identified due to new products (e.g. nicotine-free e-liquids, cannabidiol products and non-tobacco nicotine pouches) that cannot be categorised as within the scope of the TPD because they do not contain tobacco (see Tier 1 section on Art. 2 for details).
- **Art. 4** sets out the measurement methods, using ISO standards for TNCO for cigarettes placed on the market or manufactured in the Member States. Some Member State, HE, and CSO experts view these as no longer relevant in light of scientific and technological developments in measurement approaches. They have suggested the use of alternative measurements and methods (see Tier 1 section on Art. 4).
- **Art. 5** requires manufacturers and importers of tobacco products to submit certain information on the ingredients and emissions of tobacco products to competent authorities. The use of EU-CEG was described as complex by all stakeholders and resource limitations mean that not all Member States are able to make equal use of these data (see Tier 1 section on Art. 5 and Annex 9 for the regulation of ingredients case study).
- **Art. 19** specifies that manufacturers and importers are required to notify Member States about novel tobacco products. These provisions have not kept abreast of market developments and are not sufficiently detailed to address all aspects related to the products within its scope (e.g. devices for HTPs, hybrid products).
- **Art. 20** stipulates that manufacturers and importers of e-cigarettes and refill containers must notify Member States before placing them on the market, and that notification must contain certain information (e.g. ingredients, emissions, toxicological data, nicotine dose). However, the market for e-cigarettes and refill containers has developed substantially, creating challenges around submissions of notifications in EU-CEG (e.g. incorrect or non-compliant submissions, difficulty in assessing technical information, high volume of product submissions). Additionally, the number of submissions for each product has created a substantial administrative burden for Member States (see Tier 1 section on Art. 20).
- **Art. 21** provides for herbal products for smoking, including health warnings, and **Art. 22** contains provisions on the reporting of ingredients and quantities. There is some indication that the market for herbal products is changing and the TPD

may not be fully relevant. Some stakeholders recommended that the TPD adapt to these newer products, such as CBD products. For example, one Member State suggested that it should be allowed to ask for proof of the THC percentage of CBD products. CSOs and HEs also stressed that CBD and cannabis products, nicotine-free cigarettes, and herbal mixes for waterpipes are increasingly used in some countries. As a growing issue, there have been some individual cases of untested and unregulated herbal products being released onto the market (see Tier 1 section on Art. 21).

Not all structures and procedural arrangements introduced by the TPD have sufficiently adapted to new market, scientific, and technological developments in the tobacco industry and companies producing tobacco related products (i.e. e-cigarettes; HTPs).

In the last five years, the market for tobacco products has become more diverse and challenging to regulate, with multiple novel ways of delivering tobacco and nicotine to consumers. All groups (Member States, economic operators, CSOs, HEs) noted that the market is developing rapidly and new product categories have emerged that circumvent existing regulations such that they cannot be completely addressed by existing provisions in the TPD⁴⁶⁶. This includes products currently within the scope of the TPD, such as HTPs, but also new products that have emerged and that are not currently regulated by the TPD, such as nicotine-free e-liquids, and non-tobacco containing nicotine products (e.g. nicotine pouches). This is viewed by Member States as a contributing factor to the lack of harmonisation across Member States⁴⁶⁷.

The section below expands on provisions related to definitions, ingredients and emissions, labelling and packaging, novel tobacco products, e-cigarettes and herbal products for smoking.

Definitions (Art. 2)

The fact that definitions used in the TPD have not kept pace with market developments⁴⁶⁸ has contributed to a lack of appropriate regulation of novel tobacco products, particularly in relation to labelling and packaging and taxation (see Tier 1 section on Art. 2 for details). However, stakeholders had differing views on whether regulations should be more uniform across all products or if they should be differentiated further for different product types, with industry stakeholders particularly supportive of the latter. This includes challenges around adapting definitions for products within the scope of the TPD (e.g. HTPs) and products that may need to be considered in the next iteration of the TPD, such as those containing nicotine but not tobacco, and products containing cannabidiol.

In addition, the lack of appropriate definitions and regulation for emerging products was reported to result in different national regulations, leading to a variation in the approaches implemented across the EU. The result is a lack of harmonisation across the market, particularly given that some Member States have developed tobacco control legislation that goes beyond the TPD (see Section 4.1 on effectiveness).

Ingredients and emissions (Art. 4, Art. 5, Art. 7)

⁴⁶⁶ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020.

⁴⁶⁷ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁶⁸ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

Some CSOs, HEs, and Member States expressed the view that provisions relating to procedures for **assessing and regulating ingredients and emissions have not remained relevant** in view of scientific and technological developments⁴⁶⁹. More specifically, the TNCO emissions and the related measurement method was criticised, with opponents suggesting that alternative approaches may be more appropriate.

There are challenges related to the **emergence of products with characterising flavours that are not within the remit of the current ban**. For example, some Member States, CSOs and HEs raised concerns about the growing market for emerging products with menthol capsules/strings⁴⁷⁰, the emergence of flavoured cigarillos and cigars (covered by Art. 7 but exempt from certain provisions), and an increase in flavoured products sold separately (e.g. cigarette paper tubes, menthol sticks)⁴⁷¹. This may be indicative of a displacement effect or attempts to circumvent the ban on characterising flavours. It should be noted that even though they are exempt from the EU ban on characterising flavours, sales of cigars and cigarillos have been steadily decreasing for the past decade (falling from 10.76 to 8.97 billion pieces since the introduction of the TPD). The trend needs to be further reassessed following the full menthol ban application. There are concerns that the absence of a ban on characterising flavours for all tobacco and related products may simply lead to a change in which products are consumed (see Sections 4.1 and 4.2.1, and Annex 9 for the e-cigarette flavourings case study), rather than a reduction in overall use of tobacco and related products.

- There have been some issues with the **regulation and reporting of ingredients on EU-CEG that relate to the relevance of the existing system to certain products**. EU Member State competent authorities reported experiencing difficulties in regulating and monitoring products via the EU-CEG, in particular e-cigarettes⁴⁷², but also products currently outside the scope of the TPD, such as those that do not contain tobacco, and products containing cannabidiol⁴⁷³. For example, the EU-CEG does not require the submission of information on THC content, as this is not mandatory; however, collecting such information would better support monitoring of herbal hemp products⁴⁷⁴.

Labelling and packaging (Art. 8-14)

Although labelling and packaging requirements are perceived to have broadly remained relevant to addressing current technological, scientific, or market developments, it was recommended that labelling provisions be made clearer and stricter⁴⁷⁵. Specific improvements included: increasing the size of health warnings to 85% of the surface; mandatory plain packaging; not allowing exemptions for certain products; regulating further aspects such as edges and seals; and establishing a maximum number of cigarettes per package. The case study on plain packaging (see

⁴⁶⁹ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁷⁰ DG SANTE (2018). 11th Meeting of the Group of Experts on Tobacco Policy: 15 March 2018.

⁴⁷¹ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Follow up interviews, June-July 2020; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁷² <http://jaotc.eu/wp-content/uploads/2019/09/WP67-D6.1-D7.1-Needs-Assessment-Evaluation-from-EU-MS-regulators.pdf>.

⁴⁷³ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁷⁴ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁷⁵ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

Annex 9) highlighted the differences between Member States in terms of the introduction of plain packaging, due to potential barriers such as perceived lack of political support, scientific evidence, concerns around public approval, and the threat of legal action by tobacco companies. Member States were in support of EU-level legislation of plain packaging, which they felt would represent an important facilitator in introducing plain packaging at national level.

Novel tobacco products, e-cigarettes and herbal products for smoking (Art. 19-22)

The market for several types of products covered by the TPD (novel tobacco products, e-cigarettes and herbal products for smoking) has grown and/or changed since the introduction of the TPD (see Section 4.2.2.2 for an overview of market changes). These developments present challenges to the relevance of the provisions governing these product types, with some products not completely regulated. In particular, devices used in HTPs are not clearly captured by the TPD, although some Member States have separate regulating legislation⁴⁷⁶. Herbal products present a similar challenge, with some Member States reporting devices for heating or 'vaporising' these products appearing on the market, and some products being designed for 'heating' rather than smoking⁴⁷⁷. The herbal product market raises an additional challenge due to the increase in products containing THC or CBD, as these psychoactive substances are not explicitly addressed by the TPD⁴⁷⁸. Some Member States were unsure whether such products should be considered herbal products or treated as a different product type, and how this related to EU legislation on illicit drugs⁴⁷⁹. There is some discussion in the research literature as to whether some herbal products derived from cannabis should be regulated as foodstuffs and harmonised under EU law⁴⁸⁰.

The main challenge related to Art. 20 is the rapidly evolving nature of the e-cigarette market, which may have implications for how Art. 20 is enacted in practice (see Section 4.2.2.2 for a more detailed overview of the e-cigarette market). Member States highlighted that there were new types of products being created that were not covered by the TPD⁴⁸¹. Emerging products that were considered insufficiently covered by the TPD typically included novel tobacco products' devices, hybrids or particular e-liquids⁴⁸², such as: single use and pod products; 0% nicotine PG/VG mixes known as short fills, which are sold in volumes exceeding 10ml; products that use nicotine salts; hybrid devices combining liquids and tobacco or herbal products; and products with more than one tank. Over time, there has been a shift in preference to larger 'tank' style devices with longer battery lives, larger e-liquid reservoirs, a higher level of vapour⁴⁸³, and high wattage devices. There is also evidence that the use of nicotine salts in certain products increases nicotine delivery⁴⁸⁴. Together, these developments

⁴⁷⁶ ICF Gap Filling Questionnaire, December 2020.

⁴⁷⁷ ICF Gap Filling Questionnaire, December 2020.

⁴⁷⁸ ICF Gap Filling Questionnaire, December 2020.

⁴⁷⁹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁸⁰ Tallon, M.J. (2020). Cannabis sativa L. and Its Extracts: Regulation of Cannabidiol in the European Union and United Kingdom. *J Diet Suppl.*, 17(5), 503-16.

⁴⁸¹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁴⁸² Note that detailed information was not provided, and products were generally presented in a list format.

⁴⁸³ IFF Research (2016). Understanding the Online E-cigarette market. HM Revenue and Customs.

⁴⁸⁴ Goniewicz, M.L., Boykan, R., Messina, C.R., et al. (2018). High exposure to nicotine among adolescents who use Juul and other vape pod systems ('pods'). *Tobacco Control*, 28, 676-677.

mean that consumers are consuming higher volumes of e-liquids and greater nicotine delivery, with potentially greater harmful constituents⁴⁸⁵.

4.2.2.2 Ability to adapt and respond to future product and market developments

The TPD provisions have not fully enabled Member States to respond quickly and effectively to market developments and regulator needs, including future ones.

During the period 2013-2019, the **size of the market for e-cigarettes⁴⁸⁶ and HTPs has more than quadrupled**, from just below €2 billion to almost €9 billion, **with a total growth in retail value of 416%**. Data from Euromonitor International suggests that the upward trend in the market value of non-traditional tobacco and nicotine products is continuing – over the period 2013-2019, the retail value of the entirety of the tobacco market increased by approximately €13 billion, of which €4 billion was growth in e-cigarettes and €3 billion in HTPs. Overall, the growth of these products accounted for 52% of the growth of the retail value of the total market over the period 2013-2019. This is an important development as although non-traditional nicotine and tobacco products only account for a relatively small portion of the total value of the tobacco market, they have been responsible for most of its growth in recent years. Data from Euromonitor International indicates that the market size for e-cigarettes was estimated to be almost €6 billion in 25 EU Member States⁴⁸⁷ in 2019, having experienced an overall growth rate of 237% between 2013-2019. In comparison the retail value of cigarettes increased by 2% (from €122 billion to €125 billion) and retail volume decreased by 11% (approximately 510 to 450 billion sticks). This growth led to the overall share of e-cigarettes in the tobacco market increasing from 1% in 2013 to 4% in 2019. Although e-cigarettes and HTPs represent a small proportion of the overall tobacco market, it is an area of substantial expansion and diversification and this appears likely to continue. It has been challenging for TPD provisions to remain relevant to this part of the market.

There is growth in other areas of the market as well. Smokeless tobacco (excluding HTPs) experienced an increase in retail value of 4% between 2013-2019. Based on Euromonitor International data, the retail volume of both moist snuff and chewing tobacco saw increases of 12% and 38%, respectively. This indicates that consumers in some countries are demanding more smokeless tobacco products⁴⁸⁸. There is some indication that the market for herbal products is also changing and that the TPD may not be fully relevant to address these market developments. For example, the TPD may need to be adapted to products, such as cannabidiol and cannabis products, nicotine-free e-cigarettes, and herbal mixes for waterpipes. However, data on this were perceived to be lacking by CSOs and HEs.

As the market size for different products increases and changes, a growing number of products that are not directly connected to tobacco but have other risks could be left unregulated. Regulation is also likely to become more challenging due to the wide variety of products that may be introduced. The evidence suggests that the TPD

⁴⁸⁵ Smets, J. et al. (2019). When Less is More: Vaping Low-Nicotine vs. High-Nicotine E-Liquid is Compensated by Increased Wattage and Higher Liquid Consumption. *Int J Environ Res Public Health*, 16(5).

⁴⁸⁶ Trends in e-cigarettes are determined using the Euromonitor International product category “e-vapour products”. Euromonitor International confirmed that HTPs are treated in the category “Heated tobacco products” and are not included in the E-vapour category as defined in their data used for this study.

⁴⁸⁷ In the Euromonitor International data collection, information was collected in the 27 Member States and the UK, except for Malta, Luxembourg and Cyprus. These Member States were omitted due to their small size.

⁴⁸⁸ Data on smokeless tobacco was only available for the following countries: Bulgaria, Czechia, Denmark, Slovakia, Spain, Sweden.

encompasses many different product types, which may limit its ability to respond in an agile manner to market developments. To ensure future-proofing of the TPD, the following areas should be considered:

- **Definitions.** Formulation of definitions related to novel tobacco products will need to be considered, although given the rapidly evolving nature of the market, care needs to be taken to ensure that definitions and other provisions are not prematurely revised and/or incorporate flexibility.
- **Regulation of novel tobacco products, e-cigarettes, and emerging products.** These products, including nicotine pouches and nicotine free e-liquids, raise many regulatory issues, including labelling requirements, applying health warnings and nicotine limits for these products, and regulation of CBDS.
- **Marketing and sales methods** (particularly marketing to young people). The tobacco industry has invested in innovative marketing and sales methods. Independent CSOs noted that the **marketing** of e-cigarettes to young people using social media has risen significantly recently and provisions on 'commercial communication' should be updated for digital methods of communication.
- **Availability of new scientific evidence.** Regulation should be science-based and risk-proportionate and the TPD should be flexible to consider the availability of new scientific evidence, including: **maximum** emission levels and respective measurement methods; health impacts of different products; and potential harms associated with the use of novel tobacco products and e-cigarettes.
- **Flavoured cigarillos and cigars.** There have been reported increases in menthol cigars and cigarillos on the market following the introduction of the characterising flavour ban, as well as other non-tobacco products that can be used to flavour cigarettes and tobacco. CSOs and HEs reported the presence of the following products to add menthol to cigarettes: menthol flavoured cards to add to packs of cigarettes and roll-your-own tobacco, menthol flavoured filters, and click-in menthol capsules. This could extend to other flavours in future.

4.3 Efficiency

Main findings: The practical implementation of the TPD created an additional financial burden for Member States, both in terms of compliance and enforcement costs. In most Member States, these costs were not outweighed by the direct revenue generated from fees and penalties charged to industry for breaches. A key driver of costs related to staff salaries to ensure implementation and enforcement.

In relation to implementation costs borne by the different actors:

- The available information suggests that the level of costs and benefits, and their composition, varies between Member States. Smaller Member States face disproportionate costs in implementing the TPD, the main issue being insufficient human resources.
- Economic stakeholders reported facing a large increase in costs to implement the TPD. However, there is a lack of economic information to make a proper judgement. Economic stakeholders reported facing the highest costs for the redesign of packaging, changing the process for printing and packaging, product redesign and testing to meet reporting obligations.

The study was unable to assess whether the benefits of the TPD to society outweighed the overall implementation costs faced by all actors. Key benefits (reduced healthcare costs and health gains (as people may be encouraged to reduce or quit smoking as a result of the TPD, reduced law enforcement costs as new tools to fight the illicit trade in tobacco products become available) could not be quantified, as the degree to which the TPD impacts these cannot be determined. Nevertheless, the TPD has several beneficial effects that are increasingly identified and recognised in the Member States.

The requirements of the TPD were perceived by affected operators to provide insufficient flexibility for SMEs, with specific Member State supports for SMEs considered limited. Overall, SMEs reported facing disproportionately higher costs for implementing and complying with the TPD. However, the evidence is scarce.

4.3.1 EQ7: Have the costs borne by regulators to correctly implement the TPD been reasonable in relation to the benefits?

This evaluation question seeks to understand the financial burden imposed by the TPD and its magnitude in relation to the benefits arising from the TPD. It focuses first on the costs incurred by regulators and implementing authorities in the Member States for implementing and enforcing the Directive, setting these against the financial benefits gained as a result of its implementation. It then presents the costs borne by economic stakeholders. Finally, it considers the benefits, such as impact on public health.

The information on costs and financial benefits was obtained through a standardised financial costs template developed for this study and circulated to Member States and selected economic stakeholders. Respondents were asked to provide information by type of cost or benefit, including human and capital resources. The inputs received were analysed systematically, with the objective of constructing overall monetary estimates.

4.3.1.1 Costs borne by Member States

The costs borne by regulators to implement the TPD can be grouped into three broad categories: (1) Reviewing submissions to the **EU-CEG**, (2) **Compliance costs**, and (3) **Enforcement costs**. In total, 12 Member States provided inputs that could be

used to estimate costs. The respondents were asked to use 2019 as the reference year and to provide information that could be used to construct estimates. The annual costs related to the EU-CEG ranged from €16,346 to €856,547⁴⁸⁹.

A key driver of all three types of costs was staff time, which was estimated as the amount of time, measured in hours multiplied by an average salary amount, which was provided by the respondent or proxied with the average national wage available from Eurostat. Overall, costs are likely to be underestimated, as the study did not collect data from all relevant public agencies and not all responding Member States were able to submit cost data for all questions. Member States in general found that reviewing the **information submitted to the EU-CEG system** created high **administrative and technical burdens**. Member States described issues in processing and assessing submitted products information, and problems were often related to a lack of capacity to analyse submissions (reported in 11 Member States). For example, in one Member State, only certain limited staff members were dedicated to processing and assessing the information, and they have limited time and opportunities to train others to carry out such checks.

The second category assessed was **compliance costs**. This category reflected activities that Member States had to carry out to comply with the articles of the TPD, including:

- Monitoring of ingredients, additives and emissions of tobacco products (Art. 3-7);
- Monitoring of labelling and packaging standards for tobacco products (Art. 8-13);
- Facilitating the function of traceability and security features systems for tobacco products (Art. 15-16); and
- Monitoring of cross-border sales for tobacco products (Art. 18).

Compliance activities are typically carried out by more than one governmental body, but there was typically only one respondent to the cost template. Respondents could provide relevant information only for the compliance activities with which they were familiar. For this reason, it is likely that compliance costs are underestimated. For example, the costs of traceability and security systems (Art. 15-16) are often not reflected, as they are typically managed by customs authorities, which were not surveyed.

The analysis is summarised in Table 17. The structure of compliance costs differed between the Member States surveyed.

Table 17. Overview of estimated compliance costs (reference year = 2019). Each row indicates one Member State.

Member State	Novel tobacco products	Tobacco products	E-cigarettes	Total
A		€537,000	€341,000	€878,000
B		€374,739	€481,808	€856,547
C	€42,728	€256,370	€493,839	€792,937
D		€40,008	€33,340	€473,356
E	€68,890		€103,334	€172,224
F		€90,000	€64,000	€154,000
G	€14,500	€45,153	€16,932	€76,585

⁴⁸⁹ Some of these differences may stem from wage differences across countries due to cost of living.

H	€32,352	€32,352
I	€13,475	€13,475
J	€9,152	€9,152

Source: ICF analysis of inputs provided to cost data template. All Member States were invited to respond. In Italy, the cost template was sent to the Ministry of Health, but it is the Ministry of Finance (agency for customs and monopolies) that handles most of the costs.

In one Member State, a system was established for monitoring the placing on the market of tobacco products and related products, as well as a market surveillance system. The **implementation of traceability** and the introduction of security features also had to be established, which meant numerous coordination meetings with the European Commission, competent authorities and with other stakeholders, including the provider of the secondary repository are necessary. It also required identification and instalment of a national ID issuer and its transformation into national law, development of a software tool (app for smartphones) for controls to ensure the review of marketable products on the market, new contracts between industry and independent parties, new kinds of control administration, more interdisciplinary communication between stakeholders, and reporting obligations. In another Member State, the obligation of **notification for e-cigarettes** generated a substantial amount of work, with eight people working full-time on these notifications.

Three Member States (Table 18) provided sufficient information to allow for a review of compliance costs by activities related to specific articles. With respect to tobacco products, the traceability and security features systems contributed to 40% or more of identified compliance costs in two Member States. In the third Member State, most of the identified costs were in relation to the monitoring of labelling and packaging. For e-cigarettes, costs of monitoring of ingredients, additives and emissions were relatively higher than for tobacco products.

Table 18. Breakdown of compliance costs, by Member State. Each column indicates one Member State

	Tobacco products			E-cigarettes		
	A	B	C	A	B	C
Monitoring of ingredients, additives and emissions of tobacco products (Art. 3-7)	17%	20%	2%	40%	25%	82%
Monitoring of labelling and packaging standards for tobacco products (Art. 8-13)	33%	20%	98%	40%	25%	0%
Facilitating the function of the traceability and security features systems for tobacco products (Art. 15-16)	50%	40%	0%	20%	25%	18%
Monitoring of cross-border sales for tobacco products (Art. 18)	0%	20%	0%	0%	25%	0%

Source: ICF analysis of inputs provided to cost data template.

Finally, the third category of costs refer to **enforcement costs**, which relate to costs incurred from product testing activities and inspection. Table 19 presents an overview of the costs related to enforcement, provided by the authorities in the cost data template.

Table 19. *Overview of enforcement costs – product testing carried out from 2016-2019. Each row indicates one Member State.*

Member State	Number	Aggregate costs (€)	Cost per test (€)
A	818	654,400	800
B	880	616,000	700
C	484	119,393	247
D	140	27,985	200
E	140	27,985	200
F	95	25,650	270
G	200	15,000	75
H	200	15,000	75
I	200	15,000	75
J	67	13,420	200
K	144		

Source: ICF analysis of inputs provided to cost data template. All Member States were invited to respond. Blank cells indicate that information was not provided by respondents.

Table 20. *Overview of enforcement costs – inspections carried out from 2016-2019. Each row indicates one Member State.*

Member State	Number	Aggregate costs (€)	Cost per inspection (€)
A	4,775	764,000	160
B	13,359	667,950	50
C	5	338,645	a
D	174	262,392	1,508
E	534	240,300	450
F	724	94,120	130
G	245	41,650	170
H	41	2,870	70
I	5270		
J	489		
K	2,063		

Source: ICF analysis of inputs provided to cost data template. All Member States were invited to respond. Blank cells indicate that information was not provided by respondents.

Certain Member States reported several limitations related to the costs of enforcing product compliance, due to an overall lack of capacity and technical expertise.

Relevant findings of case study 3 on monitoring and enforcement

A recurring theme across articles was that a **lack of capacity and/or technical expertise** hindered Member States from fully applying the TPD articles:

- **A lack of capacity for effective enforcement:** For example, there were overarching issues related to product submissions and reporting through the EU-CEG system (Art. 5). This was partially related to Member State authorities lacking capacity to properly assess, process, and react to the large volume of submissions, which also hindered the application of Art. 6, 19 and 20. However, improvements could be made to the technological system itself, and an EU-wide database containing information about products could potentially increase communication and reduce workload among NCAs. Another example is that Member States may not have fully applied the provisions on TNCO laboratories, as they lacked resources to appoint approved labs which would be independent from industry (Art. 4).
- **A lack of expertise and technical knowledge for effective monitoring and enforcement:** Similarly, the provisions of Art. 7 (characterising flavours) were not fully applied, largely due to a lack of Member States' technical capacity to properly identify, assess and process non-compliant products, or to perform tests to verify the composition of tobacco products. Analysis of the reports on priority additives (Art. 6) was also hindered by a lack of expertise, as well as insufficient quality of the documentation submitted by the industry.
- The full case study can be found in Annex 9.

4.3.1.2 Financial benefits to Member States

Where Member States incurred costs associated with implementing the TPD, some charged fees, as permitted by the Directive, to help to recover those costs^{490,491}. Product fees may be charged in relation to:

- Receiving product reports and notifications;
- Storing and handling submitted information; and
- Analysis and verification of submitted information.

These fees may be applied to tobacco products (mainly Art 5-6), novel tobacco products (Art. 19) and e-cigarettes (Art. 20). Product fees may also be charged in relation to:

- Verification of measurements (and methods) for ingredients and/or emissions (Art. 4(6));
- Peer reviews of reports on additives produced by tobacco manufacturers and importers (Art. 6(4)); and
- Assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used, and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the CMR properties of the tobacco product concerned (Art. 7(13)).

Member State regulators may also benefit from penalties received from administrative actions taken.

The cost data template gathered information on the types of fees and penalties collected in the 2016-2019 period, as well as the amounts collected. In total, 11 of 19 Member States charged fees for products or procedures covered by the TPD (0).

⁴⁹⁰ DG SANTE (2019). Meeting of the Group of Experts on Tobacco Policy: 21 March 2019.

⁴⁹¹ DG SANTE (2018). 11th Meeting of the Group of Experts on Tobacco Policy: 15 March 2018.

Differences were evident in terms of product type: for example, Portugal charges fees for tobacco products and novel tobacco products, but not for e-cigarettes. The Netherlands also charges fees on herbal smoking products.

Some Member States charge fees for verification of measurements while only two reported a fee for peer reviews.

Table 21. Types of fees charged by Member States

Type of fee	Member States where type of fee is present
Fees for products or procedures?	12 Member States
Tobacco products except novel tobacco products (Art. 5-6)	13 Member States
Novel tobacco products (Art. 19)	12 Member States
E-cigarettes (Art. 20)	12 Member States
Other	1 Member State (herbal products)
Other fees?	
Verify measurements	6 Member States
Peer review	2 Member States
Do not charge fees	8 Member States

Source: ICF analysis of inputs provided to cost data template. All Member States were invited to respond. Unless otherwise indicated, fees for products or procedures include fees for receiving product reports/notifications, storing and handling submitted information and analysis /verification of submitted information. Two Member States provided overall cost figures and did not break them down by product type. Three Member States did not reply to the cost data template; this information is from DG SANTE.

The study did not explicitly gather information on the level of fees, although several Member States provided them through the survey. In one Member State, for example, the fee for notification of e-cigarette products is approximately €5,000. In another Member State, it is €4,000⁴⁹². Only one Member State provided information on the amount of measurement verification fees collected, estimated to be €5,880.

The amounts of fees collected differed between the surveyed Member States. Table 22 presents an overview of product fees collected for seven Member States that provided sufficient information to make estimations. Not all Member States provided breakdowns by product type.

Table 22. Overview of product fees collected, by type of tobacco and related products, in € (2016-2019). Each row indicates one Member State.

Member State	Tobacco products (except novel tobacco products)	Novel tobacco products	E-cigarettes products	Costs related to other procedure s/products	Total fees collected
A	4,222,000		3,838,000		8,060,000
B				6,819,693	6,819,693
C				3,946,000	3,946,000
D	979,930	28,000	1,784,778		2,792,708
E	75,643	857	342,474		424,854

⁴⁹² Interview with NCA.

F	85,350	132,375	79,275	297,000
G	203,900	50,350		254,250

Source: ICF analysis of inputs provided to cost data template. All Member States were invited to respond. Blank cells indicate where information that was not provided by respondents.

Respondents to the cost data template also indicated the number of products for which administrative action was taken since 2016 and the amount collected in **penalties**. Two Member States reported the number of penalties applied to operators but did not report enough information to estimate the associated costs.

Table 23. Overview of penalties collected (2016-2019). Each row indicates one Member State.

Member State	Number of products where administrative action was taken	Penalties collected
A	312	€418,080
B		€281,000
C	50	€229,715
D	820	€3,669
E	47	€1,400
F	21	€1,260
G	4,909	
H	3,544	
I		
J	4	€386

Source: ICF analysis of inputs provided to cost data template. All Member States were invited to respond. Blank cells indicate where information that was not provided by respondents.

4.3.1.3 Costs versus financial benefits borne by Member States

The costs of implementing the TPD did not outweigh the direct revenue gained by most Member States. Table 24 presents an overview of the findings from the partial cost-benefit analysis, by Member State. Blank cells indicate that information was not provided or was inadequate for the construction of a monetary estimate.

Due to the lack of complete information from most Member States, it is not possible to conclude whether the costs to regulators were on a par with their financial benefits. The financial benefits for regulators (fees and penalties) should not be conflated with the social and economic benefits for society as a whole, including health and social security budgets. Nevertheless, the present analysis provides some insights that can be triangulated against the qualitative findings from the surveys and interviews. Firstly, the annual costs faced by regulators varied substantially between Member States, ranging from €174,000 to €8.2 million. Secondly, EU-CEG and compliance costs accounted for the biggest proportions of the costs faced by regulators, while enforcement costs were lower but still substantial.

Lastly, information for all categories of administrative costs and benefits were only available for two Member States. In one, the financial benefits exceeded the costs (by €356,344 over a four-year period) while in the other, the costs exceeded the benefits (by €158,089 over a four-year period). However, information reported by Member

States through the consultation activities carried out as part of this consultation⁴⁹³ confirmed that the costs of implementing the TPD did not outweigh the revenue gained by most Member States.

⁴⁹³ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

Table 24. Overview of costs and financial benefits, by Member State (2016-2019). Each row indicates one Member State.

Member State	Benefits (€)			Costs (€) ⁴⁹⁴			
	Penalties collected	Fees collected	Total	Enforcement costs	Compliance costs	EU-CEG costs	Total
A	-	3,946,000	3,946,000	856,300	3,644,000	134,934	4,635,234
B	281,000	2,792,708	3,073,708	693,600	1,893,428	1,200,252	3,787,280
C	229,715	-	229,715	5,916	-	381,888	387,804
D	3,669	-	3,669	13,420	3,171,752	1,717,682	4,902,854
E	418,080	8,060,000	8,478,080	1,418,400	3,426,189	3,426,189	8,270,779
F	-	-	-	600	12,674,711	1,231,252	13,906,563
G	-	297,000	297,000	141,102	306,340	812,748	1,260,189
H	-	8,377,225	8,377,225	177,000	-	4,054,757	4,231,757
I	1,260	-	1,260	2,870	616,000	720,000	1,338,870
J	-	424,854	424,854	119,393	129,408	532,397	781,198
K	-	-	-	262,392	463,412	313,182	1,038,986
L	-	-	-	-	-	112,804	112,804
M	386	-	386	69,635	36,608	109,824	216,067
N	-	50,000	50,000	-	-	2,804,518	2,804,518
O	1,400	68,197	69,597	109,120	-	65,383	174,503
P	-	1,105,994	1,105,994	1,255,800	2,780,000	447,153	4,482,953
Q	-	335,205	335,205	-	201,228	905,524	1,106,751

⁴⁹⁴ The compliance costs and costs related to the EU-CEG were multiplied by four, assuming that the annual costs were repeated in each year in the 2016-2019 period.

R	-	-	-	2,655,235	833,015	3,488,250
S	-	254,250	254,250	98	688,896	1,653,350

Source: ICF analysis of inputs provided to cost data template. Compliance costs and EU-CEG costs were multiplied by four to allow for comparison with other costs and benefits. Blank cells indicate that information was not provided by respondents. 19 Member States were included in this analysis, as they provided information on costs using the costs data template.

4.3.1.4 Costs for economic stakeholders

Overall, economic stakeholders reported facing a large increase in costs to implement the TPD. However, they did not underpin these claims with economic information that could substantiate a proper judgement. Economic stakeholders reported facing the highest costs for the redesign of packaging, changing the process for printing and packaging, product redesign and testing to meet reporting obligations.

The assessment of costs and benefits should take into consideration the costs for industry to comply with the TPD. A standardised financial costs template gathered information on (1) packaging and labelling, and (2) ingredients and emissions in relation to e-cigarettes and tobacco products. In total, eight organisations completed the template for tobacco products, while just one responded for e-cigarettes. Due to the limited sample size for the latter, the assessment drew only on the data gathered for tobacco products. The number of products for which labelling and packaging changed due to TPD requirements ranged from 146 to 4,000 among the respondents.

Table 25 presents the ranges in the estimated costs per relabelled/repackaged product for the organisations that responded to the cost template. The ranges are quite wide, suggesting significant heterogeneity in industry experience in responding to TPD requirements. The highest costs appear to be for the **redesign of packaging and changing the process for printing and packaging**.

Table 25. Overview of labelling and packaging costs faced by industry – costs per relabelled/repackaged product

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

Source: ICF analysis of inputs provided to cost data template. Inputs on costs and number of relabelled/repackaged products was provided by six organisations, none of which were SMEs.

Table 26 presents an **overview of costs related to reformulation of products to meet ingredient and emissions standards**. The costs are presented per reformulated product, showing that product redesign and testing was reported to be the costliest activity. The ranges reported for the first two items are very broad (possibly due to differences in interpretation of the scale and type of activities that are included in the reformulation of a product) and these figures should be considered with caution.

Table 26. Overview of costs related to ingredients and emissions faced by industry – costs per reformulated product

Activities relating to reformulating products	Overview of replies
Understanding of the provisions related to product formulation	€154 to €36,667
Product redesign and testing	€309 to €33,333 per product
Changing the manufacturing process	€617 ^a per product

Changing the materials or ingredients	€309 to €2,066 per product
Changing the materials or suppliers used for printing or packaging	€45 to €137 per product

Source: ICF analysis of inputs provided to cost data template. Inputs on costs and number of relabelled/repackaged products was provided by six organisations, none of which were SMEs. ^aOnly one organisation responded to this cost category.

The cost of carrying out **comprehensive testing for priority additives** (Art. 6) ranged from €83 to €5,305 per product submitted to the EU-CEG. Table 27 presents an overview of the initial and recurring costs related to meeting reporting obligations under Art. 5. These costs are presented for an average product – the initial costs are typically higher than the recurrent costs.

Table 27. Overview of costs of meeting reporting obligations, per reformulated product (Art. 5)

Reporting obligations	Initial costs (per product)	Recurring costs (per product)
Understanding the reporting requirements	€56 to €16,667	€4 to €3,063
Product testing	€23 to €46,667	€7 to €3,063
Establishing/running IT tools for data submission	€20 to €3,063	€24 to €61
Maintaining and regularly updating submitted data for a product	€34 to €6,667	€31 to €3,222

Source: ICF analysis of inputs provided to cost data template. Inputs on costs and number of relabelled/repackaged products was provided by six organisations, none of which were SMEs.

4.3.1.5 Benefits of the TPD for society vs overall costs borne by all actors

The study was unable to determine whether the benefits brought by the TPD to society outweighed the overall costs faced by all actors. Key benefits, such as reduced healthcare costs and health gains (people may be encouraged to reduce or quit smoking as a result of the TPD) or reduced law enforcement costs (new tools to fight the illicit trade in tobacco products become available) could not be quantified, as the degree to which the TPD impacts on these is difficult to determine. Nevertheless, as explained in Section 4.1, and discussed further below, the TPD has had several beneficial effects, which, although not included in the cost-benefit analysis, are increasingly identified and recognised by Member States.

In addition to the financial benefits identified and, where possible, quantified in the subsections above, the TPD has other important expected benefits. The 2011 study⁴⁹⁵ supporting the DG SANCO Impact Assessment of the TPD envisaged that the proposed tobacco regulation could have an immediate effect on smoking behaviour, which, in turn, would impact on mortality, morbidity and costs several decades into the future (the study assumed an average time lag of about 17 years before any effect on mortality and morbidity, i.e. in 2027). The study assumed that a 1% reduction in the number of smokers would lead to a 0.5% reduction in predicted mortality, morbidity and costs of smoking by the year 2027. The authors stressed, however, that the burden of smoking (and hence mortality, morbidity and costs) was already expected to decline as part of the baseline scenario, due to existing EU and national policies

⁴⁹⁵ RAND Europe (2011). Assessing the impacts of revising the Tobacco Products Directive.

aiming to reduce smoking and the already declining trend in smoking prevalence. Using the WHO European Health for All database, the study assumed a ‘baseline’ trend (i.e. without any additional EU intervention), which would reduce smoking prevalence by nearly 8pp between 2007 and 2021 (from approximately 23% of daily smokers in 2007), corresponding to an average reduction of 0.57pp annually.

Eurobarometer⁴⁹⁶ results⁴⁹⁷ in relation to smoking prevalence suggest that across the EU and the UK, there has been a 9pp decline between 2006 and 2020 in the proportion of those who smoke (from 32% to 23%), corresponding to an average reduction by 0.64pp per year. This trend appears to roughly confirm the baseline forecasted in the support study for the TPD impact assessment, although it is not possible to make any reliable comparisons, given the different data sources used. The same Eurobarometer shows a 2pp decline in smoking prevalence between 2020 and 2017 in the EU-27, which, with an annual average of 0.67pp per year, is slightly higher than the baseline trend, and which may potentially be attributed to the TPD (which was expected to be applied in practice in the Member States by May 2016, with transitional provisions up to May 2017 for some products). Using the same assumptions as the support study for the TPD impact assessment, this difference of 2% should thus result to a 1% reduction in predicted mortality, morbidity and costs of smoking by the year 2033.

In addition to overall effects on health, a reduction in smoking behaviour in certain population groups will also help to reduce health inequities. A 2014 guidance document from the WHO estimated that mortality from smoking-related conditions accounted for 22% of the overall inequities in death rate from any cause among men, and 6% among women⁴⁹⁸. The extent to which the TPD has contributed to a reduction in inequities (and their costs) cannot be calculated, however. Similarly, other important cost savings (e.g. reduced law enforcement costs due to the availability of new tools to fight the illicit trade in tobacco products, increased revenue from sanctions and confiscations) cannot be quantified.

It is not yet possible to provide an economic assessment of whether the benefits to society outweigh the costs faced by all actors. However, the qualitative evidence collected⁴⁹⁹ suggests that this may have been the case, to a certain extent. Half of the Member States surveyed reported that the benefits of the TPD to society outweighed the costs (10 countries fully agreed, and four countries agreed with this statement to some extent). Some of the comments supporting this statement referred to the fact that the benefits outweighed the cost (mortality, morbidity but also attributable social-economic costs), with examples provided below.

- In one Member State, a cost evaluation study estimated social tobacco use cost at €120 billion in 2015. That cost evaluation considered the lost quality of life and years lived. The tobacco use reduction not only had an impact on mortality and morbidity but decreased social costs.
- Some other benefits highlighted referred to the fact that the TPD creates substantial added value at EU level and helps to protect human health and consumers’ safety, thus administrative costs can be justified by the higher aim of protecting public health and consumers’ safety. One Member State

⁴⁹⁶ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

⁴⁹⁷ Based on a different data collection method than the WHO report and hence showing different % in terms of prevalence.

⁴⁹⁸ WHO (2014). Tobacco and inequities – Guidance for addressing inequities in tobacco-related harm.

⁴⁹⁹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

considered the observation period since the Directive entered into force to be too short to draw any serious conclusions.

- In another Member State, overall, smoking-attributable costs represented 3.5% of the total Compulsory Health Insurance Fund, whereas social security system costs represented around 1% of the total budget. The TPD was considered to help to reduce smoking prevalence, with benefits outweighing the costs of implementing the TPD.

4.3.2 EQ8: To what extent have the administrative requirements been flexible for catering to the needs of SMEs active in the industry?

The evaluation question explores the extent to which the administrative requirements imposed by the TPD considered the characteristics of SMEs⁵⁰⁰ and potential challenges that those industries could face when complying with the requirements of the TPD provisions (avoiding market distortions).

The evidence collected through this study suggests that flexibility to cater to the needs of SMEs has been limited, although the evidence is scarce.

4.3.2.1 Flexibility of administrative requirements for SMEs

The response to this assessment question draws on the literature review, information gathered from the surveys of Member State NCAs and industry, as well as interviews with operators and Member States. The evidence suggests that some Member States provided specific support to SMEs, including establishing a helpline, disseminating information materials and organising coordination meetings. However, the SMEs that responded to the economic stakeholders' survey⁵⁰¹ were largely negative about the additional supports and flexibility of Member State authorities in relation to the new TPD requirements. More than half (56%) considered that the TPD did not allow for sufficient flexibility for SMEs and pointed out that the implementation of the TPD was overly complex and costly for SMEs, while favouring large cigarette companies. General comments highlighted that the characteristics of mid-sized and smaller companies were ignored by the TPD. A large share (74%) were not aware of any specific supports for SMEs (Table 32). According to respondents, 15% received support, but this was likely to be general support provided to industry, rather than specifically to SMEs.

Table 28. Specific support provided to SMEs

Response given	Number of Member States
Yes	4
Yes, to some extent	5
No	12
Did not respond to the survey or the specific question	6

Source: Overview of replies to the survey question – 'Has your Member State provided any specific support to small and medium enterprises affected by the TPD?'

⁵⁰⁰ Note that Art. 6(5) exempts SMEs from the priority list of additives and enhanced reporting obligations required in Art 6, if a report on that additive is prepared by another manufacturer or importer.

⁵⁰¹ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

Table 29. Overview of SME industry responses to survey

Survey question	Overview of responses
Does the TPD allow for sufficient flexibility to cater to small and medium enterprises? For example, in relation to Art. 6(5) exempting small and medium enterprises from provisions on priority lists of additives and enhanced reporting obligations	56% responded no; 33% did not know
Are you aware of any support available for SMEs from the Member States to implement specific provisions of the TPD?	74% responded no; 22% did not know
Have you received any support from the MS to implement specific provisions of the TPD?	48% said no 19% said they do not know 15% received some support

Source: Overview of SME replies to the industry survey. 26 organisations responded to the selected survey questions. 22 of these organisations had less than 50 employees, while the remaining four had 50-250 employees.

4.3.2.2 Costs and administrative requirements for SMEs

Several studies highlighted the costs faced by SMEs and the need for flexibility in administrative requirements. This is especially relevant in relation to the traceability and security features systems, where SMEs claimed to face a disproportionate level of costs per production unit.

One study carried out prior to the implementation of the TPD noted that the legislation was expected to increase the cost of producing e-cigarettes and e-liquid, leading to the departure of SMEs from the market. This would lead to a consolidation of the market in favour of larger economic operators⁵⁰². Research indicates that from 2012 onwards, transnational tobacco companies did begin buying leading manufacturers of novel nicotine delivery systems, including e-cigarettes and later, HTPs, and investing in those that could provide competitive advantages (e.g. via patent rights or distribution networks)⁵⁰³.

Members of DG SANTE's subgroup on traceability and security features noted that the costs borne by tobacco companies should be proportionate to their market share, and DG SANTE confirmed that particular attention was paid to SMEs when assessing the financial aspects of those measures⁵⁰⁴. Another study noted that the burden of these features fell almost entirely on the tobacco industry, with limited costs for Member State authorities⁵⁰⁵.

Some examples of the costs faced by SMEs are highlighted below, the majority of which relate to the implementation of the traceability system.

⁵⁰² IFF Research. (2016). Understanding the Online E-cigarette market. HM Revenue and Customs.

⁵⁰³ Mathers, A., Hawkins, B., & Lee, K. (2019). Transnational Tobacco Companies and New Nicotine Delivery Systems. American Journal of Public Health, 109(2).

⁵⁰⁴ DG SANTE (2017). Meeting of the Subgroup on traceability and security features Summary Record of 22 June 2017.

⁵⁰⁵ Borkowski, F. & Twomey, C. (2019). European Union: Confronting Illicit Tobacco Trace: An Update on EU Policies. In: Confronting Illicit Tobacco Trade: a Global Review of Country Experiences. WBG Global Tobacco Control Program Washington, D.C.: World Bank Group. Available at: <http://documents.worldbank.org/curated/en/677451548260528135/Confronting-Illicit-Tobacco-Trade-a-Global-Review-of-Country-Experiences>.

- In one Member State, implementation of the TPD introduced proportionately higher costs on SMEs, in particular for the traceability system (Art. 15). One respondent representing economic operators highlighted that SMEs could not afford the computer equipment and did not receive assistance from the government⁵⁰⁶;
- Another Member State highlighted the proportionately higher level of costs related to the traceability and security features systems for SMEs compared to larger companies. Regulations related to reporting and warning systems were challenging for SMEs to implement. SMEs sought exemptions but had to comply fully with the regulations⁵⁰⁷.
- In another Member State, a key issue for SMEs was not having adequate access to guidance and legal assistance, for example, how to notify a product before putting it in the market⁵⁰⁸.
- In a final Member State, SMEs without a dedicated IT infrastructure had less capacity to collect data and process submissions. While no figures are available, it appears that some SMEs were merged or acquired to better cover the compliance costs of the TPD⁵⁰⁹.

4.3.2.3 Member State supports for SMEs

The Member States surveyed⁵¹⁰ indicated whether or not they provided specific support to SMEs affected by the TPD, and about 43% had provided support in a variety of forms and to varying degrees. This included **technical supports** to comply with the requirements, **information sessions and** meetings, and a helpline/email support.

- In one Member State, specific information for SMEs was disseminated through the monopoly agency and the Chamber of Commerce;
- In another Member State, the Ministry of Health, Directorate of Health and the Administration of Customs and Excise Tax offered a helpline and email support to SMEs.
- In a third Member State, support was limited to the introduction of the traceability and security features systems. The new requirements were communicated to SME operators through a helpdesk.

Over half of the economic operators (56%) considered that the support provided to implement the TPD was not specifically adapted to SMEs, while 74% indicated that they were unaware of any specific support for SMEs being made available in the Member State(s) in which they were active.

⁵⁰⁶ Interview with economic operator (4).

⁵⁰⁷ Interview with competent authority.

⁵⁰⁸ Interview with competent authority.

⁵⁰⁹ Interview with competent authority.

⁵¹⁰ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

4.4 Coherence

Main findings: Overall, stakeholders agreed that the TPD is broadly coherent internally, with other relevant EU legislation, and with the FCTC. However, a few inconsistencies were identified at each of these levels:

- **Coherence of TPD provisions**
 - The TPD provides certain stricter rules for cigarettes and roll-your-own tobacco, for example in relation to flavours.
 - Although devices used for the consumption of e-liquids are covered by the definition in the TPD, those used to consume heated tobacco are not, creating an inconsistency in the regulation of devices used to consume products containing tobacco or nicotine.
- **Coherence of TPD with other EU legislation**
 - Product definitions used in the TPD are sometimes different to those used in other legislation related to advertising and sponsorship, although in some cases stakeholders noted that those used in the TPD are preferable.
 - CBDS of products, while permitted under the TPD, may be inconsistent with regulations on online advertising.
 - Inconsistencies on whether information on alternatives to single-use plastics could be construed as advertising.
- **Coherence of TPD with FCTC: Potential for industry involvement or influence in some areas regulated by the TPD was claimed to be inconsistent with FCTC and ITP obligations, particularly in respect of traceability and security systems.**

This criterion seeks to understand the extent to which the TPD is still coherent and consistent internally, i.e. with its own provisions, as well as with other relevant EU and international legislation linked to the TPD.

4.4.1 E.Q9: Have the TPD provisions been intrinsically coherent and complementary with each other?

This evaluation question explores whether provisions within the TPD are consistent with one another or whether there have been any challenges associated with incoherencies between the provisions of the TPD.

4.4.1.1 Internal coherence of TPD

The TPD provisions largely complemented each other and remain coherent, although minor inconsistencies were reported.

From the perspectives of key stakeholders, TPD provisions are generally internally consistent. In the questionnaire to Member States⁵¹¹, five NCAs reported facing significant issues with inconsistent TPD provisions, while the majority reported no such issues (13) or only to a certain extent (two). Similarly, nearly half of industry respondents⁵¹² and over half of CSO and HE⁵¹³ survey respondents either strongly agreed or somewhat agreed that TPD measures were internally coherent with one another, with only 2% of industry respondents and 5% of CSO and HE respondents strongly disagreeing.

⁵¹¹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵¹² ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵¹³ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

However, there are a few areas where there is perceived incoherence in TPD provisions. The **different treatment of cigarettes and roll-your-own tobacco versus e-cigarettes and HTPs** (based on the scope of the TPD with respect to these categories of products) was seen as inconsistent, **particularly with respect to regulations on flavours**. The resulting difference in which products are permitted to have characterising flavours was identified as incoherent by three Member States and more than 10% of CSOs and HEs surveyed⁵¹⁴.

This discrepancy in how different types of products are treated by the TPD also caused a perceived **lack of coherence in relation to product labelling**. Characterising flavours are prohibited in tobacco products by Art. 7(1), however there is a derogation to this clause in Art. 7(12), which exempts tobacco products other than cigarettes and roll-your-own tobacco. Packaging provisions are considered distinctly to flavour provisions, and Art. 13(1)(c) prohibits packaging from including information about flavour. Several economic operators reported their dissatisfaction with the fact that flavours continue to be permitted, while packaging cannot include information about flavour. However, the only way to resolve this would be to remove the exemption and prohibit characterising flavours in other tobacco products. E-cigarettes are also considered distinctly to these provisions, and Art. 20(4)(b) exempts e-cigarettes from the ban on flavouring information in Art. 13(1)(c). These perceived instances of incoherence were highlighted by about 15% of industry representatives and two Member State survey respondents⁵¹⁵. Some Member States and economic stakeholders also reported issues in relation to **e-cigarette warnings**, particularly the lack of clarity on what information leaflets should include, the information on the outside packaging, and the types of products (e.g. refill containers) that need to be labelled.

Lastly, **devices** used in the consumption of the novel tobacco product but not connected to tobacco itself, are left unregulated, and Member States considered this a loophole in current EU legislation. In a parallel study, similar confusion and inconsistency related to HTP devices was noted for advertising, promotion and sponsorship rules not in the scope of the TPD⁵¹⁶. This incoherence in the regulation of tobacco-related products that do not contain nicotine was mentioned by two Member States that responded to the survey⁵¹⁷.

4.4.2 E.Q10: To what extent is the TPD coherent with other relevant EU legislation on tobacco and related products?

This evaluation question explores whether provisions within the TPD are consistent with other EU legislation.

The TPD provisions are largely coherent with other relevant EU legislation, although there are some perceived inconsistencies that require clarification.

There are many pieces of EU legislation and the TPD is generally coherent with those other directives. When asked directly about the coherence of the TPD and different EU-level legislation, eight Member States surveyed stated that they had not faced any

⁵¹⁴ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵¹⁵ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵¹⁶ Study on smoke-free environments and advertising of tobacco and related products (ongoing).

⁵¹⁷ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

issue in terms of a lack of coherence⁵¹⁸. A detailed breakdown of stakeholders' views on the coherence of TPD and other relevant EU legislation is provided in Table 30 and summarised below.

Industry representatives that responded in respect of specific pieces of EU legislation reported strong coherence between the TPD and the Smoke Free Environments Recommendation (0% disagreed), Market Surveillance Regulation (0% disagreed), Audio-visual Media Services Directive (AVMSD; 0% disagreed), the Tobacco Taxation Directive (4% disagreed), the TAD (4% disagreed), the General Product Safety Directive (4% disagreed) and REACH Regulation (6% disagreed). However, more industry representatives disagreed that the TPD is coherent with the SUP Directive (13% disagreed) and CLP Regulation (16% disagreed)⁵¹⁹. CSO and HE respondents to the survey tended to say that the TPD was incoherent with more pieces of EU legislation, but generally agreed that the TPD was coherent with the Smoke Free Environments Recommendations (2% disagreed), REACH Regulation (5% disagreed), Market Surveillance Regulation (5% disagreed), the CLP Regulation (5% disagreed), and the General Product Safety Directive (7% disagreed). However, more CSO and HE respondents disagreed that the TPD is coherent with the SUP Directive (42% disagreed), Tobacco Taxation Directive (37% disagreed), the TAD (35% disagreed) and the AVMSD (33% disagreed)⁵²⁰.

One of the main issues identified in respect of a lack of coherence between the TPD and other pieces of EU regulation⁵²¹ was the potential incoherence between definitions of 'placing on the market' and terms such as 'hazard' and 'risk' between the TPD and CLP regulation (mentioned by two Member States). Several respondents in both categories pointed to the advantages of the TPD definitions compared to other pieces of EU legislation, and **the need to update definitions in other regulations, although there are also areas where the TPD's definitions may be improved (see the Tier 1 section of this report, on Art. 2)**.

There was potential for incoherence between several pieces of EU legislation and the **packaging and labelling requirements** set out in the TPD. Industry representatives responding to the survey⁵²² noted that the overlapping regulations contradicted one another and that the physical space on products (especially e-cigarette refills, where CLP Regulation and REACH Regulation also apply) did not allow for both sets of regulation to be implemented. In particular, they pointed to a lack of harmonisation between the TPD and the CLP regulation. Lastly, there was a general lack of understanding about **how TPD provisions on herbal products for smoking** (Art. 21 and 22) interact with other EU-level regulations.

⁵¹⁸ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵¹⁹ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵²⁰ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵²¹ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵²² ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

Table 30. Coherence of the TPD and other EU legislation, according to Member States, economic stakeholders, CSOs and HEs⁵²³

Regulation	Member States	Economic stakeholders	CSOs and HEs
CLP Regulation		<p>More likely to agree that the CLP and TPD are coherent than to disagree (44% strongly or somewhat agreed, compared to 16% somewhat or strongly disagreed).</p> <p>Eight respondents reported that e-cigarette manufacturers need to comply with both the TPD and CLP Regulation when labelling products, but they are not aligned with one another.</p> <p>Two reported that different requirements between the TPD and CLP Regulation cause issues in terms of the physical space available on packaging.</p>	<p>More respondents agreed that the TPD is consistent with CLP Regulation than disagreed (30% somewhat or strongly agreed, compared to 5% somewhat or strongly disagreed).</p>
REACH Regulation	<p>One Member State reported that Art. 7 of the TPD refers to REACH, which is not designed for products that are intentionally inhaled or consumed, and which has a tonne limit inappropriate for the tobacco sector.</p>	<p>Of those that provided a view, most viewed the TPD as coherent with REACH⁵²⁴ (only 6% somewhat disagreed).</p> <p>Five respondents reported that e-cigarette manufacturers need to comply with both the TPD and REACH when labelling</p>	<p>More survey respondents agreed that the TPD is coherent with the REACH than disagreed (21% strongly or somewhat agreed, compared to 5% somewhat or strongly disagreed).</p>

⁵²³ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵²⁴ Nearly half (48%) of respondents provided a view on whether the TPD is consistent with REACH.

Regulation	Member States	Economic stakeholders	CSOs and HEs
SUP Directive	<p>A few Member States noted potential inconsistencies between packaging provisions in the TPD and the SUP Directive.</p> <p>The SUP Directive requires consumers to be informed about reusable alternatives, while the TPD may prohibit this due to the promotion of reusable alternatives amounting to tobacco promotion.</p>	<p>products, and they are not aligned with one another.</p> <p>More economic stakeholders agreed that they are coherent than disagreed, although views were mixed⁵²⁵ (23% somewhat or strongly agreed, while 13% somewhat or strongly disagreed).</p> <p>Ten respondents reported that the TPD requirements on packaging and labelling are incoherent with the requirement to report plastics and recycling information as per the SUP Directive, particularly due to physical space constraints on packaging and because of TPD prohibition on promotional markings.</p>	<p>More respondents disagreed that the TPD is coherent with the SUP Directive than agreed (42% somewhat or strongly disagreed, compared to 12% somewhat or strongly agreed).</p> <p>Several independent CSOs and one HE reported a loophole in the SUP Directive that may allow the tobacco products industry to promote tobacco products through merchandise and corporate responsibility claims, which runs contrary to the TPD.</p>
TAD	<p>A few Member States reported inconsistencies between the TPD and the TAD in respect of the definition of tobacco products and advertising and promotion.</p>	<p>Half of all respondents provided a view on whether the TPD is coherent with the TAD, nearly all of whom agreed or strongly agreed that they are coherent (46%).</p>	<p>A similar proportion of respondents agreed and disagreed that the TPD is coherent with the TAD (33% strongly or somewhat agreed, and 35% somewhat or strongly disagreed, with the remainder stating they did not know or preferred not to say).</p>

⁵²⁵ Only about one-third (36%) of respondents provided a view on whether the TPD is coherent with the SUP Directive.

Regulation	Member States	Economic stakeholders	CSOs and HEs
Tobacco Taxation Directive	A few Member States reported inconsistencies between the TPD and the Tobacco Taxation Directive with respect to definitions in the two directives.	<p>Of those that provided a view, most economic operators reported that the TPD was coherent with the Tobacco Taxation Directive. One-third (33%) of respondents strongly agreed that the TPD is coherent with this legislation; a further 12% somewhat agreed.</p> <p>One respondent reported that there is inconsistency in how the Tobacco Taxation Directive and the TPD treat different categories of products, with the Tobacco Taxation Directive not differentiating between traditional and novel tobacco products.</p>	<p>More survey respondents disagreed that the TPD is coherent with the Tobacco Taxation Directive than agreed.</p> <p>Only 9% of survey respondents strongly agreed that the TPD is coherent with this legislation; a further 21% somewhat agreed. On the other hand, 37% of respondents somewhat disagreed that the TPD is coherent with the Tobacco Taxation Directive. The remainder either did not know or preferred not to say.</p> <p>12 respondents reported inconsistencies in the definitions in the TPD and the Tobacco Taxation Directive.</p>
AVMSD	No information was provided by Member States on inconsistencies and incoherencies between the TPD and AVMSD.	All of those that provided a view agreed or strongly agreed that they are coherent. Over one-third (40%) of respondents strongly agreed that the TPD is coherent with this legislation.	More survey respondents disagreed that the TPD is coherent with the AVMSD than agreed.

4.4.3 E.Q11: To what extent is the application of the TPD in compliance with rules and policies of the WHO FCTC guidelines?

This evaluation question explores whether provisions within the TPD are coherent with the WHO FCTC guidelines.

The TPD has been largely consistent with the WHO FCTC, although some stakeholders perceived a lack of coherence with respect to the TPD complying with the independence criteria of WHO FCTC guidelines.

The TPD has been largely consistent with the WHO FCTC, including the ITP. When asked about coherence between these two measures in the survey, most Member States reported no issues with coherence. In addition, the majority of industry representatives (56%) either agreed or strongly agreed that they were coherent, along with about one-third (30%) of CSO and HE respondents⁵²⁶.

There are, however, **several areas where the TPD has possibly not complied with the rules and policies of the WHO FCTC and its Protocol on Illicit Trade in Tobacco Products**. The WHO FCTC specifies that Parties **shall - in setting and implementing their public health policies with respect to tobacco control - protect these policies from commercial and other vested interests of the tobacco industry** (Art. 5(3) FCTC). However, the traceability measures in Art. 15 of the TPD requires the tobacco industry to carry out certain tasks, which was perceived by some stakeholders (mainly CSOs) to be incoherent. For instance, Art. 15(8) specifies that manufacturers and importers of tobacco products will 'conclude data storage contracts with an independent third party' and that these third parties will be monitored by an 'external auditor, who is proposed and paid by the tobacco manufacturer,' although these auditors also need to be approved by the European Commission. This perceived incoherence was mentioned by a small number of Member States (although not all Member States have ratified the WHO FCTC Protocol on Illicit Trade) and a large number of CSO and HE survey respondents⁵²⁷. However, despite these concerns (see Tier 1 assessment of Art. 15 and 16), many Member States also felt that there was sufficient independence of traceability and security features measures from the tobacco industry⁵²⁸, and a chapter in a World Bank review listed a series of measures aimed at protecting the traceability system from vested interests⁵²⁹.

Several Member States expressed concerns that the **ability of Member States to exempt products other than cigarettes, roll-your-own tobacco and waterpipe tobacco from requirements around labelling** (as per Art. 11(1) of the TPD) has caused issues in complying with WHO FCTC guidelines. Some Member States suggested that these exemptions were based on political pressure from industry, rather than scientific evidence and best practice, which would be in violation of the WHO FCTC guidelines on the independence of tobacco regulation from industry

⁵²⁶ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵²⁷ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵²⁸ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵²⁹ Borkowski, F. & Twomey, C. (2019). European Union: Confronting Illicit Tobacco Trace: An Update on EU Policies. In: Confronting Illicit Tobacco Trade: a Global Review of Country Experiences. WBG Global Tobacco Control Program Washington, D.C.: World Bank Group. Available at: <http://documents.worldbank.org/curated/en/677451548260528135/Confronting-Illicit-Tobacco-Trade-a-Global-Review-of-Country-Experiences>.

influence. The potential influence of the industry on the TPD was also highlighted in the literature as a concern⁵³⁰.

Finally, there was a potential perceived incoherence between the **WHO FCTC's call to integrate scientific evidence and best practices in tobacco control, and the methods set out in the TPD to measure TNCO emissions of tobacco and related products** (see discussion in Tier 1 section on ingredients and emissions). Art. 4(1) of the TPD specifies that ISO standards will be used for measuring emissions. ISO standards have (potentially) not kept pace with scientific evidence and best practice in measuring emissions, which several CSOs and HEs perceived as a potential failure to adhere to the WHO FCTC. Several stakeholders from NCAs within Member States speculated that the use of the ISO standard is linked to industry pressure, which would be in violation of WHO FCTC guidelines⁵³¹. The WHO itself reflected similar concerns around ISO standards, highlighting the influence that the industry exerts on ISO testing methods for tobacco and related products, particularly through technical committees. In response to the potential for the ISO testing method to result in 'misleadingly low levels of the measured compounds', WHO established the WHO Tobacco Laboratory Network to develop improved methods for measuring emissions⁵³². There is, however, international consensus, that none of the currently used TNCO measurement methods adequately reflect real smoking behaviour, nor is there any guidance or recommendation on which method to use.

⁵³⁰ Hawkins, B. and Holden, C. (2018). European Union implementation of Article 5.3 of the Framework Convention on Tobacco Control. *Globalisation and Health*, 14, 79.

<https://doi.org/10.1186/s12992-018-0386-1>.

⁵³¹ ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵³² World Health Organization. (2020). Information sheet on WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products. Available at: <https://apps.who.int/iris/rest/bitstreams/1272036/retrieve>.

4.5 EU added value

Main findings: While it may be too early to conclude on the extent to which the TPD has contributed to public health, it has clearly generated a number of significant positive outcomes for public health and the internal market. It has also strengthened consumer protection and positively contributed to efforts to reduce smoking prevalence and the use of tobacco and related products in the EU. It has brought further harmonisation of Member States' legislation, reduced the fragmentation of the internal market, facilitated its functioning, and allowed the EU to play a pivotal role in coordinating and supporting Member States' action.

Looking at the benefits to the internal market and coordination, it is clear that these outcomes cannot be achieved by Member States acting alone.

While similar public health outcomes could theoretically be attained by Member States alone, the EU facilitates their achievement by providing political, legal and technical support and allowing for action at a greater scale.

E.Q12: To what extent has the legislative framework at EU level added value to the regulation of tobacco and tobacco-related products across the EU, in a manner that could not have been achieved at national level?

4.5.1 Main outcomes delivered by the TPD and its implementation

The TPD has helped to promote public health.

It is still too early to draw conclusions on the overall effect of the TPD on public health, especially since the ban on characterising flavours has only been fully applicable since May 2020. The latest 2021 Eurobarometer shows a reduction in smoking prevalence, including among young people, but no clear change in the use of other tobacco products and tobacco-related products⁵³³. It is not yet possible to clearly link the TPD to any of these trends. However, some key changes brought by the TPD are widely regarded by various stakeholders as having positively contributed to **furthering the protection of EU citizens' health**⁵³⁴.

The introduction of combined **health warnings** on tobacco products for smoking and the increase in their size (Art. 10) is cited by most stakeholders in the surveys⁵³⁵ and targeted interviews as the main contribution of the TPD to public health. These new rules have been effectively implemented and offer encouraging preliminary results in increased consumer awareness of health warnings and perception of the harmfulness of tobacco products⁵³⁶.

The **ban on characterising flavours** in cigarettes and roll-your-own tobacco (Art. 7) is considered one of the major contributions of the TPD to public health, especially in protecting young people from smoking initiation. Considering that the prohibition on the use of menthol flavouring has only been applicable since May 2020, it is too early to draw any significant conclusion on its actual effect, but past evidence allows a

⁵³³ DG SANTE (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>; see Annex 3 for further information.

⁵³⁴ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵³⁵ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵³⁶ See the answers to E.Q3 above.

degree of confidence in its likely contribution to lowering smoking uptake and smoking rates⁵³⁷.

Among the various aspects of the TPD that have helped to protect public health is the regulation of **ingredients** and the common **reporting obligations** (Art. 5, 6, and 7), in particular the prohibition of CMR ingredients and the presence of the first EU-wide framework for the regulation of **e-cigarettes (Art. 20)**, in particular the limits of recharges, tanks and nicotine concentration, the prohibition on additives (including vitamins, caffeine, and additives with CMR properties) in e-liquids and the child-proof tampering regulations.

The TPD has helped to achieve harmonisation across the Member States, which contributed to a better functioning of the internal market.

Prior to the entry into force of the TPD, discrepancies between Member States constituted obstacles to trade, impairing the proper functioning of the internal market. The dynamic nature of the market for tobacco products made further regulatory fragmentation likely to occur. The TPD sought to eliminate these discrepancies. Despite the existence of some gaps and unclear elements in the Directive, stakeholders' widely acknowledged⁵³⁸ (economic operators to a lesser extent⁵³⁹) that the TPD has effectively achieved a **greater level of harmonisation** of Member States' legislation and contributed to **better functioning of the internal market**.

This is particularly true for the rules on **packaging and labelling (Art. 8-14)**, where divergences were clearly noticeable prior to the TPD, the TPD provides a high level of harmonisation and has established clear guidance and regulations on health warning labels, with a few minor clarity issues. It is also the case for rules on **e-cigarettes (Art. 20)**, where no common legal framework existed prior to the TPD. The rules on **emissions and ingredients (Art. 3-7)**, **traceability and security features (Art. 15 and 16)** and **novel tobacco products (Art. 19)** are also regarded as significant in the better functioning of the internal market, although not without their faults and implementation challenges (see earlier sections).

The EU has played a coordinating role and facilitated the achievements of the objectives of the TPD.

The TPD has allowed Member States to cooperate with one another more closely and to benefit from the coordination efforts and support provided by the European Commission. Most Member States reported benefitting from it, especially those with less technical expertise and fewer resources available, and which sometimes reported difficulties in meeting their obligations under the TPD. Most stakeholders, including CSOs and HEs, see this **cooperation and coordination as one of the great successes of the TPD**.

An example often cited concerns the **JATC**, which was welcomed by Member States as a very useful initiative to help them to assess, treat and share the information received on ingredients and emissions, and for enforcement purposes. Most Member States also expressed strong satisfaction with the **Group of Experts on Tobacco Policy** and the guidance it has provided for the transposition of the Directive.

⁵³⁷ Chatton, M.O, Nicolau, I., Schwartz, R., et al. (2020). 'Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1 year: a population cohort study'. *Tobacco Control*, 29, 341-347; Zatoński, M., Herbeć, A., Zatoński, W, et al. (2018). 'Characterising smokers of menthol and flavoured cigarettes, their attitudes towards tobacco regulation, and the anticipated impact of the Tobacco Products Directive on their smoking and quitting behaviours: The EUREST-PLUS ITC Europe Surveys'. *Tobacco Induced Diseases*, 16(2), 4.

⁵³⁸ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵³⁹ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

4.5.2 Possibility to reach these outcomes without action at the EU level

The TPD generated significant outcomes that would not have been achieved through Member States acting alone.

This is particularly true of the TPD's contribution to **better functioning of the internal market** and **better coordination** between Member States. These are objectives that, by definition, can only be achieved through action at EU level. It is doubtful that cooperation between Member States outside the framework provided by the EU would have yielded the same results. This EU added value is evident in the benefits brought by a **joint EU system and database for the regulation of ingredients and emissions**⁵⁴⁰.

Regarding the benefits for the protection of **public health**, in terms of reduced mortality, morbidity and also social-economic costs attributable to tobacco⁵⁴¹, it can be concluded that similar outcomes would not have been achieved through Member States acting alone. While nothing formally prevented Member States from pursuing an independent and ambitious tobacco control policy in the absence of harmonisation measures, it is unlikely that **a degree of protection similar to that provided by the TPD would have been achieved by Member States acting alone**. First of all, Member States' rules diverged prior to the entry into force of the TPD and continue to diverge in areas that are not harmonised by the TPD. **Political willingness** to enact strict tobacco control measures **can vary, often considerably, between Member States**. Action at EU level helped to mainstream the level of protection for all EU citizens and residents and helped certain Member States to overcome domestic political opposition.

Action at EU-level also helped Member States who wished to enact stricter tobacco control measures but were rebutted by **tobacco companies' opposition** and/or threat of legal challenges. This is evident in Member States' experiences with plain packaging and e-cigarette flavours. The difficulties experienced by Member States when acting alone and the value of EU-level action can be illustrated with two initiatives in tobacco control that are currently left to Member States' discretion: **plain packaging** and **banning flavours in e-cigarettes**. The case studies show that some Member States have not yet adopted these rules due to domestic difficulties, industry opposition, or simply lack of scientific evidence, rather than due to a lack of political will. In view of these considerations, a number of Member States favour action at the EU level. Plain packaging and a full ban of flavours are now being considered by the European Commission for further harmonisation⁵⁴².

Relevant findings of case study 2 on e-cigarette flavours

Member States that implemented e-cigarette flavour bans faced substantial challenges, with companies selling liquids that can be used in e-cigarettes at times circumventing bans by portraying them as foodstuffs. Additionally, Member States have limited capacity to keep abreast of the large number of e-cigarettes that are notified to them. An EU-wide e-cigarette flavour ban would potentially address some of these challenges.

- The full case study can be found in Annex 9.

⁵⁴⁰ See the case study on a European system for the regulation of ingredients used in tobacco products.

⁵⁴¹ See E.Q7 above.

⁵⁴² European Commission (2021). 'Europe's Beating Cancer Plan', Communication from the Commission to the European Parliament and the Council, COM(2021) 44 final, p. 9.

Relevant findings of case study 4 on plain packaging

- The major impediment highlighted by Member States that have not yet introduced plain packaging was the threat of legal action by tobacco companies and the depth of resources required to counter such action.
- Most countries support EU-level legislation for plain packaging, believing it would represent an important facilitator in helping to overcome some of the national barriers to introducing plain packaging and harmonising the (currently) fragmented regulations across the EU.
- The full case study can be found in Annex 9.

One Member State stated that a regulation would have been preferable to a directive, as this would have avoided differences between the Member States (including in transposition periods).

Finally, there is an inherent value in having one overarching piece of legislation regulating tobacco products and tobacco-related products in terms of coherence and effectiveness of tobacco control.

5 Conclusions

The implementation and transposition of the TPD was overall a success. Problems encountered by Member States to transpose the Directive were moderate. *Compliance* with the Directive has overall been appropriate with some variations, however, there were a number of issues with non-compliance by economic operators, leading to impaired effectiveness and outcomes. A high number of Member States reported problems with fully *implementing* the Directive due to lack of capacity, expertise and resources, as well as certain challenges brought through diverging interpretation, definitions and scope of the Directive.

Implementation of the TPD is an achievement that would not have happened at this pace at national level, and with the same high level of EU-wide harmonisation of minimum standards and requirements. Additionally, the flexibility of the TPD to allow Member States to maintain or introduce further requirements, such as plain packaging, has led to further legislation being implemented in several Member States with the goal of further protecting public health.

Effectiveness

The structures and procedural arrangements of the TPD facilitated the transposition of the TPD; Member States found guidance clear and were able to fulfil the obligations to transpose the TPD with some problems and variations. Member States have also largely fulfilled their obligations to apply the TPD in practice, with some problems and enforcement issues. Generally, economic stakeholders have complied with the rules and provisions set by the Directive, however non-compliance with a number of provisions, such as demonstrated for Art. 18, impaired effectiveness.

The application of the TPD facilitated the internal market, particularly regarding labelling and packaging, although difficulties were highlighted with CBDS, possibly hindering effectiveness of EU-wide rules.

Although it is too early to conclude on to what extent the TPD has improved public health and contributed to the downward trend in tobacco use in the EU, there is some evidence that awareness of harmful effects of tobacco has increased, and the overall prevalence of smoking and tobacco use has mostly decreased. It was not possible to determine to what extent decreases can be attributed specifically to the TPD. Evidence collected as part of this study does, however, conclude that certain provisions, such as the prohibition on characterising flavours in cigarettes, and the packaging and labelling provisions contributed positively towards improving public health.

In terms of the outputs and outcomes of the TPD, the legal provisions concerning tobacco and related products have mostly been harmonised across Member States, and Member States have made use of opportunities to implement additional requirements. The latter in most cases have not created obstacles to the successful implementation and harmonisation of TPD standards (however stakeholders did report that in a few cases, for example plain packaging, harmonisation could be improved). It may be too early to draw conclusions on whether the TPD has established effective systems to reduce illicit trade.

Relevance

The TPD has made significant achievements in addressing identified needs related to the regulation on tobacco and related products, but, in some areas, has not remained relevant due to the rapid development and diversification of the market.

The TPD has overall addressed the need for minimum regulation and led to harmonisation and minimum standards across the EU for regulating health warning labels, packaging formats, maximum emission levels, characterising flavours for cigarettes and roll-your-own tobacco, ingredients and additives, traceability and

security features. The flexibility the TPD provides in permitting Member States to go beyond the certain provisions outlined maintains its relevance; where Member States have used this flexibility, they provide an example that others can follow, resulting in other Member States implementing new policies.

The implementation of the TPD traceability and security features systems have addressed the need to reduce the availability of illicit tobacco products, although it is too early to evaluate the outcomes of these systems. A significant issue remains with cross-border flow of products that are permitted in some Member States and not in others, an issue particularly pertinent for countries that border with non-EU countries.

The TPD has addressed the need to reduce the use of traditional tobacco products by young people, but due to the internal inconsistencies in the TPD relating to the treatment of different products, particularly e-cigarettes and novel tobacco products, it has not addressed the broader use of tobacco or nicotine-containing products by this age group to the same degree. Additionally, allowance of CBDS without a harmonised method of age-verification means that this remains a route by which underage people can gain access to these products.

The TPD has met the need to provide a strong basis for the regulation of tobacco and related products across the EU. However, due to the pace at which new products have developed and the market for them has increased, there have been problems with the regulation maintaining its relevance with novel and innovative products. Marketing, labelling and packaging, and sales methods of novel and innovative products have challenged the TPD in remaining relevant to the current market.

Overall, and although relatively small, the market for e-cigarettes, HTPs, and smokeless products has quadrupled since the TPD came into force, accounting for over half of the growth in retail value of the total market for tobacco and related products. Such pace and developments of this market have made it challenging for all aspects of the Directive to remain relevant. Although it forms a strong basis for the regulation of tobacco products, strengthening and adapting regulation of e-cigarettes and novel tobacco products is key to ensuring the TPD remains relevant to future market developments.

Efficiency

The ability to assess the efficiency of the TPD was limited by the availability of information on costs to Member States and economic stakeholders, as well as the lack of data to quantify the public health and societal benefits at the EU level.

Notwithstanding these challenges, the available evidence indicates that the practical implementation of the TPD created an additional financial burden for Member States, both in terms of compliance and enforcement costs. These costs were in most Member States not outweighed by the direct revenue generated from fees and penalties charged to the tobacco industry. A key driver of the administrative costs related to the salaries of staff necessary to ensure implementation and enforcement. The available information on costs and benefits pertaining to compliance and enforcement suggests that their level as well as their composition vary across Member States. Smaller Member States face disproportionate burden in implementing the TPD, the main issue being the insufficiency of human resources.

Economic stakeholders reported to have faced a large increase in costs to implement the TPD, however there is a lack of factual economic evidence to make a proper judgement. Economic stakeholders report to have faced the highest costs for the redesigning of packaging, changing the process for printing and packaging, product re-design and testing to meet reporting obligations.

The study was unable to assess whether the benefits brought by the TPD to society outweighed the overall costs faced by all actors. Key benefits, such as reduced

healthcare costs and health gains as people may be encouraged to reduce or quit smoking as a result of the TPD, or reduced law enforcement costs as new tools to fight the illicit trade in tobacco products become available, could not be quantified, as the degree of to which the TPD impacts on these are complex to determine. Nevertheless, the TPD has several beneficial effects which are increasingly being identified and recognised in the Member States.

The requirements in the TPD were perceived by the affected operators as providing insufficient flexibility for SMEs while the support provided by Member States specifically catered to SMEs was limited. Overall, SMEs reported to face disproportionately higher costs for implementing and complying with the TPD. However, the evidence on this matter is scarce.

Coherence

Overall, the study finds that the TPD is broadly coherent internally, with other relevant EU legislation, and with the FCTC. Although only a few inconsistencies were identified at each of these levels, these warrant close consideration.

For the most part, the TPD provisions are coherent and complementary with each other. However, differential treatment of cigarettes and roll-your-own tobacco compared to other product categories, e-cigarettes and devices designed for consumption of HTPs creates inconsistencies within the TPD which then have an impact on the market. The effect of this differential treatment appears to be particularly strong in relation to packaging and labelling, advertising, and flavouring and may lead to product displacement rather than a reduction in consumption, particularly among young people.

Incoherence between the TPD and other EU legislation, while minimal overall, did create some issues, notably relating to packaging and labelling requirements.

Overall coherence with the FCTC was high. However, there were still a few key areas where CSOs claimed potential inconsistencies, such as the perceived role of industry in the traceability and security features systems. Potential incoherence was also identified with the ability of Member States to exempt products other than cigarettes, roll-your-own tobacco, and waterpipe from labelling requirements.

EU Added Value

The TPD has generated a number of significant positive outcomes for the internal market and public health. It has strengthened the level of consumer protection and positively contributed to the effort to reduce smoking prevalence and tobacco products use in the EU (in particular, labelling and packaging, ban on flavours, regulation of ingredients). It has brought further harmonisation of Member States legislation, reduced fragmentation of the internal market and facilitated its functioning. It has allowed the EU to play a pivotal role in coordinating and supporting Member States.

Regarding the benefits brought by the TPD to the internal market and to Member States coordination, these are outcomes that cannot be achieved by Member States acting alone. Regarding public health, while similar outcomes could theoretically be attained by Member States alone, the EU facilitates their achievement by providing a political (domestic resistance), legal (threat of legal action) and technical support (lack of expertise, resources) and allowing for action at a greater scale.

Annexes

- Annex 1 Analytical Frameworks
- Annex 2 Template used for document review
- Annex 3 Eurobarometer data analysis
- Annex 4 Euromonitor International data analysis
- Annex 5 Substantial change of circumstances
- Annex 6: EU-CEG notification information
- Annex 7: Economic operator survey respondent information
- Annex 8: Field Research – additional data analysis
- Annex 9: Case studies
- Annex 10: Mystery shopping task
- Annex 11 Market developments, public health, and perception information of HTPs
- Annex 12: Bibliography used in this study.

Annex 1 Analytical Framework

At the start of the study, a Tier 1 analytical framework was developed, which set out the TPD articles the present study was to focus on, including article-specific questions and indicators mapped to the consultation tools. However, throughout the course of this study, it became apparent that all key articles of the TPD (Art. 2-24) were important to explore, and the article-specific points of difficulty or focus arose more organically from the desk and field research. The Tier 1 section of the main report is therefore not structured according to the analytical framework and is rather presented as information, which relates to the whole article, followed by in-depth sub-article analysis.

The Tier 2 analytical framework that has guided the study is presented below.

Tier 2: Overall assessment

Tier 2 focuses on the overall assessment of the Directive and its implementation following the five criteria set out below.

- **Effectiveness:** This criterion examines how successful EU legislation on tobacco and related products has been in achieving or supporting progress towards its objectives. The assessment questions on effectiveness aim to understand the extent to which the legislation contributed towards the following:
 - Increased clarity in TPD application, in view of scientific, technological and market developments (Q1 in the analytical framework)
 - Facilitating the smooth functioning of the internal market, relating to tobacco products (Q2);
 - Ensuring a high level of public health protection (in particular for young people) (Q3);
 - Highly effective outputs, outcomes as a result of TPD implementation (Q4).
- **Relevance:** This criterion looks at the relationship between the needs and problems in society and the extent to which the objectives and design of the intervention adequately captured these. In the context of the TPD, the criterion intends to determine if the assessed legislation is still pertinent, adequate and flexible enough to adapt to the continuous evolution and particularities of the sector and market, and national health care services or governments.
 - The assessment questions on Relevance (Q5 and Q6 of the analytical framework) aim at highlighting the extent to which the legislation and its objectives are still relevant and meeting needs, considering scientific, technical and epidemiological developments.
- **Efficiency:** This criterion explores the administrative burdens imposed by the legislation on different stakeholders and their magnitude in relation to the benefits generated. Efficiency considers the relationship between the resources used by an intervention and the changes generated by the intervention (which may be positive or negative). It draws on the available data to explore:
 - The cost-effectiveness of legislative implementation for the public sector (Q7);
 - The economic impact of the legislation on the industry (Q7);
 - The economic burden of requirements on NCAs and other operators (Q7);
 - The clarity of administrative requirements and level of burden for SMEs active in the industry (Q8).
- **Coherence:** The extent to which the legislation is still coherent and consistent internally, i.e. with its own provisions, as well as with other relevant EU and international legislation that is linked to the TPD, is assessed. Specifically, the study explores the extent to which the TPD is:
 - Coherent with its own provisions (also in view of new market, technological and scientific developments) (Q9);
 - Coherent with other relevant EU legislation in this area: (Q10);
 - Coherent with the WHO FCTC guidelines (Q11).
- **EU added value:** The assessment question (Q12) on EU-added value draws on the collective evidence and the findings from the four previous criteria to consider the extent to which the legislation adds value at the EU level, in a way that may not be attainable at a national or global level.

Tier 2: Overall assessment

Assessment question	Sub-question	Judgement criteria	Indicators
Effectiveness			
	To what extent has the transposition guidance for the TPD been clear to MS?	MS have found the transposition guidance for the TPD clear. Economic operators have found the transposition guidance for the TPD clear.	Opinions of MS regulators about clarity of transposition guidance (field research)
Q1. To what extent are the structures and procedural arrangements of the TPD clear about how to Has transposition occurred in all transpose the TPD? MS?		MS have fulfilled obligations to transpose the TPD, with minimal problems/enforcement issues. Member States have fulfilled obligations to apply the TPD, with minimal problems/enforcement issues.	Transposition status of Directive in the MS (desk research-conformity assessment and SANTE internal documentation) Number and types of notifications made by MS, including on ICSMS and Safety Gate systems (data – Safety Gate System / documentation review - Administrative Cooperation Groups (AdCos)) Number of ECJ cases and conclusions from ECJ case law related to TPD transposition (desk research: case law)
	To what extent have all economic stakeholders been compliant with rules and provisions?	Limited non-compliance has been identified for economic stakeholders.	Rate of compliance with TPD, by issue (e.g. warning labels, ingredients) and stakeholder group Opinions from key stakeholders of facilitators and barriers of compliance (field research)

Assessment question	Sub-question	Judgement criteria	Indicators
Q2. To what extent has the current application of the TPD contributed health warning labels to the facilitation of the internal market?	To what extent has the TPD regulated tobacco and related products to ensure the regulation of: maximum emission levels market placement and labelling cross border sales	The TPD has established clear guidance and regulations on: Labelling and packaging Setting maximum emission levels in accordance with relevant scientific research and data Market placement and labelling ⁵⁴³ Cross border distance sales	Market size of tobacco and related products; by product type (data - Euromonitor) Number and volume of cross-border sales / data - EUREST-PLUS to be explored) Opinions from key stakeholders on the extent to which the TPD has facilitated the smooth functioning of the internal market (field research)
Q3. To what extent has the TPD contributed to improving public health? Have there been any trends observed in the prevalence of tobacco use, particularly among young people?	How effectively has the TPD responded to its objectives for improving public health?	Awareness of harmful effects of tobacco has increased (overall and among young people). Prevalence and incidence of smoking and using tobacco related products (overall and among young people) has decreased. The TPD has contributed to decreasing consumer appeal (attractiveness) and misperceptions of the harmfulness of cigarettes (including those with a	Proportion of respondents aware of harmful effects of electronic cigarettes or e-cigarettes (including skim cigarettes) and that considers slim cigarettes less harmful than normal cigarettes (overall, by age group: including young people -15-24 years of age) (data - Eurobarometer) Prevalence of smoking (cigarettes, cigars, cigarillos, pipe, heated tobacco)/consumption (electronic cigarettes of any similar electronic devices) overall, by age group and Member State (data - Eurobarometer) Smoking/consumption intensity by type of product, age group and Member State (data - Eurobarometer) Attitudes to tobacco and electronic cigarette control policies, overall and for young people (data - Eurobarometer and field research) Use of quit lines/cessation services (quit ratio or quit rates) (data – EUREST-PLUS)

⁵⁴³ This judgement criterion was not examined independently, as it comprised part of labelling and packaging.

Assessment question	Sub-question	Judgement criteria	Indicators
		diameter of less than 7.5 mm, i.e. slim cigarettes).	Opinions from key stakeholders about activities related to TPD provisions that promote consumer awareness of the harmfulness of cigarettes (field research)
Does the TPD sufficiently take into account market developments of tobacco and related products, and their use among young people and non-smokers?		The patterns and types of tobacco and related products consumed by young people have changed (market/scientific developments), however the TPD remains effective.	<p>Prevalence of smoking (cigarettes, cigars, cigarillos, pipe, heated tobacco)/using (electronic cigarettes or e-cigarettes) overall, by age group and Member State (data - Eurobarometer)</p> <p>Smoking/using (of electronic cigarettes) intensity by type of product, age group and Member State (data - Eurobarometer)</p> <p>Proportion of respondents aware of harmful effects of electronic cigarettes or e-cigarettes (including slim cigarettes) and that considers slim cigarettes less harmful than normal cigarettes (overall, by age group: including young people -15-24 years of age) (data – Eurobarometer, EUREST-PLUS)</p> <p>Opinions from key stakeholders on clarity and effectiveness of the current TPD in regulating new products emerging in the market (particularly targeting young people/non-smokers).</p>
Q4. What outputs and outcomes have been achieved as a result of harmonised and coordinated approach across MS to implementing the TPD? To what extent has there been a contribution to the objectives of the TPD?		Regulations of tobacco and related products have been harmonised across MS.	<p>Opinions about harmonisation across MS from key stakeholders (field research) including for the following:</p> <ul style="list-style-type: none"> reporting of ingredients and emissions; addressing priority additives; prohibitions on flavourings; additives and other ingredients; labelling and packaging; banning snus

Assessment question	Sub-question	Judgement criteria	Indicators
	To what extent have MS implemented additional requirements more restrictive than the TPD?	MS have made use of opportunities to implement additional requirements, which have not created obstacles to the successful implementation and harmonisation of TPD standards.	Deviations from harmonisation in MS (desk research, conformity checks, field research) Opinions from key stakeholders on additional measures taken by individual Member States (field research).
	What role has the TPD played in reducing illicit trade/smuggling of tobacco and related products?	The TPD has established effective systems to track and tackle illicit trade; Illicit trade/smuggling has declined since the implementation of the TPD.	Number of seizures of illegal tobacco reported by MS (data source to be discussed) Opinions from key stakeholders on the role the TPD has played in reducing illicit trade/smuggling (field research)
	To what extent have consumer preferences for tobacco and related products changed? ⁵⁴⁴	Consumer preferences for tobacco and related products have changed following the entry into force of the TPD.	Consumer preferences for tobacco and related products in market studies (data- Eurobarometer); Opinions from key stakeholders on changes in consumer preferences, that can be attributed to the TPD (field research)
	To what extent has the TPD been effective in meeting its obligations under the WHO FCTC? ⁵⁴⁵	TPD provisions have complied with the FCTC guidelines.	Alignment of TPD with FCTC guideline obligations (desk/ field research) Opinions from key stakeholders about alignment of TPD with FCTC guideline obligations (field research)
Relevance			

⁵⁴⁴ This sub-question was not examined independently, as this information is contained within Effectiveness Q3A, as well as Relevance.

⁵⁴⁵ This sub-question was not examined independently, as this information is contained within Coherence Q11.

Assessment question	Sub-question	Judgement criteria	Indicators
Q5. To what extent have the specific objectives underlying the TPD proven to be appropriate for addressing the problems/ identified needs?	To what extent has the TPD addressed the availability of illicit tobacco and related products in the EU and the variations in tobacco and related products across the MS?	The TPD has adequately addressed the availability of illicit tobacco and related products in the EU.	Seizures of illicit tobacco (data source to be explored) Opinions from key stakeholders on the role the TPD has played in reducing illicit trade/smuggling (field research) Identified variations in labelling, additives etc. reported by stakeholders (field research) Opinions from key stakeholders on the role the TPD has played in addressing variations in tobacco and related products across MS (field research)
	To what extent has the TPD addressed the problem of smoking in the EU overall and for specific vulnerable populations (e.g. youth)?	The TPD has adequately addressed the problem of smoking in the EU and for vulnerable populations.	Prevalence of smoking (cigarettes, cigars, cigarillos, pipe, heated tobacco)/using (electronic cigarettes or any similar electronic devices) overall, by age group and Member State (data – Eurobarometer, Euromonitor) Smoking/using (of electronic cigarettes) intensity by type of product, age group (only in Eurobarometer) and Member State (data – Eurobarometer, Euromonitor) Opinions from key stakeholders of obstacles to health objectives (field research)
Q6. To what extent have the TPD provisions remained relevant to tackle today's reality? How have they responded to scientific, economic or technological developments and new products?	What have been the main implications of new sector developments on the TPD?	The TPD provisions have remained relevant in light of new and emerging sector developments.	Opinions of key stakeholders on relevance of TPD provisions to new and emerging sector developments (field research) Opinions from key stakeholders on key new developments (field research)
	Structures and procedural arrangements introduced by the TPD sufficiently adapted to new market, scientific, and technological developments in the tobacco industry and companies producing tobacco	Opinions from key stakeholders on the TPD's adaptation to new developments (field research) ECJ case law related to new technologies and tobacco and related products (desk research: case law). Market data on substantial changes of circumstances.	

Assessment question	Sub-question	Judgement criteria	Indicators
		related products (i.e. e-cigarettes; HTPs).	
	To what extent is the TPD able to adapt and respond to future product and market developments?	The TPD provisions have enabled Member States to respond quickly and effectively to market developments and regulator needs, including future ones.	Opinions of key stakeholders on expected developments in tobacco and related products (new products, market shares, etc.) in the near future (field research) Opinions of key stakeholders on number of TPD provisions that may interact with these developments (field research)
Efficiency			
	To what extent has the implementation of the revised TPD created administrative burdens? ⁵⁴⁶	The implementation of the revised TPD has not resulted in excessive administrative burdens.	Administrative burden of TPD for MS (desk/field research) Opinions from key stakeholders about burden of administrative costs (field research)
Q7. Have the costs borne by regulators to correctly implement the TPD been reasonable in relation to the benefits?	Do the benefits brought by the TPD to consumers outweigh the overall costs borne by all actors?	The cost of implementing the TPD has not outweighed the direct revenue gained by Member States.	Administrative burden and compliance costs of TPD, by stakeholder group (desk/field research) Costs for MS and economic stakeholders to set up new structures (training, infrastructure, administration) Compliance costs for economic stakeholders of enhanced reporting Enforcement costs for MS Sanctions faced by economic stakeholders Fees for economic stakeholders to cover the costs of data collection and analysis work

⁵⁴⁶ This sub-question was not examined independently, as this information is discussed in general sense in the Efficiency section.

Assessment question	Sub-question	Judgement criteria	Indicators
			<p>Application fees for new tobacco or related product</p> <p>Views of key stakeholders about the magnitude, proportionality, and fairness of costs imposed by the TPD in relation to the benefits</p> <p>Types of benefits (e.g. greater awareness of the risks of tobacco and related product use and reduced consumption; reduced costs for healthcare providers and the States) (data -, Eurobarometer, EUREST-PLUS)</p> <p>Opinions from key stakeholders on costs and types of benefits (desk research- literature and reports; field research).</p>
	In cases where the Member States do not charge full application costs to economic stakeholders, have costs been distributed fairly among actors? ⁵⁴⁷	Costs of implementing the revised TPD provisions have been proportionate to the fees paid to competent authorities.	<p>In these MS, proportion of fees paid by economic stakeholders (desk/field research)</p> <p>Extent of proportionality of fees for different types of economic stakeholders (e.g. SMEs) (field research)</p>
Q8. To what extent have the administrative requirements been flexible for catering to the needs of SMEs active in the industry?	Have the administrative requirements in the TPD provided sufficient flexibility for SMEs specifically?	SMEs have had clarity on the administrative requirements of the TPD.	Administrative burden and compliance costs of TPD for different stakeholders (training, infrastructure, administration); differences by organisation size (desk/field research))
	What type of support have MS provided to SMEs?	The TPD has provided administrative flexibility for SMEs.	Opinions from key stakeholders on clarity and flexibility of the admin requirements for SMEs to ensure compliance as outlined in TPD Article 1 (field research)
		Available support has enabled SMEs to adhere to the TPD.	Evidence of support available for SMEs (desk research)

⁵⁴⁷ This sub-question was not examined independently, due to a lack of disaggregated data and information from Member States.

Assessment question	Sub-question	Judgement criteria	Indicators
			Opinions from key stakeholders on effectiveness of support available to SMEs (field research)
Coherence			
Q9. Have the TPD provisions been intrinsically coherent and complementary with each other?	To what extent have the TPD provisions been consistent and coherent with each other?	The TPD provisions have complemented each other and remain coherent.	Coherence and consistency assessment, based on relevant literature (desk research: literature); Opinions from key stakeholders on consistency and coherence of TPD provisions (field research)
Q10. To what extent is the TPD coherent with other relevant EU legislation on tobacco and related products?	To what extent is the TPD coherent with: The Tobacco Taxation Directive The Audio-visual media services Directive Tobacco Advertising Directive	The TPD provisions are coherent with other relevant EU legislation and remain clear.	Coherence and consistency assessment, based on relevant literature (desk research: literature); Opinions from key stakeholders on consistency and coherence of TPD provisions (field research)
Q11. To what extent is application of the TPD in compliance with rules and policies of the WHO FCTC guidelines?	To what extent has the TPD been coherent with the FCTC guidelines?	The TPD has not been contradictory to the FCTC.	Coherence and consistency assessment, based on relevant literature (desk research: literature); Opinions from key stakeholders on consistency and coherence of TPD provisions (field research).
EU added value			
Q12. To what extent has the legislative	What has been the EU added value delivered by the TPD	The EU has played a coordinator role, facilitating	Results triangulated from all evaluation criteria above

Assessment question	Sub-question	Judgement criteria	Indicators
framework at EU level added value to the regulation of tobacco and tobacco-related products across the EU-28, in a manner that could not have been achieved at national level?	Directive and its implementation?	<p>the achievements of the objectives of the TPD.</p> <p>The EU action has helped to achieve harmonisation across Member States, which further helps the functioning of the internal market.</p> <p>The EU action has helped to promote consumer public health.</p>	Key stakeholder perceptions and documented evidence on the achievement of the TPD across MS and collectively at EU level (field research)
Could the main findings (results/outputs) presented in the assessment have been achieved without EU intervention? In the absence of EU level action, to what extent did Member States have the ability or possibility to enact appropriate measures?		<p>The TPD has generated significant outcomes that would not have been achieved through Member States acting alone.</p>	<p>Results triangulated from all evaluation criteria above</p> <p>Key stakeholder perceptions and documented evidence on the achievement of the TPD across MS and collectively at EU level (field research)</p>

Annex 2 Template used for document review

Table 31. Document review template

DOCUMENT INFORMATION	
Name of the document	...
Source (Harvard Style)	...
Type of source	Scientific article; (Academic) Research paper; Report; Handbook; Information sheet; Meeting minutes; Legislation; White/Green Paper; other (please specify)
Year	...
Source of document	...
Read by (researcher)	...
Topic/ area	...
Links	...
Summary (3-5 bullet points)	...
Relevance for data analysis	...
Stakeholders mentioned	Government and regulators; Economic stakeholders (e.g. retailers, manufacturers and importers of tobacco and related products); Civil society organisation; Health experts
Assessing of specific Articles of TPD (Yes/no, which ones)	...
Assessing specific implementation act or delegated act (Yes/no, which ones)	...
Relevance to assessment questions (High/Medium/Low)	...
EFFECTIVENESS	
Q1. To what extent are the structures and procedural arrangements of the TPD clear about how to transpose the TPD?	a) To what extent has the transposition guidance for the TPD been clear to MS? ... b) Has transposition occurred in all MS? ... c) To what extent have all economic stakeholders been compliant with rules and provisions? ...
Q2. To what extent has the current application of the TPD contributed to the facilitation of the internal market?	a) To what extent has the TPD regulated tobacco and related products to ensure the regulation of: -health warning labels -maximum emission levels -market placement and labelling -cross border sales ...
Q3. To what extent has the TPD contributed to improving public health? Have there been any trends observed in the prevalence of tobacco use, particularly among young people?	a) How effectively has the TPD responded to its objectives for improving public health? ... b) Does the TPD sufficiently take into account market developments of tobacco and related products, and their use among young people and non-smokers? ...
Q4. What outputs and outcomes have been achieved as a result of the TPD and have they contributed to the objectives of the TPD?	a) To what extent has there been a harmonised and coordinated approach across MS to implementing the TPD? ... b) To what extent have MS implemented additional requirements more restrictive than the TPD? ... c) What role has the TPD played in reducing illicit trade/smuggling of tobacco and related products? ... d) To what extent have consumer preferences for tobacco and related products changed? ... e) To what extent has the TPD been effective in meeting its obligations under the WHO FCTC? ...
Art2	Have the definitions in the TPD been clear enough to allow effective implementation and transposition? ...

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Art 5	Are the provisions on reporting of ingredients and emissions being implemented? ...
Art 6	Are the provisions on priority additives and reporting been implemented (i.e. the creation of a database on products)? ...
Art 7	To what extent is the ban on characterising flavours being implemented? What has been the impact of this? To what extent have provisions on additives been implemented (bans of certain additives and changes of circumstances related to additives)? What has been the impact of this? ...
Art 8-9	<i>NOTE: Q ALSO IN RELEVANCE</i> To what extent are general provisions on labelling and packaging being implemented? What issues exist, if any? ...
Arts 10 & 12	To what extent are provisions on combined health warnings being implemented? What issues exist, if any? ...
Art 11	To what extent have MS exempted tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations of Articles 9 and 10? What benefits or disadvantages has this had? ...
Art 13	To what extent have provisions on product presentation been implemented? ...
Art 15-16	To what extent is track and trace being implemented? What have been the major implementation challenges? ...
Art 18	Have provisions on cross-border distance sales impacted the type and number of cross-border sales of tobacco and related products? What issues exist, if any? To what extent have provisions on cross-border distance sales been correctly implemented, and new products been sold online and cross-border? ...
Art 19	Have provisions on notification of novel tobacco and related products been implemented successfully and effectively? What have been the trends surrounding novel products and change of circumstances? What is the market share and prevalence of novel products being sold in MS? ...
Art 20	Have provisions on electronic cigarettes effectively accounted for changes in the e-cigarette market? How have these provisions been implemented in MS? <i>NOTE: Q ALSO IN RELEVANCE</i> What relevant changes have happened in the e-cigarette market (in relation to paragraph 7)? How have these market developments been monitored at the MS or EU level, and what have been the main challenges faced? ...
Art 21-22	<i>NOTE: Q ALSO IN RELEVANCE</i> To what extent are provisions on herbal products for smoking being implemented? What issues exist? ...
Art 23	<i>NOTE: Q ALSO IN EFFICIENCY</i> How have MS ensured compliance with the TPD? If there have been penalties for non-compliance in MS, what has been the scale of enforcement? ...
Art 24	<i>NOTE: Q ALSO IN COHERENCE</i> To what extent have MS implemented plain/standardised packaging, as permitted in Article 24? ... <i>NOTE: Q ALSO IN COHERENCE</i> To what extent have MS banned categories of tobacco or related products, as permitted in Article 24? ...

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RELEVANCE		
Q5. To what extent have the specific objectives underlying the TPD proven to be appropriate for addressing the problems/ identified needs?	a) To what extent has the TPD addressed the availability of illicit tobacco and related products in the EU and the variations in tobacco and related products across the MS? ... b) To what extent has the TPD addressed the problem of smoking in the EU overall and for specific vulnerable populations (e.g. youth)? ...	
Q6. To what extent have the TPD provisions remained relevant to tackle today's reality? How have they responded to scientific, economic or technological developments and new products?	a) What have been the main implications of new sector developments on the TPD? ... c) To what extent is the TPD able to adapt and respond to future product and market developments? ...	
Art 2	Have definitions laid out in the TPD remained relevant in view of scientific, technological and market developments? ...	
Art 3	Have the provisions on maximum emissions levels remained relevant in view of scientific and technological developments? ...	
Art 4	Have the provisions on measurement methods remained relevant in view of scientific and technological developments? ...	
Art 8-9	NOTE: Q ALSO IN EFFECTIVENESS ... To what extent are general provisions on labelling and packaging being implemented? What issues exist, if any?	
Art 19	Have provisions on notification of novel tobacco and related products remained relevant in view of new products and scientific developments? ...	
Art 20	NOTE: Q ALSO IN EFFECTIVENESS ... What relevant changes have happened in the e-cigarette market (in relation to paragraph 7)? How have these market developments been monitored at the MS or EU level, and what have been the main challenges faced? ...	
Art 21-22	NOTE: Q ALSO IN EFFECTIVENESS ... To what extent are provisions on herbal products for smoking being implemented? What issues exist? ...	
EFFICIENCY		
Q7. Have the costs borne by regulators to correctly implement the TPD been reasonable in relation to the benefits?	a) To what extent has the implementation of the revised TPD created administrative burdens? ... b) Do the benefits brought by the TPD to consumers outweigh the overall costs borne by all actors? ... c) In cases where the Member States do not charge full application costs to economic stakeholders, have costs been distributed fairly among actors? ...	
Q8. To what extent have the administrative requirements been flexible for catering to the needs of SMEs active in the industry?	a) Have the administrative requirements in the TPD provided sufficient flexibility for SMEs specifically? ... b) What type of support have MS provided to SMEs? ...	
Art 23	NOTE: Q ALSO IN EFFECTIVENESS ... How have MS ensured compliance with the TPD? If there have been penalties for non-compliance in MS, what has been the scale of enforcement? ...	
COHERENCE		
Q9. Have the TPD provisions been intrinsically coherent and complementary with each other?	a) To what extent have the TPD provisions been consistent and coherent with each other? ...	
Q10. To what extent is the TPD coherent with other relevant EU legislation on tobacco and related products?	a) To what extent is the TPD coherent with: - The Tobacco Taxation Directive - The Audio-visual media services Directive - Tobacco Advertising Directive ...	
Q11. To what extent is application of the TPD in compliance with rules and policies of the WHO FCTC guidelines?	a) To what extent has the TPD been coherent with the FCTC guidelines? ...	

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Art 2	Have the different definitions been implemented in a way which is consistent with other EU legislation (e.g. Taxation Directive, Audio-visual Media Services Directive)?	...
Art 24	<i>NOTE: Q ALSO IN COHERENCE</i> To what extent have MS implemented plain/standardised packaging, as permitted in Article 24?	...
	<i>NOTE: Q ALSO IN COHERENCE</i> To what extent have MS banned categories of tobacco or related products, as permitted in Article 24?	...
EU ADDED VALUE		
Q12. To what extent has the legislative framework at EU level added value to the regulation of tobacco and tobacco-related products across the EU-28, in a manner that could not have been achieved at national level?	a) What has been the EU added value delivered by the TPD Directive and its implementation? b) Could the main findings (results/outputs) presented in the assessment have been achieved without EU intervention? In the absence of EU level action, to what extent did Member States have the ability or possibility to enact appropriate measures?	...
FINAL NOTES		
Useful points/questions for follow up (mention type of stakeholder)		...
Other comments		...

Annex 3 Eurobarometer data analysis

5.1 Introduction and purpose

The report for *Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes*⁵⁴⁸ was prepared and published by Kantar in February 2021. That published report was used as a basis for this annex, and all figures came directly from that report, with the exception of Table 43, which was prepared specifically for this present assessment study.

This annex presents the key results from this Special Eurobarometer report which relate to the TPD and were used to further substantiate the main findings of the assessment study. The purpose of this annex is to pull out such relevant results and present the descriptive analysis accompanying them. Responses related to tobacco for oral use (corresponding to Art. 17), novel tobacco products (Art. 19), E-cigarettes (Art. 20), and general prevalence information about the products which the TPD regulates were of most relevance. Where appropriate, information is presented by Member State and age group, due to the TPD's focus on young people. Trends over time between the years of the Eurobarometer are also highlighted, however some items of interest were only asked in the 2020 wave (response options are included in parentheses):

- **QC3.2:** Thinking about the following products, which of the following applies to you? *Heated tobacco products* (you currently use it / you used to use it but you have stopped / you have tried only once or twice / you have never used it / don't know)
- **QC4a.8:** How often did you use the following tobacco and related products? *Heated tobacco products* (every day / every week / every month / less than monthly / you have tried only once or twice / never)
- **QC8:** In recent years e-cigarettes and heated tobacco products have been increasingly marketed in Europe. Do you think that they are harmful or not to the health of those who use them? *Heated tobacco products* (yes / no / don't know)
- **QC9b.1:** Do you find the following products appealing? *E-cigarettes* (yes / no / don't know)
- **QC9b.2:** Do you find the following products appealing? *Heated tobacco products* (yes / no / don't know)
- **QC11c:** Do you think that these products should be regulated as strictly as cigarettes? *Heated tobacco products* (yes / no / don't know)
- **QC11c:** Do you think that these products should be regulated as strictly as cigarettes? *E-cigarettes* (yes / no / don't know)

The Eurobarometer study for the most part uses the same terminology and product categorisations as the present report and the TPD, however a few categorisations do not directly mirror those used in the TPD:

- Eurobarometer considers "Oral tobacco (snus), chewing or nasal tobacco (snuff)" together, whereas the TPD defines three types of "smokeless tobacco products": "chewing tobacco", "nasal tobacco", and "tobacco for oral use".
- Eurobarometer often considers "cigarettes" as a category, which the TPD does as well. However, Eurobarometer also sometimes distinguishes "boxed cigarettes" and "hand-rolled cigarettes", which the TPD does not do in the same way. The TPD does define "roll-your-own tobacco".

⁵⁴⁸ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>

5.2 Art.17: Tobacco for oral use

All respondents, regardless of being a current, former or non-smoker, were asked if they had tried oral tobacco (snus) and chewing or nasal tobacco (snuff), and also how frequently they did so.

A large number of those surveyed confirmed to have never tried oral tobacco. For those respondents that did so, the data shows a two-percentage point increase in those respondents that have tried oral, chewing or nasal tobacco (7%), compared to the proportions in March 2017 (5%).

Despite the above-mentioned percentage increases, there is very low proportion of respondents that have used oral chewing and nasal tobacco in the EU, and those who report having used these products say that they do so infrequently.

There are different reasons behind the low percentages in the use of oral tobacco products. However, an important point to consider is that oral tobacco is illegal in the EU, except for Sweden. In Sweden, the proportion of those who have tried oral and nasal tobacco clearly stands out from the rest of countries, with 46% of respondents confirming that they have tried this type of tobacco products. However, this share has dropped by four percentage points compared to the 50% reported in 2017.

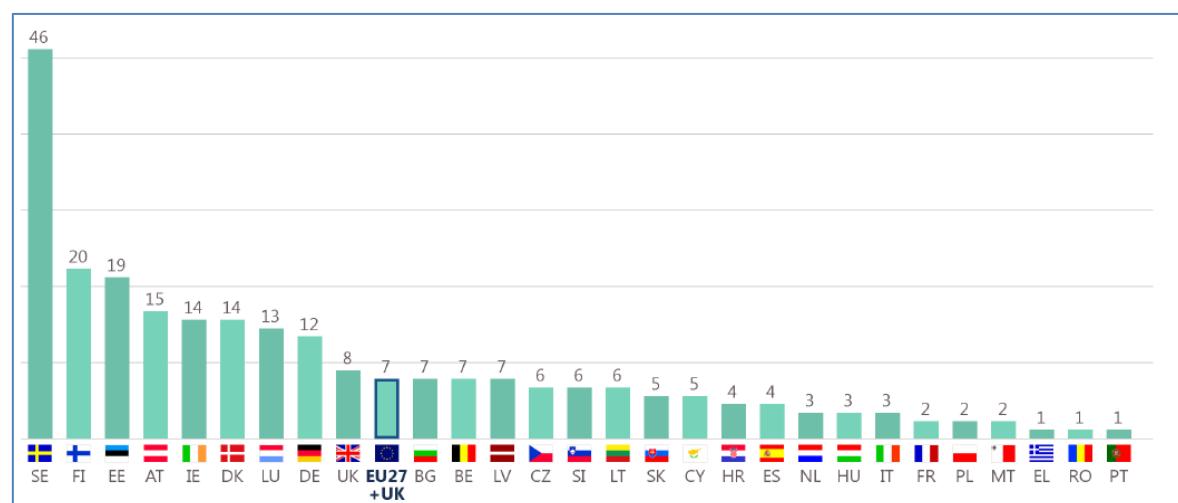
Other countries that report a relatively high number of respondents having tried these products are: Finland (20%), Estonia (19%), Austria (15%), Ireland (14%) and Denmark (14%).

Overall, few changes have been reported over time in the country level proportions of those who have used these products. Experience of oral, chewing, or nasal tobacco has increased since March 2017, particularly in Ireland (+13pp) and Estonia (+8 pp).

In the EU, there has been a 2% increase in the percentage of respondents who have tried oral tobacco (snus), chewing or nasal tobacco. In 2020, there are 20 EU countries less than 1 in 10 have tried these products.

Regarding the frequency of use, in Sweden, 16 % of all respondents' report using oral tobacco daily (20% was the proportion in 2017), 3% in Estonia, and 1 % in Ireland and Denmark. Across the rest of surveyed countries, the proportion of respondents using oral tobacco every day is low.

Figure 9. QC6.2 Have you ever used or tried any of the following products? Oral tobacco (snus), chewing or nasal tobacco (snuff) (% - TOTAL 'YES')



Base: All respondents, N = 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.48

Table 32. Have you ever used or tried any of the following products? Oral tobacco (snus), chewing or nasal tobacco (snuff)

Age	Total 'Yes' (%)	
	2017	2020
15-24	5	8
25-39	7	10
40-54	5	7
55+	3	4

Base: All respondents, N= 28,300

Source: ICF, based on Eurobarometer 2017 and 2020

By age group, those respondents aged 25-30 represent the highest proportion of users of oral, chewing or nasal tobacco products (10%), compared to 7% in March 2017. As can be observed in the table, the percentages have also slightly increased for the other age groups since the previous Eurobarometer survey in 2017.

5.3 Art.19: Novel tobacco products

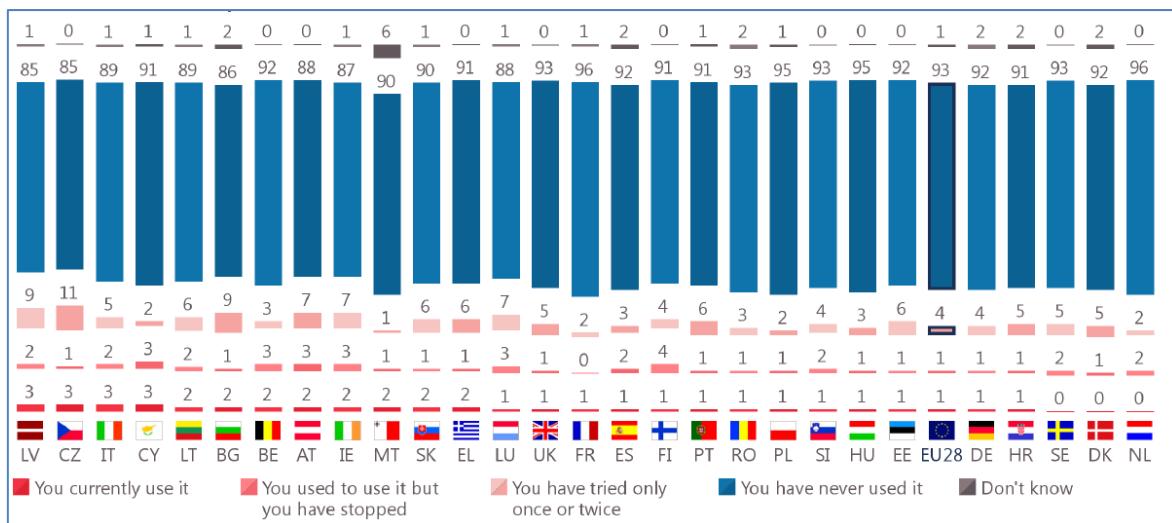
Respondents were asked for the first time⁵⁴⁹ if they have tried heated tobacco products and how often they used such products. Around 6% of the respondents confirmed to have tried heated tobacco products whereas 93% have never used these products, and only 1% used to use them but have stopped. Regarding the usage patterns of such products these look similar to the usage patterns for e-cigarettes: less than 4% say they have tried them once or twice, while a very small proportion (1%) currently use them.

At country level, more than 80 % of the respondents in all countries have never used heated tobacco products. In 8 countries, at least 10% have tried those products at least one or two times. The highest shares are recorded in Czechia (15%), Latvia (14%), and Austria, Bulgaria and Ireland (all 12%). On the other side, less than 3% have used them in France and 4% in the Netherlands, Malta and Poland.

In nearly all countries, the use of heated tobacco products is mostly occasional (only once or twice) and there is a very little proportions of current users in all countries.

⁵⁴⁹ This question was not included in the previous in 2017 Eurobarometer survey

Figure 10. QC3.2 Thinking about the following products, which of the following applies to you? Heated tobacco products (%)



Base: All respondents, N = 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.64

The analysis by age group shows that the younger the respondents, the more likely they are to have at least tried heated tobacco products. For instance, 11% of young people (aged 15-24), and 10 % of those aged 25-39 have at least tried heated tobacco products, compared with 3% of the oldest respondents (aged 55 or over).

Table 33. Thinking about the following products, which of the following applies to you? Heated tobacco products (%)

Age	You currently use it	You used to use it but you have stopped	You have tried only once or twice	You have never used it
15-24	2	2	7	88
25-39	2	2	6	89
40-54	1	1	4	93
55+	1	0	2	96

Base: All respondents, N= 28,300

Source: ICF, based on Eurobarometer 2017 and 2020. The remaining participants did not know.

Regarding the frequency of use, almost 58 % of current users of heated tobacco products use these products every day, and an additional 12% report doing so on a weekly basis.

One in 20 respondents report using heated tobacco products every month or less, while 3% say they have tried them once or twice.

The country-level and socio-demographic analyses on the results of this question are not possible due to low sample sizes.

Respondents were also asked for their opinions on whether heated tobacco products are harmful to the health of those who use them. Among all respondents, 64% think that heated tobacco products are harmful to the health of their users. On the contrary,

a bit more than a quarter (26%) consider that these products are not harmful. 10% say they don't know.

Table 34. In recent years e-cigarettes and heated tobacco products have been increasingly marketed in Europe. Do you think that they are harmful or not to the health of those who use them? Heated tobacco products (%)

Age	Yes	No	Don't know
15-24	68	24	8
25-39	64	28	8
40-54	67	25	8
55+	62	26	12

Source: ICF, based on Eurobarometer 2020

Looking at the different age groups, there are no substantial differences in the percentages of those that consider heated tobacco products as being harmful (between 60 % and 70% in all age groups).

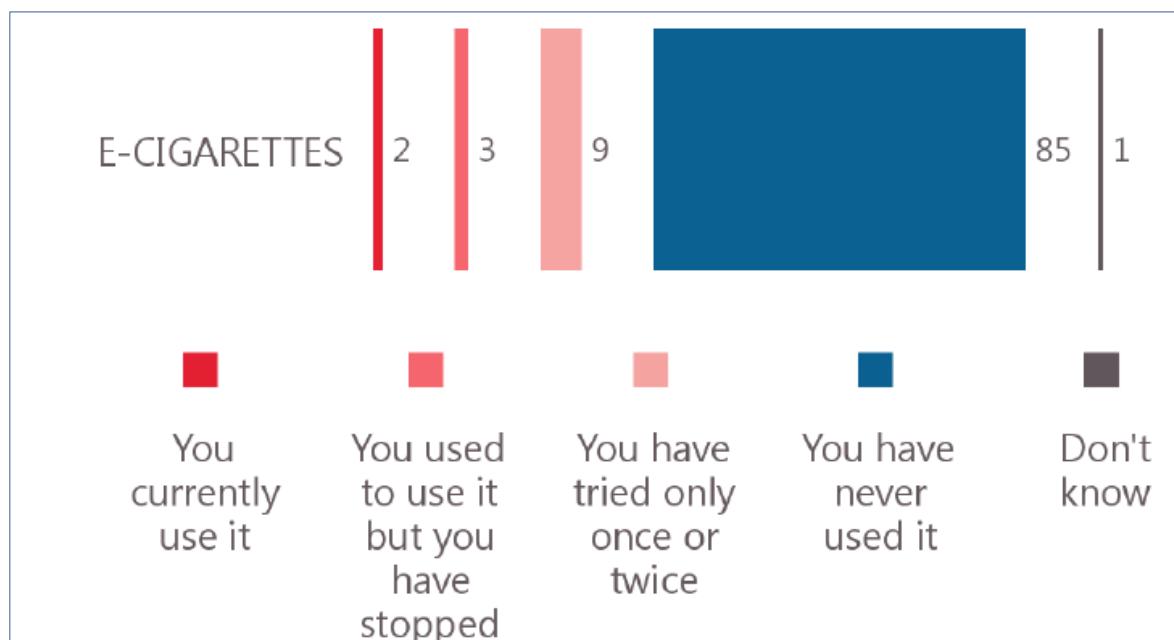
Although the differences between age groups were very small, it is interesting to see that the age group more likely have at least tried heated tobacco products (age group 15-24), is also the age group with a higher proportion of respondents thinking that they are harmful (68%). Therefore, it is difficult to establish any type of relation between perception of harmful effects and age groups.

5.4 Art.20: E-cigarettes

Electronic cigarettes (e-cigarettes) have become increasingly available in the last few years and are marketed as an alternative to smoking. All respondents were asked if they had used electronic cigarettes. Those who used them or used to use them, were asked about their frequency of use.

In total, more than one in ten (14%) of the respondents have tried e-cigarettes.

Figure 11. QC3 Thinking about the following products, which of the following applies to you? (% - EU27 + UK)



Base: All respondents, N = 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.62

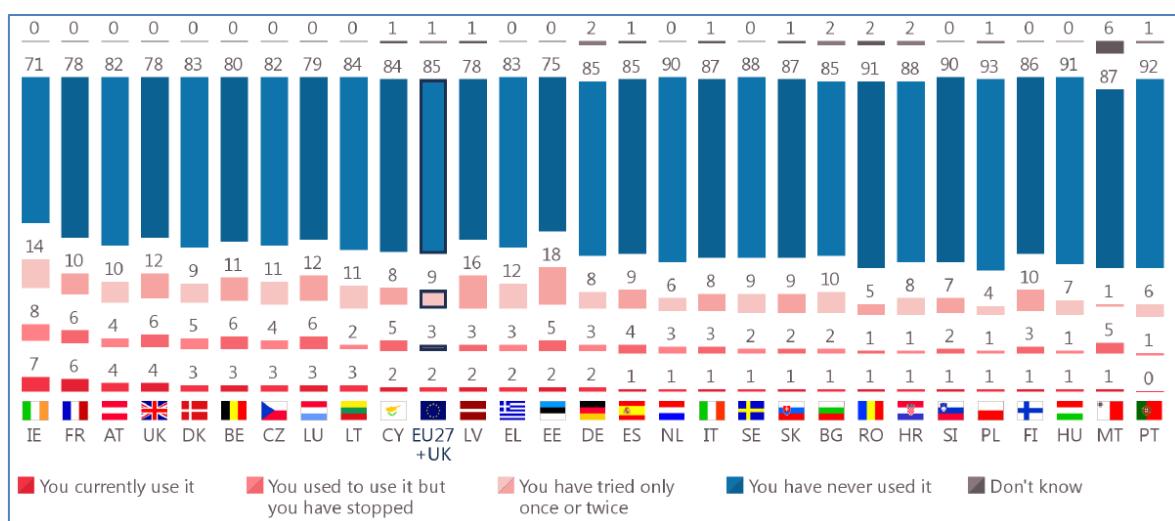
Regarding the frequency of use, nearly one in ten (9%) say they have tried them only once or twice, while 3% used to use them but have stopped. A small proportion (2%) say they currently use them. There are no significant changes in the results compared to March 2017.

Among those who currently use e-cigarettes, country-level differences are minimal. The country-level analysis shows that more than 70% respondents in all EU countries+ UK have never used e-cigarettes. In all countries, less than one in twenty are current e-cigarette users.

As the Kantar analysis reveals⁵⁵⁰, several differences at country level arise in the case of the frequency of use. Less than one in ten of respondents say to have tried e-cigarettes at least once or two times in Poland (6%), Malta, Portugal and Romania (all 7%) and Hungary (9%). On the other hand, on seven countries, 20% of respondents say to have tried e-cigarettes at least one or two times: Ireland (29%), Estonia (25%), France and the United Kingdom (both 22%), Luxembourg and Latvia (both 21%) and Belgium (20%).

If these figures are compared with those of 2017, the proportions of respondents who have at least tried e-cigarettes once or twice has substantially increased in two countries: Ireland (+16 pp) and Luxembourg (+9 pp) since 2017. Conversely, in some other countries a decrease of those that have at least tried e-cigarettes once or twice has been observed: Poland (-7 pp), Cyprus (-6 pp), and Malta and the Netherlands (both -5 pp). No substantial changes can be observed in the proportions of current e-cigarette users compared to 2017, except for an increase by five percentage points in Ireland.

Figure 12. QC3.1 Thinking about the following products, which of the following applies to you? E-cigarettes (%)



Base: All respondents, N = 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.63

⁵⁵⁰ Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.64

Similarly to heated tobacco products, the socio-demographic analysis reveals that the younger the respondents, the more likely they are to have at least tried e-cigarettes. For instance, 25% of young people (aged 15-24) have at least tried e-cigarettes, compared with 8% of the oldest respondents (aged 55 or over), or 14% of those aged (40-54).

In comparison/ to 2017 figures, the proportion of younger respondents that use e-cigarettes has remained the same for those aged 15-24, has slightly increased for those aged 25-39 (+1pp), and also for adults+55 (+2 pp). Finally, the use has slightly decreased for adults aged 40-54 (-1pp).

Table 35. Thinking about the following products, which of the following applies to you? E-cigarettes (%) (2020)

Age	You currently use it	You used to use it but you have stopped	You have tried only once or twice	You have never used it
15-24	4	3	18	74
25-39	3	6	13	78
40-54	2	4	8	85
55+	2	2	4	91

Base: All respondents, N= 28,300

Source: ICF, based on Eurobarometer 2020

Table 36. Which of the following statements about the use of electronic cigarettes or any similar electronic devices (e-shisha, e-pipe) applies to you? (% - EU) (2017 vs 2020)

Age	At least tried (2017)	At least tried (2020)
15-24	25	25
25-39	21	22
40-54	15	14
55+	6	8

Base: All respondents, N= 28,300

Source: ICF, based on Eurobarometer 2017 and 2020

Respondents were also asked about type of e-cigarettes used, and how frequently they use them. Among those who currently use e-cigarettes, nearly half of them (48%) say they use e-cigarettes with nicotine every day, and 16% do so every week. There is a small proportion that use e-cigarettes with nicotine every month (5%) or less than monthly (4%), while only 1% say they have tried them once or twice.

The use of e-cigarettes without nicotine is less common across respondents. One in 10 (10%) report to smoke such products on a daily basis, whereas 9% do so on a weekly basis. There is a small proportion of those that use them every month (5%) and less than monthly (5%).

Table 37. How often do you use the following tobacco and related products? E-cigarettes (both with and without nicotine) (%)

	E-cigarettes with nicotine	E-cigarettes without nicotine
Every day	48	10
Every week	16	9
Every month	4	5
Less than monthly	5	5

Source: ICF, based on Eurobarometer 2020

Compared to the previous survey in 2017, there has been a 12 percentage points decrease in daily e-cigarette users. Kantar analysis highlights that as the question was asked differently in 2017 results are not directly comparable, and also that a country-level analysis on the results of this question is not possible due to low sample sizes.

The socio-demographic analysis reveals that more than 60% of those aged 40 or more use e-cigarettes daily, compared with around four in ten (41%) of the youngest users (aged 15-24).

Table 38. How often do you use the following tobacco and related products? E-cigarettes (both with and without nicotine) (%)

Age	Every day	
	2017	2020
15-24	52	41
25-39	72	53
40-54	65	64
55+	71	60

2017 Base: respondents who use e-cigarettes, N=565

2020 Base: Respondents who use e-cigarettes, N= 708

Source: ICF, based on Eurobarometer 2017 and 2020

Respondents were also asked if they considered e-cigarettes to be harmful to the health of their users. More than 65% of the respondents considered that e-cigarettes are harmful to the health of those who use them. At the same time almost 30% of respondents think they are not, while one in ten or less (8% and 10%, respectively) say they don't know.

Compared to 2017, the proportion of respondents who consider e-cigarettes to be harmful to the health of their users has increased by ten percentage points.

The socio-demographic analysis reveals that there has been a significant increase in the proportion of those that think that e-cigarettes are harmful products, compared to 2017. This increase ranges from +6pp in those aged 15-24, to +13pp on those aged +55. At the same time respondents seem to have receive information on e-cigarettes, as the percentage of those that do not know have increased for all stakeholder groups.

Table 39. In recent years e-cigarettes have been increasingly marketed in Europe. Do you think that they are harmful or not to the health of those who use them? E-cigarettes (%)

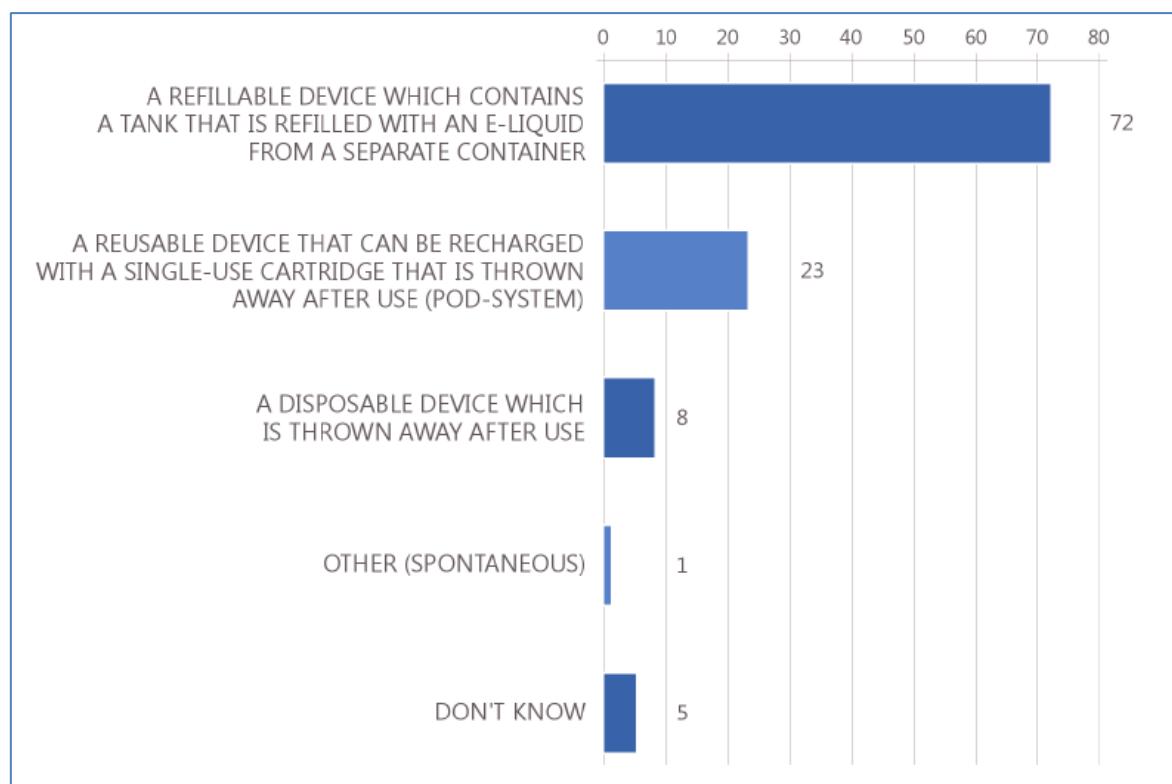
Age	Yes		No		Don't know	
	2017	2020	2017	2020	2017	2020
15-24	59	66	32	27	9	7
25-39	58	64	28	29	14	7
40-54	57	67	27	26	16	7
55+	50	63	28	27	22	10

Source: ICF, based on Eurobarometer 2017 and 2020

More than 72% of current and former e-cigarette users say they use or had used a refillable device which contains a tank that is refilled with an e-liquid from a separate container. A little less than 23% use a pod-system, while a much smaller proportion (8%) use a disposable device which is thrown away after use.

A country-level analysis on the results of this question is not possible due to low sample sizes.

Figure 13. QC9a Which type of e-cigarette do you use or did you use in the past? (MULTIPLE ANSWERS POSSIBLE) (% - EU27 + UK)

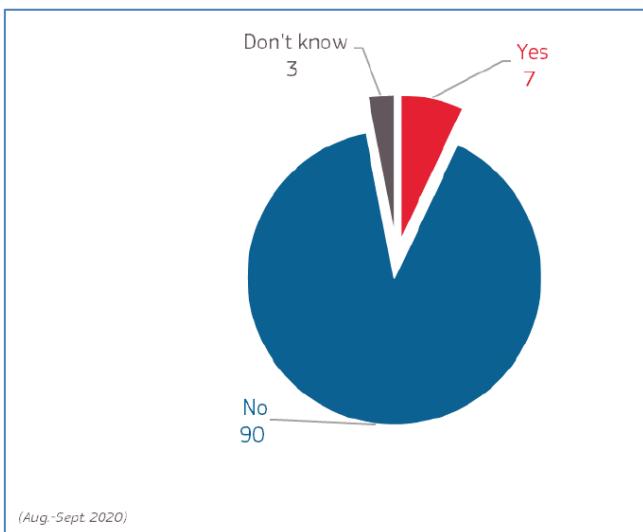


Base: Respondents who use or used e-cigarettes, N = 1,696

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.79

Respondents were also asked if they found e-cigarettes appealing. Most respondents (90%) confirm that e-cigarettes are not attractive to them. Less than one in ten (7%) of those respondents who have never used e-cigarettes or have only tried them once or twice find this type of product attractive.

Figure 14. QC9b.1 Do you find the following products appealing? E-cigarettes (% - EU27 + UK)



Base: Respondents who have never used e-cigarettes or have only tried them, N = 26,354

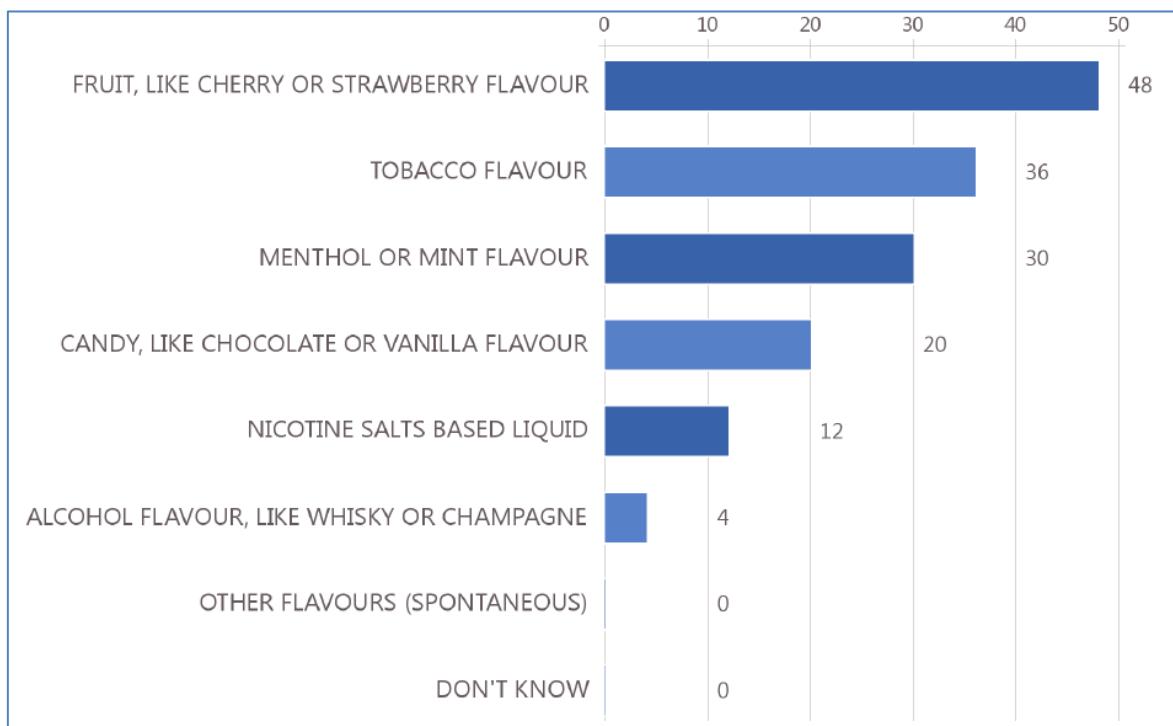
Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.82

Among current e-cigarette users who use them at least on a monthly basis, the most popular flavour of e-cigarette is fruit flavour, such as cherry or strawberry flavour (48%), followed by tobacco flavour (36%). Similarly, 30% of respondents say they use menthol or mint flavour, while around 20% opt for vanilla, candy, or chocolate flavour and more than one in ten use nicotine salts-based liquid (12%). Alcohol flavour, like whisky or champagne is the least popular, favoured by 4% of respondents.

Compared to 2017, those that use e-cigarettes on a monthly basis are now much more likely to use menthol or mint flavour (+8 pp) and also slightly more likely to use candy or alcohol flavours (both +2 pp).

As per other previous questions, an analysis by country on the results of this question was not possible due to low sample sizes.

Figure 15. **QC10a** Which of the following e-cigarette liquid variants did you use at least on a monthly basis? (MULTIPLE ANSWERS POSSIBLE) (% - EU27 + UK)



Base: Respondents who use e-cigarettes at least on monthly basis, N= 565

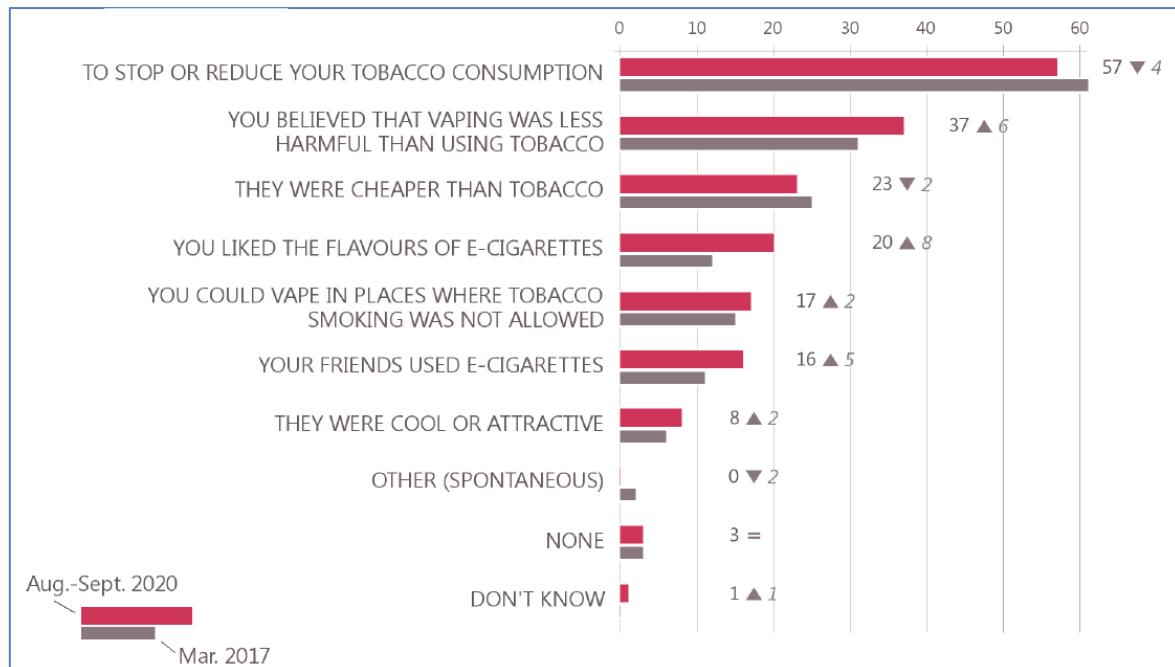
Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.73

The factor most frequently reported as a reason for taking up e-cigarettes is to stop or reduce tobacco consumption (57%). Also, 37% confirmed they have started because they thought vaping was less harmful than using tobacco. Others justify this choice for economic reasons (23%). Other reasons include those who cite the fact that they liked the flavours of e cigarettes (20%), that they could vape in places where tobacco smoking was forbidden (17%) and that their friends used e-cigarettes (16%). Finally, around less than 8% mentioned to have started using them because they were cool or attractive.

When comparing these results with those of the previous survey in 2017, the most notable changes are a decrease in the proportion of users saying they started using e-cigarettes to stop or reduce tobacco smoking (-4 percentage points) and significant increases in the shares of those who mention that they liked the flavours of e-cigarettes (+8 pp), that they believed that vaping was less harmful than using tobacco (+6 pp) and that their friends used e-cigarettes (+5 pp).

A country-level analysis on the results of this question is not possible due to low sample sizes.

Figure 16. QC11a Which of the following factors, if any, were important in your decision to start using e-cigarettes? (MAX. 3 ANSWERS) (% - EU27 + UK)



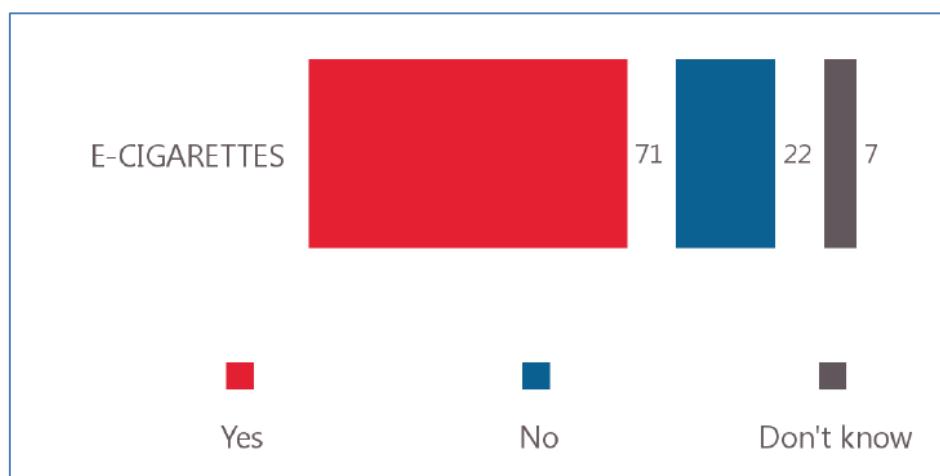
Base: Respondents who use or used e-cigarettes, N= 1,696

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.122

Finally, those respondents who have never used, or only tried, e-cigarettes or heated tobacco products were asked if they think that these products should be regulated as strictly as cigarettes. Most respondents (72 %) are in favour of a stricter regulation for heated tobacco products, whereas one in five (21%) do not think these products should be regulated as strictly as cigarettes.

Likewise, 71% of respondents think that e-cigarettes should be regulated as strictly as standard cigarettes, with more than (22%) saying the opposite.

Figure 17. QC11c Do you think that these products should be regulated as strictly as cigarettes? (% - EU27 + UK)



Base: Respondents who never used or only tried e-cigarettes or heated tobacco products, N= 25,882

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.229

5.5 Additional measures

An important proportion of respondents are in favour of other measures as mentioned in the survey: banning flavours in e-cigarettes and introducing plain packaging.

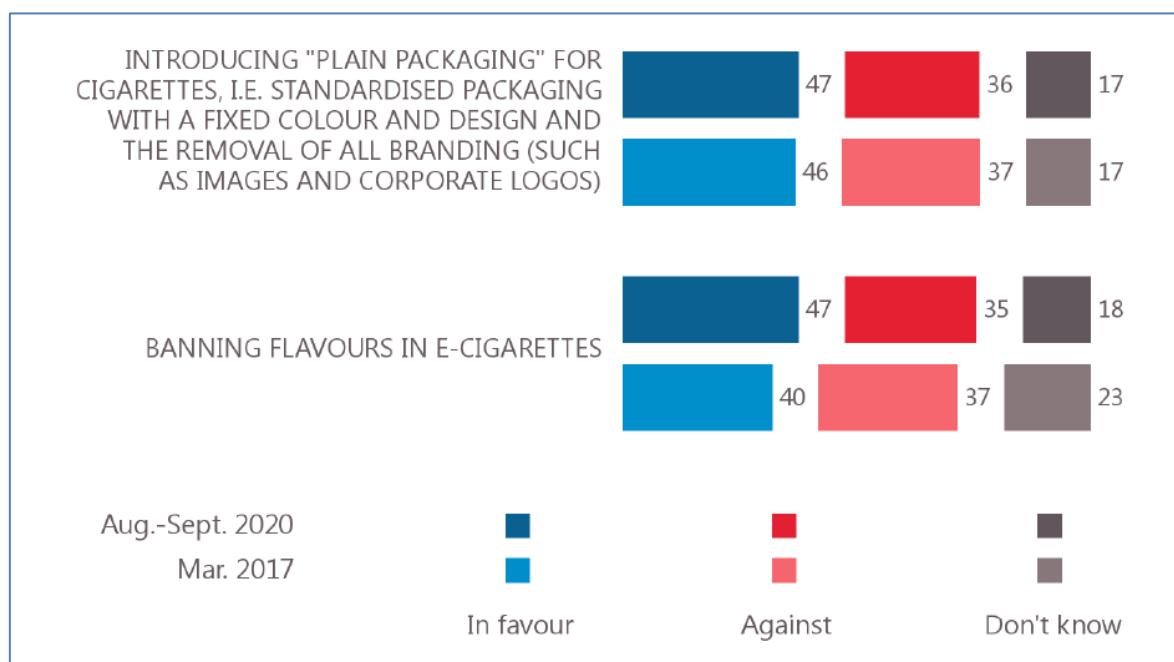
a) Banning flavours in e-cigarettes: 47% are in favour of banning flavours in e-cigarettes (vs 35% who are against). The proportion of respondents in favour of banning flavours in e-cigarettes has increased by seven percentage points since 2017 when the question was last asked. The socio-demographic analysis reveals that older the respondents, the more likely they are to be in favour of banning flavours in e-cigarettes (41% of those aged 15-24, compared with 49% of those aged 55 or more).

b) Plain packaging

Almost half of the respondents (47%) are in favour of introducing 'plain packaging' for cigarettes, i.e. standardised packaging (vs 36% who are against).

The share of respondents in favour of introducing 'plain packaging' for cigarettes has remained broadly stable (+1 pp). By age group, we can see that those respondents aged 25-54 have the highest proportion of respondents in favour of introducing plain packaging (49%), however there are not significant differences across age groups.

Figure 18. QC17 Would you be in favour or against any of the following measures? (%) - EU27 + UK)



Base: All respondents, N= 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.218

Table 40. Would you be in favour or against any of the following measures? Banning flavours in e-cigarettes (%)

Age	In favour		Against		Don't know
	2017	2020	2017	2020	2020
15-24	35	41	49	44	15
25-39	39	44	42	43	13
40-54	40	48	39	36	16
55+	43	49	29	28	23

Base: All respondents, N= 28,300

Source: ICF, based on Eurobarometer 2017 and 2020

*Table 41. Would you be in favour or against any of the following measures?
Introducing "plain packaging" for cigarettes, i.e. standardised packaging
with a fixed colour and design and the removal of all branding (such as
images and corporate logos) (%)*

Age	In favour		Against		Don't know
	2017	2020	2017	2020	2020
15-24	48	47	39	36	17
25-39	48	49	38	39	12
40-54	47	49	39	38	13
55+	45	45	34	34	21

Base: All respondents, N= 28,300

Source: ICF, based on Eurobarometer 2017 and 2020

Smoking prevalence

Methodology

The smoking prevalence indicator in the Eurobarometer data is measured by the following question: Regarding smoking cigarettes, cigars, cigarillos or a pipe, which of the following applies to you? The prevalence of use is calculated by taking the proportion of those who indicated that they 'currently smoke'. Please note that the question does not include the use of electronic cigarettes.

Smoking prevalence

The table below presents the estimates of smoking prevalence for 2014, 2017 and 2020. The results show that the prevalence of smoking at EU level remained stable between the years 2014 and 2017 (26 % in both years), however the *proportion of smokers has decreased since 2017*. In 2020 there has been a three-percentage point decline in (23 %)⁵⁵¹ compared to 2017. When the results for the EU27 (without the UK) are considered, it can be observed that this proportion has not varied since 2014.

If we focus in young people, the Eurobarometer data reveals that the proportion of young people who smoke has decreased by nine percentage points compared to 2017 data.

Table 42. Smoking for the overall population in the EU and for youth at three time points

Eurobarometer	
2014 – overall	26%
2014 – youth	25%
2017 – overall	26%
2017- youth	29%
2020– overall	23%
2020– youth	20%

Source: ICF based on Eurobarometer 2014, 2017 and 2020, Note: Youth in the Eurobarometer data represents those between 15 and 24 years of age

In the vast majority of EU countries (all but seven) at least one in five are smokers. However, significant differences can be observed between countries with regards to the prevalence of smoking.

the results show that in 2020 the smoking prevalence was equal or exceeded 30% in 5 Member States (EL, FR, BG, HR, LV, PL) and was the highest in Greece (37%), France and Bulgaria (both 36%). The proportion of current smokers was lowest in Sweden (7%) and the UK (17%).

In 2020, 5 Member States continue having smoking prevalence rated equal or higher than 30 % (EL, BG, HR, LV, PL). In 2020, the highest smoking prevalence is observed in Greece where the smoking rate has increased by 4 percentage points up to (42%), followed by Bulgaria and Croatia (28%). Slightly more than half of Member States (15) have experienced a downward trend in the proportion of smokers between the years 2014 and 2020. In most EU countries (all but seven) at least one in five are smokers. However, significant differences can be observed between countries with regards to the prevalence of smoking. In 2020 the highest smoking prevalence is

⁵⁵¹ EU 27+ UK 23% / EU 27 25%

observed in Greece where the smoking rate has increased by 4 percentage points up to (42%), followed by Bulgaria and Croatia (28%). Slightly more than half of Member States (15) have experienced a downward trend in the proportion of smokers between the 2017 and 2020. This trend has been most pronounced in France (-8%), the Netherlands (-7%) and Portugal, Estonia, Finland, and the UK (all -5%). Countries with the highest increase in the prevalence of smoking were Greece (+5%), and Bulgaria, Romania, Luxembourg, and Belgium (all +2%).

With regard to young people, the prevalence of smoking in 2017 ranged from 3% (SE) to 44% (BG). The proportion of smokers among young people was also high in France, Hungary (both 39%) and Croatia (38%). Having the highest increase in the proportion of smokers over time, Denmark and Belgium interestingly belong to countries with the lowest prevalence of smoking among young people - 13% and 15% respectively.

In total, 19 out of 28 Member States have experienced an increase in the prevalence of smoking among young people over time. The proportion of smokers increased by 10 percentage points and more in seven Member States (SK, PT, IT, HU, FR, CY, ES), being the highest in Slovakia and Portugal (an increase by 21 pp and 15 pp respectively). The prevalence remained unchanged in Romania (33%) and Austria (29%) between 2014 and 2017.

Sweden and Belgium are the countries where the proportion of smokers among young people greatly decreased (by more than 10 pp), amounting to 3% and 15% respectively in 2017.

Table 43. Prevalence of smoking across EU member states (overall and youth)

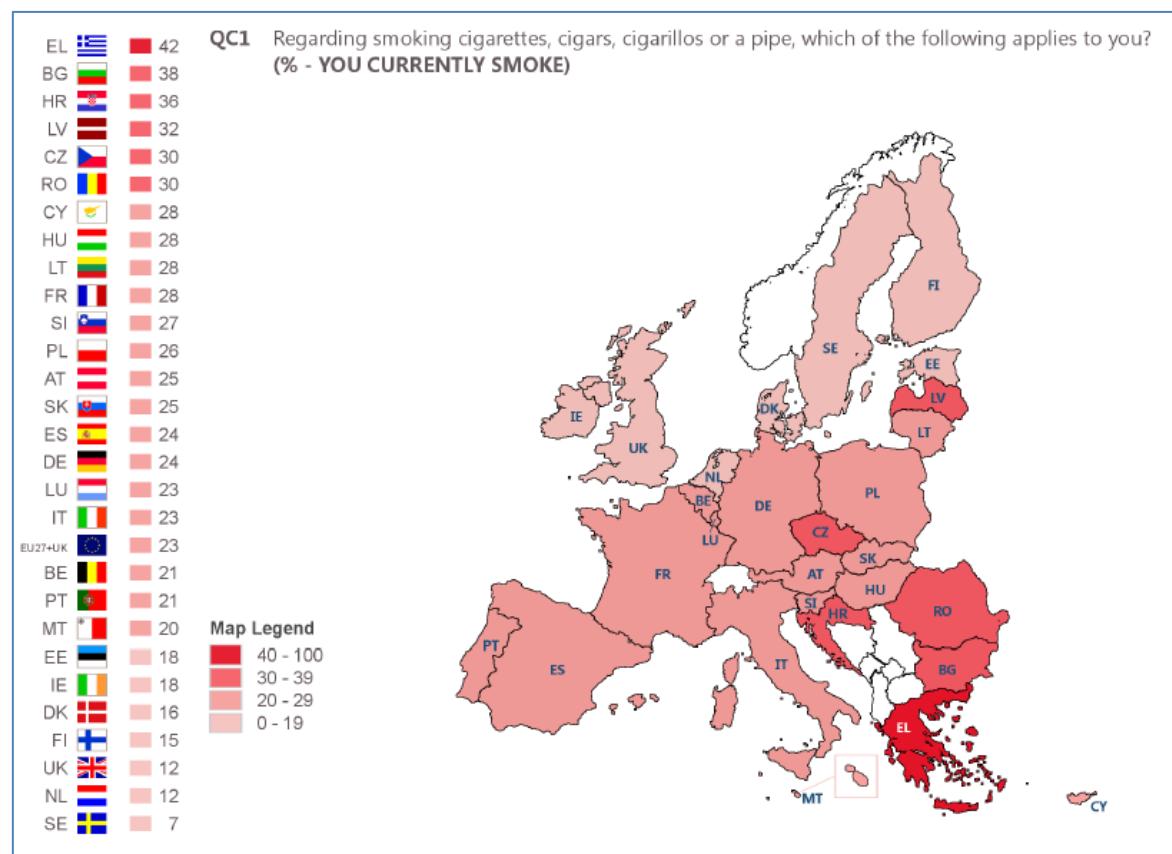
Country	Overall			Youth		
	2014	2017	2020*	2014	2017	2020*
Overall EU 27	-	-				
Overall EU 27+UK	26%	26%	24%	x	x	23%
Austria	28%	26%	27%	29%	29%	26%
Belgium	19%	25%	20%	15%	26%	25%
Bulgaria	36%	35%	39%	44%	42%	31%
Croatia	35%	33%	37%	38%	36%	33%
Cyprus	28%	31%	25%	26%	16%	29%
Czechia	29%	25%	31%	36%	32%	28%
Denmark	19%	23%	15%	13%	18%	11%
Estonia	23%	22%	19%	19%	14%	11%
Finland	20%	19%	14%	20%	19%	13%
France	36%	32%	27%	39%	28%	26%
Germany	25%	27%	28%	31%	28%	21%
Greece	37%	38%	44%	29%	33%	34%
Hungary	27%	30%	27%	39%	25%	36%
Ireland	19%	21%	18%	25%	22%	18%
Italy	24%	21%	23%	34%	20%	22%

Latvia	32%	30%	30%	35%	30%	27%
Lithuania	29%	26%	22%	34%	30%	26%
Luxembourg	21%	21%	22%	30%	24%	25%
Malta	24%	20%	18%	19%	21%	19%
Netherlands	19%	23%	13%	24%	20%	11%
Poland	30%	28%	26%	29%	27%	15%
Portugal	26%	25%	20%	37%	22%	22%
Romania	28%	27%	31%	33%	33%	27%
Slovakia	26%	21%	22%	35%	14%	33%
Slovenia	28%	30%	25%	33%	34%	28%
Spain	28%	29%	26%	31%	21%	24%
Sweden	7%	11%	6%	3%	23%	3%
United Kingdom	17%	22%	10%	18%	25%	8%

Source: ICF, based on Eurobarometer 2014, 2017, 2020. Note: Youth in the Eurobarometer data represents those between 15 and 24 years of age

* 2020 calculations were made without using weighting, and therefore do not match exactly the calculations made for the Eurobarometer report.

Figure 19. QC1 Regarding smoking cigarettes, cigars, cigarillos or a pipe, which of the following applies to you? (% - YOU CURRENTLY SMOKE)



Base: All respondents, N = 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.14

Respondents were also asked about which type of tobacco products they used, and how frequency they use them.

Less than a quarter (23%) of the respondents are current smokers of cigarettes, cigars, cigarillos or pipe, which represents a decline by three percentage points compared to 2017. On the contrary, more than half of respondents (55%) have never smoked and more than one in five (22%) used to be smokers but have stopped.

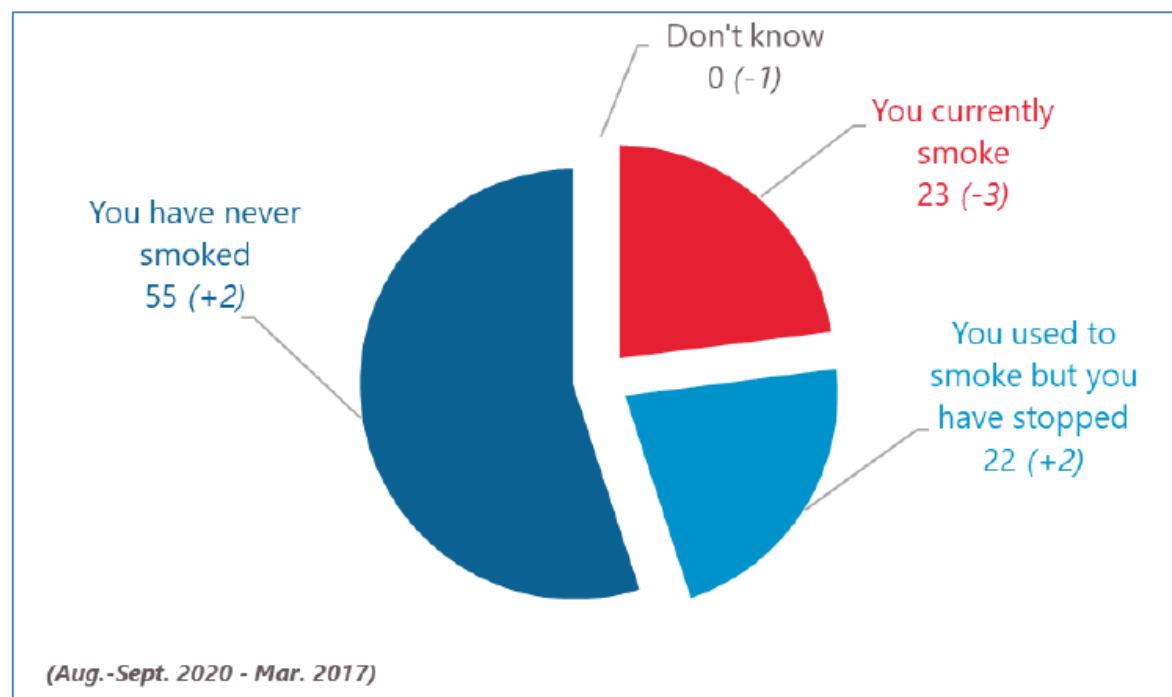
The socio-demographic analysis reveals that the profile of smokers is very similar to the one observed in March 2017. Around 27-30% of those aged (25-54) are smokers, compared with 18 % of those in the oldest age group (55+) or 20% in the youngest (15- 24). There has been an important decrease in the proportion of smokers aged 15-24 since 2017 (-9 pp, from 29% to 20%).

Table 44. Regarding smoking cigarettes, cigars, cigarillos or a pipe, which of the following applies to you? (%)

Age	You currently smoke
15-24	20
25-39	30
40-54	27
55+	18

Source: ICF, based on Eurobarometer 2020

Figure 20. QC1 Regarding smoking cigarettes, cigars, cigarillos or a pipe, which of the following applies to you? (% – EU27 + UK)



Base: All respondents, N = 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.13

Following previous ones from previous Eurobarometer surveys both smokers and ex-smokers were asked how often they smoke (or used to smoke) different types of tobacco products.

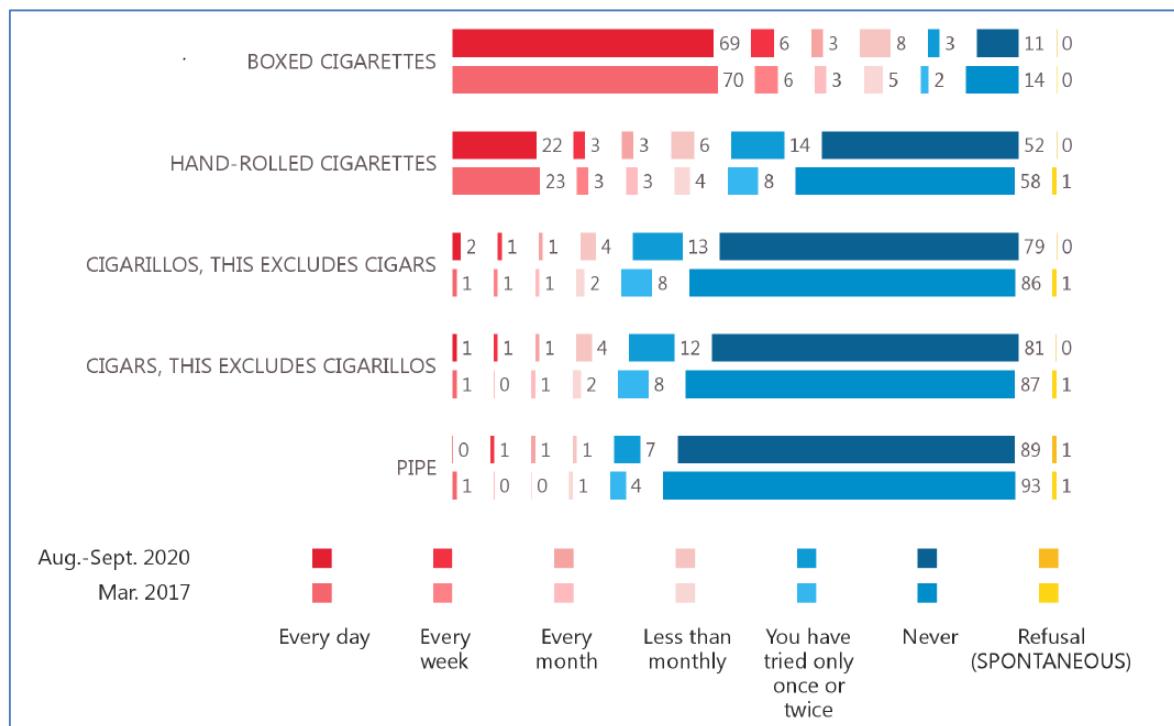
Boxed cigarettes are the most popular choice among smokers. Among smokers, almost eight in ten (78%) are regular users (at least monthly) of boxed cigarettes and almost seven in ten (69%) smoke boxed cigarettes at least once a day. The proportion of those smoking boxed cigarettes on a daily basis has remained stable compared to March 2017 (-1pp). However, when observing the long-term trend, this share has continued to decline, from 76% in December 2014.

On the other hand, hand-rolled cigarettes are consumed by 28% of tobacco users and more than one in five (22%) consume hand-rolled cigarettes daily. The proportion of daily users of hand-rolled cigarettes also appears to be broadly stable compared to 2017 (-1pp).

Finally, the only small proportion use cigarillos (4%), cigars (3%), or pipes (2%).

Only 2% or less smoke cigarillos, cigars or pipes on a daily basis. These tobacco products are more likely to be smoked on an occasional basis or tried only once or twice. Following a decline between 2014 and 2017, the proportion of those occasionally smoking cigarillos (13%, +5 pp), cigars (12%, +4pp), or pipes (7%, +3 pp) has increased again in the current survey.

Figure 21. QC4a How often do you use the following tobacco and related products? (%) - EU27 + UK)



Base: Respondents who smoke, N=6,775

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.26

By age group, we can observe those aged 25 or more are more likely than the youngest cohort to smoke boxed cigarettes (77-80% compared with 67%). The same pattern applies for daily consumption (68-74% compared with 50%).

On the other hand, respondents aged 15-24 are significantly more likely to smoke hand-rolled cigarettes, with 41% of respondents giving this response, compared with 22-29% of those aged 25 or more. Young smokers are also more likely than those in older age groups to smoke hand- rolled cigarettes daily (30% compared with 19- 21%).

Table 45. How often do you use the following tobacco and related products? (%)

Age	Boxed cigarettes		Hand-rolled cigarettes	
	Every day	Regular user	Every day	Regular user
15-24	50	67	30	41
25-39	68	77	21	29
40-54	73	80	21	27
55+	74	80	19	22

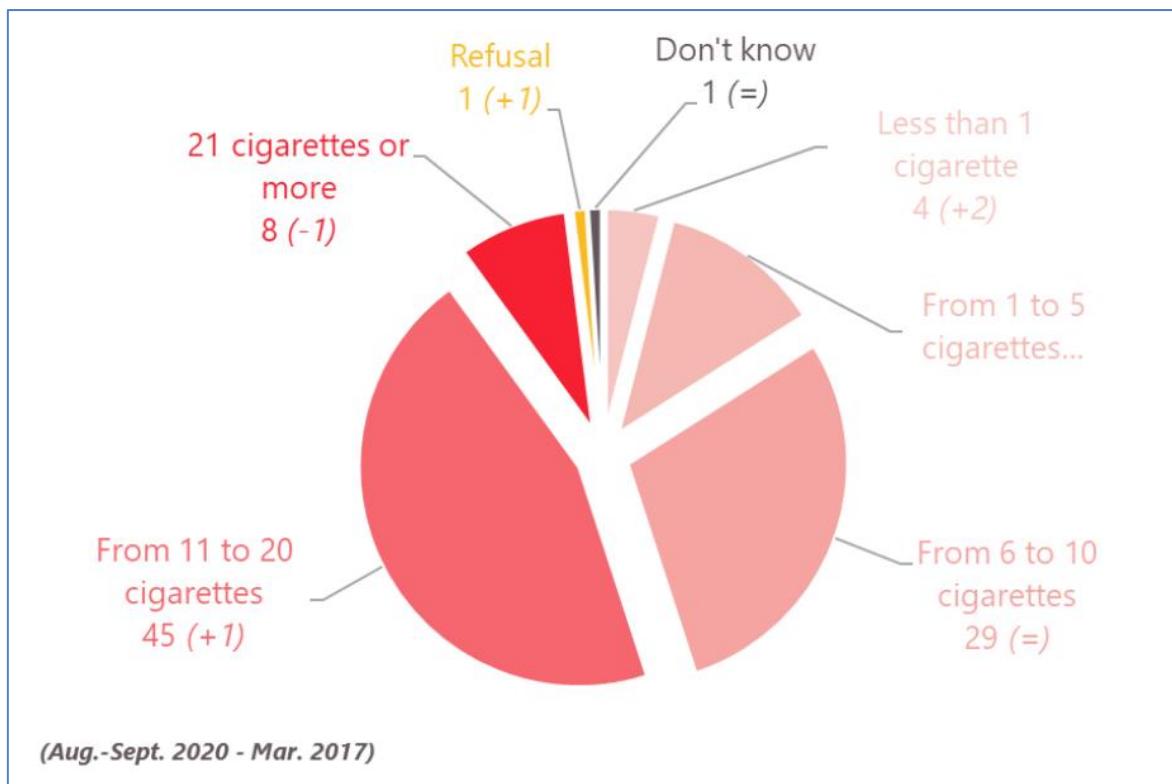
Base: Respondents who smoke, N=6,775

Source: ICF, based on Eurobarometer 2020

Regarding the number of cigarettes current cigarette smokers use each day, Eurobarometer results depict an average of 14 cigarettes per day (14.2) The average of daily consumption has increased by 0.5 since March 2017, when it was 13.7.

Almost half of current cigarette smokers smoke between 11 and 20 cigarettes, while barely one third smoke between six and ten cigarettes. Less respondents smoke lower or higher amounts of cigarettes: 8% smoke 21 cigarettes or more, while 12% smoke between one and five cigarettes and 4% have a daily average of less than one cigarette.

Figure 22. QC5a On average, how many cigarettes do you smoke each day? (%) - EU27 + UK)



Base: Respondents who smoke cigarettes, N= 6,507

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.36

The socio-demographic analysis reveals that the number of cigarettes smoked per day increases with age: 10.9 cigarettes among those aged 15-24, 15.4 among those aged 40 to 54 and 14.8 of those aged 55 or more. It is not clear why this trend occurs, but note the same pattern was seen in 2017.

Table 46. QC5a On average, how many cigarettes do you smoke each day? (%)

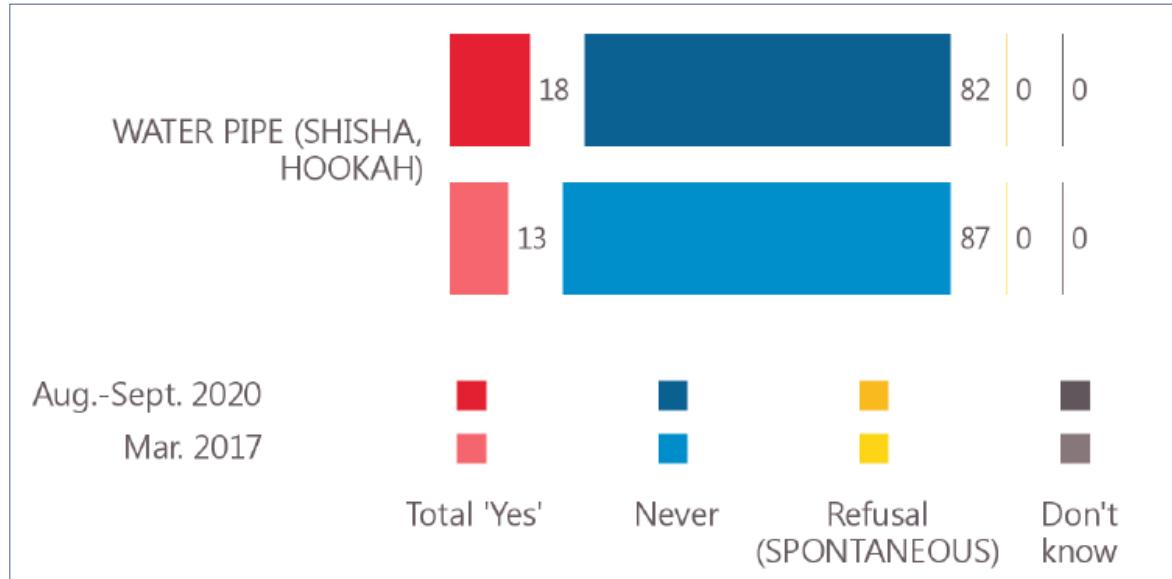
	Less than 1	From 1-5	From 6-10	From 11-20	21 or more	Refusal	Don't know
15-24	10	21	31	30	3	1	3
25-39	4	14	31	44	7	0	0
40-54	2	10	26	52	10	0	1
55+	4	9	29	47	8	2	1

Base: Respondents who smoke cigarettes, N= 6,507

Source: ICF, based on Eurobarometer 2020

As per previous Eurobarometer surveys, all respondents regardless of whether they were a current smoker, former smoker, or non-smoker, were asked if they had tried water pipes (shisha, hookah) and how frequently did they so. While most of surveyed have never tried these tobacco products, a 18% have tried a water pipe, which represents an increase from the 13% who gave this answer in March 2017.

Figure 23. QC6 Have you ever used or tried any of the following products? (% - EU27 + UK)

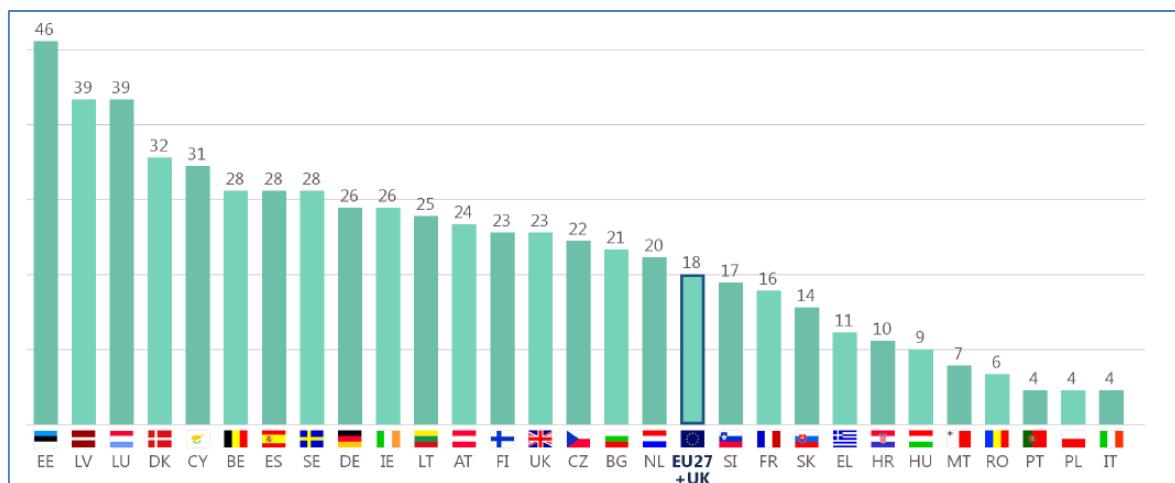


Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.43

It is worth noting that there are substantial differences across MSs in the proportions of those who have used a water pipe at least once or twice. Almost half of respondents say they have used (or still use) this product in Estonia and 39 % in Luxembourg and Latvia, while only 4% answer this way in Italy, Poland and Portugal.

The largest increases can be observed in Ireland (+23 pp), Spain (+17 pp), and Estonia and Luxembourg (both +15 pp), and are mostly due to a rise in the share of those who have used a water pipe only once or twice.

Figure 24. QC6.1 Have you ever used or tried any of the following products? Water pipe (shisha, hookah) (% - TOTAL 'YES')



Base: All respondents, N= 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.45

Figure 25. QC6.1 Have you ever used or tried any of the following products? Water pipe (shisha, hookah) (%)

	Total 'Yes'	Diff. August/September 2020 - March 2017		Never	Diff. August/September 2020 - March 2017	Refusal (SPONTANEOUS)	Diff. August/September 2020 - March 2017
		EU27+UK	IE				
EU27+UK	18	▲ 5	82	▼ 5	0	=	
IE	26	▲ 23	74	▼ 23	0	=	
ES	28	▲ 17	71	▼ 18	0	=	
EE	46	▲ 15	54	▼ 15	0	=	
LU	39	▲ 15	61	▼ 14	0	▼ 1	
UK	23	▲ 13	77	▼ 13	0	=	
BE	28	▲ 11	72	▼ 11	0	=	
BG	21	▲ 10	79	▼ 10	0	=	
DE	26	▲ 10	74	▼ 10	0	=	
FI	23	▲ 6	78	▼ 5	0	=	
HR	10	▲ 4	90	▼ 4	1	▲ 1	
CY	31	▲ 4	69	▼ 4	0	=	
HU	9	▲ 2	91	▼ 2	0	=	
RO	6	▲ 2	94	▼ 1	0	▼ 1	
LV	39	▲ 1	61	▼ 1	1	▲ 1	
AT	24	▲ 1	76	▼ 1	0	=	
DK	32	=	68	=	0	=	
FR	16	=	84	=	0	=	
LT	25	=	75	=	0	=	
PT	4	=	96	=	0	=	
IT	4	▼ 1	95	▲ 1	0	▼ 2	
SI	17	▼ 1	83	▲ 1	0	=	
SK	14	▼ 1	85	=	1	=	
EL	11	▼ 2	89	▲ 2	0	=	
CZ	22	▼ 3	77	▲ 2	1	▲ 1	
MT	7	▼ 3	88	▼ 1	1	=	
PL	4	▼ 3	95	▲ 3	1	▲ 1	
NL	20	▼ 4	80	▲ 4	0	=	
SE	28	▼ 4	72	▲ 4	0	=	

Base: All respondents, N= 28,300

Source: Special Eurobarometer 506 – Wave EB93.2 – Kantar; p.46

Looking at the analysis by age group, those aged 15-24 are generally more likely to have at least tried water pipes. Overall, 29% of young people say they have used them. A large proportion say that they have only tried them once or twice (17%) whereas 6% say they use them on a monthly basis.

*Table 47. Have you ever used or tried any of the following products? Water pipe
(shisha, hookah)*

Age	Total 'Yes' (%)
15-24	29
25-39	31
40-54	17
55+	7

Source: ICF, based on Eurobarometer 2020

Base: All respondents, N= 28,300

Annex 4 Euromonitor data analysis

5.5.1 Overview of the data and methodology

The categories of data collected by Euromonitor are presented in the table below. Due to the nature of Euromonitor's data collection strategy, these categorisations do not directly mirror those used in the TPD. Therefore, particular caution must be paid to the interpretation of this analysis with regard to its applicability to the categories described in the TPD (especially with regard to e-vapour products).

Table 48. Euromonitor and TPD product category definitions

Category	Euromonitor category definition	TPD category definition	Subcategory	Euromonitor subcategory definition	TPD subcategory definition
Cigarettes	The cigarettes category includes duty-paid, machine manufactured white-stick products.	Cigarette means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 3(1) of Council Directive 2011/64/EU	-	-	-
Cigars and cigarillos	Cigars and cigarillos are made of tobacco wrapped in leaf as opposed to paper. They generally consist of three sections: the filler, the binder and the wrapper.	The TPD cites the definition contained in Directive 2011/64/EU which states that cigars and cigarillos are defined as: rolls of tobacco made entirely of natural tobacco; rolls of tobacco with an outer wrapper of natural tobacco; rolls of tobacco with a threshed blend filler and with an outer wrapper of the normal colour of a cigar, of reconstituted tobacco, covering the product in full, including, where appropriate, the filter but not, in the case of tipped cigars, the tip, where the unit weight, not including filter or	Cigars	This category is the aggregation of large, standard and small cigars only.	Cigars must weigh over 3 grams each.
			Cigarillos	Cigarillos are defined as miniature cigars weighing less than 3 grams each, with a ring gauge of <29.	Cigarillos are cigars of a maximum weight of 3 grams each ⁵⁵² .

⁵⁵² Article 8(1) of Council Directive 2007/74/EC as referenced in the TPD

Category	Euromonitor category definition	TPD category definition	Subcategory	Euromonitor subcategory definition	TPD subcategory definition
		mouthpiece, is not less than 2,3 g and not more than 10 g, and the circumference over at least one third of the length is not less than 34 mm.			
Other tobacco products for smoking	Smoking tobacco consists of cut tobacco sold in packaged format for smoking either in pipes or for use in roll-your-own (RYO). This category includes products within the remit of pipe tobacco and fine cut tobacco.	There is no aligning definition of smoking tobacco/other tobacco products for smoking in the TPD. The TPD does mention the category of "tobacco products for smoking" which covers tobacco products other than a smokeless tobacco product. However, it is key to understand that this is not the same as the "smoking tobacco" category defined by Euromonitor, which only includes pipe tobacco and fine cut tobacco.	Pipe tobacco	Pipe tobacco includes cut tobacco sold in packaged format for smoking in pipes. It also includes water pipe tobacco.	Pipe tobacco means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe. Waterpipe tobacco means a tobacco product that can be consumed via a waterpipe.
			Fine cut tobacco	Fine Cut tobacco includes tobacco sold in packaged format for use in roll-your-own (RYO) and make-your-own (MYO) cigarettes	There is no definition of fine cut tobacco in the TPD. Roll-your-own tobacco means tobacco which can be used for making cigarettes by consumers or retail outlets.
E-vapour products	E-Vapour devices are distinguished from traditional combustible tobacco products by their production of vapour through a process of heating rather than the burning associated with the consumption of cigarettes, cigars, cigarillos or smoking tobacco. E-Vapour devices	There is no aligning definition of e-vapour products in the TPD. The TPD does cite the definition of electronic cigarettes (see below), however these only form a subset of the category provided by Euromonitor and therefore the two are not directly comparable.	Open vaping systems	This category is the aggregation of charging and vaporising devices and e-liquid. These systems are comprised of a power source (battery), a tank to hold e-liquid (vaporiser), and the e-liquid itself.	There is no definition of open vaping systems in the TPD.

Category	Euromonitor category definition	TPD category definition	Subcategory	Euromonitor subcategory definition	TPD subcategory definition
	usually include electronic circuitry and a power source supplying energy to the heating mechanism. E-Vapour products are not distinguished by the absence of tobacco. While the majority of current devices (e-cigarettes) are intended for use with a non-tobacco nicotine containing liquid the category includes tobacco products where it is heated and not combusted, such as heat-not-burn devices ⁵⁵³ .	Electronic cigarette means a product that can be used for consumption of nicotine-containing vapour via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.	Closed vaping systems	Closed vaping systems is split between cig-a-likes and non-cig-a-like closed systems	There is no definition of closed vaping systems in the TPD.
Heated tobacco products	Heated tobacco products include sales of products, generally manufactured by major tobacco companies, which heat rather than combust tobacco to produce vapour rather than smoke	There is no definition in the TPD explicitly covering heated tobacco products. However, these products do fall under the remit of novel tobacco products. Novel tobacco products refer to any product which does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and was placed on the market after 19 May 2014.	Tobacco heating devices	Tobacco heating devices are any piece of technology or equipment which allow the consumer to heat rather than combust a tobacco product	There is no definition of tobacco heating devices in the TPD.
			Heated tobacco	Heated tobacco is the consumable element of tobacco vapour products and can come in the form of tobacco pods or in specially designed cigarettes	There is no definition of heated tobacco in the TPD.
Smokeless tobacco	Smokeless tobacco is the general term used to describe	There is no aligning definition of smokeless tobacco as an overall	Chewing tobacco	Chewing tobacco consists primarily of two types of	Chewing tobacco means a smokeless tobacco

⁵⁵³ Euromonitor International confirmed that HTPs are treated in the category "Heated tobacco products" and are not included in the E-vapour category as defined in their data used for this study.

Category	Euromonitor category definition	TPD category definition	Subcategory	Euromonitor subcategory definition	TPD subcategory definition
(excluding HTPs)	tobacco products that are utilised without combustion. Smokeless tobacco is used either in the mouth or in the nose, by chewing inhaling or sucking, and traditionally has been divided into two subcategories, snuff and chewing tobacco	category of tobacco products in the TPD.	Moist snuff	product: Asian-style, US-style available in those specific geographic areas and other chewing tobacco available in all other markets	product exclusively intended for the purpose of chewing; There is no definition of moist snuff in the TPD. The TPD does provide a definition of nasal tobacco as a smokeless tobacco product that can be consumed via the nose.

Source: Euromonitor International; Tobacco Industry Edition, 2021 , TPD

Market size analysis

Market size was calculated using two separate measurements

- **Retail value:** the value of sales based on their retail selling price (RSP) in millions of Euros. This was calculated using year-on-year exchange rates, to account for inflation over the time period.
- **Retail volume:** the volume of sales, the units of which depended on the individual product. The units included were millions of sticks, million units, and tonnes depending. A breakdown of the units and product types can be found in Table 49.

Since it was not possible to aggregate retail volume data at the overall market level, an aggregate market analysis was conducted using retail value data. A similar approach to analysing market size was conducted in the Consumer Preference and Perceptions study⁵⁵⁴. This measurement alone however does not allow us to differentiate whether changes in the market have been driven by prices or volumes. Therefore, retail volume data on specific tobacco products has been used to complement these aggregate findings.

For both variables, aggregate totals for all Member States were manually created to provide an aggregate description of the state of play across 25 EU countries. Data was not provided for CY, MT, and LU.

For the retail value data, variables were re-categorised to form the categories presented in Table 49. Firstly, cigarettes, cigars and cigarillos, and other tobacco products for smoking were aggregated into a single category. Whilst initially smokeless tobacco, e-vapour products, and heated tobacco products were categorised together, these were separated to form three separate groups, with heated tobacco products falling under the category of novel tobacco products. E-vapour and smokeless tobacco (excluding HTPs) were considered as individual categories.

Table 49. Indicator mapping

Overall category	Type of tobacco product	Specific product	Units	Relevant section in AF
Cigarettes, cigars and cigarillos, and other tobacco products for smoking	Cigarettes	-	Retail Value RSP (€ million)	AFT2. Q2
			Retail Volume (million sticks)	
	Cigars and cigarillos	Cigars	Retail Value RSP (€ million)	AFT2. Q2
		Cigarillos	Retail Volume (million units)	
	Other tobacco products for smoking	Pipe tobacco	Retail Value RSP (€ million)	AFT2. Q2
		Fine cut tobacco	Retail Volume (tonnes)	

⁵⁵⁴ Consumer preference and perception of specific categories of tobacco and related products, LSE and Partners Consortium (Feb 2020)

E-vapour products	Closed vaping systems	-	Retail Value RSP (€ million)	Article 20 AFT2. Q2
	Open vaping systems	-		AFT2. Q6a
Novel tobacco products	Heated tobacco products (HTPs)	Tobacco heated devices	Retail Value RSP (€ million)	Article 19 AFT2. Q2
		Heated tobacco	Retail Value RSP (€ million)	Retail Volume (million units) AFT2. Q6a
		Heated tobacco	Retail Value (million sticks)	Retail Volume (million sticks)
Smokeless Tobacco (excluding HTPs)⁵⁵⁵	Chewing tobacco	-	Retail Value RSP (€ million)	AFT2. Q2
	Moist snuff	-		Retail Volume (tonnes)

Source: Euromonitor International; Tobacco Industry Edition, 2021 (2020)

The Euromonitor market size data provided values in retail volume for the following products using the units specified in Table 50 below.

Table 50. Retail volume data available in Euromonitor

Overall category	Type of tobacco product	Specific product	Units
Cigarettes, cigars and cigarillos, and other tobacco products for smoking	Cigarettes	-	Million sticks
	Cigars and cigarillos	Cigars	Million units
		Cigarillos	Million units
	Other tobacco products for smoking	Pipe tobacco	Tonne
		Fine cut tobacco	Tonne
Smokeless tobacco (excluding HTPs)	Smokeless tobacco	Chewing tobacco	Tonne
		Moist snuff	Tonne
Novel tobacco products	Heated tobacco products	Tobacco heated devices	Million units
		Heated tobacco	Million sticks

Source: Euromonitor International; Tobacco Industry Edition, 2021 (2020)

Due to the discrepancies in the measurement units across tobacco products, the analysis of retail volumes focuses on the individual products in the table above. The difference in units between type of tobacco products inhibited the study team from conducting an aggregate market size analysis using retail volumes to complement their analysis of retail value. Furthermore, data on retail volumes was not available for E-vapour products. Overall, this makes it impossible to form volume specific

⁵⁵⁵ Data only available for BG, CZ, DK, ES, SE, SK

inferences about the development of the whole tobacco market over time, in addition to that of E-vapour products.

Finally, retail value and retail volume data on smokeless tobacco products was only available for BG, CZ, DK, ES, SE, SK.

5.5.1.1 Prevalence analysis

The prevalence analysis was conducted using smoking prevalence data provided by Euromonitor. This detailed the number of smokers in thousands and smokers as a proportion of the population in % for the following product categories:

- Cigarettes
- E-Vapour products
- Heated tobacco products

Data was available for 25 Member States⁵⁵⁶, where CY, MT, and LU were not included.

Population data was obtained from EUROSTAT. This was aggregated for the relevant 25 EU Member States and used as the denominator to calculate the proportion of the EU population using the tobacco products specified above between 2014-19. Table 51 details the indicators used in the prevalence analysis.

Table 51. Indicators used in prevalence analysis

Indicator	Units	Relevant section in AF	Source
Smoking population: number of adult smokers	Thousands	AF2 Q5.b	Euromonitor
Smoking population: % of population	%		
Population	Persons		EUROSTAT

Source: Euromonitor International; Tobacco Industry Edition, 2021 , EUROSTAT

5.5.2 Market size of products covered by the TPD

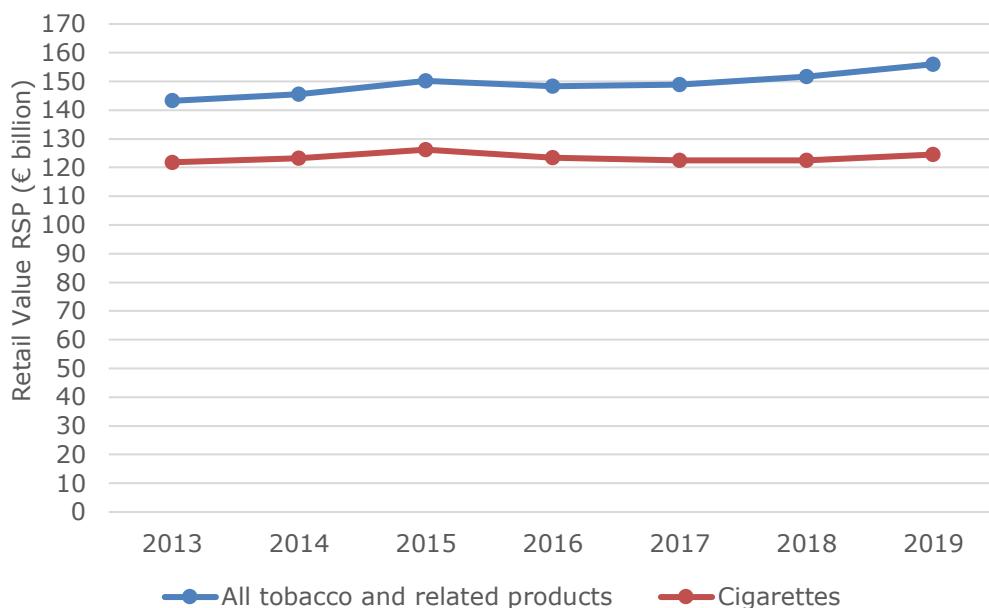
5.5.2.1 Retail value and retail volume trends

Overall picture: retail value

Figure 26 shows the trends in market size for all tobacco and related products, and cigarettes. Figure 27 presents these same trends for cigars and cigarillos, other tobacco products for smoking, smokeless tobacco (excluding HTPs), and e-vapour products, and heated tobacco products. Figure 26 demonstrates that the EU tobacco market consists mostly of sales of cigarettes, which in 2019 contributed €124.5 billion to the €156 billion market. This is significantly more than any other product category, with other tobacco products for smoking being the second largest contributor with a retail value of €17.5 billion in 2019. Sales for cigarettes, despite decreasing between 2015-16, have remained relatively stable. This trend was also reflected by the market for tobacco and related products as a whole.

⁵⁵⁶ 24 EU Member States and the UK; as in the main report these are referred to as "Member States" in the annexes.

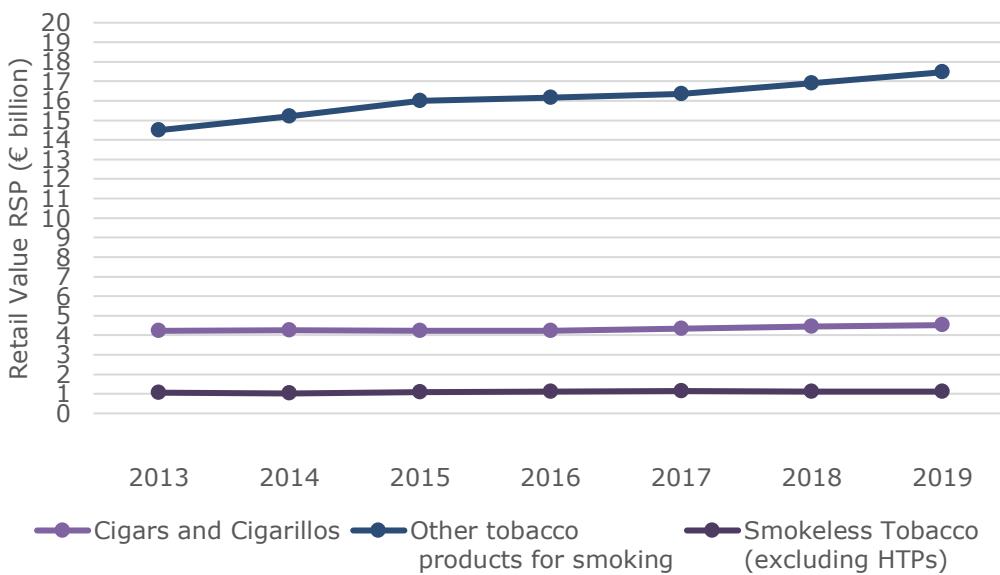
Figure 26. Evolution of market size of all tobacco products and cigarettes



Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Sales of cigars and cigarillos remained relatively constant at EU level, increasing by €0.3 billion over the period. A similar trend is observed for smokeless tobacco, where retail value remained constant. Other tobacco products for smoking experienced a relatively fast rise between 2013-15 which then re-emerged between 2017-19, with an overall increase of €3 billion between 2013-19.

Figure 27. Evolution of market size of cigars and cigarillos, other tobacco products for smoking, smokeless tobacco (excluding HTPs)

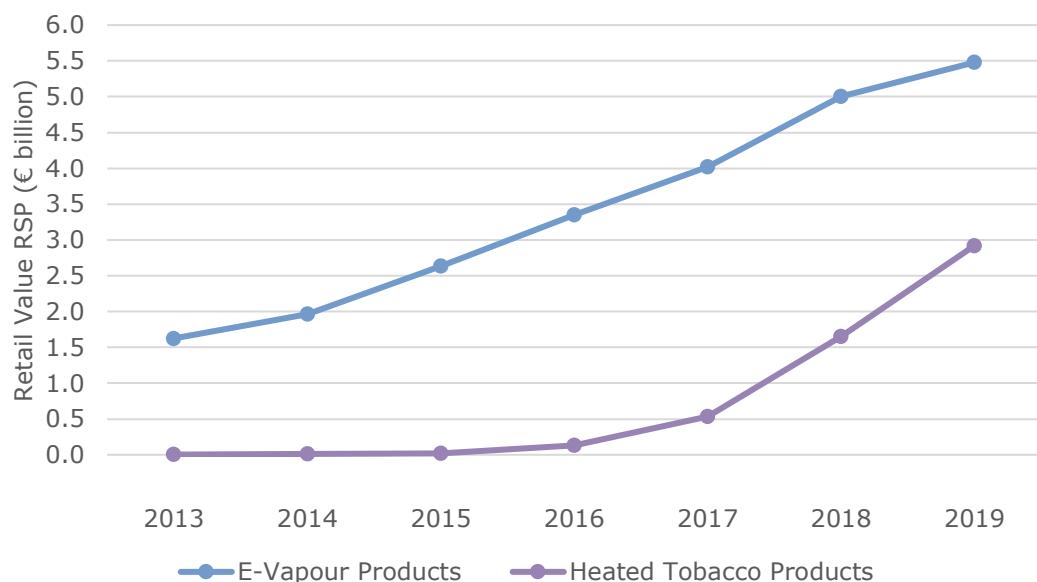


Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Over the period 2013-19 the size of the market for e-vapour products increased by a total of 237% in terms of retail value, following a consistent upward year-on-year

upward trend before starting to flatten off in 2019⁵⁵⁷. The trend for heated tobacco products however only started to substantially increase after 2015. Data on heated tobacco products before 2016 was only available for AU, FR, IT. This indicates that the market for heated tobacco products is relatively new in the majority of member states, and explains the high levels of growth in their retail value from 2016 onwards.

Figure 28. Evolution of market size of e-vapour products and HTPs

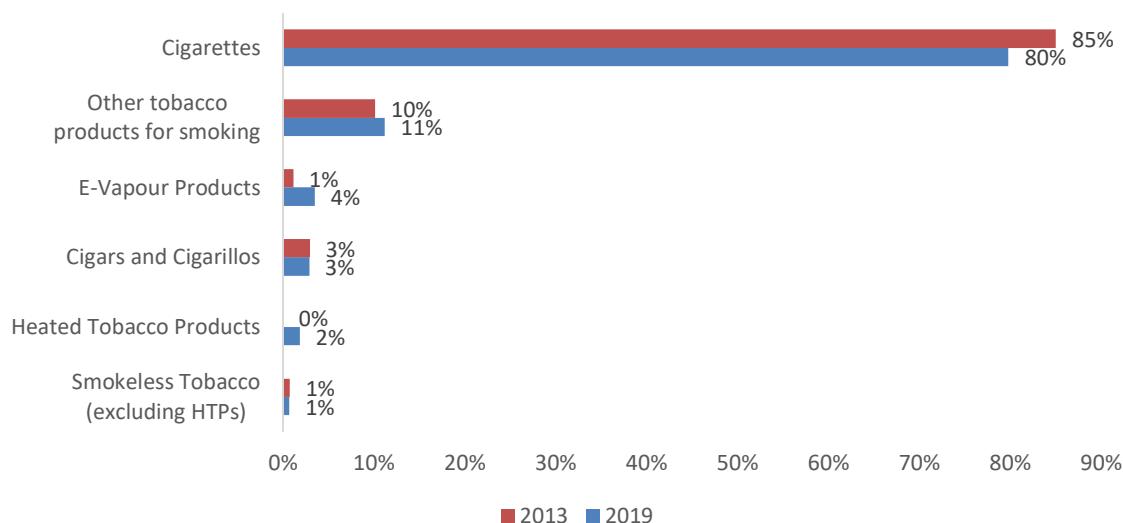


Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Figure 29 represents the change in the market share of different products in the tobacco market in 2013 and in 2019. In 2013, 85% of the retail value of the tobacco market came from the sale of cigarettes. Other tobacco products for smoking were the second largest contributor, with a share of 10%. In 2013, e-vapour products constituted only 1% of the retail value of the market, and heated tobacco products 0%. In 2019, the market share of cigarettes decreased by five percentage points to 80%. This change can be attributed mostly to the growth of e-vapour products and heated tobacco products to , which respectively increased to 4% and 2%. This transfer of market share from cigarettes to e-vapour/heated tobacco products supports the indication of a substitution effect, with consumers replacing their use of cigarettes with alternatives.

⁵⁵⁷ There is no retail volume data available for E-vapour products. Therefore, it is not possible in this case to make inferences about whether prices or volumes are driving the increase in retail value RSP.

Figure 29. Retail value market shares in 2013 and 2019



Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Product breakdown by retail value and retail volume

Table 52 details the market size and growth in retail value for all tobacco products, in aggregate categories and individually, from 2013-19. Table 53 includes analogous information for retail volume, except for the exclusion of e-vapour products and information on the categories at an aggregate level. It is important to clarify that although all products experienced growth in their retail value, this does not necessarily imply the same changes in retail volume, as retail value calculations are also influenced by prices. Therefore, in order to gauge market developments independent of prices, retail volume acts as a more precise indicator.

Table 52. Market size and growth of retail value for tobacco and related products between 2013-2019 (€ billion)

Product category	Market size in 2013	Market size in 2019	Market growth (2013-19)
All tobacco products	143.2	156.0	9%
Cigarettes, Cigars and Cigarillos, and Other tobacco products for smoking	140.5	146.5	4%
Cigarettes	121.8	124.5	2%
Cigars and Cigarillos	4.2	4.5	7%
Cigars	2.1	2.2	2%
Cigarillos	2.1	2.4	12%

Product category	Market size in 2013	Market size in 2019	Market growth (2013-19)
<i>Other tobacco products for smoking</i>	14.5	17.5	20%
Pipe tobacco	0.5	0.8	71%
Fine cut tobacco	14.0	16.6	19%
Smokeless tobacco (excluding HTPs)	1.1	1.1	4%
<i>Chewing tobacco</i>	0.0	0.0	28%
<i>Moist snuff</i>	1.1	1.1	4%
E-vapour products	1.6	5.5	237%
Closed vaping systems	0.3	1.2	277%
Open vaping systems	1.3	4.3	227%
Heated tobacco products	0.5⁵⁵⁸	2.9	445%⁵⁵⁹
Tobacco heated devices	0.0 ⁵⁶⁰	0.3	403% ⁵⁶¹
Heated tobacco	0.5 ⁵⁶²	2.7	450% ⁵⁶³

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Table 53. Market size and growth of retail volume for tobacco and related products between 2013-2019

Product category	Units	Market size in 2013	Market size in 2019	Market growth (2013-19)
Cigarettes, Cigars and Cigarillos, and Other tobacco products for smoking				
<i>Cigarettes</i>	Billion sticks	510.9	453.4	-11%
<i>Cigars and Cigarillos</i>	Billion units	10.5	9.7	-7%
<i>Cigars</i>	Billion units	1.4	1.1	-16%

⁵⁵⁸ Data point is for 2017

⁵⁵⁹ Growth rate between 2017-19 due to recent introduction of products on the EU market

⁵⁶⁰ Data point is for 2017

⁵⁶¹ Growth rate between 2017-19 due to recent introduction of products on the EU market

⁵⁶² Data point is for 2017

⁵⁶³ Growth rate between 2017-19 due to recent introduction of products on the EU market

Product category	Units	Market size in 2013	Market size in 2019	Market growth (2013-19)
Cigarillos	Billion units	9.2	8.6	-6%
<i>Other tobacco products for smoking</i>	Thousand Tonnes	91.2	85.0	-7%
Pipe tobacco	Thousand Tonnes	3.5	6.5	88%
Fine cut tobacco	Thousand Tonnes	87.7	78.5	-11%
Smokeless tobacco (excluding HTPs)				
<i>Chewing tobacco</i>	Thousand Tonnes	0.012	0.023	38%
<i>Moist snuff</i>	Thousand Tonnes	6.3	7.0	12%
Novel tobacco products				
<i>Heated tobacco products</i>				
Tobacco heated devices	Billion units	0.001 ⁵⁶⁴	0.003	300% ⁵⁶⁵
Heated tobacco	Billion sticks	2.2 ⁵⁶⁶	12.3	447% ⁵⁶⁷

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Cigarettes, Cigars and Cigarillos, and other tobacco products for smoking

The retail value data indicates that over the period 2013-19 cigarettes, cigars and cigarillos, and other tobacco products for smoking experienced overall growth of 4%. The retail value of cigarettes and cigars remained relatively constant, however higher rates of growth were experienced by cigarillos (12%) and fine cut tobacco (19%). The retail value of pipe tobacco increased by over half during this period (71%), the highest growth rate experienced by all the products in this category.

However, in terms of retail volumes all products in this category experienced negative growth rates except for pipe tobacco (88%). This indicates that the growth experienced in retail value was due to price increases rather than increases in the volume of tobacco products sold. The largest declines were experienced by cigarettes (-11%), fine cut tobacco (-11%), and cigars (-16%).

E-vapour products

Figure 30 considers the composition of the market for e-vapour products, which has remained relatively stable over the period 2013-19. Open vaping systems constituted most of the market's retail value across the period whilst closed vaping systems accounted for between 13% and 22% across individual years. Open vaping systems include charging and vaporising devices, and e-liquids and closed vaping systems refer

⁵⁶⁴ Data point is for 2017

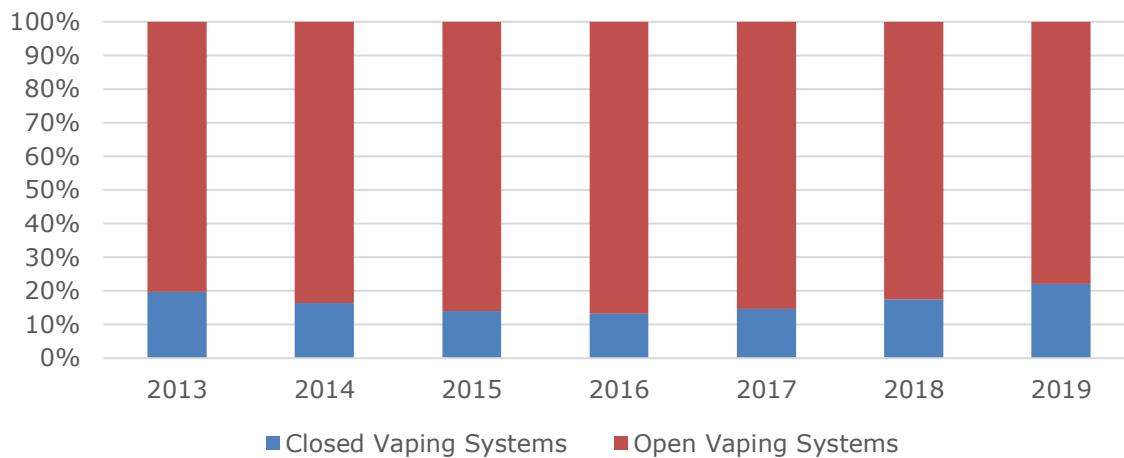
⁵⁶⁵ Growth rate between 2017-19 due to recent introduction of products on the EU market

⁵⁶⁶ Data point is for 2017

⁵⁶⁷ Growth rate between 2017-19 due to recent introduction of products on the EU market

to cig-a-likes and non cig-a-like closed systems (see Table 48 for a more detailed description of these categories).

Figure 30. Composition of the market for e-vapour products 2013-19 (retail value)

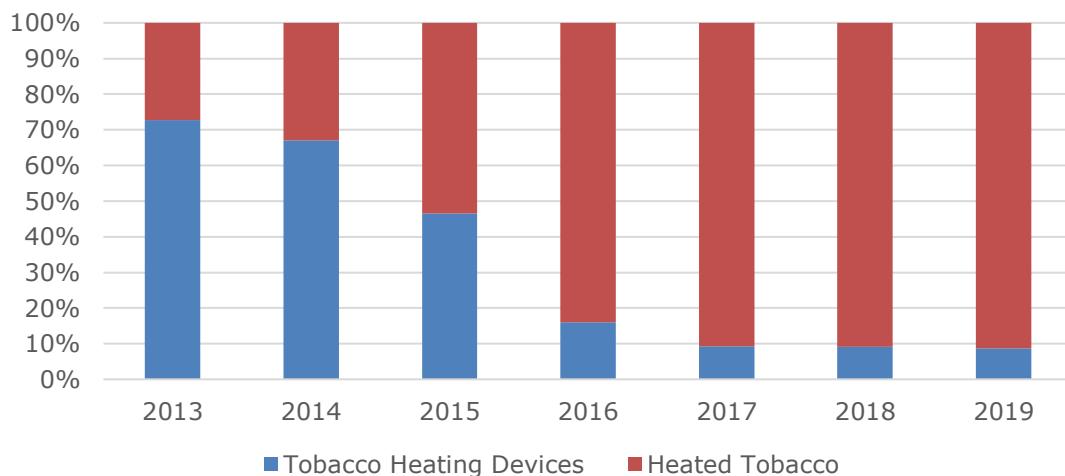


Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Heated Tobacco Products

Figure 31 describes the composition of the market for heated tobacco products. Tobacco heated devices are any piece of technology or equipment which allow the consumer to heat rather than combust a tobacco product, and heated tobacco refers to the consumable element of tobacco vapour products (i.e. tobacco pods). In 2013 73% of the retail value of the market was generated by tobacco heated devices, whilst the remaining 27% was generated by heated tobacco. By contrast, in 2019 91% of retail value came from heated tobacco, and 9% from tobacco heated devices. This can be explained by the fact that tobacco heated devices can be considered as a one-off sunk cost for those using heating tobacco products, which does not need to be replaced frequently. Heated tobacco on the other hand includes the pods necessary to use tobacco heated devices and need to be purchased regularly. Therefore, this change in market composition is indicative of heated tobacco products becoming more established amongst tobacco users, as those who are using heated tobacco products have already purchased tobacco heating devices.

Figure 31. Composition of the market for Heated Tobacco Products 2013-19 (Retail Value)



Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Smokeless Tobacco Products (excluding HTPs)

Data on smokeless tobacco was only available for the following countries: BG, CZ, DK, SK, ES, SE. Overall, smokeless tobacco experienced increase in retail value of 4% between 2013-18. The retail volume of both moist snuff and chewing tobacco also reported increases of 12% and 38% respectively. Overall, this indicates that consumers are demanding more smokeless tobacco products in the countries in which they are available.

5.5.2.2 Breakdown by Member State

All tobacco and related products

Figure 32 presents the retail value of all tobacco products across 25 individual EU MS (hereinafter EU-25) in 2013 and in 2019. Only 25 of the EU-28 Member States have been included as data was not made available for CY, LU, and MT. It was not possible to calculate data on retail volume for all tobacco products due to the differences in measurement units across products. The four largest member states based on retail value are Germany, the UK, France, and Italy, which is to be expected given their large population size relative to other Member States.

Table 54 categorises the growth rate of retail value of each of the 25 Member States between 2013-19 based on quartile ranges. Member states in the first quartile experienced the slowest growth rates, and in some cases negative growth, whilst those in the fourth quartile experienced the fastest growth rates of the Member States. For heated tobacco products, data for some countries was not available, and the 2017-19 growth rate was used as for most countries no data on heated tobacco products was available before this period.

Overall, the countries which experienced the highest rates of growth for all tobacco products were Bulgaria, Czechia, Finland, Latvia, Lithuania, Malta, and Slovakia, where between 2013 and 2018 the retail value of the tobacco market increased by 23%-55%. Most countries experienced increases in the retail value of all tobacco products between 2013-18, except for Belgium, Denmark, Greece, Spain, and Sweden where the retail value decreased.

Figure 32. EU-25 breakdown of market size of tobacco and related products in 2013 and 2019 (retail value)

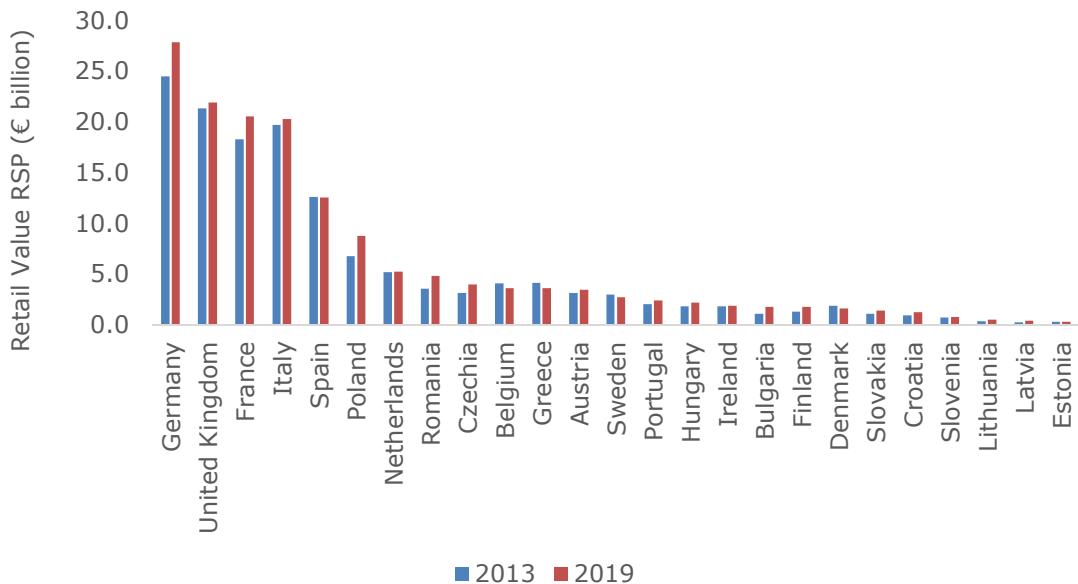


Table 54. Typology of distribution of growth rates across EU-25 (2013-2019)

Growth quartile	All tobacco products	Cigarettes, cigars and cigarillos, and other tobacco products for smoking	E-Vapour products ⁵⁶⁸	Heated tobacco products (2017-19) ⁵⁶⁹
First quartile (slowest growth)	BE, DK, EL, IE, ES, SE	BE, DK, EL, IE, SE, UK	EE, HU, PT, RO, DK, EL, RO, UK SK, ES	
Second quartile	AT, EE, IT, NL, SI, UK	AT, EE, IT, NL, SI, ES	BG, CZ, FR, EL, HR, FR, IT, PT IT, SI	
Third quartile	HR, CZ, FR, DE, HU, PL, PT	HR, CZ, FR, DE, HU, PL, PT	AT, BE, DK, IE, LT, SK, ES LT, NL, PL	
Fourth quartile (fastest growth)	BG, FI, LV, LT, RO, SK	BG, FI, LV, LT, RO, SK	HR, FI, DE, LV, SE, UK	DE, NL, PL, SI

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

⁵⁶⁸ Data for SK is from 2014-2019 as no data were available for 2013

⁵⁶⁹ Data is for 2017-18 due to recent introduction of HTPs in market. No data available for AT, BE, BG, CY, EE, FI, HU, IE, LV, LU, MT, SE

Cigarettes, Cigars and Cigarillos, and Other Tobacco Products for Smoking

Cigarettes

Given that cigarettes make up the majority of the tobacco market across all countries in the EU, the breakdown of retail value is somewhat analogous to that presented in Figure 32, with Germany, Italy, the UK, and France acting as the main drivers of the market.

Table 55 shows that the highest growth in retail value and retail volume of cigarettes between 2013-18 was observed in Bulgaria, at 51% and 18% respectively. Only 2 of the 25 Member States experienced an increase in the retail volume of cigarettes over the period (BG, SK). This indicates that the purchase of cigarettes is going down in the majority of EU countries, with any observed rise in the retail value of cigarettes being due to increases in the price of cigarettes rather than volume. The largest decreases in retail volume over the period were observed in Ireland (-22%), the UK (-28%), and Greece (-36%).

Table 55. Matrix of growth rates across EU-25 in retail value and retail volume for cigarettes, cigars, and cigarillos (2013-2019)

Member State	Cigarettes		Cigars		Cigarillos	
	RSP	VOL	RSP	VOL	RSP	VOL
Austria	8%	-10%	25%	7%	19%	6%
Belgium	-4%	-20%	-20%	-29%	-14%	-19%
Bulgaria	51%	18%	45%	43%	5%	13%
Croatia	21%	-2%	168%	150%	35%	20%
Czechia	18%	-1%	17%	2%	18%	12%
Denmark	-14%	-20%	-16%	-32%	-37%	-64%
Estonia	3%	-17%	52%	-33%	53%	30%
Finland	31%	-19%	37%	1%	24%	2%
France	5%	-21%	23%	-13%	27%	-8%
Germany	10%	-6%	4%	-9%	-6%	-24%
Greece	-23%	-36%	-27%	-21%	-12%	16%
Hungary	19%	-11%	40%	13%	138%	124%
Ireland	-9%	-22%	-14%	-31%	0%	-18%
Italy	-6%	-14%	11%	8%	114%	109%
Latvia	41%	0%	44%	-13%	-17%	-57%
Lithuania	29%	-6%	57%	25%	36%	15%
Netherlands	6%	-10%	-17%	-25%	2%	-5%
Poland	20%	-4%	-13%	-25%	-26%	-34%
Portugal	17%	-2%	-3%	-14%	29%	44%
Romania	24%	-1%	156%	129%	217%	724%
Slovakia	20%	3%	34%	25%	43%	35%

Member State	Cigarettes		Cigars		Cigarillos	
	RSP	VOL	RSP	VOL	RSP	VOL
Slovenia	6%	-12%	4%	-13%	-24%	-39%
Spain	0%	-5%	-10%	-22%	-6%	-10%
Sweden	-15%	-10%	2%	3%	-20%	-4%
United Kingdom	-14%	-28%	-23%	-28%	-1%	-4%

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Cigars and Cigarillos

The market for cigars and cigarillos is largest in Germany, followed by France, Spain and Italy. This suggests that the market for these products is concentrated in large Western European countries.

Croatia experienced the highest growth the market size of cigars, with retail value increase g by 168% and retail volume 150%. This was followed by Romania where retail value increased by 156% and retail volume by 129%. Negative growth rates for retail volume were observed in 14 out of the 25 MS, which explains the overall decrease in cigar volumes across the EU during this period (-16%). The largest declines in were observed in Estonia, Denmark, and Ireland, where retail volume of cigars decreased by approximately one-third from 2013-19.

Significant growth in the market size of cigarillos over the period was observed in Romania, Italy, and Hungary. In Romania, retail value more than doubled (217%) and retail volume increased by over seven-fold (724%). In 13 out of the 25 MS, the retail volume of cigarillos increased between 2013-19. Decreases in the retail volume of cigarillos were most prevalent in Denmark (-64%), Latvia (-57%) and Slovenia (-39%).

Other tobacco products for smoking

Table 56 shows that, as in the case of cigarettes and cigars and cigarillos, the main drivers of the market for smokeless tobacco are Germany, the UK, and France; all of which experienced positive growth rates between 2013-19. Euromonitor data indicates that the market size for other tobacco products for smoking was highest in Germany, at just under €4 billion in 2019.

Table 56 presents the growth in retail value and retail volume for the constituents of other tobacco products for smoking: fine cut tobacco and (water-)pipe tobacco. In 2019, the Member States with the largest retail value of the market for fine cut tobacco were the UK, Germany, and France. Between 2013-19, Romania experienced the largest growth in the fine cut tobacco market, with retail value and retail volume increasing by over ten-fold (1008% and 1024% respectively). Growth rates of over 100% in the retail volume of fine cut tobacco were also observed in Slovakia, Lithuania, and Latvia. This indicates that despite the market for fine cut tobacco being concentrated in Western Europe, it is currently experiencing rapid growth in Eastern Europe. The retail volume of fine cut tobacco decreased by over half in Portugal (-64%) and Sweden (-55%).

The pipe tobacco market is smaller than the fine cut tobacco market. The Member States with the largest pipe tobacco markets (retail value) in 2019 were, similarly to fine cut tobacco in order of highest retail sales; Germany, France, and the UK. Between 2013 and 2019, Portugal and Germany saw both the retail value and the retail volume of pipe tobacco grow by over 200%. Other Member States where the retail value and volume more than doubled over the period included Romania,

Bulgaria, and Spain. The retail volume of pipe tobacco decreased the most in Sweden (-47%), Denmark (-43%), and Hungary (-43%).

For both fine cut and pipe tobacco, 13 of the 25 MS experienced a fall in retail volume. These countries differed depending on the product, for example Germany experienced a contraction in the retail volume of fine cut tobacco (-8%), whilst concurrently observing and growth in the retail volume of pipe tobacco (207%). A similar trend was observed in Portugal, where retail volume for fine cut tobacco fell (-64%) whilst rising for pipe tobacco (360%). The Member States that experienced a decrease in the retail volume of both fine cut and pipe tobacco were: Belgium; Denmark; Finland; Hungary; Netherlands; Sweden.

Table 56. Matrix of growth rates across EU-25 in retail value and retail volume for other tobacco products for smoking by product category (2013-2019)

Member State	Fine cut tobacco		Pipe tobacco	
	RSP	VOL	RSP	VOL
Austria	51%	4%	74%	91%
Belgium	-35%	-43%	-31%	-33%
Bulgaria	15%	4%	129%	126%
Croatia	54%	14%	-13%	-29%
Czechia	9%	-14%	20%	-7%
Denmark	-29%	-34%	-38%	-43%
Estonia	54%	6%	7%	-8%
Finland	49%	-14%	43%	-15%
France	43%	-20%	103%	23%
Germany	9%	-8%	203%	207%
Greece	17%	-4%	0%	0%
Hungary	20%	-18%	-33%	-43%
Ireland	64%	39%	-34%	-39%
Italy	75%	42%	13%	5%
Latvia	196%	115%	24%	-13%
Lithuania	323%	235%	17%	-12%
Netherlands	-14%	-28%	-3%	-23%
Poland	97%	89%	29%	11%
Portugal	-44%	-64%	260%	360%
Romania	1008%	1024%	133%	164%
Slovakia	367%	315%	33%	27%
Slovenia	-32%	-48%	100%	61%
Spain	-4%	-13%	110%	101%
Sweden	-56%	-55%	-47%	-47%
United Kingdom	41%	7%	-14%	-26%

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

E-vapour products

Table 57 describes the breakdown of the retail value of e-vapour products by country and year. The UK is the driver of the growth of e-vapour within the EU and accounted for just under €3 billion of the total market value products in 2019. The closest Member States in terms of generating retail value in 2019 were in descending order; France, Germany, and Poland . The countries which experienced the highest rates of growth in the retail value of e-vapour products included Croatia (1912%), Latvia (1875%) and Sweden (1025%). The only countries that observed falls in the retail value of e-vapour products were Hungary (-18%) and Spain (-35%).

Table 57. EU-25 breakdown of the market size and market growth of e-vapour products in retail value between 2013-19 (€ million)

Member State	2019	Growth 2013-19
Austria	38	297%
Belgium	79	157%
Bulgaria	25	113%
Croatia	34	1912%
Czechia	87	64%
Denmark	71	157%
Estonia	2	15%
Finland	16	933%
France	847	68%
Germany	673	533%
Greece	56	109%
Hungary	9	-18%
Ireland	83	287%
Italy	337	80%
Latvia	8	1875%
Lithuania	6	142%
Netherlands	116	156%
Poland	414	301%
Portugal	17	4%
Romania	10	17%
Slovakia	13	33%
Slovenia	2	64% ⁵⁷⁰
Spain	86	-35%
Sweden	32	1025%

⁵⁷⁰ Data is for 2014-2019 as there was no data point for 2013

Member State	2019	Growth 2013-19
United Kingdom	2,417	682%

When analysed by e-vapour product type, the retail value of closed vaping systems increased by the largest proportion in Poland (2404%). This was followed by Belgium, where over the period the retail value of closed vaping systems increased by 1716%. Sales of closed vaping systems decreased between 2013-19 in 5 MS: Slovakia; Czechia; Spain; Italy; Portugal.

Almost all Member States with available data (22 out of 24) experienced an increase in the retail value of open-vaping systems between 2013-19. The Member states with the highest growth rates were Croatia (2667%), Latvia (2533%), and Sweden (1112%). Spain and Hungary were the only Member States where the retail value of open vaping systems fell, by 36% and 21% respectively.

Heated Tobacco Products

Table 58 presents the size of the market for heated tobacco from 2017 to 2019 across the 25 Member States. Due to the relatively recent emergence of heated tobacco products in the market, data was not available for all time points for all Member States. In 2019, Italy had the largest market for heated tobacco products valuing at just under €1 billion. This was more than double than that of Romania, the Member State with the second-largest market, valuing just over €350 million. Other Member States where the value of the market for heated tobacco products exceeded €100 million were Germany; Czechia; Greece; Poland; Bulgaria; and Portugal. For all of the years considered, no data on the retail value of heated tobacco products was available for Austria, Belgium, Estonia, Finland, and Ireland.

Table 58. EU-25 breakdown of the market size for heated tobacco products in retail value between 2017-19 (€ million)

Member State	2019	Growth 2017-19
Austria	-	-
Belgium	-	-
Bulgaria	124	67% ⁵⁷¹
Croatia	39	330%
Czechia	225	638%
Denmark	16	251%
Estonia	-	-
Finland	-	-
France	37	352%
Germany	305	2248%
Greece	218	294%

⁵⁷¹ Growth rate is for 2018-19 due to absence of data point in 2017

Hungary	4	-
Ireland	-	-
Italy	925	352%
Latvia	22	696% ⁵⁷²
Lithuania	47	423%
Netherlands	31	875%
Poland	208	1241%
Portugal	114	347%
Romania	352	241%
Slovakia	78	653%
Slovenia	23	1945%
Spain	91	398%
Sweden	8	-
United Kingdom	51	114%

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

There was relatively little retail volume data available regarding sale of tobacco heated devices⁵⁷³. In 2019, the highest retail volume of tobacco heating devices was observed in Italy, where 700,000 units were sold. This was followed by Czechia where the retail volume sold was 400,000 units, then by Germany and Greece at 300,000 units each. The growth rate in the retail volume of tobacco heated devices between 2017-19 was in the range of 200%-300% for the Member States where data was available. Market growth calculated using retail value, where data for more countries was available, ranged from 93% in the UK and Slovakia to 688% in Poland.

For heated tobacco, market growth rates calculated using retail value and retail volume were similar in the majority of Member States, indicating little variation in prices between 2017-19. In 2019, Italy had the largest market for heated tobacco , recording, recoding a retail volume of just over 3 billion sticks. This was followed by Romania, Poland, and Czechia. Overall, these countries contributed to 60% of the total retail volume of heated tobacco across the 25 Member States. In terms of market growth between 2017-19, Germany experienced the highest growth in retail volume of 3329%. Substantially high growth rates were also seen in Slovenia (2110%), Poland (1271%), and Slovakia (1088%). The lowest growth rate over this period was seen in the UK, where the market size increased by 98%.

Smokeless Tobacco (excluding HTPs)

Data on smokeless tobacco products was only available for Bulgaria, Czechia, Denmark, Slovakia, Spain, and Sweden. The market size of smokeless tobacco in retail value for these Member States is presented in Table 59 This clearly shows that Sweden is the driver of the market for smokeless tobacco, which can be explained by the implementation of Article 17 of the TPD which prohibits the sale of most types of smokeless tobacco outside of Sweden. In Spain, total sales for smokeless tobacco only consisted of chewing tobacco, whilst in Bulgaria, Czechia, Slovakia, and Sweden,

⁵⁷² Growth rate is for 2018-19 due to absence of data point in 2017

⁵⁷³ Data was only available for the following Member States: IT, CZ, DE, EL, BG, FR, ES, LI, PO, PT, RO, SK

smokeless tobacco sales only consisted of moist snuff. In Denmark, the market for smokeless tobacco was made up of sales of both chewing tobacco and moist snuff up until 2017, after which no data was recorded for moist snuff.

Table 59. EU-25 breakdown of the market size and growth of smokeless tobacco products in retail value between 2017-19 (€ million)

Member State	2019	Growth
Bulgaria	0	0% ⁵⁷⁴
Czechia	12	520%
Denmark	12	0%
Slovakia	7	431%
Spain	0	0%
Sweden	1079	2.4%

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

Table 60 presents the market growth for chewing tobacco and moist snuff between 2013-2019. The size of the market for chewing tobacco fell by half in terms of retail volume over the period, yet conversely almost doubled in size in Denmark. The market for moist snuff experienced rapid growth in Czechia, increasing by 427% in retail volume. Slovakia experienced similarly high growth for moist snuff, with a 328% increase in retail volume. In Sweden, where the majority of the market for most snuff is located (see Table 60), retail volume increased by only 11%.

Table 60. Matrix of growth rates across EU-25 in retail value and retail volume for smokeless tobacco products by product category (2013-2019)

Member State	Chewing tobacco		Moist snuff	
	RSP	VOL	RSP	VOL
Bulgaria	-	-	0%	17%
Czechia	-	-	520%	427%
Denmark	28%	46%	-50% ⁵⁷⁵	-49% ⁵⁷⁶
Slovakia	-	-	431% ⁵⁷⁷	328% ⁵⁷⁸
Spain	0%	-53%	-	-
Sweden	-	-	2%	11%

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

⁵⁷⁴ Data only available for 2018-19

⁵⁷⁵ Growth rate represents trend from 2013-16. No data points were available after 2016.

⁵⁷⁶ Growth rate represents trend from 2013-16. No data points were available after 2016.

⁵⁷⁷ Growth rate represents trend from 2014-2019. No data point was available for 2013.

⁵⁷⁸ Growth rate represents trend from 2014-2019. No data point was available for 2013.

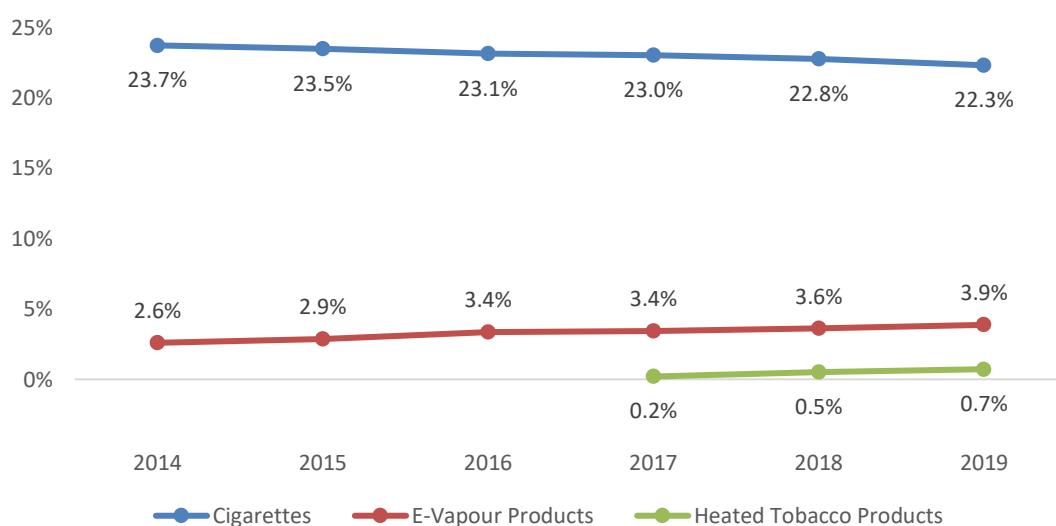
5.5.3 Smoking Prevalence

5.5.3.1 Aggregated EU analysis

Figure 33 shows the trends in the proportion of the population using cigarettes, e-vapour products, and heated tobacco products across the 25 EU Member States considered in this analysis. This suggests that in 2019 just over one-fifth (22.3%) of the adult population⁵⁷⁹ smoked cigarettes. The prevalence of cigarette use gradually decreased between 2013 and 2019, shrinking in total by 1.41 percentage points over this period. This is consistent with the decrease in the retail volume of cigarettes at market level.

In 2019, e-vapour products were used by 3.9% of the adult population, whilst 0.7% used heated tobacco products. The prevalence of both e-vapour products and heated tobacco products have experienced gradual upward trends, with the proportion of the population using e-vapour products increasing by 1.3 percentage points from 2014-2019, and that of heated tobacco products by 0.5 percentage points between 2017-2019. This is consistent with the increase in the retail value of e-vapour products and heated tobacco products across the period and provides further evidence for the hypothesis that consumers are these alternatives as a substitute for cigarette use.

Figure 33. Prevalence of use of tobacco and related products across 25 Member States (% of the total population)



- Source: Euromonitor International; Tobacco Industry Edition, 2021 , EUROSTAT (ICF Calculations)

It should be noted that data was not available for across all observation years for all Member States. Where data was not available the Member State was omitted from the EU average under the assumption that the data on the use of heated tobacco products for that country had not been reported. The Member States that were included in the EU average for the prevalence of heated tobacco products between presented in Figure 33 are detailed in the Table 61 below. No data was available for AT, BE, EE, FI, and IE for any of the years between 2017 and 2019, and they were therefore omitted from the analysis.

⁵⁷⁹ Based on population data from EUROSTAT on the population of 15+ year olds

Table 61. Member States included in analysis of prevalence of heated tobacco products

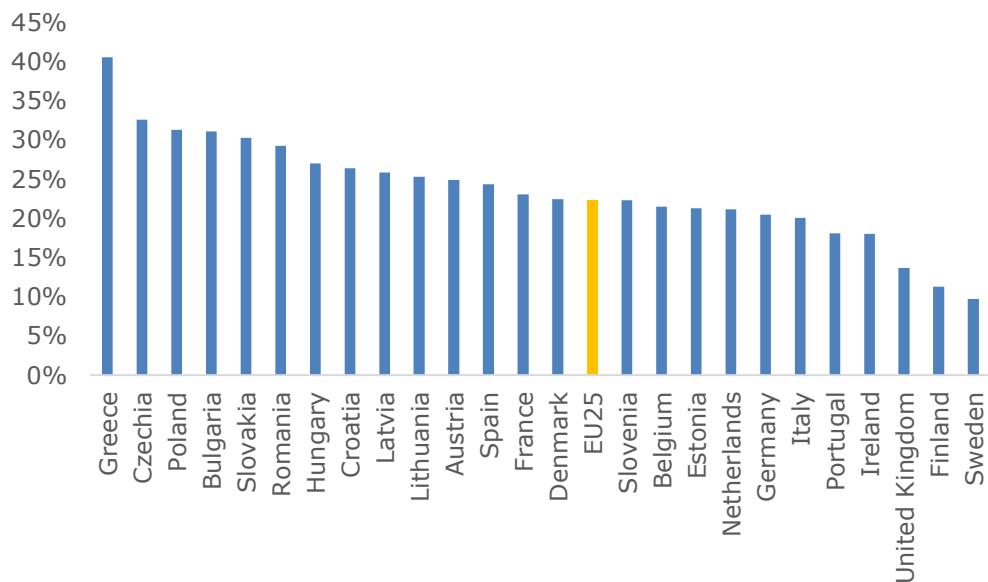
Measurement	2017	2018	2019
Number of MS included	17	19	21
Member States included	HR, CZ, DK, FR, DE, EL, IT, LI, NL, PO, PT, RO SK, SI, ES, UK	BG, HR, CZ, DK, FR, DE, EL, IT, LI, NL, PO, PT, RO SK, SI, ES, UK	HR, CZ, DK, FR, DE, EL, HU, IT, LI, LT, NL, PO, PT, RO SK, SI, ES, UK

5.5.3.2 Breakdowns by Member State

Cigarettes

As shown in Figure 34, in 2019, the proportion of the population using cigarettes ranged from 10% in Sweden to 41% in Greece. Countries in Eastern Europe were more likely to have a level of smoking prevalence above the EU25 average. Only 4 of the 25 Member States experienced an increase in the prevalence of cigarette smoking between 2014 and 2019 (RO, DK, IT, CZ). Table 62 shows that the largest decline in cigarette use over the period was observed in the UK, where prevalence decreased by 4.3%. This was followed by Ireland (-3.3%), Finland (-3.1%) and France (-3.0%).

Figure 34. Proportion of the population using cigarettes in 2019: breakdowns by Member State



Source: Euromonitor International; Tobacco Industry Edition, 2021 , EUROSTAT (ICF Calculations)

Table 62. Change in the proportion of the population using tobacco and related products between 2014 and 2019 in percentage points

Member State	Cigarettes	E-Vapour	Heated Tobacco Products
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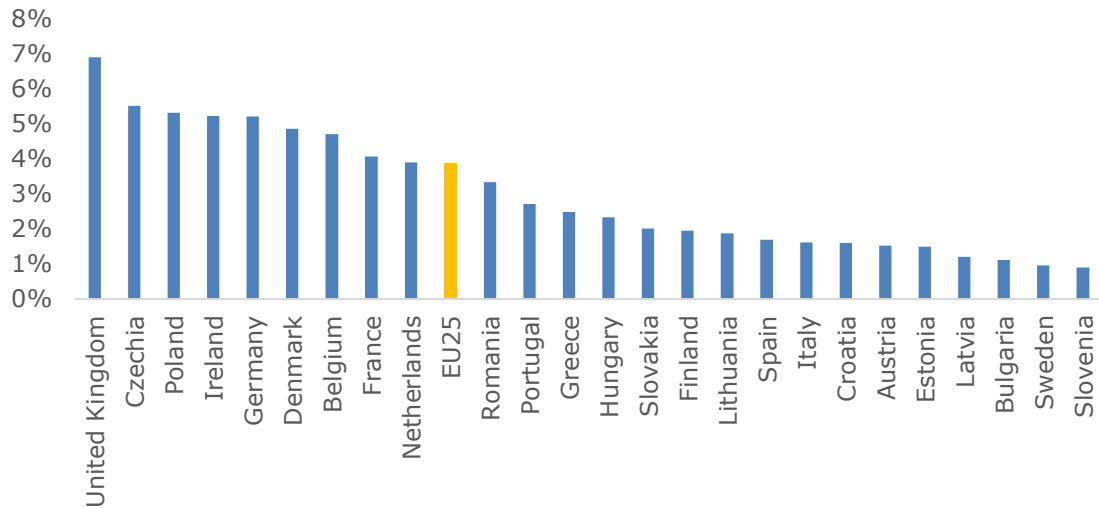
EU25 Average	-1.4%	1.3%	0.5%
Austria	-2.2%	0.9%	-
Belgium	-1.4%	2.1%	-
Bulgaria	-1.3%	0.3%	-
Croatia	-0.4%	1.3%	0.6%
Czechia	0.7%	1.6%	4.3%
Denmark	2.8%	1.2%	0.2%
Estonia	-1.0%	-1.9%	-
Finland	-3.1%	0.3%	-
France	-3.0%	0.0%	0.1%
Germany	-1.0%	1.4%	0.2%
Greece	-2.2%	1.5%	1.2%
Hungary	-0.6%	0.8%	-
Ireland	-3.3%	1.8%	-
Italy	1.0%	1.1%	0.8%
Latvia	-0.9%	0.9%	-
Lithuania	-0.7%	1.2%	3.4%
Netherlands	-2.0%	1.2%	0.2%
Poland	-2.1%	1.7%	0.4%
Portugal	-1.2%	0.6%	1.2%
Romania	4.3%	1.7%	0.5%
Slovakia	-0.2%	0.5%	2.2%
Slovenia	-1.2%	0.4%	0.7%
Spain	-1.0%	1.1%	0.3%
Sweden	-1.2%	0.0%	-
United Kingdom	-4.3%	2.8%	0.0%

Source: Euromonitor International; Tobacco Industry Edition, 2021 , EUROSTAT (ICF Calculations)

E-vapour products

In 2019 the proportion of the population using e-vapour products ranged from 0.9% in Slovenia to 6.9% in the UK (see Figure 35 below). Other Member States with relatively high levels of e-vapour prevalence included Czechia (5.5%), Poland (5.3%), Ireland (5.2%) and Germany (5.2%). Estonia was the only Member State to experience a decrease in the prevalence of e-vapour products over the period (see Table 62), whilst the proportions in Sweden and France remained constant. The largest increase in the prevalence of e-vapour products was observed in the UK, where the proportion rose by 2.8 percentage points. Relative to e-vapour products, the prevalence of heated tobacco products is still lower in the majority of countries.

Figure 35. Proportion of the population using e-vapour products in 2019: breakdowns by Member State

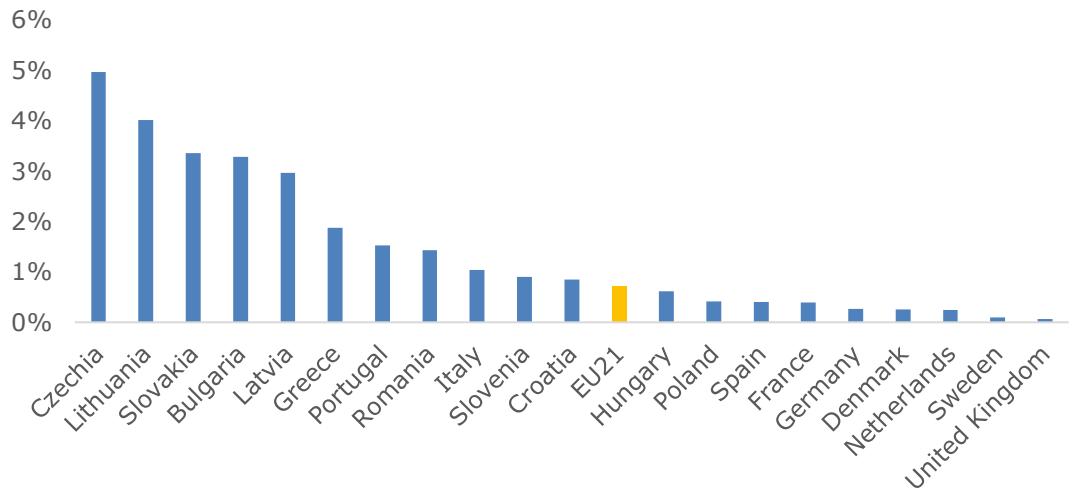


Source: Euromonitor International; Tobacco Industry Edition, 2021 , EUROSTAT (ICF Calculations)

Heated tobacco products

As shown in Figure 36, in 2019 the proportion of the population using heated tobacco products ranged from 0.07% in the UK to 4.96% in Czechia. The five member states with the highest proportion of heated tobacco product users were all in Eastern Europe, indicating an overall higher level of popularity of heated tobacco products in that region. Between 2017 and 2019 the highest level of growth was observed in Czechia, where the proportion of adults using heated tobacco products increased by 4.3 percentage points. None of the Member States included in the analysis experienced a decrease in the prevalence of heated tobacco products.

Figure 36. Proportion of the population using heated tobacco products in 2019: breakdowns by Member State



Source: Euromonitor International; Tobacco Industry Edition, 2021 , EUROSTAT (ICF Calculations)

Annex 5 Substantial change of circumstances

Regarding the conditions for a substantial change in circumstance, the Directive states the following:

"... a substantial change in circumstances occurs when there is either:

- An increase of the sales volumes by product category by at least 10 % in at least five Member States based on sales data transmitted in accordance with Article 5(6) or*
- An increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies;*

In any case, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2,5 % of total sales of tobacco products at Union level."

The aim was to assess the first and the overall criteria using data from Euromonitor, and the second using data from Eurobarometer. See the sections below for further information.

5.6 First change of circumstance criteria: Euromonitor data

Due to inconsistencies in the units used to measure retail volume across products, it was not possible to calculate the share of each product in market volume at the EU level. Therefore, it was not feasible to try and identify a substantial change of circumstances in this analysis. However, Euromonitor data was used to assess the first criteria: an increase of the sales volumes by product category by at least 10% in at least five Member States. This was done by calculating the growth in sales volumes for the different tobacco products from 2015-2019. The table below presents the products that met this criterion:

Table 63. Tobacco and related products that have experienced at least a 10% increase in retail volume in at least 5 Member States from 2015-2019

Product	Number of Member States > 10%	List of MS	Growth rate 2015-19
Cigars	6	HR	67%
		BG	37%
		RO	33%
		LI	25%
		HU	21%
		SK	14%
Cigarillos	8	IT	116%
		RO	94%
		LT	31%
		SK	28%
		HU	22%
		EE	21%

Product	Number of Member States > 10%	List of MS	Growth rate 2015-19
Pipe tobacco	8	HR	13%
		BG	11%
		PT	271%
		DE	111%
		AT	81%
		BG	73%
		ES	66%
		FR	58%
		SK	17%
		SI	12%
Heated tobacco	16	DE	3275%
		SI	2110%
		PL	1285%
		SK	1107%
		NL	832%
		CZ	668%
		FR	544%
		LT	445%
		ES	400%
		PT	358%
		IT	334%
		HR	324%
		EL	285%
		DK	253%
		RO	215%
		UK	98%

Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

The products that experienced an increase of at least 10% in at least five Member States were:

- Cigarillos
- Cigars
- Pipe tobacco
- Heated tobacco

Although it is not possible to strictly estimate a substantial change in circumstances for these products due to the restrictions described above, it is possible to use the retail value market shares as a starting point for discussion.

Given that cigars and cigarillos constituted around 3% of the total tobacco market in retail value in 2019, there could be some basis for considering a substantial change in circumstances. However, it is unclear to what extent the influence of prices has determined their standing in the market when measured in retail value. The comparison of the changes in retail value and retail volume of these products in Table 52 and Table 53 show that although retail value for both cigars and cigarillos increased between 2013 and 2019, retail volume fell.

Other tobacco products for smoking obtained an 11% market share in retail value in 2019, the majority of which consists of fine cut tobacco. Pipe tobacco experienced an increase in sales volume of 88% between 2013-18. The market share for heated tobacco products in 2019 was around 2%. As a result of this, it remains to be seen whether heated tobacco would reach in 2020 the 2.5% market share (in retail volume) threshold in order to trigger a substantial change in circumstances. However, given that heated tobacco products are a relatively new addition to the market and their generally lower taxation level, it is possible that in this case, retail value could act as an underestimate of their standing in the market relative to other products.

5.7 Second change of circumstance criteria: Eurobarometer data

Alternatively, a substantial change of circumstances can also mean ("or" in the Directive) an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category.

The table below presents the prevalence of use of each product type in the under-25 age group. Cells in **dark grey** denote where use of a product in youth is below five percent, therefore **there could not have been a substantial change of circumstances for this product type**, as that would require an increase in prevalence of at least five percentage points. An analysis of the actual changes in prevalence of use in the under 25 age group over time would require further disaggregation by all of Member State, product type, and age.

*Table 64. Users of tobacco and related products by Member State in 2020 (under-25 age group only) **

MS	Cigarillos, this excludes cigars	Cigars, this excludes cigarillos	Pipe	HTPs
EU 27+UK	1.0%	0.7%	0.8%	1.9%
AT	1.7%	0.9%	3.4%	5.1%
BE	2.2%	0.0%	1.1%	2.2%
BG	1.7%	1.7%	1.7%	1.7%
CY	6.3%	4.2%	2.1%	2.1%
CZ	3.8%	1.0%	1.9%	5.8%
DE	0.0%	0.0%	0.0%	0.0%
DK	0.0%	0.0%	0.0%	1.5%
EE	1.1%	0.0%	0.0%	1.1%
EL	0.0%	0.0%	0.0%	0.9%

MS	Cigarillos, this excludes cigars	Cigars, this excludes cigarillos	Pipe	HTPs
ES	0.0%	0.0%	0.0%	1.1%
FI	0.0%	0.0%	0.0%	0.0%
FR	0.7%	1.5%	0.7%	1.5%
HR	0.7%	2.1%	0.0%	0.7%
HU	0.0%	0.0%	0.0%	2.9%
IE	1.5%	1.5%	2.2%	2.2%
IT	0.0%	0.0%	0.0%	4.4%
LT	1.0%	1.0%	1.0%	2.1%
LU	0.0%	0.0%	3.5%	1.8%
LV	1.6%	0.0%	1.6%	4.1%
MT	0.0%	0.0%	0.0%	0.0%
NL	1.1%	2.3%	0.0%	1.1%
PL	1.1%	1.1%	1.1%	1.1%
PT	1.0%	0.0%	0.0%	0.0%
RO	1.9%	1.3%	0.0%	0.6%
SE	0.0%	0.7%	0.0%	0.7%
SI	0.0%	0.0%	0.0%	1.6%
SK	0.0%	0.0%	0.0%	3.8%
UK	1.4%	0.0%	1.4%	0.0%

Base: 2896 participants under 25 years old.

"Users" denotes participants who reported using a product every day, every week, or every month.

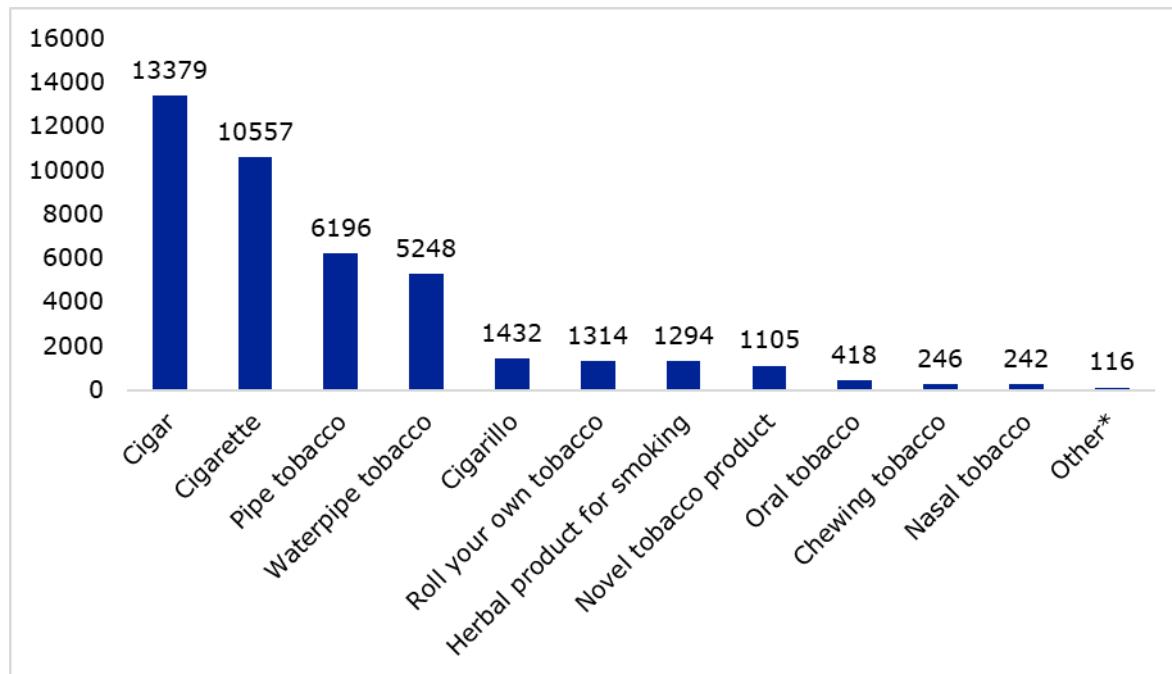
* 2020 calculations were made without using weighting, and therefore do not match exactly the calculations made for the Eurobarometer report.

Using the second alternative criteria set out in the TPD, a substantial change of circumstances did not occur for any of these products, as even where an increase in prevalence greater than five percentage points was measured, these in **fewer than five Member States** (cigarillos: above 5% in only one Member State; cigars: 0 Member States; pipe: 0 Member States; HTPs: two Member States).

Annex 6: EU-CEG notification information

On 12 January 2021, DG SANTE provided a document detailing the number of TPIDs and ECIDs notified by Member State and product type. This information is detailed in the figures and tables below.

Figure 37. Active tobacco and related product notifications by product type (total: 41,519 distinct TPIDs)



Source: EU-CEG data provided by DG SANTE in January 2021.

Table 65. Active tobacco and related product notifications by product type and Member State (total: 41,519 distinct TPIDs)

MS	Chewing tobacco	Cigar	Cigarette	Cigarillo	Herbal product for smoking	Nasal tobacco	Novel tobacco product	Oral tobacco	Other ⁵⁸⁰	Pipe tobacco	Roll your own tobacco	Waterpipe tobacco	Total
AT	4	1745	809	156	475	25	48		23	176	92	906	4459
BE	10	1384	322	201	465	10	8		21	109	174	164	2868
BG		1334	529	117	42	7	54		23	27	42	294	2469
CY		735	434	126	40		22		27	53	32	120	1589
CZ	72	2871	834	181	46	41	154		23	445	104	706	5477
DE	105	5678	1181	655	99	167	50		38	5157	371	3399	16900
DK	92	643	277	73	38	3	15		1	272	50	140	1604
EE		1284	243	43	20		34		24	44	41	725	2458
ES	15	2712	1232	336	88	8	113		23	241	254	2059	7081
FI		231	168	57	39				25	43	23	34	620
FR	7	1166	894	249	91	5	89		23	87	147	343	3101
GB	57	1273	604	77	81	135	71		16	444	83	176	3017
GR	15	380	733	153	40	2	91		27	25	47	85	1598
HR	4	735	469	65	39	2	116		23	50	50	45	1598
HU	23	918	498	102	39	8	36		23	35	144	139	1965
IE	2	218	266	19	42	2	6		23	26	28	20	652
IT	16	1756	931	219	65	8	177		24	196	137	243	3772
LT		753	222	68	39		26		23	49	44	268	1492
LU	4	965	383	110	280	4	7		25	42	157	259	2236

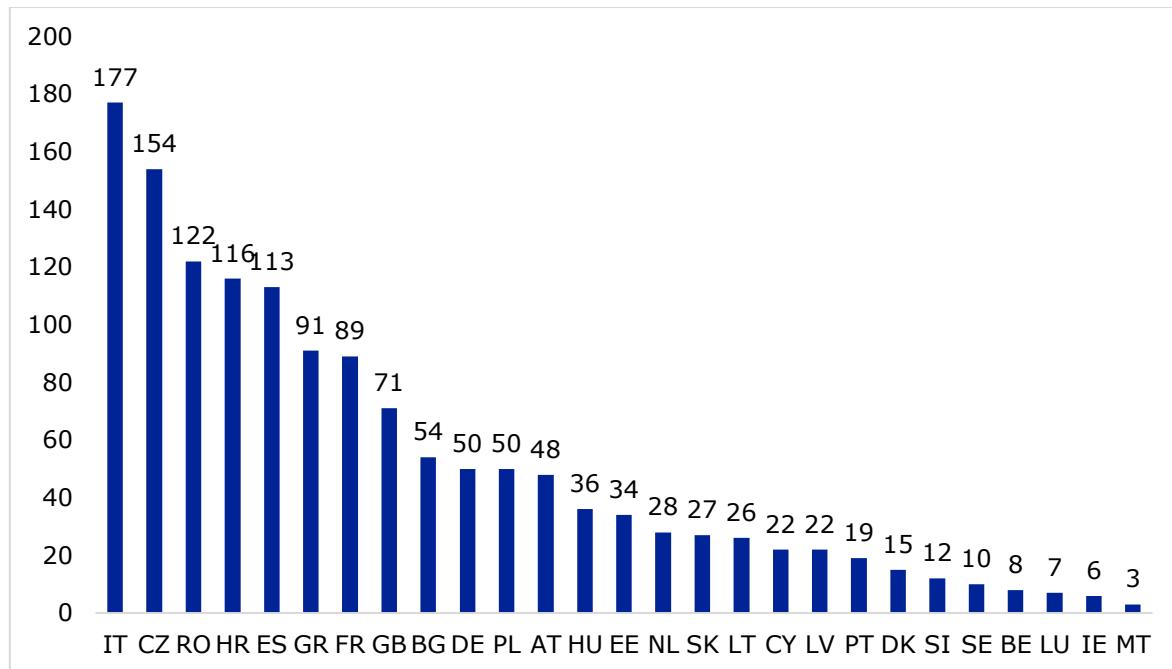
⁵⁸⁰ Product placed on the market before 19 May 2014, not covered by categories 1-9

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LV	397	228	62	12		22		3	33	55	208	1020	
MT	1037	222	73	56		3		23	60	32	20	1526	
NL	7	3329	501	276	57	5	28		24	131	143	264	4765
PL	15	1964	670	129	68	72	50		27	237	122	313	3667
PT		803	396	171	56	1	19		23	24	60	435	1988
RO	5	1556	604	110	41	2	122		23	77	58	170	2768
SE	52	1144	277	84	40	7	10	418	54	94	26	42	2248
SI	43	699	545	32	40	3	12		23	27	33	20	1477
SK	50	1795	399	106	40	27	27		23	132	45	438	3082
Tota l	598	39505	14871	4050	2478	544	1410	418	658	8336	2594	12035	87497

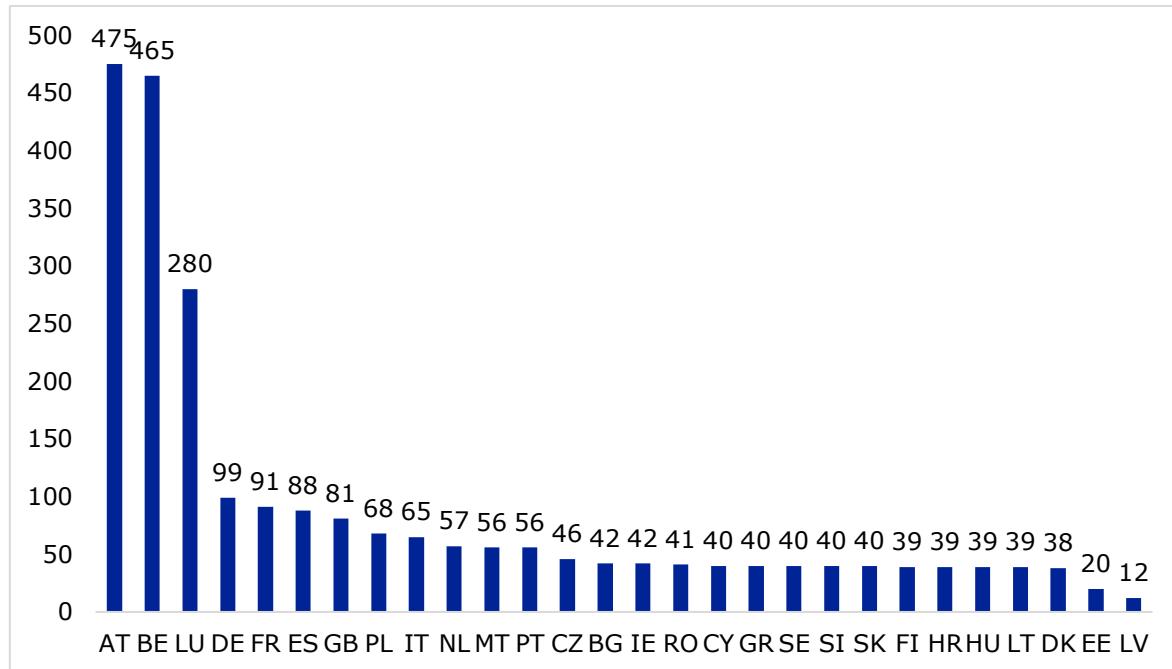
Source: EU-CEG data provided by DG SANTE in January 2021.

Figure 38. Active novel tobacco product notifications by Member State (total: 1,105 distinct TPIDs)



Source: EU-CEG data provided by DG SANTE in January 2021.

Figure 39. Active herbal product for smoking notifications by Member State (total: 1,294 distinct TPIDs)



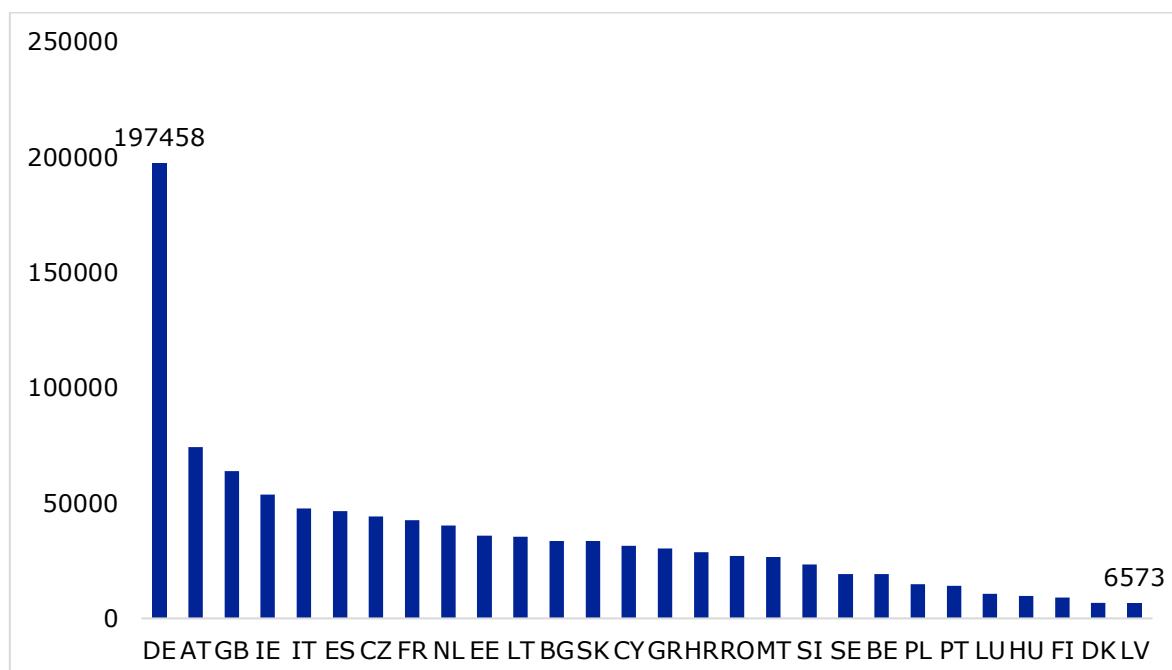
Source: EU-CEG data provided by DG SANTE in January 2021.

Table 66. Active e-cigarette notifications by product type (total: 270,997 distinct ECIDs)

Product Type	Count distinct ECIDs
Refill container/cartridge containing e-liquid.	143141
Other	64102
Individual part of electronic cigarette capable of containing e-liquid.	20933
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge.	17592
Electronic cigarette – Refillable, device only.	16701
Electronic cigarette – Rechargeable, device only Any rechargeable which can also be used as a refillable should be reported under the refillable category.	4880
Electronic cigarette – Disposable.	3041
Electronic cigarette – Refillable, placed on the market with one type of e-liquid (fixed combination).	822
Electronic cigarette – Rechargeable, placed on the market with one type of e-liquid (fixed combination). Any rechargeable which can also be used as a refillable should be reported under the refillable category	302

Source: EU-CEG data provided by DG SANTE in January 2021.

Figure 40. Active e-cigarette notifications by Member State (total: 270,997 distinct ECIDs)



Source: EU-CEG data provided by DG SANTE in January 2021.

Annex 7: Economic operator survey respondent information

Descriptive characteristics of the economic operators which responded to the offline survey are given in Table 67. Four organisations sent an offline survey response without completing the online survey. Three of these organisations had completed enough items to determine the below information, but one did not, therefore the information in the table below is provided for 18 organisations.

Table 67. Economic operator offline survey respondents' characteristics

Size of organisation						Total
< 50 employees (n = 3)	50-250 employees (n = 2)	251-1000 employees (n = 5)	> 1000 employees (n = 7)	Don't know (n = 1)		
Organisation type*						
Grower/ Processor	-	-	-	1	-	1
Other upstream supplier	-	-	-	1	-	1
Manufacturer	3	2	5	7	1	15
Importer	1	1	-	4	1	7
Distributor / agent	1	-	-	1	1	3
Wholesaler	1	-	1	-	1	3
Products organisation concerns*						
Pipe tobacco	-	2	5	2	-	9
Roll your own tobacco	-	2	4	4	-	10
Chewing tobacco	-	1	2	2	-	5
Nasal tobacco	-	1	2	-	-	3
Tobacco for oral use	-	1	1	4	-	6
Cigarettes	1	1	4	4	-	10
Cigars	2	-	4	3	1	10
Cigarillos	2	-	3	4	1	10
Waterpipe tobacco	-	-	2	1	-	3
Smokeless tobacco products, including heated tobacco products	-	-	-	4	-	4
Herbal products for smoking (containing no tobacco)	-	-	-	-	-	-
Electronic cigarettes (devices)	-	-	1	5	-	6
E-liquids: cartridges and pods	-	-	1	5	-	6
E-liquids: refill bottles	-	-	1	3	-	4
E-cigarette parts in contact with e-liquids	-	-	-	2	-	2
E-cigarette parts not in contact with e-liquids	-	-	-	3	-	3

	Size of organisation					
	< 50 employees (n = 3)	50-250 employees (n = 2)	251-1000 employees (n = 5)	> 1000 employees (n = 7)	Don't know (n = 1)	Total
Flavourings	-	-	-	-	-	-
Rolling papers	-	-	3	1	-	4
Filters	-	-	4	1	-	5
Other paraphernalia	-	-	1	-	-	1
Packaging, printing equipment	-	-	-	-	-	-
Tipping paper, other paper for cigarette production, cellulose	-	-	-	1	-	1
Nicotine pouches	-	1	1	3	-	5
Approximate yearly turnover of organisation						
€1 – €10 million	2	-	-	-	-	2
€50 million - €100 million	-	1	1	1	-	3
€100 million -€500 million	1	1	4	-	-	6
> €500 million	-	-	-	5	-	5
Prefer not to say	-	-	-	1	1	2
Member States the organisation operates in*						
EU27	-	1	2	5	-	8
Some EU MS	AT; CZ; FI; NL DE; HU; NL; RO; SK; SE.		AT; BE; FR; BE; CZ; FR; AT; BE; FR; DE; HU; IT; DE; IE; IT; DE; NL; ES LU; NL; PL; PL; PT; ES.		AT; BE; FR; BE; CZ; FR; AT; BE; FR; DE; HU; IT; DE; IE; IT; DE; NL; ES LU; NL; PL; PL; PT; ES.	
	AT; BE; DE; NL; PT. DE.		PT; RO; SI; ES. All MS except DK & IE.		CZ; DK; DE; SK; SI; ES; SE. HU; SK.	
UK	2	-	2	5	1	10

* Respondents were able to select more than one response for these items.

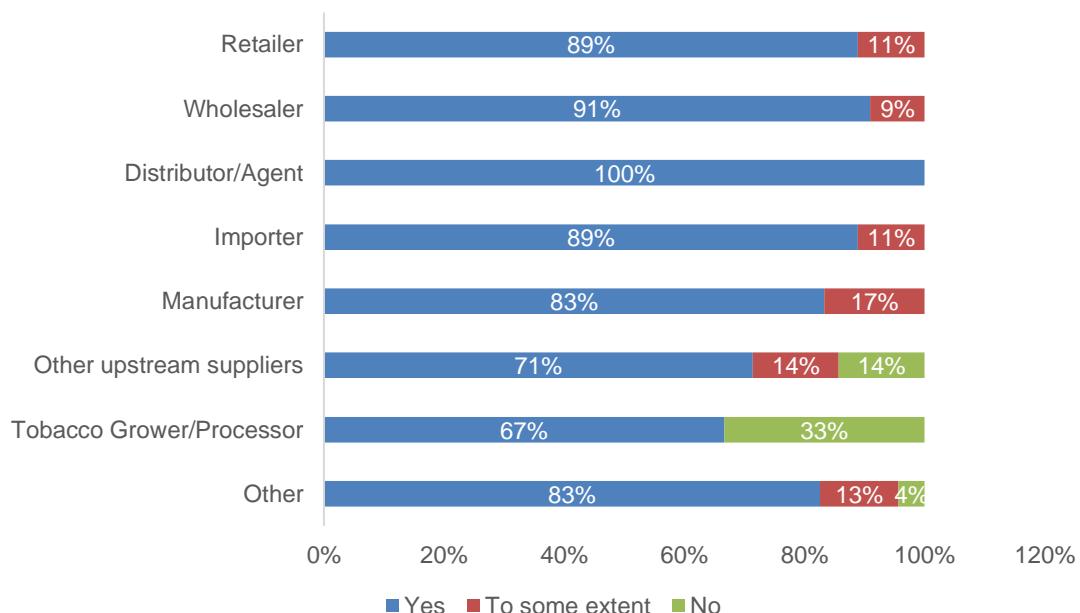
Annex 8: Field Research – additional data analysis

5.8 Evaluation Criteria

5.8.1 Effectiveness

As illustrated by Figure 41 below, the only types of organisations to state that there were no issues with implementing the Directive were tobacco growers and processors, other upstream suppliers, and an association representing brands (incorporated into "other"). All economic stakeholders in the distributor/agent category stated that they had encountered difficulties in the application of the Directive, however they only comprise 4 out of the 52 respondents so this figure must be interpreted with caution.

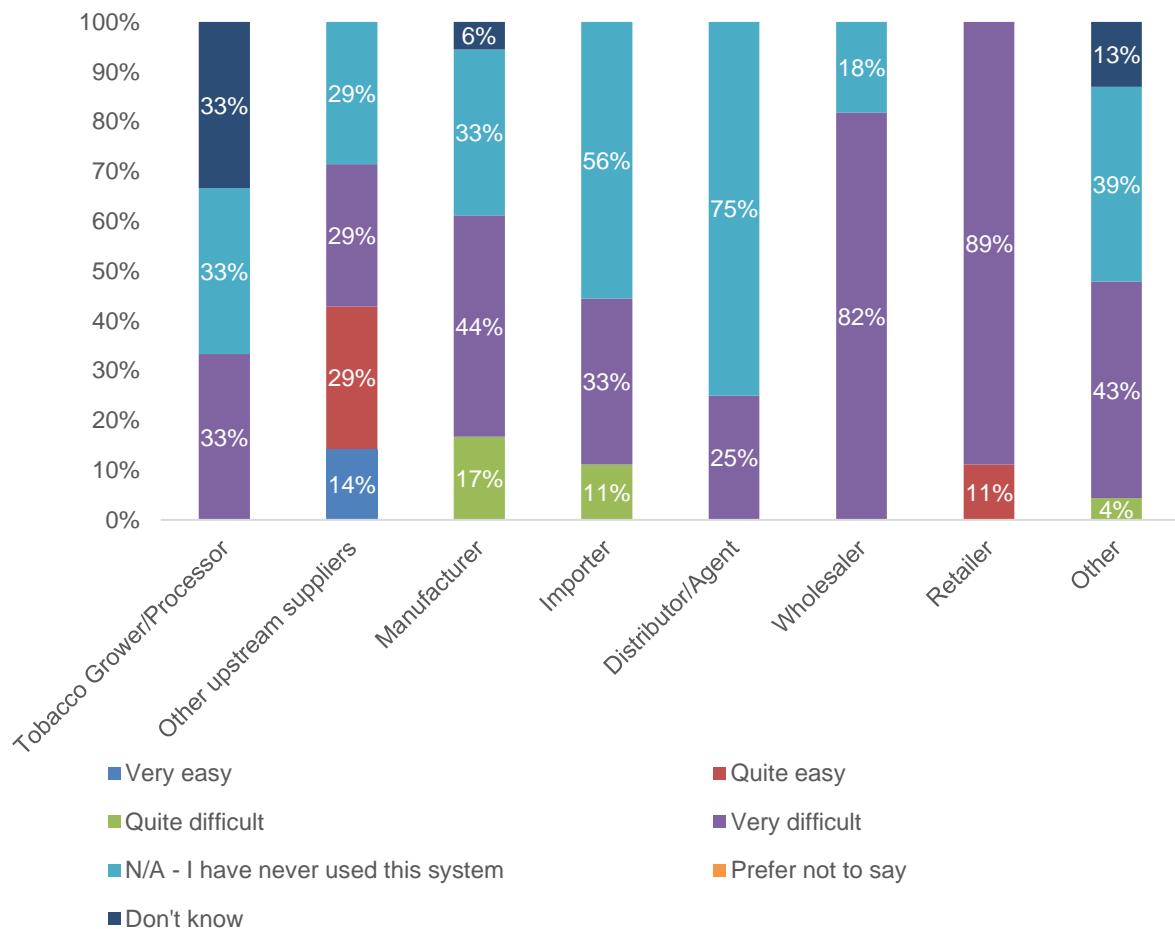
Figure 41. Difficulties in the application of the Directive by type of organisation



ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: Has your organisation encountered any difficulties in the practical application of any of the provisions of this Directive? Base: 52 respondents⁵⁸¹

⁵⁸¹ Please note identical or near-identical open-ended responses to this survey question were received from eight respondents. These groups of respondents likely shared responses amongst themselves.

Figure 42. Ease of implementing track and trace system (Art. 15-16)



ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: How easy have you found the track and trace system to implement within your organisation (Art. 15&16 TPD)?: Base: 52 respondents

Table 68. Effectiveness of provisions by stakeholder type (% agree or disagree)

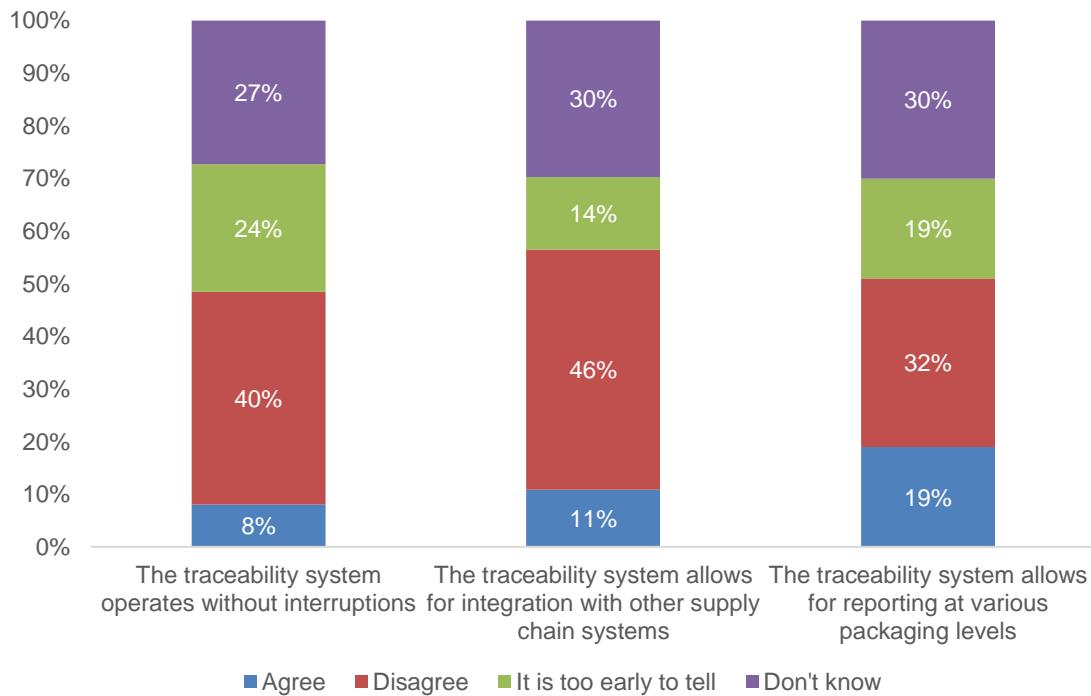
Article	All		CSOs		HEs		Organisations representing consumers	
	Agree	Disagree	Agree	Disagree	Agree	Disagree	Agree	Disagree
Base	43		21		18		4 ⁵⁸²	
Definitions (Art. 2)	53	42	29	67	83	11	50	50
Maximum emission levels and related measurement methods (Art. 3-4)	47	42	24	67	72	11	50	50
Reporting of ingredients (Art. 5)	56	33	43	43	72	17	50	50
Priority list of additives (Art. 6)	54	30	43	48	66	17	50	0
Regulation of ingredients (Art. 7)	45	44	24	62	67	22	50	50
Labelling and packaging provisions (Art. 8-14)	82	12	86	5	83	11	50	50
Traceability and security features (Art. 15 & 16)	49	37	29	62	72	17	50	0

⁵⁸² Caution: low sample size

Prohibition of tobacco for oral use (Art. 17)	75	14	76	19	78	6	50	25
CBDs of tobacco products (Art. 18)	49	30	43	52	56	11	50	0
Novel tobacco products (Art. 19)	35	49	14	76	61	22	25	25
E-cigarettes (Art. 20)	47	47	19	76	78	11	50	50
Herbal tobacco products (Art. 21 & 22)	44	5	29	5	61	6	50	0
Enforcement (Art. 23 & 24)	47	35	24	67	72	6	50	0

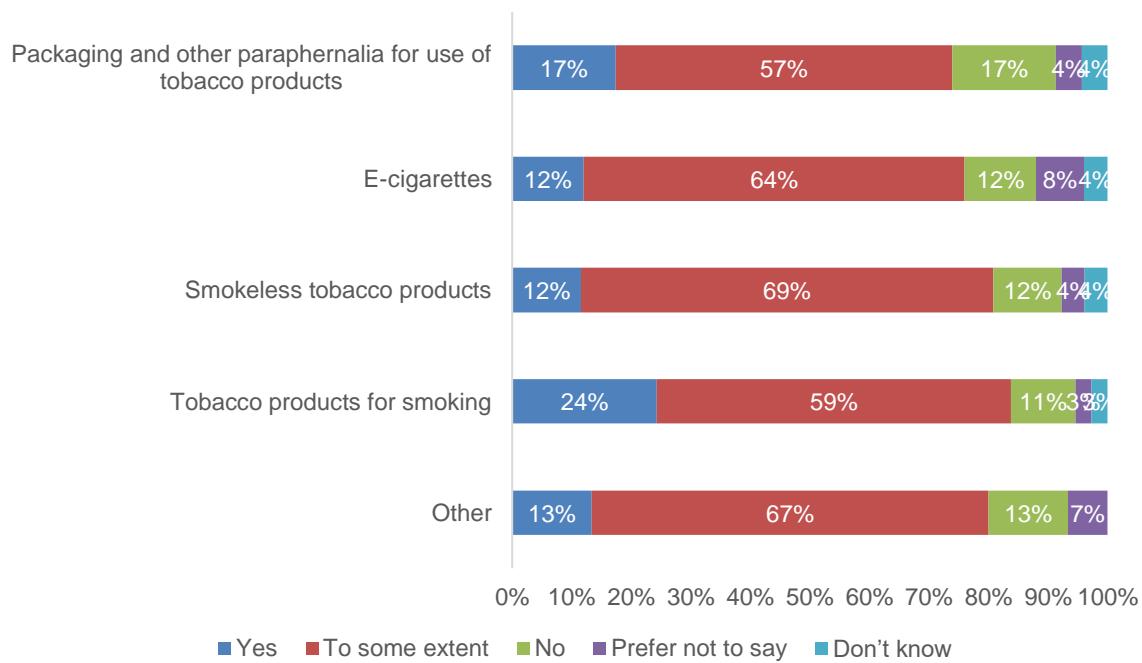
ICF CSO and HEs Online Survey 2020 – Q: To what extent do you agree or disagree that the provisions in the TPD are clear regarding the transposition requirements? Base: 43 respondents.

Figure 43. Do you agree or disagree that the TPD has facilitated an effective traceability system across the EU (Art. 15 TPD)?



ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: Do you agree or disagree that the TPD has facilitated an effective traceability system across the EU (Art. 15 TPD)? Base: 37 respondents. Figures may not sum to 100% due to rounding. Note: strongly agree and somewhat agree have been merged to form "Agree", and strongly disagree and somewhat disagree have been merged to form "Disagree".

Figure 44. Usefulness of guidance received by economic stakeholders by organisation products



ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: Was this guidance clear and useful? Base: 48 respondents

Table 69. Extent to which the TPD is effectively achieving its objective of facilitating the functioning of the internal market for tobacco and related products

	All	CSOs	HES	Organisations representing consumers
Base	43	21	18	4 ⁵⁸³
Yes: fully effective	7%	5%	11%	0%
To a large extent	23%	10%	44%	0%
To a limited extent	51%	76%	11%	100%
No: not effective at all	2%	0%	6%	0%
Don't know	16%	10%	28%	0%
Effective (to at least a limited extent)	81%	90%	67%	100%

ICF CSO and HEs Online Survey 2020 – Q: In your opinion, is the TPD effectively achieving its objective of facilitating the functioning of the internal market for tobacco and related products?

Table 70. Has the TPD been effective at improving public health?

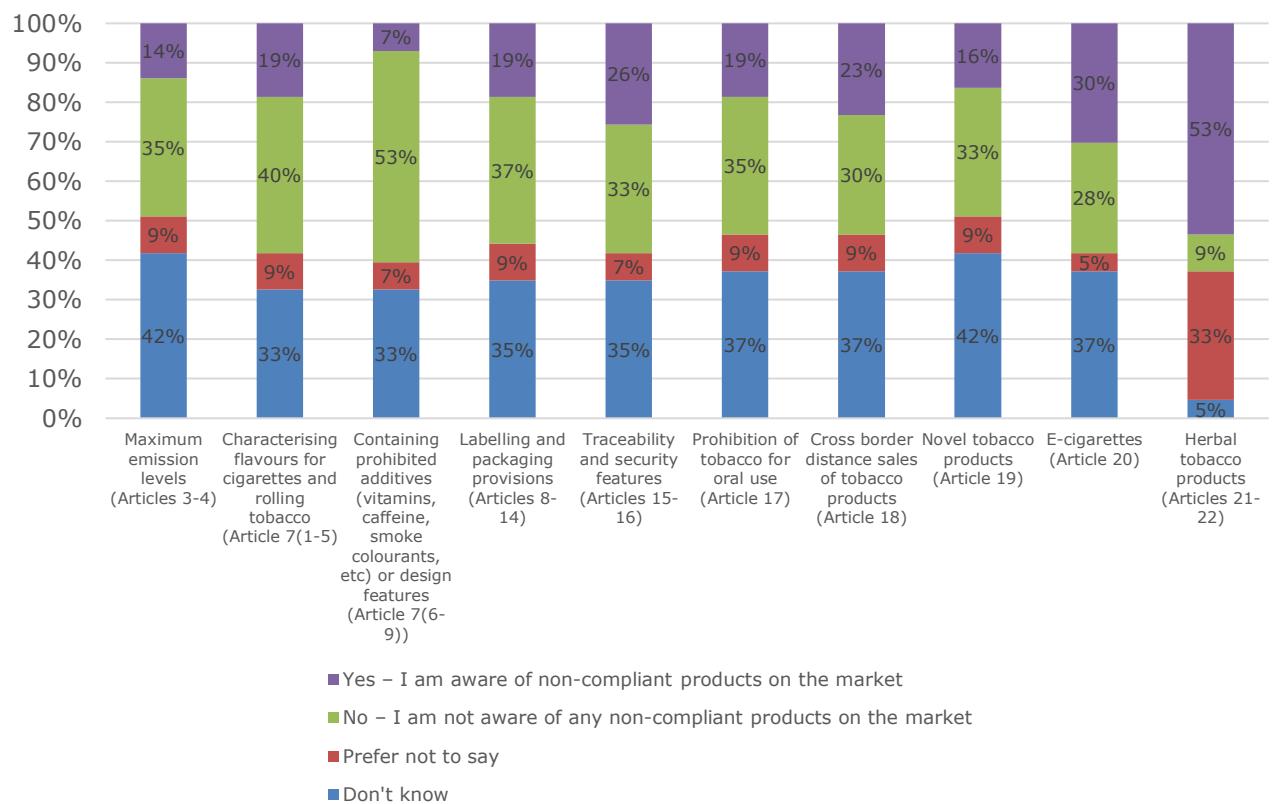
Response	Frequency	Percentage (%)
Yes	1	2
To some extent	11	21
No	5	10
Prefer not to say	4	8
Don't know	31	60

ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: Do you think that the TPD has been effective in achieving its objective of improving public health? Base: 52 respondents

⁵⁸³ Caution: low sample size

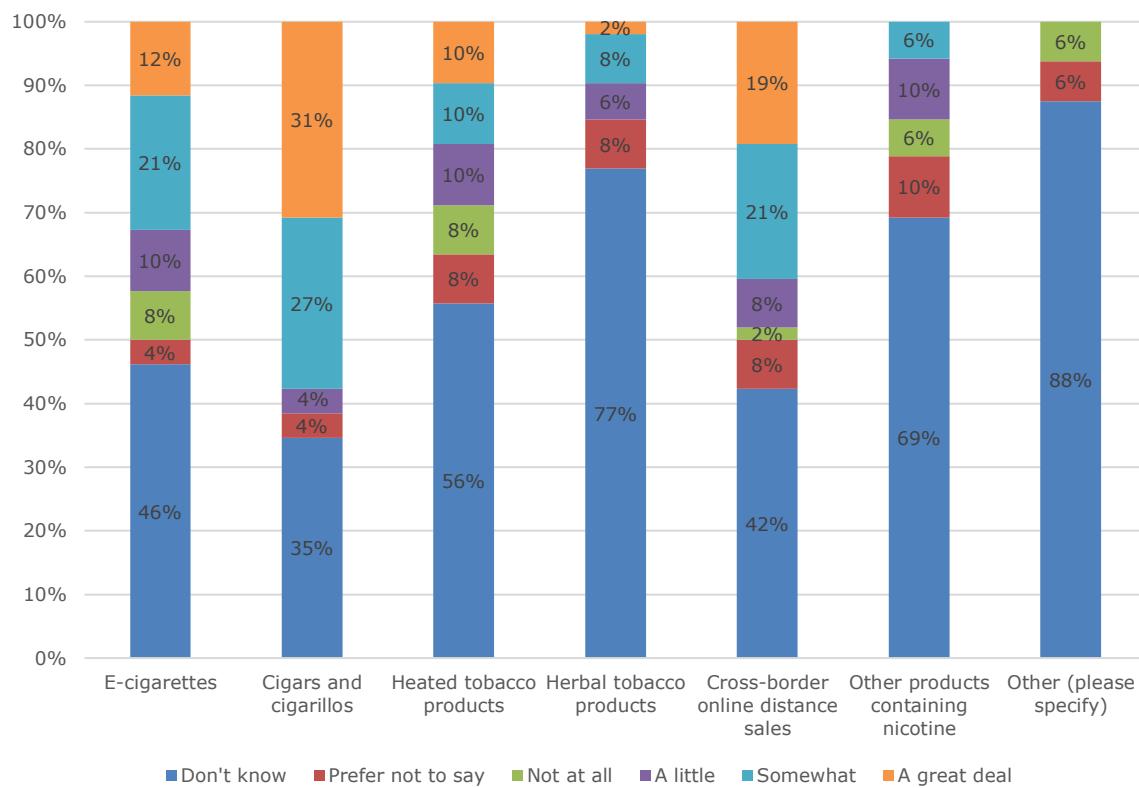
5.8.2 Relevance

Figure 45. Awareness of non-compliant products on the market



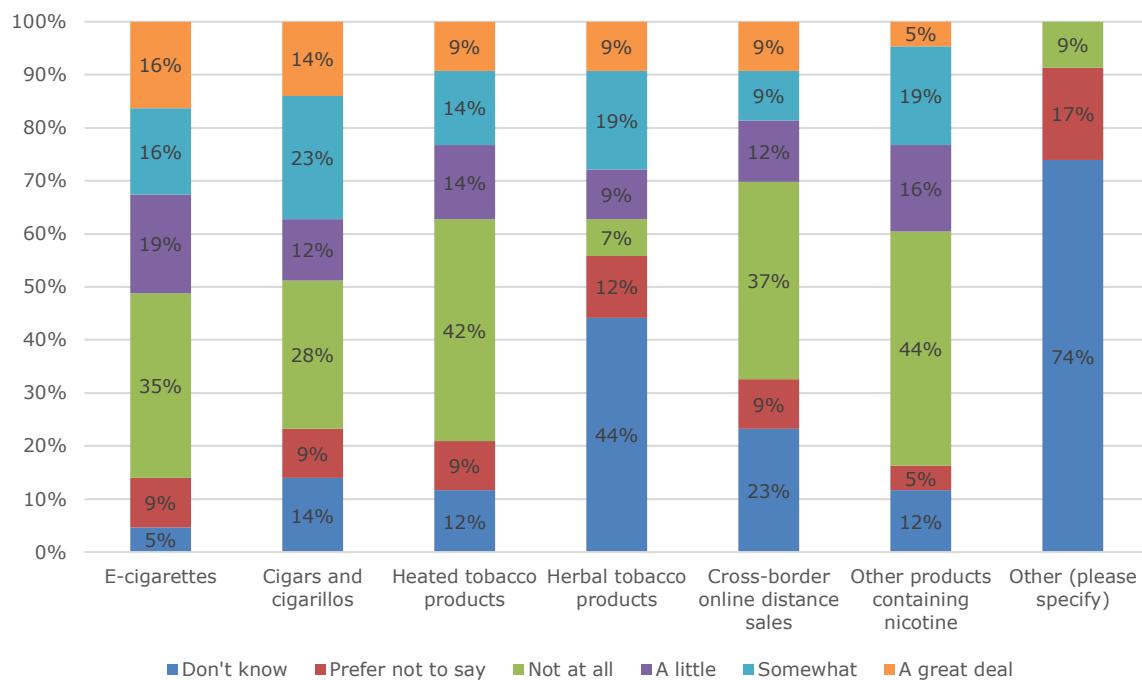
ICF CSO and HEs Online Survey 2020 – Q: Are you aware of any products which are currently on the market which are not compliant with any of the following provisions? Base: 43 respondents

Figure 46. The extent to which the TPD sufficiently addresses the following new developments in the tobacco industry and related industries (Industry responses)



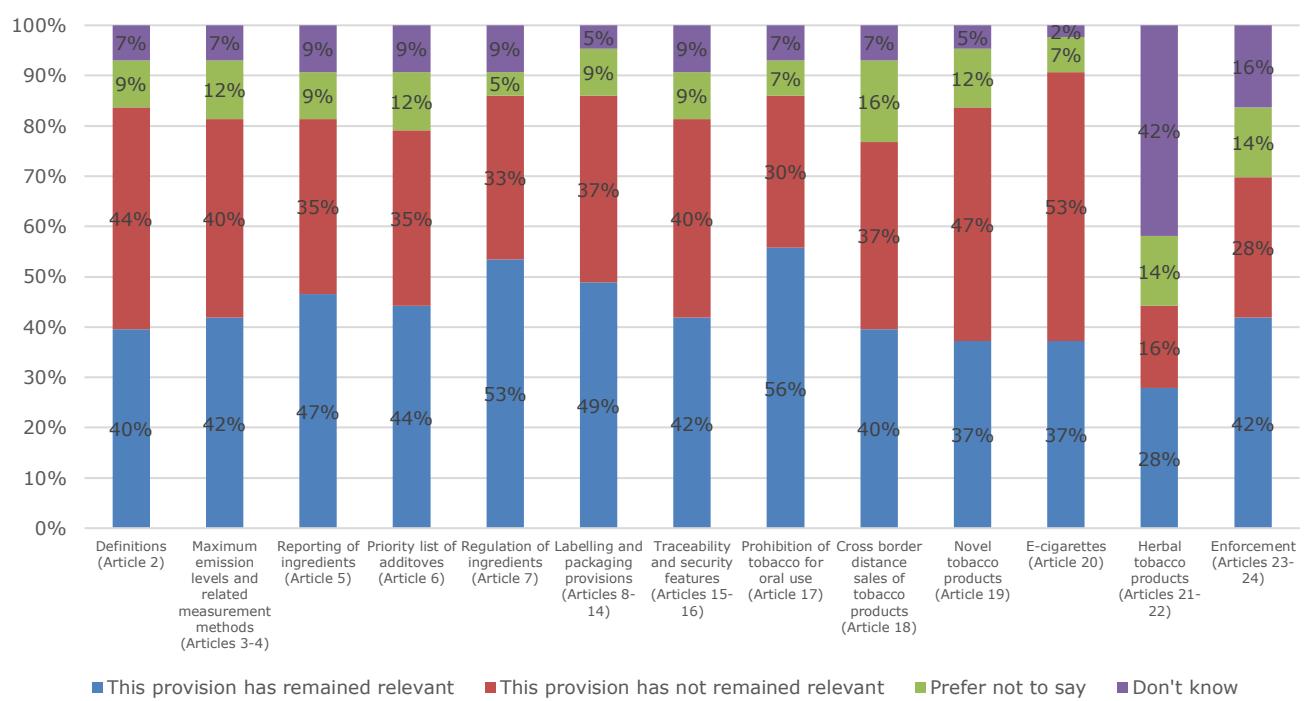
ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: To what extent do you think the TPD sufficiently addresses the following new developments in the tobacco industry and related industries? Base: 52 respondents

Figure 47. The extent to which the TPD sufficiently addresses the following new developments in the tobacco industry and related industries (CSO/HE responses)



ICF CSO and HEs Online Survey 2020 – Q: To what extent do you think the TPD sufficiently addresses the following new developments in the tobacco industry and related industries? Base: 43 respondents

Figure 48. Which provisions remain relevant to address current developments in the tobacco and related industries including technological, scientific, or market developments?



ICF CSO and HEs Online Survey 2020 – Q: Which of the following provisions, if any, do you think remain relevant to address current developments in the tobacco and related industries including technological, scientific, or market developments? Base: 43 respondents

5.8.3 Efficiency

Method

Respondents to the cost data template reported the estimated number of FTEs dedicated to different types of tobacco and related products during the 2019 calendar year. Estimated FTEs were reported for receiving product reports/notifications, storing and handling submitted information, and analysis/verification of submitted information. The FTEs were aggregated and multiplied by the average hourly wage in the Member State⁵⁸⁴ to obtain an overall cost figure⁵⁸⁵.

With respect to compliance costs, respondents to the cost data template were requested to provide an indication of costs for different categories (e.g. IT infrastructure, data assessment, laboratory testing) with respect to different types of tobacco and related products. Most of the reported cost information was in terms of FTE, which was monetised into euro average national wages.

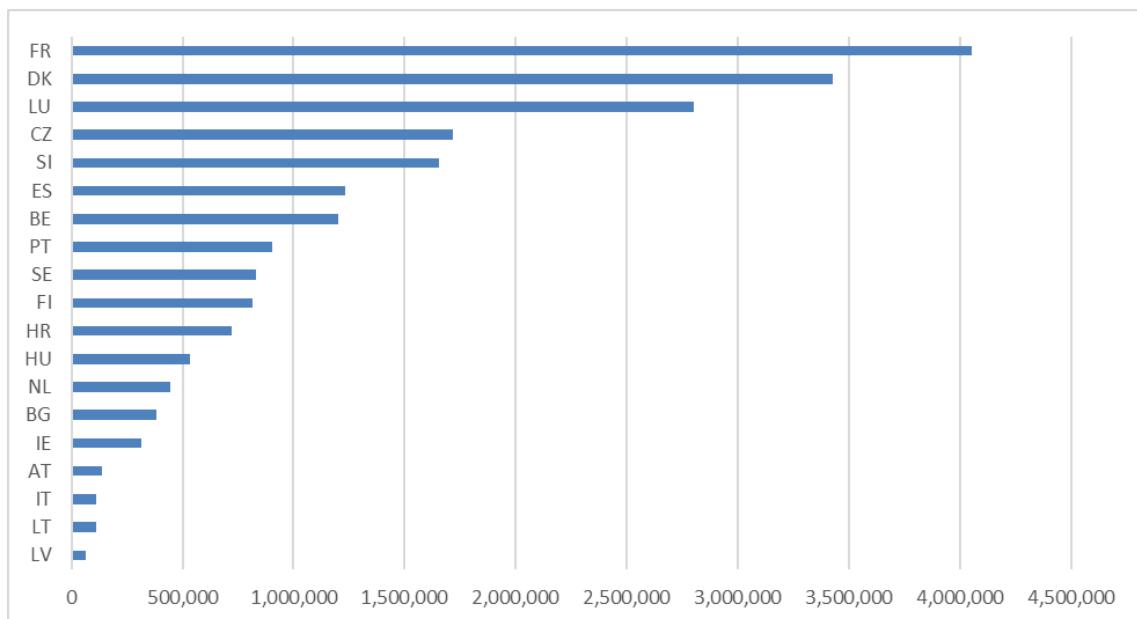
Enforcement costs are primarily related to the costs of carrying out tests and inspections. Respondents provided information on the unit cost for a product test and an inspection, as well as the number of tests and inspections conducted annually since 2016. Unit costs for tests included a fixed cost for maintenance of the equipment and a variable cost for running the test. In some cases, the number of tests and inspections were reported, but not enough additional information was provided to estimate a cost⁵⁸⁶. In the case of Ireland, the state laboratory incurs the cost but they were not asked to complete the template.

⁵⁸⁴ These figures were obtained from Eurostat. While some Member States provided information on wages, we used Eurostat figures for the calculations to promote a standardised approach.

⁵⁸⁵ The figures are not adjusted by cost of living differences across Member States. This is because the objective of the study question is to compare costs with benefits, which is done at the Member State level and thus the cost of living differences net out.

⁵⁸⁶ This was the case for Finland, Ireland, Italy and inspections for Czechia.

*Table 71. Estimated costs by Member State to review submissions to the EU-CEG (2016-2019)*⁵⁸⁷



Source: ICF analysis of inputs provided to cost data template. All Member States were invited to respond.

Table 72. Specific support provided to SMEs

Response given	Number of MS
Yes	4
Yes, to some extent	5
No	12
Did not respond to the survey or the specific question	6

Source: Overview of replies to the survey question – "Has your Member State provided any specific support to small and medium enterprises affected by the TPD?"

Table 73. Overview of SME industry responses to survey

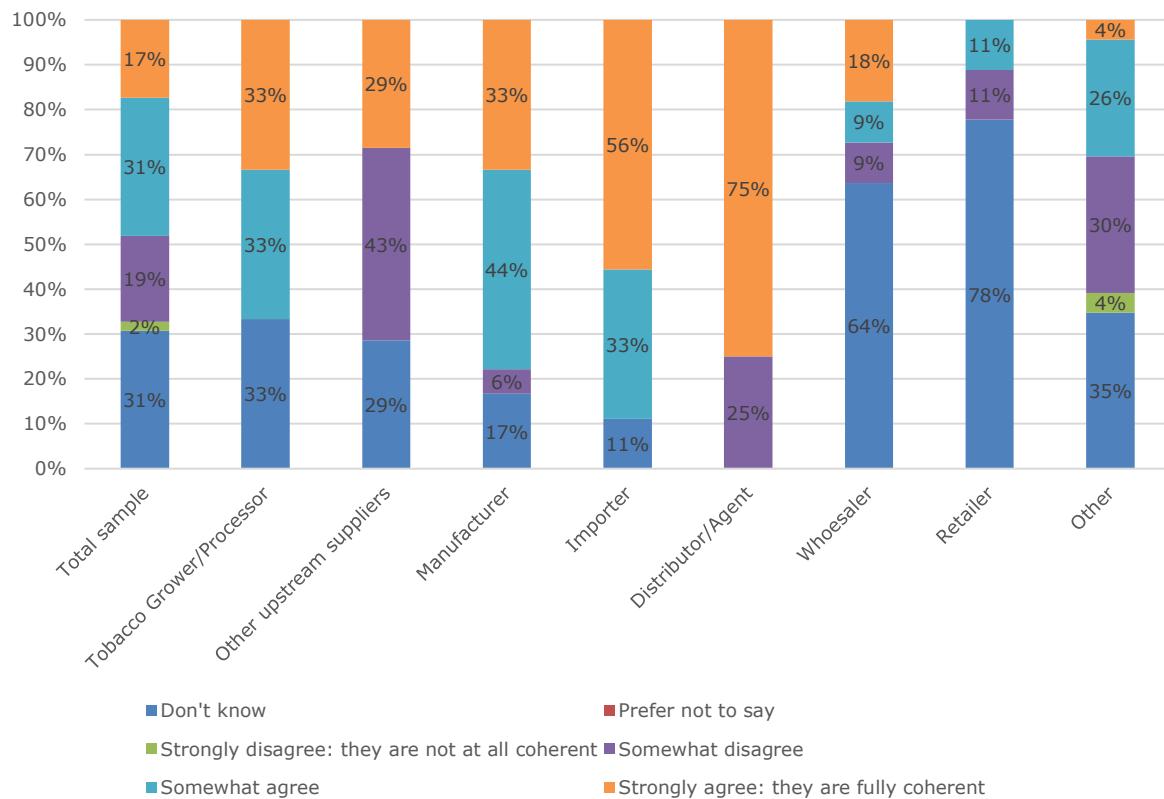
Survey question	Overview of responses
Does the TPD allow for sufficient flexibility to cater to small and medium enterprises? For example, in relation to Article 6(5) exempting small and medium enterprises from provisions on priority lists of additives and enhanced reporting obligations.	56% responded no; 33% did not know
Are you aware of any support available for SMEs from the Member States to implement specific provisions of the TPD?	74% responded no; 22% did not know
Have you received any support from the MS to implement specific provisions of the TPD?	48% said no 19% said they do not know 15% received some support

⁵⁸⁷ 19 Member States were included in this analysis, as these were the MS that provided information regarding costs using our costs data template

Source: Overview of SME replies to the industry survey. 26 organisations responded to the selected survey questions. 22 of these organisations had less than 50 employees while the remaining four had between 50 and 250 employees.

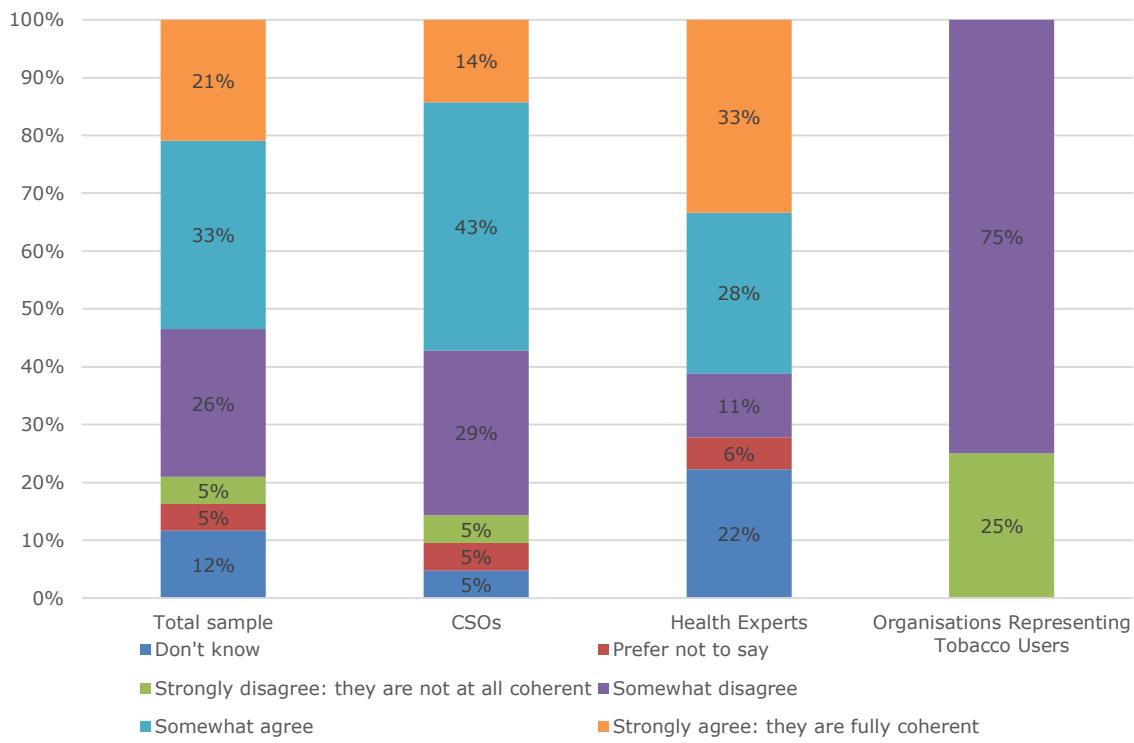
5.8.4 Coherence

Figure 49. Extent to which TPD provisions are coherent with each other (Industry responses)



ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: To what extent do you agree that the provisions of the TPD are coherent with each other? In other words, how well do the provisions fit together and how consistent are they with each other? Base: 52 respondents

Figure 50. Extent to which TPD provisions are coherent with each other (CSO/HE responses)



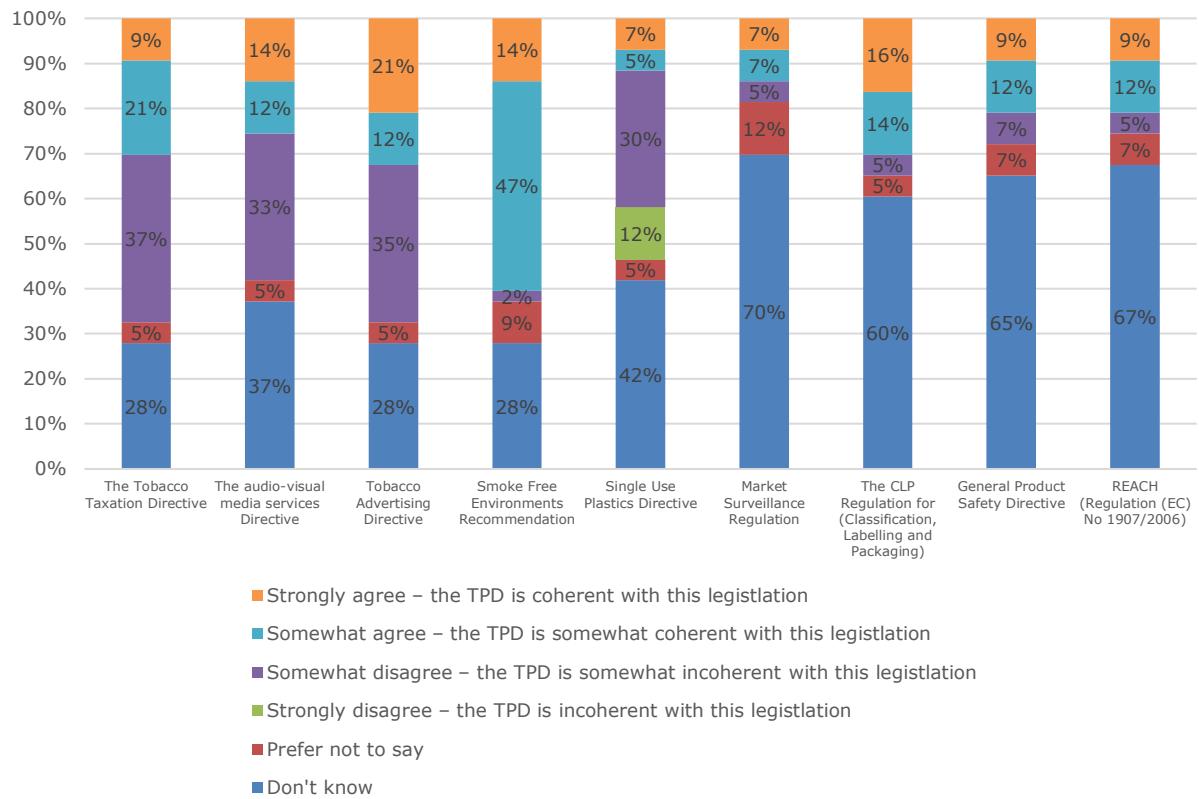
ICF CSO and HEs Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: To what extent do you agree that the provisions of the TPD are coherent with each other? In other words, how well do the provisions fit together and how consistent are they with each other? Base: 43 respondents

Figure 51. Extent to which TPD is coherent with other applicable EU legislation (Industry responses)



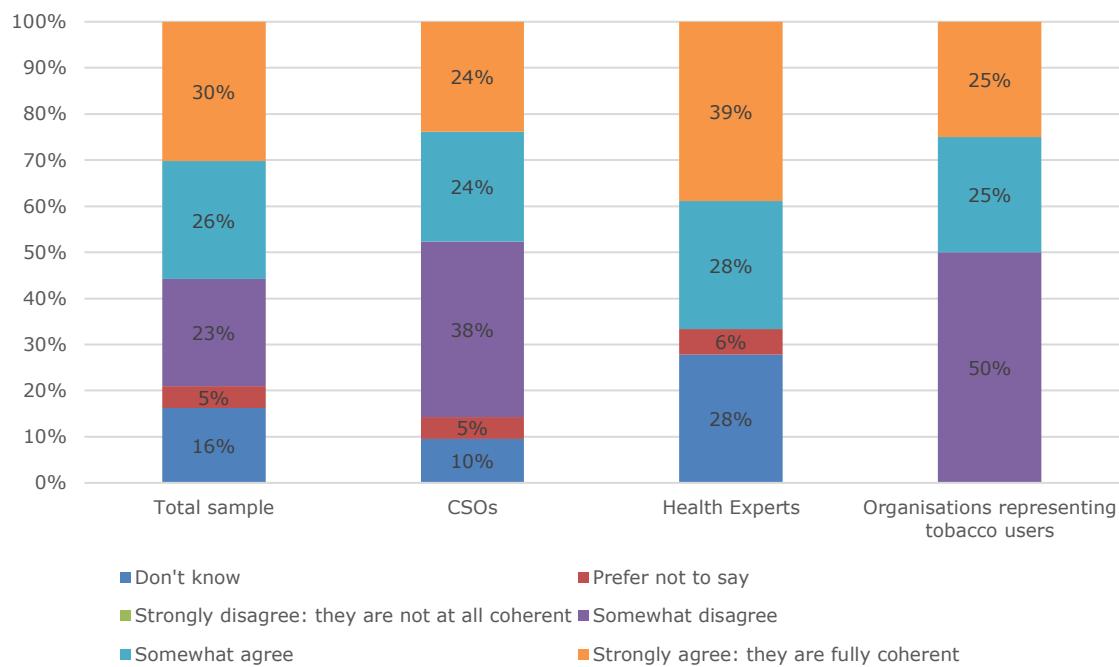
ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: To what extent do you agree that the TPD is coherent with other applicable EU legislation with relevance to tobacco control? Base: 52 respondents

Figure 52. Extent to which TPD is coherent with other applicable EU legislation (CSO/HE responses)



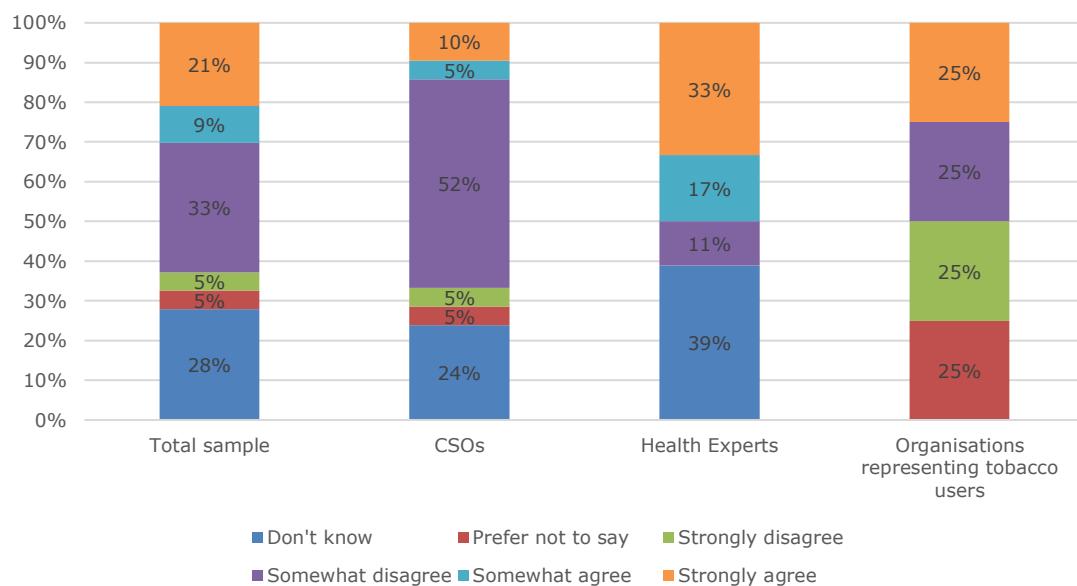
ICF CSO and HEs Questionnaire on the Assessment of the Tobacco Products Directive 2020 Q: To what extent do you agree that the TPD is coherent with other applicable EU legislation with relevance to tobacco control? Base: 43 respondents

Figure 53. To what extent to which the TPD are coherent with national rules within the Member States that you are familiar with other than the ones directly implementing the Directive?



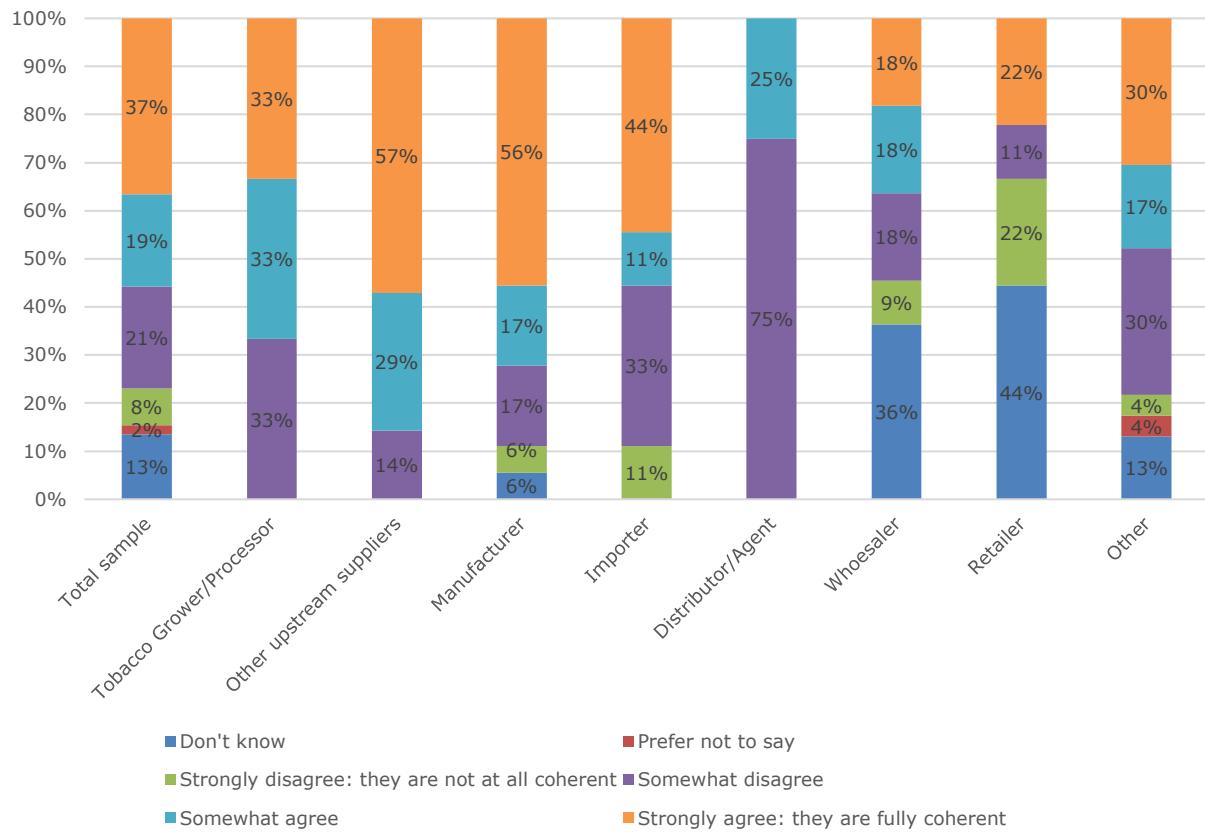
ICF CSO and HEs Questionnaire on the Assessment of the Tobacco Products Directive 2020 QICF CSO and HEs Questionnaire on the Assessment of the Tobacco Products Directive 2020 Q: To what extent do you agree that the TPD is coherent with other applicable EU legislation with relevance to tobacco control? Base: 43 respondents

Figure 54. Extent to which the TPD is coherent with the WHO FCTC (CSO/HE responses)



ICF CSO and HEs Questionnaire on the Assessment of the Tobacco Products Directive 2020 QICF CSO and HEs Questionnaire on the Assessment of the Tobacco Products Directive 2020 Q: To what extent do you agree or disagree that the provisions of the TPD are coherent with the FCTC, including the Protocol to Eliminate Illicit Trade in Tobacco Products. Base: 43 respondents

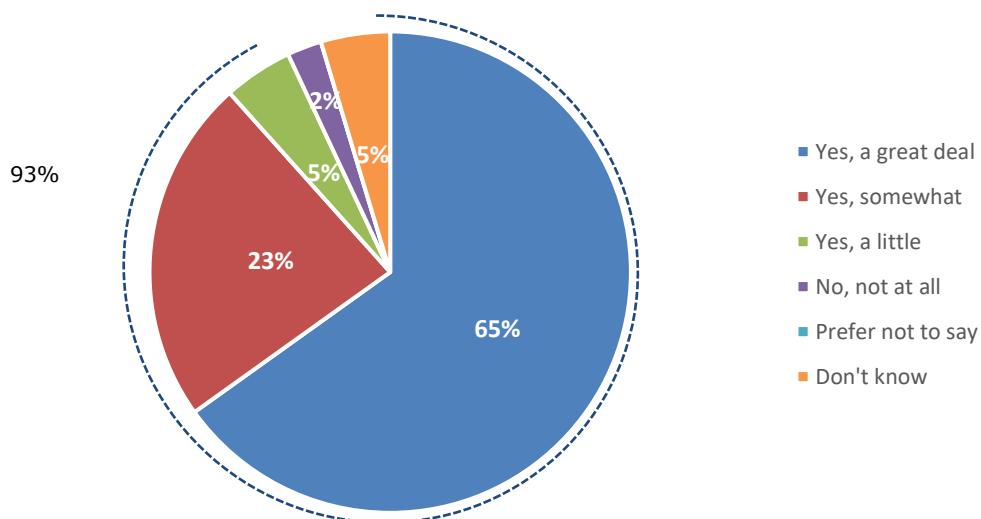
Figure 55. Extent to which the TPD is coherent with the WHO FCTC (Industry responses)



ICF Industry Survey and Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: To what extent do you agree or disagree that the provisions of the TPD are coherent with the FCTC, including the Protocol to Eliminate Illicit Trade in Tobacco Products? ? Base: 52 respondents

5.8.5 EU Added Value

Figure 56. Perceived added value of TPD among CSOs and HEs



ICF CSO and HEs Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: Has the TPD added value to the regulation of tobacco and tobacco-related products across the EU? Base: 43 respondents

Table 74. Do you feel that the effects of the TPD on smoking consumption or the illicit trade could have been achieved at the level of your Member State, without EU-level involvement?

Response	Number of Member States
Yes	0
To some extent	7
No	13
No answer	8

ICF MS Questionnaire on the Assessment of the Tobacco Products Directive 2020 – Q: Do you feel that the effects of the TPD on smoking consumption or the illicit trade could have been achieved at the level of your Member State, without EU-level involvement? Base: 24 respondents (3 did not respond to the survey)

Annex 9: Case studies

5.9 Case study 1: European system for the regulation of ingredients used in tobacco products

Key findings

The current system for the regulation of ingredients operates at the Member State level with EU-level support for certain aspects (e.g. electronic submissions database, data sharing), but not all aspects adequately meet the needs of stakeholders and Member States. Implementation of an EU-level system incorporating a centralised list of ingredients and database of information from economic operators could have benefits across three broad areas:

- More efficient **submission and publication of data** submitted by economic operators on products and priority additives via a single submission to an EU-wide database that would incur a single fee but cover all relevant Member States;
- Pooling resources and expertise would **improve the analysis and assessment** of submitted data, while also removing the administrative burden and reducing disparities between Member States;
- Provide **simplified access to EU-wide data** for Member States to support collaboration, learning, and enforcement.

However, alterations to the current system would **require in-depth consideration** of:

- How an EU-level system would be co-ordinated and which body/agency would take a lead;
- Resource implications, both in terms of those required for a centralised system and those that may be reduced for Member States through the transfer of tasks to an EU-level system;
- Minimisation of duplication of effort between the European Commission and Member States while also ensuring that individual Member State needs are met;
- Current Member State differences regarding regulation of ingredients and emissions, resources and enforcement responsibilities and how this would be addressed in the creation of an EU-level system.

5.9.1 Introduction and background

The aim of this case study is to provide evidence to support the requirements set out in Art. 28 of the TPD regarding regulation of ingredients used in tobacco products:

In the report, the Commission shall indicate, in particular, the elements of the Directive, which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco and related products. The Commission shall pay special attention to:

(d) the feasibility, benefits and possible impact of a European system for the regulation of the ingredients used in tobacco products, including the establishment, at Union level, of a list of ingredients that may be used or present in, or added to tobacco products, taking into account, inter alia, the information collected in accordance with Articles 5 and 6;

(f) the **feasibility, benefits and possible impact of a Union database containing information on ingredients and emissions** from tobacco products collected in accordance with Articles 5 and 6.

5.9.1.1 Case study objective

The objective of this case study is to conduct a high-level, small comparative analysis of the *status quo* regarding regulation of ingredients used in tobacco products and the models outlined by Art. 28 of the TPD. It will consider:

- The potential positives and negatives of current and proposed models;
- Resource and regulatory requirements;
- The potential role for existing agencies.

5.9.1.2 The current system for the regulation of ingredients used in tobacco products

Currently regulation of ingredients used in tobacco products is under the remit of individual Member States. Art. 7 of the TPD, i.a., specifies that Member States have responsibility for ensuring that products are not placed on the market if they have a characterising flavour (at the moment, only cigarettes and roll-your-own tobacco are concerned) or contain the following:

- vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;
- caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
- additives having colouring properties for emissions;
- additives that facilitate inhalation or nicotine uptake (for tobacco products for smoking);
- additives that have CMR properties in unburnt form.

It further covers products that contain flavourings in any of their components, including: filters, papers, packages, capsules or any technical features that allow the modification of the smell or taste of the tobacco products. Art. 7 also specifies that Member States should, based on scientific evidence, prohibit the placing on the market of tobacco products that contain additives in quantities that increase the toxic or addictive effect, or the CMR properties of a tobacco product, at the stage of consumption to a significant or measurable degree. Member States are permitted to charge manufacturers and importers of tobacco products fees for assessing whether a tobacco product has a characterising flavour; whether prohibited additives or flavourings are used; and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the CMR properties of the tobacco product.

Art. 5 of the TPD specifies the information on the ingredients and emissions of tobacco products that should be collected from economic operators by Member States to support the regulation of ingredients. This includes data on product emissions, in particular those specified in Art. 3(1) and Art. 4 of the TPD, data on all ingredients including a statement of the reasons for their inclusion, toxicological data, health effects, any addictive effects, and any market research or consumer preference data and sales data. Art. 5 also requires that all information submitted by economic operators be published on a public website, with the exception of data classified as a trade secret by economic operators. Member States are permitted to charge economic

operators fees for the receipt, storage, handling, analysis and publication of these data.

To further support the regulation of ingredients, Art. 6 of the TPD specifies enhanced reporting obligations for manufacturers and importers that apply to certain additives contained in cigarettes and roll-your-own tobacco, which are included in a priority list. A priority list of 15 additives was adopted by 20 May 2016. Specifically, Member States should require manufacturers and importers of cigarettes and roll-your-own tobacco that contain an additive included in the priority list to carry out comprehensive studies, to examine for each additive whether it:

- contributes to the toxicity or addictiveness of the products concerned, and whether this has the effect of increasing the toxicity or addictiveness of any of the products concerned to a significant or measurable degree;
- results in a characterising flavour;
- facilitates inhalation or nicotine uptake; or
- leads to the formation of substances that have CMR properties, the quantities thereof, and whether this has the effect of increasing the CMR properties in any of the products concerned to a significant or measurable degree.

The studies should examine in particular the emissions resulting from the combustion process involving the additive, and the interaction of that additive with other ingredients contained in the product.

EU-level lists of ingredients used in tobacco products

At present, there is no EU-level list of ingredients that may be present in, or added to, tobacco products. Art. 6 of the TPD provides for the establishment, by implementing acts, of a priority list of additives that have additional reporting requirements for economic operators. This list currently includes Carob bean, Cocoa, Diacetyl, Fenugreek, Fig, Geraniol, Glycerol, Guaiacol, Guar gum, Liquorice, Maltol, Menthol, Propylene glycol, Sorbitol, and Titanium dioxide⁵⁸⁸. Member States were required to collect additional reports from economic operators on these additives by 1 July 2018⁵⁸⁹. The reports were required to provide detailed data on whether the additive increases the toxicity or addictiveness of a product, results in a characterising flavour, facilitates inhalation or nicotine uptake, or increases the CMR properties of products. Member States may have these reports peer reviewed and are permitted to charge economic operators fees for this.

As outlined above, through Art. 7(6) the TPD also provides an indication of ingredients that *should not* be included in tobacco products, but does not provide a definitive list of named substances. In order to ensure that provisions on characterising flavours can be applied in a uniform manner throughout the Union, the Commission has established

⁵⁸⁸ 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 (2016). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0787&from=EN>

⁵⁸⁹ 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 (2016). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0787&from=EN>

common procedures to help determine whether a tobacco product has a characterising flavour⁵⁹⁰, including an independent advisory panel⁵⁹¹.

EU-level database containing information on ingredients and emissions from tobacco products

Information on the ingredients and emission levels for tobacco products and priority additive reports required by Art. 5 and 6 of the TPD, as well as further relevant product information, from manufacturers and importers of these products is currently collected through submissions to the EU-CEG system, which has been in operation since May 2016. It is also used for the collection of product submissions on e-cigarettes as required by Art. 20, and herbal products for smoking by Art. 22. National authorities can access these data via the Member States Reporting Tool (MS-REP). The aim of the EU-CEG system is to reduce administrative burden for economic operators and regulators and to allow Member States to retrieve, analyse, and compare product data. However, although the submission system is centralised, the responsibility for collecting and controlling data lies with each Member State, although they do have the possibility to store data submitted to them at Commission facilities.

5.9.2 Methods

The methods for this case study included synthesis of data already collected as part of this assessment, new desk research and integration of data collected as part of workshops and an online survey.

5.9.2.1 Desk research

The desk research included a search of both academic and grey literature, and a review of responses from Member States, CSOs, and HEs to surveys undertaken for this study. Searches were conducted in Google (to identify grey literature), and Google Scholar (academic literature). The search string used is provided below; the first 50 search results were examined.

- '*European Union*' AND '*tobacco products directive*' AND ('*ingredients*' OR '*additives*' OR '*emissions*')

Along with studies identified from the literature searches, 'snowballing'⁵⁹² and forward searching⁵⁹³ were also used to identify relevant sources.

5.9.2.2 Gap filling workshops

Dedicated workshops were conducted to fill gaps in the evidence, including with CSOs/HEs, and representatives from NCAs responsible for tobacco control in Member States. The workshops aimed at filling gaps in the evidence for the study as a whole and also specifically discussed the feasibility, benefits and possible impact of a European system for the regulation of the ingredients used in tobacco products, including an EU-level list.

⁵⁹⁰ Commission Implementing Decision (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour (2016). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0779&from=EN>

⁵⁹¹ Commission Implementing Decision (EU) 2016/786 of 18 May 2016 laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour (2016). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0786&from=EN>

⁵⁹² A process in which a small number of additional relevant studies are found through the quick review of the reference list of studies identified for inclusion at the end of the screening stage.

⁵⁹³ A process to identify any articles that cite the identified article.

5.9.2.3 Gap filling survey

An online gap filling survey was conducted to fill gaps in the evidence with representatives from NCAs responsible for tobacco control in Member States. The survey was conducted to fill gaps in the evidence for the study as a whole.

5.9.3 Results

Detailed findings regarding the current system from individual Member States and other stakeholders are presented in **Section 3.2 subsections on Art. 5 and Art. 7** of the main report and are not repeated here. Instead, this case study focuses on developing high-level inferences and conclusions about the possible impact of the proposed EU-level system, list of ingredients, and database.

5.9.3.1 Stakeholder perspectives on the status quo

The current approach to submission and publication of product information, and priority additive report submissions, is viewed as inefficient and raises issues for all stakeholders

The current **product submission requirements are viewed as engendering a substantial administrative burden** by many economic operators and Member States. In particular, economic operators identified the differences between Member States in terms of fees and submission requirements as problematic, and expressed the view that the volume of information that must be submitted for each product in each Member State is a considerable burden⁵⁹⁴. Some economic operators also expressed that they were **unsure about how the concept of trade secrets should be applied to submission data**, leading to some classifying most of the information they submit as a trade secret⁵⁹⁵.

Many Member States, CSOs, and HEs expressed **dissatisfaction with the data received from economic operators for products and priority additives**. The data provided by economic operators was reported to be of poor quality overall, often missing information on sales, toxicology, statements of reasoning, additives, and research studies⁵⁹⁶. Similarly, reports on priority additives from some manufacturers did not contain data about additives or were incomplete, as was found in a previous JATC study⁵⁹⁷. Additionally, information is not necessarily submitted in the appropriate language for each Member State, making it challenging to assess and use the data provided. Like economic operators, Member States also found the concept of trade secrets in relation to submission data problematic⁵⁹⁸. The practice of some economic operators of classifying the majority of the information they submit in this way makes it challenging for Member States to fulfil their publication responsibilities regarding product data⁵⁹⁹.

⁵⁹⁴ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵⁹⁵ ICF Economic Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁵⁹⁶ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; ICF CSO and HE Stakeholders Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Gap-filling workshops, November 2020.

⁵⁹⁷ JATC. (2019). WP9-D9.2: Inventory of Industry documents: A report on the type of information from the EU-CEG system on enhanced reporting of priority additives. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.2-Inventory-of-Industry-A-report-on-the-type-of-information.pdf>; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020

⁵⁹⁸ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Gap-filling workshops, November 2020.

⁵⁹⁹ Gap-filling workshops, November 2020.

Some CSOs and HEs reported that these challenges mean the **currently available data are of limited use** to them. Even though a large volume of records is available, substantial parts of each record are often not disclosed due to being classified as a trade secret by the economic operators or are missing key data (e.g. on emissions)⁶⁰⁰. Additionally, CSOs and HEs noted that the approach to publication differs by Member State which may be related to their capacity and resources, but makes comparative analyses more challenging⁶⁰¹.

Although Member States recognise the benefits of the list of priority additives, the use of Union level ingredient lists could be taken further

Art. 28 includes consideration of the establishment, at Union level, of a list of ingredients that may be used or present in, or added to tobacco products. A few Member States reported having created lists of substances that are not permitted to be included in tobacco and related products⁶⁰². France is also considering the development of a negative list of additives that are considered to increase the toxicity or addictiveness or the CMR properties of products, following the work of the JATC in this area, and has already created a validated list of substances to support the product reporting process^{603,604}. Member States expressed **support for the use of Union level lists** to facilitate the implementation of the provisions in Art. 7 more broadly, particularly in relation to substances “associated with energy and vitality” or that “facilitate inhalation or nicotine uptake”⁶⁰⁵. However, there is no single preferred format for any such lists, with some Member States suggesting a list of *prohibited* substances, others suggesting a list of *permitted* substances, and still others suggesting both types of list be used⁶⁰⁶.

The current EU database, EU-CEG, is valuable but could be strengthened by further modifications, particularly to support data sharing

Overall, the current EU-CEG system serves an important purpose in supporting industry to submit required information on ingredients, emissions and additives for tobacco products and Member States to collect, review, and publish this information, as well as enabling consumers and researchers to access information about products across the EU^{607,608,609,610}. However, all stakeholders have noted some limitations of the current system. Some economic operators viewed the EU-CEG system as effective,

⁶⁰⁰ Gap-filling workshops, November 2020.

⁶⁰¹ Gap-filling workshops, November 2020.

⁶⁰² ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Gap-filling workshops, November 2020.

⁶⁰³ ANSES (2020) Tobacco and vaping products: ANSES is publishing an unprecedented overview of products sold in France. Accessed on January 4th 2020. Available at: <https://www.anses.fr/en/content/tobacco-and-vaping-products-anses-publishing-unprecedented-overview-products-sold-france>

⁶⁰⁴ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Gap-filling workshops, November 2020.

⁶⁰⁵ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Gap-filling workshops, November 2020.

⁶⁰⁶ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Gap-filling workshops, November 2020.

⁶⁰⁷ DG SANTE (2019) Meeting of subgroup on ingredients: 6-7 February 2019.

⁶⁰⁸ Havermans A, Krüsemann EJZ, Pennings J, De Graaf K, Boesveldt S, Talhout R. (2021) Nearly 20 000 e-liquids and 250 unique flavour descriptions: An overview of the Dutch market based on information from manufacturers. *Tob Control*; 30(1):57–62.

⁶⁰⁹ Krüsemann EJZ, Havermans A, Pennings JLA, de Graaf K, Boesveldt S, Talhout R. (2020) Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid’s flavour category. *Tob Control*. Published Online First: 10 February 2020. doi: 10.1136/tobaccocontrol-2019-055447.

⁶¹⁰ Rebollar A, Perea MD, Doncel JC, Panero J, Gómez-Chacón MC. (2019) Productos de tabaco y relacionados: portal europeo EU-CEG. *Rev Esp Salud Pública*; 93.

although others expressed the view that the **submission formats are onerous and use of the system is very resource intensive** (in terms of IT, human resources, and time). Some Member States, CSOs, and HEs reported that **extracting data from the EU-CEG system is burdensome** due to the sheer volume of information available and the limited system-level capacity for filtering data. Limitations and potential improvements of EU-CEG are provided in more detail in the JATC report^{611,612} and this assessment study **Section 3.2; subsection on Art. 5.**

In addition to supporting the collection of data from economic operators, EU-CEG is intended to support data sharing between Member States. However, uptake of this has been limited in practice. We found that more than half of Member States had not used EU-CEG data from other Member States⁶¹³. **Broad interest in making more use of these data** was expressed by Member States in our data collection activities as they recognise the potential benefits of learning from the experiences of others, although a few Member States indicated that current resources limit their ability to do this⁶¹⁴.

Analysis of product and priority additive submissions is limited by Member State resources

Some Member States reported **limited capacity to review product submissions and reports submitted on priority additives due to lack of human resources, technical expertise, and laboratory infrastructure**. Member States reported challenges in implementing the requirements of Art. 5 due to factors related to the volume of data submitted, the associated administrative and technical burden this places on national competent authorities, and human resource limitations relating to available staff and their scientific knowledge⁶¹⁵. This means that not all data submitted can be extensively reviewed, and in some cases not all requirements have been enforced (e.g. the statement of reasoning of certain Member States). This lack of resources was also reported by a few Member States to limit capacity to make use of EU-CEG data from other Member States.

Reports submitted on priority additives were described as presenting similar challenges for many Member States due to limited expertise and resources. Resource limitations included not just staff but also the ability to conduct laboratory assessments of products to determine the presence of additives, which is needed to enforce prohibitions⁶¹⁶. These resource limitations may also impact enforcement of TPD provisions relating to ingredients and emissions. Although fifteen Member States reported identifying inadequate product submissions and contacting industry submitters, only five reported they had undertaken severe actions in relation to this including product withdrawal or fines⁶¹⁷. In relation to priority additive reports, only

⁶¹¹ Joint Action on Tobacco Control (2019) WP5 - D5.6: Report for M1-18 on the potential improvements/alterations identified through Task 3.1. <http://jaotc.eu/wp-content/uploads/2019/09/WP5-D5.6-Report-for-M1-18-on-the-potential-improvementsalterations-identified-through.pdf>

⁶¹² Joint Action on Tobacco Control (2020) D5.7 – Addressing potential improvements. Note this document is not currently available on the JATC public website.

⁶¹³ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

⁶¹⁴ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Gap-filling workshops, November 2020; ICF Gap Filling Questionnaire, December 2020.

⁶¹⁵ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020; Gap-filling workshops, November 2020; ICF Gap Filling Questionnaire, December 2020.

⁶¹⁶ ICF Gap Filling Questionnaire, December 2020.

⁶¹⁷ ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

three Member States explicitly reported taking actions such as product withdrawal or fine.

5.9.3.2 The impact of EU-level initiatives on the regulation of ingredients at the Member State level

EU-level initiatives have supported Member States to overcome challenges presented by implementing the regulation of ingredients and emissions of tobacco products. The areas targeted by these initiatives and their success provide some insight into the potential benefits that could be derived from implementing an EU-level system for the regulation of ingredients.

- *Product data submission:* The EUREST project provided an input for a common format for reporting product data^{618,619}, and the EU-CEG system provides a single submission portal that has been iteratively improved by DG SANTE and the JATC since it became operational in 2016^{620,621}.
- *Product data publication:* The JATC WP.5 directly addressed the issue of “trade secret” classification of data, providing guidance on identifying public non-confidential data and exploring the most efficient way to make these data publicly available^{622,623}. As part of this Work Package, the JATC also made recommendations for a centralised web-based reporting tool that could be developed by the Commission to support Member States to implement the JATC guidance and publish appropriate data⁶²⁴.
- *Sharing data between Member States:* Supporting Member States to share EU-CEG data was a key element of the JATC project. Through WP.5, the JATC defined both the legal and technical requirements for sharing these data^{625,626}, including a multilateral data sharing agreement for both JATC partners and non-JATC partners. Through this, the JATC supported NCAs and National Administrators of EU-CEG to liaise with Member States to facilitate sharing of information via MS-REP. As of November 2020, the agreement had been signed by 19 Members States and Norway⁶²⁷. Although the JATC project ended in December 2020, the JATC developed a proposal for

⁶¹⁸ European Regulatory Science on Tobacco Consortium (EUREST). (2015) Study on the development of an EU common reporting format for submission of data on ingredients contained in tobacco and related products, and disclosure of the collected data to the public. Brussels: European Commission.

⁶¹⁹ Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products (2015). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D2186&from=EN>

⁶²⁰ Joint Actions on Tobacco Control (2019). WP5 - Deliverable 5.6: Report for M1-18 on the potential improvements/alterations identified through Task 3.1. <http://jaotc.eu/wp-content/uploads/2019/09/WP5-D5.6-Report-for-M1-18-on-the-potential-improvementsalterations-identified-through.pdf>

⁶²¹ Joint Action on Tobacco Control. (2018) WP5 - D5.2 Defined legal aspects of accessing other MS data in the JATC project.

⁶²² Joint Action on Tobacco Control (2020) D5.1 - Report on what data is public and non-confidential in EU-CEG. Note this document is not currently available on the JATC public website.

⁶²³ Joint Action on Tobacco Control (2020) D5.4 – Technical solution for public non-confidential data. Note this document is not currently available on the JATC public website.

⁶²⁴ Joint Action on Tobacco Control (2020) D5.4 – Technical solution for public non-confidential data. Note this document is not currently available on the JATC public website.

⁶²⁵ Joint Action on Tobacco Control (2018). WP5 - D5.2 Defined legal aspects of accessing other MS data in the JATC project.

⁶²⁶ Joint Action on Tobacco Control (2019). WP5 - D5.3 Technical solution for securely accessing and processing public non confidential data.

⁶²⁷ Joint Action on Tobacco Control (2020). Newsletter 2. http://jaotc.eu/wp-content/uploads/2020/10/JATC_Newsletter-2.pdf [accessed 02/01/2021].

continuing support for data sharing using existing functionality within the EU-CEG system⁶²⁸.

- *Assessing priority additive reports:* The JATC developed a framework for the assessment of reports and guidance on additional information that could be requested from industry to support this, including minimum reporting requirements and a reporting template⁶²⁹, which incorporated the approach outlined in the SCHEER opinion on tobacco additives^{630,631}. The JATC also established an independent review panel and found that reports from some manufacturers did not contain data about additives or were incomplete⁶³². To address this, DG SANTE prepared letters for Member States to send to manufacturers and importers, both to request additional information and information specifically on products containing the ingredient diacetyl⁶³³.

Overall, these EU-level initiatives have been viewed by Member States as having a positive impact. The JATC guidance on product publication has been used by at least one Member State so far, but given it had been published for less than a year when we collected information on Member State use, uptake will likely increase. The JATC outlined in their proposal some key considerations in developing a centralised publication tool for use by Member States: (i) ensuring the system can accommodate differing levels of Member State technical capacity; (ii) accommodating the frequency with which the system would require updates to meet Member State needs; (iii) allowing for different Member State regulations regarding products and their approval status; (iv) accommodating linguistic diversity; (v) ensuring protection from security breaches.

JATC support for data sharing has been well-received; 19 Member States⁶³⁴ reported sharing EU-CEG data had been straightforward⁶³⁵, with five confirming that the JATC had enabled the sharing of data upon request and a further three reporting they had used data shared by other Member States. Additionally, the JATC framework for assessing priority additive reports has been used by at least six Member States. These positive impacts highlight the potential benefits of further integration of the system for regulating ingredients and emissions.

⁶²⁸ Joint Action on Tobacco Control (JATC). (2020) WP5 – D5.5 Proposal for a permanent mechanism to facilitate the sharing of EU-CEG data. Note this document is not currently available on the JATC public website.

⁶²⁹ Joint Action on Tobacco Control. (2018). WP9- D9.1 Assessment/Evaluation Framework for enhanced reporting of priority additives and guidelines for 'Good Experimental Practicing'. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.1-Assessment-Evaluation-Framework-for-enhanced-reporting-of-priority-additives-and-guidelines-for-%E2%80%98Good-Experimental-Practicing%E2%80%99.pdf>

⁶³⁰ Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) (2016). Opinion on Additives used in tobacco products (Opinion 2): Tobacco Additives II. European Union.

⁶³¹ Talhout R, Duarte-Davidson R, Hoet P, Nair U, Rydzynski K, Vermeire T, et al. (2020) Advice to the European Commission as Regards Type and Criteria for Comprehensive Studies to Be Requested from Manufacturers: The Opinion of the Scientific Committee on Health, Environmental, and Emerging Risks (SCHEER). Nicotine Tob Res. 22(5):613–8.

⁶³² JATC. (2019). WP9- D9.2: Inventory of Industry documents: A report on the type of information from the EU-CEG system on enhanced reporting of priority additives. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.2-Inventory-of-Industry-A-report-on-the-type-of-information.pdf>

⁶³³ DG SANTE. (2019). Meeting of the group of experts on tobacco policy: 21 March 2019.

⁶³⁴ Note that this study includes the UK within "Member States" for the purpose of looking at the past.

⁶³⁵ 19 Member States did not encounter any challenges giving access to the information submitted in EU-CEG to other Member States; ICF Member States Questionnaire on the Assessment of the Tobacco Products Directive 2020, April-June 2020.

5.9.3.3 Feasibility, benefits and possible impacts of EU-level system for regulation of ingredients, including a central list of ingredients and database

Assumed model for an EU-level system

There are different models that could be implemented to further centralise regulation of ingredients at the EU level, including permitted ingredients lists and expanded use of a central database. We consider a scenario in which an EU agency is tasked with all technical aspects of the submission, publication, and assessment of product and additive reports, collecting its own fees at the EU level and building the necessary technical expertise with specialised staff. This would transfer many of the data collection, analysis and publication requirements from the Member States to the EU level, including the implementation and maintenance of a database of ingredients, emissions, and additives. The agency would also lead centralised approaches to any challenges that arise, including maintaining and updating a list of prohibited and/or permitted ingredients.

Potential benefits and positive impacts

An EU-level system would **simplify the submission of product and additive reports** by requiring a single submission for the whole of the EU with a single contact point and fee. This would address concerns raised by economic operators that the current system is not consistent across Member States, which creates additional administrative burden. Similarly, publishing information at the EU level would also be more efficient, and would potentially solve the difficulties faced by Member States in determining which data submitted by economic operators should be regarded as trade secrets.

A completely centralised EU-level system would likely lead to **improvements in the quality of submissions** due to a reduction in the administrative burden and potential for feedback to economic operators. Creation of central staff with designated responsibility for assessing the information submitted on products and additives, and with access to the necessary laboratory and other technical resources, would help to **build expertise and capacity in this area, and lead to more effective analysis** of these data. It could alleviate the concerns raised by many Member States regarding resources and capability to process data submitted to EU-CEG, particularly supporting smaller Member States who have the most limited capacity and have acknowledged relying on the JATC project for support. It could also facilitate the independent assessment of products and additives, as has been suggested by a few Member States in relation to reports on priority additives, to avoid the potential for industry bias in these reports.

In addition to supporting collaboration between Member States, **sharing and assessment of data via an EU system would reduce redundancies created by the same product being marketed in multiple countries and support enforcement** activities. Inadequate product submission or additive reports would be more efficiently identified through centralised analysis, but also requests for further information from industry submitters would only need to be undertaken once. This would be particularly beneficial for products where the manufacturer is located outside the EU as Member States have reported difficulties requesting additional information in these instances⁶³⁶. Similarly, any actions undertaken for non-compliance, such as product withdrawals or fines, could occur at the EU level and, in the case of withdrawal, be effective in all relevant Member States at once. Linking all these data through the unique product identifier that is linked to the traceability system via an

⁶³⁶ ICF Gap Filling Questionnaire, December 2020.

EU-level database would improve the effectiveness of enforcement activities undertaken by Member States, and may assist in monitoring cross-border sales.

We found that **Member States were broadly supportive of an EU-level system to support the regulation of ingredients** and emissions for tobacco products. Four Member States particularly highlighted the key contributions this would make in terms of efficiency, capacity building, and improving data quality and interpretation⁶³⁷. One Member State highlighted that lists related to additives or other substances are already implemented in other EU legislation relating to food, and that doing so in relation to tobacco products would be beneficial. Many Member States took the view that the creation of an EU-level database would have some benefits including: increased efficiency in analysis of data, improved collaboration between Member States and industry, facilitating comparative research, supporting enforcement of the TPD and market surveillance, and enabling publication of data on products and ingredients⁶³⁸.

Potential challenges and negative impacts

Even if most elements of the regulation of ingredients and emissions are centralised at the EU level, implementation will still require input from Member States, and Member States will require data and analysis results from the central system. Some of the JATC considerations may also be relevant to a future EU system for regulating ingredients and emissions, e.g. ensuring the system can accommodate differing levels of Member State technical capacity; accommodating linguistic diversity and ensuring protection from security breaches.

An EU-level system presents a theoretical risk that specific **issues that are only of concern to one or two Member States may not receive the same degree of attention that they would if data were collected and analysed at a national level**, resulting in Member States lacking required data. As discussed above, there is variation between Member States in terms of the resources available for activities related to regulation of ingredients in tobacco products, not just in terms of analysing data submitted to EU-CEG, but also in terms of enforcement (See case study 4 on monitoring and enforcement). Therefore, any EU system would need to accommodate the differing capacity and capability of the Member States, as well as meeting their individual needs regarding the regulation of ingredients and emissions for tobacco products. In our gap-filling workshop, a few Member States expressed concern that moving from the current system to a completely centralised EU-level system could result in **duplication of effort** if national-level databases need to be maintained to meet Member State needs⁶³⁹.

Accommodation of current variation between Member States in the regulation of ingredients and/or emissions may also present a challenge for an EU-level system. Member States will have the best understanding of the issues within their market, and while there will be some issues that are shared (e.g. the appearance of new tobacco products with menthol flavourings following the EU-wide ban on menthol flavouring of cigarettes and roll-your-own tobacco), there will be others that are specific to certain Member States. Implementing an EU-level system would therefore necessitate even greater harmonisation across Member States than has already been achieved. However, although greater harmonisation achieved via an EU-level system would address the concerns raised by economic operators regarding administrative burden, they may not always view it as the optimal solution. Some economic operators have reported they prefer to have separate identifiers for a product for each Member State if they tailor the product presentation to each country.

⁶³⁷ Gap Filling Workshop, November 2020.

⁶³⁸ Gap Filling Workshop, November 2020; ICF Gap Filling Questionnaire, December 2020.

⁶³⁹ Gap filling workshop, November 2020.

In addition to these potential issues, collecting fees for product submissions and review of additive reports at the EU-level could be problematic if it **deprives Member States of funds for tobacco control** activities. We found that most Member States do levy fees for product submissions. A few Member States reported that they charged fees specifically for review of priority additive reports, while a further two indicated that these costs were accounted for as part of global or annual fees charged to manufacturers and importers.

If the single EU database integrated data for all product submissions and additive reports, facilitation of data sharing between Member States would no longer be of concern, but this could raise new considerations regarding **ownership and responsibility of submitted data on products and additives**. Under the current system, although data are submitted through the central EU-CEG system, each Member State retains responsibility for data relating to products marketed in their country; whether this would still hold if data were collected and stored at EU-level, and the implications of this, would need further consultation and investigation.

Feasibility and resources

The work of the JATC has demonstrated that a centralised EU approach to the regulation of ingredients and emissions can be beneficial, and the existing level of integration suggests that such an approach is conceptually feasible. However, Member States have consistently highlighted the substantial resource requirements generated by implementing the TPD articles related to tobacco product submissions, priority additive reports, and assessment of prohibited ingredients. In order to implement an EU-level system for the regulation of tobacco product ingredients, consideration of the following resources would be required:

- Staff with the necessary expertise to assess product submissions and priority additive reports, and available in sufficient numbers to manage the volume of data submitted by economic operators;
- Access to certified laboratories to verify product submission data and the capacity to monitor and approve such laboratories, or the development of a designated facility for verification;
- Capacity to provide support to Member States in regulating their markets, and ability to monitor the markets in all Member States to ensure Union-level lists of ingredients remain relevant and enforceable;
- Creation of an EU-level platform for publication of collected data.
- Funds for implementing an EU-level system could be raised through charging economic operators fees for product submissions and review of priority additive reports, as is already done by Member States. Existing approved laboratories in Member States could be used to support assessments conducted, although some central staff would most likely be needed to support the EU-level system and development of a designated facility may prove preferable. Solutions relating to the IT infrastructure to support data collection and publication would likely be acquired from within the Commission given its current responsibility for EU-CEG, although specific responsibility for this would depend upon the agency responsible for the overall system.

Regulation

The JATC played a key role in facilitating the regulation of ingredients by Member States. In the proposal for continuation of the data sharing approach developed by the JATC, it was suggested that the coordination role could be transferred to DG SANTE. Whether this would be appropriate depends on how an EU-level system will be implemented. The most effective would probably be to task an EU agency with the

responsibility of a system for the regulation of ingredients in tobacco products given the benefits expected from such an EU-level system, in particular building expertise and capacity as well as a more effective analysis of submitted data. This agency could also provide support for the regulation of ingredients in e-cigarettes and other tobacco related products if deemed necessary in the future.

This role could be attributed to a new agency or, preferably, an existing EU agency. The latter option would reduce the administrative burden involved in setting up a new agency and allow to build on existing expertise and capacity. The European Chemicals Agency (ECHA) would be a good candidate to take on the responsibility of an EU-level system for the regulation of ingredients. First, its scope covers a wide range of substances including most, if not all, of the ingredients referred to in the TPD⁶⁴⁰. Second, its activities – the registration, evaluation, authorisation and restriction of chemicals – closely mirror those of an EU-level system for the regulation of ingredients in tobacco products.

An EU legislative act would need to be adopted in the form of a regulation regardless of whether a new agency is established, or responsibilities transferred to an existing agency such as ECHA⁶⁴¹. This could be done via a general regulation on tobacco and related products, if this type of legal act is chosen for a future revision of the TPD. Alternatively, a specific regulation needs to be adopted to either establish a new agency or task an existing agency. In both cases, the regulation would need to clearly define the responsibilities of the agency, including the rules governing the processing and sharing of data, the agency's cooperation with national competent authorities, and, in the case of a new agency, its structure and organisation.

The agency would need to be at least partly financed by proportionate fees levied on manufacturers and importers of tobacco products, as it is already the case in the TPD⁶⁴². These fees would need to take account of the work required to be carried out by the agency and, where relevant, the NCAs, and should be sufficient to cover the cost of the services delivered when combined with other sources of revenue. The structure and amount of these should be determined through an implementing act in the form of a Commission Regulation. This regulation should also specify the circumstances under which a proportion of the fees would be transferred to the relevant national competent authority.

5.9.4 Overall conclusions

Overall, the current system for the regulation of ingredients and emissions does support Member States and economic operators, but not all aspects adequately meet their needs. Implementing an EU-level system may improve this. The work of the JATC has demonstrated the benefit of having a designated central organisation to support Members States in the application of the TPD in relation to the regulation of ingredients. We identified three broad areas where a more centralised system could lead to improvements (see Table 1 for details): (i) submission and publication of data from economic operators; (ii) analysis and assessment of data from economic operators; (iii) Data access and support.

⁶⁴⁰ Art. 3(1) and (2) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

⁶⁴¹ Based on Art. 114 of the Treaty on the Functioning of the European Union, see Case C-270/12, United Kingdom v Parliament and Council, EU:C:2014:18, para. 105.

⁶⁴² Arts. 5(8), 6(4) and 7(13) of the Tobacco Products Directive.

Table 75. Comparison of strengths and weakness of a European system for regulation of ingredients and emissions incorporating a list of ingredients and centralised database. MS indicates Member State.

	Strengths	Weaknesses/challenges
Submission and publication of data	Unified fee structure	
	More efficient submission process	MS loss of funding from submission/review fees
	Improve ability to enforce reporting requirements	Potential for duplication of MS effort
	Overcome publication obstacles relating to trade secrets	
Analysis and assessment	Single source of information on all products in EU	
	Improved data quality and assessment	Could lead to less focus on analyses of interest to single MS
	Alleviate resource burden on MS and better support for MS with resource limitations	Variation between MS regarding resources, regulation, or enforcement would need to be addressed
	Build expertise and capacity	
Data access and support	Better overview over the single market	
	Simplified data access for all MS	May need to transfer responsibilities undertaken by the JATC to new/existing organisation to support MS
	Support MS collaboration and learning	
	Better support for EU-wide enforcement activities and withdrawal of products	Clarification of data ownership and control may be required

We found that Member States, CSOs, and HEs saw substantial value in greater EU support for the regulation of ingredients⁶⁴³. CSOs and HEs particularly took the view that as the EU moves towards digitisation this is the type of service that can be provided to Member States in order to support their decision-making, particularly Member States with fewer resources. Although Art. 28 is focused on tobacco products, if successful, an EU-level approach to the regulation of ingredients could be expanded beyond tobacco products to other products within the scope of the TPD for which EU-CEG is currently used to support reporting requirements, such as e-cigarettes (Art. 20) and herbal products for smoking (Art. 22).

However, developing an EU-level system, including Union-level ingredients lists, requires careful consideration of:

- Co-ordination of, and responsibility for, an EU-level system, either via a newly formed agency or existing entity;
- Sourcing of staff and infrastructure resources;
- Quality of the input received from the industry;
- Impact on Member States of reduced income from fees;

⁶⁴³ Gap-filling workshops, November 2020.

- Minimisation of duplication of effort between the EU and Member States while also ensuring that individual Member State needs are met;
- Member State differences regarding regulations of products, resources and enforcement responsibilities, and how this would be addressed in the implementation of an EU-level system.

To reach a conclusive decision on the optimal system and its impact on the regulation of ingredients and emissions of tobacco products, further research building on the work undertaken by the JATC, EUREST, and SCHEER is needed including detailed specification of the model for such a system and consultation with stakeholders and Member States, to ensure any system implemented would meet their needs.

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5.10 Case Study 2: E-cigarette flavour bans

Key findings

To date, 3 EU Member States, Finland, Estonia and Hungary, have fully implemented bans on e-cigarette flavours. As Hungary only implemented a ban recently, there is limited evidence available from this Member State; consequently this case study focuses primarily on Estonia and Finland. The impact of EU flavour bans on use of e-cigarettes is currently unclear, as only Finland has had a ban in place for an extended time period, and because there has also been concomitant legislation around e-cigarettes in the countries where e-liquids flavours have been banned. However, despite this lack of conclusive evidence, some sources have attributed Finland's success in lowering smoking rates, while also keeping e-cigarette use to just 1% of the population, to their strict e-cigarette flavour ban.

There are indications of significant public support for e-cigarette flavour bans, and also potentially for an EU-wide e-cigarette flavour ban, with additional Member States considering or implementing bans. In particular, Denmark is currently in the process of implementing a ban, while legislation including a ban is due to be considered in Lithuania during 2021, and the Netherlands has opened a consultation for potential legislation around e-cigarette flavours. However, Member States that have implemented e-cigarette flavour bans have faced substantial challenges, particularly around companies selling liquids that can be used in e-cigarettes at times circumventing bans by portraying them as foodstuff. Additionally, Member States have limited capacity to keep up with the large number of e-cigarettes that are notified to them. An EU-wide e-cigarette flavour ban would potentially help address some of these challenges.

Member States, HEs, and CSOs have all expressed concerns that having separate rules around flavours for cigarettes, roll-your-own tobacco and other tobacco products, and e-cigarettes will simply lead to a shift in consumption towards products where flavours are allowed, rather than a decrease in the overall consumption of tobacco and related products. They have also expressed concerns around e-cigarette flavours attracting users (especially young people). Both of these concerns have likely fuelled an appetite for greater regulation around e-cigarette flavours.

Evidence for the role that flavours play in making e-cigarettes appealing to potential users is still emerging, but research to date suggests:

E-cigarette flavours attract users, particularly adolescents and young adults, and may encourage initiation of use. Sweet and fruity flavours are perceived as less harmful than tobacco flavour, and play an important role in e-cigarette appeal to younger users, but appear to be less appealing to older users.

There is some evidence that e-cigarette flavours are important in adult users switching from smoking combustible tobacco to e-cigarettes, but the SCHEER scientific opinion on electronic cigarettes found moderate evidence that for young people e-cigarettes are a gateway to smoking, and strong evidence that flavours contribute to the attractiveness and thus initiation of e-cigarette use.

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.

5.10.1 Introduction and background

Although not harmonised by the TPD⁶⁴⁴, e-cigarette flavours are a topic of international interest and debate. International bodies such as WHO and the Forum of International Respiratory Societies have recommended that countries should ban flavours in e-cigarettes and other electronic nicotine delivery systems (ENDS) to detract from their use by young people^{645,646}. Some bodies such as Public Health England in the UK have defended the use of flavours to help current smokers switch from combustible cigarettes to e-cigarettes, although this position has been met by criticism internationally^{647,648}.

To help fill some of the knowledge gaps around the use of flavours in e-cigarettes, we conducted a case study looking at:

- a) Which EU/EEA Member States have banned the use of flavours in e-cigarettes?
- b) What have been some of the legal and implementation challenges in Member States that have banned the use of flavours in e-cigarettes?
- c) What has been the impact of e-cigarette flavour bans in EU/EEA countries in terms of the use and perception of tobacco products and e-cigarettes, particularly among youth and vulnerable populations?
- d) What is the wider evidence around banning flavours in e-cigarettes?

5.10.2 Methods

5.10.2.1 Desk research

The desk research included reviewing responses from Member States, CSOs, and HEs to surveys undertaken for this study for mention of e-cigarette flavours, along with a search of both academic and grey literature. Google was used to search for grey literature, and both Google Scholar and Scopus were used to search for academic literature. Search strings varied by the search engine used, but an indicative search string is provided below:

(e-cigarette OR e-liquid OR vape) AND (flavor or flavour) AND [COUNTRY]

We also consulted results from the 'Consumer preference and perception of specific categories of tobacco and related products' report, which was made available for the

⁶⁴⁴ TPD recital 47 states "This Directive does not harmonise all aspects of electronic cigarettes or refill containers. For example, the responsibility for adopting rules on flavours remains with the Member States..."

⁶⁴⁵ WHO (2019). WHO report on the global tobacco academic: Offer help to quit tobacco use. Available from <https://www.who.int/publications/item/who-report-on-the-global-tobacco-epidemic-2019-offer-help-to-quit-tobacco-use>

⁶⁴⁶ Ferkol, T.W., Farber, J.H., La Grutta, S., et al. (2018). Electronic cigarette use in youths: a position statement of the Forum of International Respiratory Societies. European Respiratory Journal. 51: 1800278. DOI: 10.1183/13993003.00278-2018

⁶⁴⁷ Doward, J., and Fraser, T. (2019). UK attacked for defence of flavoured e-cigarettes. *The Guardian*. Available from <https://www.theguardian.com/society/2019/sep/14/vaping-flavours-health-concern-children>

⁶⁴⁸ Public Health England (2021). Vaping in England: evidence update February 2021. Available from <https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021>

purposes of this study⁶⁴⁹. Along with studies found from literature searches, we also used 'snowballing' to find relevant sources from literature found in online searches. Only research studies that were independently funded or undertaken by government organisations were included, with the addition of newspaper reports and responses to government consultations where relevant.

5.10.2.2 Stakeholder interviews

We conducted four semi-structured interviews with independent health experts⁶⁵⁰ to fill specific gaps in the evidence after conducting desk research. There were some challenges in securing interviews across all case studies, in part due to pressures from the COVID-19 pandemic on those working in public health. Although the interviews were semi-structured and based on the interviewees' areas of expertise, a common set of questions that were covered in all interviews are provided below:

- Interviewee's position and area of expertise;
- Regulations on e-cigarette flavours in country of interest (e.g. Estonia, Hungary);
- Legal challenges to passing regulation in country;
- Impact of regulation on use and perception of e-cigarette in country;
- Impact of regulation on use and perception of cigarettes and other tobacco products in country, including impact on quitting behaviour;
- Impact of regulation on use and perception of e-cigarettes and tobacco-related products among young people and vulnerable populations in country; and
- Evidence around the relationships between e-cigarette flavour bans and tobacco product use.

Interviews were audio recorded with the interviewees' consent, and notes were taken to accurately summarise the content of each interview.

5.10.2.3 Gap-filling workshops

Two gap-filling workshops were also conducted to fill gaps in evidence for the study as a whole, one with CSOs and HEs, and one with representatives from NCAs responsible for tobacco control in Member States. The workshops covered a wide range of topics, but also touched on e-cigarette flavours. Where relevant information was mentioned, it has been incorporated into the case study.

5.10.2.4 Surveys

As described in the wider study, a survey of representatives from NCAs within Member States, HEs and CSOs was also conducted. This survey was not focused on the e-cigarette flavour case study in particular, although some respondents commented on potential e-cigarette flavour bans. Relevant responses were reviewed and included in this case study in order to provide additional supporting evidence.

5.10.3 Results

5.10.3.1 Support for e-cigarette flavour bans in EU Member States

In the survey and gap-filling workshops Member States, HEs, and CSOs all expressed concerns that banning flavours only for cigarettes and roll-your-own tobacco (in Art. 7(12) of the TPD) without a ban of flavours in other tobacco and related products, and

⁶⁴⁹ This report was the output of a study that LSE & Partners Consortium produced in February 2020 for the European Commission (Specific contract number 2017 85 07). It aimed to assess how different categories of tobacco and related products are perceived by the public, the impact of these perceptions and mapping consumer preferences and use patterns.

⁶⁵⁰ One of these interviews was shared with the case study on plain packaging, and the interviewee was asked questions relating to both case studies.

leaving responsibility for e-cigarette flavours to Member States (as per Recital 47 of the TPD) is undesirable due to the potential for a displacement effect whereby consumption patterns shift from products where flavours are banned to products (such as e-cigarettes) where flavours are still allowed, rather than leading to a reduction in overall use of tobacco and related products.

From the survey conducted with Member States as part of this assessment, respondents from several other EU countries reported that the lack of regulation around e-cigarette and e-liquid flavours is a gap in the TPD (four Member States) and/or that there are issues in terms of the proliferation of flavours in both nicotine and non-nicotine e-liquids (five Member States), although it is unclear whether proposals to change national legislation are being discussed in other EU Member States.

A few HE and CSO survey respondents also commented on the need for stricter regulation of e-cigarette flavours within the TPD. An independent CSO respondent expressed a need to regulate flavours that are attractive to youth and young adults, while also maintaining a range of flavours that might be attractive to adults wanting to switch from combustible tobacco to e-cigarette use, but did not provide specific examples of this.

On flavours, the SCHEER noted that great majority of chemicals in e-cigarettes, other than nicotine and carriers (e.g. glycerol and propylene glycol), are flavourings. They added that "to date, there is no consistent data that specific flavourings used in the EU pose health risks for electronic cigarette users following repeated exposure." However, they confirm that flavours enhance the appeal of electronic cigarettes by creating sensory perceptions of sweetness and coolness and masking the aversive taste of nicotine. More so, they found that most e-liquid brands are available in a variety of youth-appealing flavours, ranging from fruits, desserts, candy, and soda to traditional tobacco and that the number of available e-liquid flavours exceeded 7500 in 2014 and is still increasing.⁶⁵¹

Six other independent CSO respondents also commented on the need to regulate flavours in both nicotine-containing and nicotine-free e-liquids, particularly because young people may not know the difference between these e-cigarettes. A HE respondent also mentioned that regulating both nicotine and non-nicotine e-liquids is important because young people may perceive flavoured e-cigarettes as less harmful, and because of safety concerns around flavour inhalation.

In contrast, two organisations representing consumers in the CSO survey expressed a desire for e-cigarette flavours to not be regulated at EU level. According to these respondents, allowing e-cigarette flavours is in line with the TPD's public health objective, and treating e-cigarettes and traditional tobacco products separately was appropriate based on the harms of each type of product. One of these respondents claimed that banning flavours except for tobacco and menthol in e-cigarettes would limit the amount of smokers that switch to e-cigarettes, and that banning flavours in e-cigarettes would be equivalent to banning flavours in nicotine replacement therapy (e.g. nicotine gums). Both of these respondents were from organisations representing consumers, and no evidence was provided to support these claims.

Survey responses also suggested that some CSOs and Member States were uncertain about the degree of autonomy of Member States to pass stricter regulation than the TPD requires regarding e-cigarette flavours. Eight CSO respondents expressed a lack of certainty around whether and how Member State can implement bans on e-cigarette flavours, and expressed that Member States should be able to implement wider bans on flavours. However, many other respondents understood that Member

⁶⁵¹ SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). (2021) Opinion on electronic cigarettes. European Commission.

States were able to implement bans on e-cigarette flavours, as is explicitly stated in Recital 47 of the TPD.

Within the EU, there is some indication of support for a potential EU-wide flavour ban. In the 2020 Eurobarometer survey, 47% of respondents were in favour of banning flavours in e-cigarettes (vs. 35% who were against this measure), which is an increase of 7 percentage points since the 2017 Eurobarometer survey when the question was last asked. Support for this measure was dependent on age, with younger respondents (15-24 years) less likely to support a ban on e-cigarette flavours than older respondents (55+ years) (41% versus 49% in favour of ban, respectively)⁶⁵². In the EUREST-PLUS survey of smokers in seven EU countries⁶⁵³, respondents were asked about potential e-cigarette policies, with support for a flavour ban at 32.3% of smokers in 2018. However, support ranged from 32.9% to 57.0%. The survey found that support increased significantly in Hungary between 2016 and 2018 from 34.3% to 43.3% of smokers supporting a flavour ban⁶⁵⁴.

When asked whether they favour an EU-wide ban on e-cigarette flavours, two of the four participants in the interviews conducted for this case study supported this idea⁶⁵⁵. They reported that an EU-wide ban would be better able to push back against industry pressures, which can negatively affect the passing of legislation in individual Member States, particularly smaller Member States (INT2, INT4). Interviewees for this case study also mentioned a 'snowballing' effect of regulations in one Member State making it easier for others to implement similar restrictions (INT2, INT4). If this holds true, it is likely that more Member States will also move towards implementing regulation on banning e-cigarette flavours even if action is not taken at EU-level.

5.10.3.2 E-cigarette flavour bans in EU/EEA Member States

We identified six EU Member States that were considering or at different stages of implementing e-cigarette flavour bans at the time this research was conducted (December 2020): Finland, Estonia, Hungary, Netherlands, Denmark, and Lithuania. At the time of this case study, only Finland and Estonia had fully implemented bans on e-cigarette flavours in place for over a year, allowing time for the impacts of these bans to be realised and information summarising the process of implementing the ban and its outcomes to become publicly available. These Member States were therefore selected for in-depth review. A summary of the available information on the stage of implementation of these six Member States is provided below, followed by the in-depth case studies of Finland and Estonia:

- **Finland**, which introduced a ban on flavours and aromas in e-cigarettes, apart from the taste and smell of tobacco, when it implemented the TPD in 2016. The ban includes nicotine-free e-liquids intended for vaporisation, and includes menthol flavour⁶⁵⁶.
- **Estonia**, which introduced a ban on all flavours except for tobacco taste and smell in July 2019, and amended this in May 2020. Current legislation is less

⁶⁵² DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

⁶⁵³ This survey gathered responses from seven European countries: England, Germany, Greece, Hungary, Poland, Romania and Spain

⁶⁵⁴ Chung-Hall J , Fong GT , Meng G , et al. Support for e-cigarette policies in seven European countries: findings from the EUREST -PLUS ITC Europe Surveys. Eur J Public Health 2020;30:iii103-12.

⁶⁵⁵ Four interviewees were consulted for this case study. The remaining two interviewees did not express that they were against an EU-wide flavour ban, but this topic was not explicitly covered during the interview.

⁶⁵⁶ Tobacco Act 549/2016. MINISTRY OF SOCIAL AFFAIRS AND HEALTH, Finland. English version available here: <https://www.finlex.fi/en/laki/kaannokset/2016/en20160549>

strict than what was originally introduced, and e-cigarettes are now allowed to be flavoured with menthol. The ban includes nicotine-free e-liquids for e-cigarettes⁶⁵⁷.

- **Hungary** has introduced a ban in May 2020 that applies to e-cigarettes and nicotine-containing refill containers, but not nicotine-free refill containers⁶⁵⁸. Due to the recent nature of this ban and the lack of published sources on the subject we do not focus on this Member State in detail in this case study.
- **Denmark**, in which a new act on tobacco was adopted in December 2020⁶⁵⁹ that bans flavours in e-cigarettes and refill containers (both nicotine-containing and non-nicotine-containing), other than tobacco and menthol. The act bans manufacturing such products from 1 April 2021, and bans the sale of such products from 1 April 2022.
- **Lithuania**, where a draft amendment of the Tobacco Control Law will be considered by Parliament between March-June 2021, which includes a ban on all e-cigarette flavours other than tobacco⁶⁶⁰.
- In **Netherlands**, the government opened a consultation on the subject of a potential e-cigarette flavour ban (for flavours other than tobacco in both nicotine and nicotine-free e-liquids and other components of e-cigarettes), which would enter into force on 1 January 2022⁶⁶¹. This consultation sparked considerable debate from the scientific and public health community in the Netherlands, with many also arguing that the proposed legislation was based on misleading information about the harms of e-cigarettes, and a simplistic approach towards considering the harms of e-cigarettes without considering the potential benefits for both young people and adults⁶⁶².

Evidence from Finland

Finland provides the most evidence on the impact of banning e-cigarette flavours, having implemented a ban in 2016 while implementing the TPD. Finland set a goal in 2010 to end the use of tobacco and other nicotine-containing products by 2030, and became the first country in the world to set such ambitious goals for national tobacco control policy. The e-cigarette flavour ban's explicit aim was to prevent children and young people from taking up e-cigarette use, while still allowing adults access to nicotine-containing e-cigarettes, especially for those that were already nicotine dependent. Another justification provided for the ban was the potential for some flavours to be hazardous to health when inhaled⁶⁶³.

A 2019 study describing the challenges of enforcing the e-cigarette flavour ban in Finland, which looked at data from tobacco control authorities, public court proceedings and legislation and legal documents, identified several challenges for enforcement⁶⁶⁴:

⁶⁵⁷ Tobacco Act. Riigi Teataja, Estonia. English version available here: <https://www.riigiteataja.ee/en/eli/ee/504062020004/consolidate>

⁶⁵⁸ Direct communication between DG SANTE and the NCA in Hungary.

⁶⁵⁹ <https://www.retsinformation.dk/eli/ltu/2020/2071>

⁶⁶⁰ Direct communication between DG SANTE and the NCA in Lithuania

⁶⁶¹ Government of the Netherlands, Consultation: regulation of e-cigarette flavours (translation), 19 December 2020

⁶⁶² Regulation of e-cigarette flavours- a response.

<https://www.clivebates.com/documents/NLFlavoursResponseJan2021.pdf>

⁶⁶³ Ollila, E. (2019). See you in court: obstacles to enforcing the ban on electronic cigarette flavours and marketing in Finland. *Tobacco Control* 0: 1-6. doi.org/10.1136/tobaccocontrol-2019-055260

⁶⁶⁴ Ibid.

- The number and variety of e-cigarettes notified for potential market access;
- The limited resources available for tobacco control (in terms of capacity within the government to review products that were notified);
- The reluctance of e-cigarette companies to comply with regulations around e-cigarette flavour bans.

The study found that after banning e-cigarette flavours, there were nine appeals made by 2 law firms⁶⁶⁵ that had occurred in Finnish courts on demands that e-cigarette shops remove flavours from their stores. All of these appeals dealt with whether the flavouring products sold by e-cigarette shops actually corresponded with the description of banned products in Finland's Tobacco Act 2016, in which the language of the Act banned flavoured liquids for e-cigarettes. All appeals argued that the language of the Tobacco Act was imprecise and was inaccurately interpreted by municipalities that had demanded that e-cigarette shops remove flavours from their stores. One law firm argued that the Tobacco Act did not prohibit flavours in liquids that could be used in e-cigarettes after being mixed with other liquids, and the other argued that Act did not prohibit flavours in liquids that could potentially be used for mixing with e-liquids (only those which purpose was to be used in e-cigarettes). The latter argued that the flavours in question were imported, produced and labelled as foodstuff, and provided leaflets that were in the e-cigarette shop describing how flavours could be used for drinks or baking as evidence. Court appeals around the e-cigarettes' flavour ban also argued that municipalities had discriminated against e-cigarette shops, since grocery stores and other vendors could sell similar products.

The first court ruling in May 2019 ruled that since the main purpose of specialised tobacco and nicotine product shops is to sell tobacco and nicotine products, it can be assumed that products in these shops are not foodstuffs. However, another judge ruled that the products in one of the e-cigarette stores in question were foodstuffs, since they were labelled and marketed as such. This decision was appealed to the Supreme Administrative Court in Finland, and was still under review at the time the article was written⁶⁶⁶.

There were also issues with vendors selling flavoured e-liquids in Finland (e.g. through Facebook), which were not under the control of Valvira (the competent authority responsible for the notification of tobacco products in Finland) due to being hosted in another country⁶⁶⁷, although this also relates to challenges presented by cross-border distance sales and not those of regulating e-cigarette flavours alone (see Section 3.6 of the main report).

The authors reporting the above finding argued that smaller countries such as Finland do not have the resources to properly investigate the number of e-cigarette and e-liquids that are being notified to competent authorities, particularly where consumers are customising flavours and where safety information about flavours is based on ingestion rather than inhalation. According to the authors of the study, Valvira's resources "amount mostly to dealing with questions and breaches reported to them"⁶⁶⁸. The lack of resources for enforcement in Finland was also reflected in our survey of Member States. A respondent from Finland suggested that an independent advisory panel to assess flavours in e-liquids across the EU would be helpful to avoid excessive administrative burden for individual Member States in reviewing and dealing

⁶⁶⁵ One appeal was signed by the owner of the e-cigarette shop, but the text was essentially the same as one of the law firms and was not counted as a separate law firm due to this.

⁶⁶⁶ Ollila, E. (2019). See you in court: obstacles to enforcing the ban on electronic cigarette flavours and marketing in Finland. *Tobacco Control* 0: 1-6. doi.org/10.1136/tobaccocontrol-2019-055260

⁶⁶⁷ Ibid.

⁶⁶⁸ Ibid.

with the large number of products that are notified through the EU-CEG, and would also help establish commonalities across Europe in how flavours are considered. This respondent mentioned that even where products are notified that potentially are against Finland's ban on e-cigarette flavours, there is a lack of resources to address these notifications.

There is little literature investigating the impact of the Finnish e-cigarette flavour ban on e-cigarette (and tobacco products) availability, perceptions and use. However, WHO reflected that despite the struggle that many European countries have faced to reduce smoking without increasing e-cigarette use, Finland has managed to reduce smoking to 14% in 2018 while keeping e-cigarette use at just 1% according to the 2018 Euromonitor survey. WHO attributes this success to Finland's focus on preventing nicotine addiction and the use of all tobacco and related products (rather than just smoking) through measures such as the flavour ban.⁶⁶⁹ Other sources have also attributed the low e-cigarette use rate in Finland, especially among adolescents (with only 1% of high school students using e-cigarettes daily), to Finland's e-cigarette flavour ban, and have reported that Finland is on track to meet their 2030 smoke-free goal^{670 671}. Despite these claims, one interviewee viewed it as being likely too early to quantitatively assess the true impact of the Finnish e-cigarette ban (INT4) based on the timeframe when legislation was implemented, along with the complexities of attributing impacts to the e-cigarette flavour ban specifically, when other regulations were also introduced in the same timeframe.

Evidence from Estonia

According to the 2020 Eurobarometer survey, e-cigarette use in Estonia is one of the highest in the EU, with 25% of respondents reporting that they have at least tried e-cigarettes and 2% using e-cigarettes currently⁶⁷².

Relatively little documentary evidence from Estonia is available on the impact of the e-cigarette flavour ban in the country. According to the notification provided to the European Commission when amending Estonia's Tobacco Act, the reasoning behind the flavour ban was that flavoured e-liquids target children and young people in particular, and are appealing to those starting smoking⁶⁷³. Preventing young people from initiating use of tobacco products was also cited as the main reason for the flavour ban by interviewees from Estonia (INT1, INT2).

Interviewees provided some information on political challenges after Estonia implemented its initial e-cigarette flavour ban in 2019 through the Tobacco Act, which also included a ban on menthol flavour in e-cigarettes. According to one interviewee, the e-cigarette market in Estonia was initially dominated by small players, which made it easy to implement the initial flavour ban. However, once the ban was introduced, these small companies received support from larger tobacco companies and

⁶⁶⁹ WHO Regional Office for Europe (2020). Strong legislation helps defeat e-cigarettes in Finland. Available from <https://www.euro.who.int/en/countries/finland/news/news/2020/5/strong-legislation-helps-defeat-e-cigarettes-in-finland>

⁶⁷⁰ Pohjanpalo, K. (2020). In world's happiest nation, teens don't want to vape anymore. Bloomberg. Available from <https://www.bloomberg.com/news/articles/2020-05-31/in-world-s-happiest-nation-teens-don-t-want-to-vape-anymore>

⁶⁷¹ Crossland, D. and Blackley, R. (2020). Finland set to stub out smoking by 2030. The Times. Available from <https://www.thetimes.co.uk/article/finland-set-to-stub-out-smoking-by-2030-9g7xmc8g3>

⁶⁷² DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

⁶⁷³ European Commission (2017). Draft amending the Tobacco Act. Notification number 2016/648/EE (Estonia). Available from <https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2016&num=648>

international associations to mount a challenge to the ban, eventually leading to the allowance of menthol flavoured e-cigarettes in May 2020 (INT2). Allowing menthol was criticised intensely by public health officials and professional groups in the medical field, although their concerns did not lead to reverting to the original ban including menthol flavours (INT1, INT2).

Estonia is a small country with limited public health resources, which has caused capacity issues in regulating e-cigarettes and enforcing the e-cigarette flavour ban. According to one interviewee, public health staff working on tobacco regulation are the same staff working on the county's response to COVID-19, so the pandemic has been disruptive to tobacco control. For example, e-liquid manufacturers and retailers have attempted to circumvent the ban by marketing flavours for e-liquids as food and the public health officials, that were trying to address this issue before the pandemic, stopped working in this area due to a lack of capacity (INT2).

No quantitative evidence is available on the impact of the flavour ban in Estonia, and interviewees reported that it is too early to determine the impacts, especially considering the range of regulations on e-cigarettes that were implemented around the same time as the flavour ban, including taxes and restrictions on use in public places and selling to minors (INT1, INT2). Nonetheless, e-cigarette economic operator sources have claimed that the ban has led to approximately 10% of e-cigarette users moving back to combustible tobacco use, and that the ban has led to a surge in black market products⁶⁷⁴. However, it is unclear whether either of these claims have any factual basis, and Estonian interviewees reported that they were not aware of an impact on black market sales (INT1, INT2).

A 2020 study found that cigarette smoking in Estonia had decreased between 2012 and 2018 (from 45.4% to 31.5% in men, and from 26.6% to 20.0% in women) - before the ban in 2019 -, although unlike Finland, there was a rise in e-cigarette use (from 1.4% to 3.7% in men, and from 0.6% to 1.2% in women)⁶⁷⁵. As this was before the ban, the impact of the new regulation remains to be seen.

5.10.3.3 Research evidence on the impact of e-cigarette flavour bans

As mentioned with respect to Finland and Estonia above, there is a lack of quantitative data that would allow conclusions to be drawn as to the impact of e-cigarette flavour bans. Furthermore, the timing of e-cigarette flavour bans with other regulation around e-cigarettes makes it challenging to draw causal inferences around the impact of e-cigarette flavour bans. Looking at the data that are available on e-cigarette use, according to the 2020 Eurobarometer survey, 14% of respondents across all Member States had at least tried e-cigarettes (compared to 15% in 2017)^{676,677}. Younger respondents were more likely to report having tried e-cigarettes (25% aged 15-24) compared to older respondents (14% of those aged 40-54 and 8% of those aged 55+). These percentages are higher than reported in the 2017 Eurobarometer survey (21% for those aged 25-39, and 6% of those aged 55 or over)⁶⁷⁸, but the consistent

⁶⁷⁴ Kurg, I. (2020). Estonia takes the first steps towards recognising tobacco harm reduction. Ethra. Available from <https://ethra.co/news/34-estonia-takes-the-first-steps-towards-recognising-tobacco-harm-reduction>

⁶⁷⁵ Reile, R., and Parna, K. (2020). E-cigarette use by smoking status in Estonia, 2012-2018. Int. J. Environ. Res. Public Health, 17(2): 519. <https://doi.org/10.3390/ijerph17020519>

⁶⁷⁶ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

⁶⁷⁷ Special Eurobarometer 458 (2017) Attitudes of Europeans towards tobacco and electronic cigarettes.

<https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/ResultDoc/download/DocumentKy/79003>

⁶⁷⁸ Ibid.

age difference points to the need to monitor preferences and use in younger populations⁶⁷⁹.

E-cigarette use varies by country. For example, according to the 2020 Eurobarometer survey, 14% of respondents from Finland reported ever having tried e-cigarettes, as compared to 25% in Estonia⁶⁸⁰. However, it is unclear whether Member State specific e-cigarette regulations, or flavour bans in particular, play a role in differences between countries. Data from the EU-CEG also do not conclusively demonstrate that banning e-cigarette flavours reduces the number of e-cigarette refill containers on the market. The number of e-liquid refill containers registered for Estonia in EU-CEG is approximately the average for all Members States, but for Finland the number is below the average. However, other Member States that did not have e-cigarette flavour bans in place at the time these data were collected also have low numbers of e-liquid refill containers being notified similar to Finland (e.g. Latvia, Denmark). Based on data from the 2020 Eurobarometer survey, Latvia and Denmark both have higher rates of e-cigarette use than Finland (21% and 17%, respectively, reported ever having tried e-cigarettes)⁶⁸¹. However, as there is no straightforward way to translate prevalence of e-cigarette use for a Member State into an expected number of refill containers notified through the EU-CEG system for that Member State, it is unclear whether these EU-CEG data indicate a deviation from what would be expected given the level of use.

We also looked at a number of academic studies and reviews to summarise the available literature on how e-cigarette flavour bans may change perceptions, availability and use of both e-cigarettes and tobacco products, as well as how bans may have an impact on public health. From the literature reviewed, there is evidence that suggests flavours play a key role in attracting potential e-cigarette users, particularly among adolescents and young adults.

A study on consumer perceptions and preferences, which included a review of the literature, concluded that flavours help attract both youth and older people to use e-cigarettes⁶⁸². Their survey found that 12% of respondents in the EU 27 + UK reported that liking the flavour was a primary reason to start e-cigarette use among current and past users, and focus group findings showed that the ability to experiment with flavours was particularly important for young people. The SCHEER final opinion on e-cigarettes also concluded that e-cigarette flavours contribute to their attractiveness and initiation, particularly amongst adolescents for whom it is an important influence on trying e-cigarettes and who are more likely to initiate use via flavoured e-cigarettes⁶⁸³.

In the 2020 Eurobarometer survey, among current e-cigarette users (at least monthly users), the most popular flavours were fruit flavours like cherry or strawberry (48%), followed by tobacco flavour (36%), menthol or mint (30%) and vanilla, candy or chocolate flavour (20%)⁶⁸⁴. Flavour preference differed by age group; 56% of those aged 55 or more prefer tobacco-flavour compared to 22% of those aged 15-24, but 75% of this age group mention fruit-flavour compared to 18% of those aged 55 or over. Menthol, mint, and candy flavours were also more popular with the youngest

⁶⁷⁹ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

⁶⁸⁰ Ibid.

⁶⁸¹ Ibid.

⁶⁸² LSE and Partners Consortium (2020). Consumer preferences and perception of specific categories of tobacco and related products. Report for CHAFEA.

⁶⁸³ SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). (2021) Opinion on electronic cigarettes. European Commission.

⁶⁸⁴ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

age group of e-cigarette users. These flavours, particularly fruit and candy, are associated with a lower perception of harm compared to tobacco flavour⁶⁸⁵. Although 57% of current e-cigarette users reported that they had started using e-cigarettes to stop or reduce tobacco consumption, a growing proportion of current users (20%, an increase of 8 percentage points compared to the 2017 survey) cited the fact they liked the flavours that e-cigarettes provide⁶⁸⁶.

A systematic review of e-cigarette preferences found that adolescents often consider flavour the most important factor in trying e-cigarettes, and that they were more likely to initiate e-cigarette use through flavoured products⁶⁸⁷. Young adults preferred sweet, menthol and cherry flavours, as compared to older age groups who tended to prefer tobacco, coffee, and menthol flavours. This review did not find evidence that e-cigarette flavours are associated with using e-cigarettes to quit smoking. Another recent systematic review of the impact of non-menthol flavours in e-cigarettes found that flavours are associated with decreased perceptions of harm and that fruit and candy-flavoured e-cigarettes, in particular, were perceived as less harmful by youth⁶⁸⁸. This review also found that the evidence regarding the role of e-cigarette flavours in facilitating quitting smoking among adults was inconclusive⁶⁸⁹.

There is a difference between the e-cigarette flavour ban in Estonia and Finland in that Estonia allows for menthol flavour in e-cigarettes, while in Finland only tobacco flavour is allowed. The SCHEER noted that the evidence for a positive interaction between menthol flavour and nicotine strength is weak in relation to e-cigarettes⁶⁹⁰. However, one interviewee noted that menthol has been more studied than other flavours based on its longevity and popularity on the market, which does not necessarily indicate that menthol flavour e-cigarettes are meaningfully different from other flavours (INT4).

There is also some evidence from independent academic research available on potential harms from e-cigarette flavour bans. Although this evidence is limited, it supports an argument that is used by the e-cigarette industry to push back on potential regulation to ban flavours. Two studies have found a potential link between the use of non-tobacco flavoured e-cigarettes and high smoking cessation rates in adults^{691,692}. While this research has not investigated the impact of a flavour ban on smoking cessation, a study from the US looking at reactions to hypothetical e-cigarette restrictions found that people would be less likely to quit combustible

⁶⁸⁵ SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). (2021) Opinion on electronic cigarettes. European Commission.

⁶⁸⁶ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

⁶⁸⁷ Zare S, Nemati M, Zheng Y. A systematic review of consumer preference for e-cigarette attributes: flavor, nicotine strength, and type. PLoS One. 2018;13(3):e0194145

⁶⁸⁸ Meernik, C; Baker, HM; Kowitz, SD; Ranney, LM; & Goldstein, AO. (2019). Impact of nonmenthol flavours in e-cigarettes on perceptions and use: an updated systematic review. BMJ Open, 2019; 9 (10): e031598. doi:10.1136/bmjopen-2019-031598

⁶⁸⁹ Ibid.

⁶⁹⁰ SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). (2021) Opinion on electronic cigarettes. European Commission.

⁶⁹¹ Friedman, A.S., and Zu, S. (2020). Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation. JAMA Netw Open, 3(6): e203826. doi: 10.1001/jamanetworkopen.2020.3826

⁶⁹² Gravely, S., Cummings, K.M., Hammond, D., et al. (2020). The Association of E-cigarette Flavors With Satisfaction, Enjoyment, and Trying to Quit or Stay Abstinent From Smoking Among Regular Adult Vapers From Canada and the United States: Findings From the 2018 ITC Four Country Smoking and Vaping Survey. Nicotine and Tobacco Research. Nttaa095. <https://doi.org/10.1093/ntr/ntaa095>

cigarettes if a flavour ban were introduced⁶⁹³, highlighting the need for additional research in this area. In the EU, the 2020 Eurobarometer survey found that among respondents who used to smoke or have tried to stop, 10% reported using e-cigarettes or similar devices to stop smoking. Additionally, of respondents who had used e-cigarettes, 54% reported that they had started to stop or reduce tobacco consumption⁶⁹⁴. Over half (59%) of e-cigarette users in the survey also reported smoking cigarettes, cigars, cigarillos or a pipe (i.e. dual use); dual users were more likely to report having attempted to stop using traditional tobacco products than current smokers (62% versus 53%)⁶⁹⁵.

One HE interviewee for this case study asserted that evidence on the attractiveness of e-cigarette flavours points to the importance of these flavours in switching from cigarettes to less harmful tobacco products (INT3). The interviewee argued that reducing youth smoking depends on policies that make cigarettes (rather than e-cigarettes) less attractive (INT3). This viewpoint was also reflected in the responses to the consultation for potential legislation banning e-cigarette flavours in the Netherlands⁶⁹⁶, as described above. However, the potential importance of e-cigarette flavours in facilitating cessation needs to be weighed against the potential unintended consequences (e.g. dual use), as well as influence of e-cigarette flavours on attracting new users, particularly younger users.

5.10.4 Overall findings

Only 3 EU/EEA Member States, Hungary, Finland and Estonia have fully implemented bans on e-cigarette flavours. However, more countries are likely considering or in the process of implementing similar bans, including Denmark, Lithuania, and the Netherlands. Member States, HEs, and CSOs have all expressed concern that exempting e-cigarettes and tobacco products that are not cigarettes and Roll Your Own tobacco from the ban on characterising flavours will simply lead to a shift in consumption to where flavoured products are allowed, rather than a reduction in overall consumption.

The impact of EU country flavour bans on the use of e-cigarettes is currently unclear as only Finland has had a ban in place for an extended time-period. However, some sources have attributed Finland's success in lowering smoking rates while also keeping e-cigarette use to just 1% of the population to their strict e-cigarette flavour ban. The implementation of the ban in Finland also highlights potential challenges that may be encountered by other Members States in implementing and enforcing these bans, namely the range of products and resources needed for enforcement, and the potential for e-cigarette companies to circumvent legislation so flavoured products remain available to consumers.

Evidence for the role that flavour plays in making e-cigarettes appealing to potential users continues to emerge, with most recent research suggesting that e-cigarette flavours attract users, particularly adolescents and young adults. However, the appeal of particular flavours appears to differ between age groups, with fruit, mint, and candy flavours preferred by younger users and tobacco flavour preferred by older users. Currently there is uncertainty around whether e-cigarette flavours are important in adult users switching from combustible tobacco to e-cigarettes, but the SCHEER

⁶⁹³ Pacek, L.R., Rass, O., Sweitzer, M.M., et al. (2019). Young adult dual combusted cigarette and e-cigarette users' anticipated responses to hypothetical e-cigarette market restrictions. Substance Use and Misuse, 55(6): 108458. <https://doi.org/10.1080/10826084.2019.1626435>

⁶⁹⁴ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

⁶⁹⁵ Ibid.

⁶⁹⁶ Regulation of e-cigarette flavours- a response.

<https://www.clivebates.com/documents/NLFlavoursResponseJan2021.pdf>

opinion on electronic cigarettes takes the view that there is moderate evidence that for young people e-cigarettes are a gateway to smoking, and strong evidence that flavours contribute to the attractiveness and thus initiation of e-cigarette use. More evidence is needed to determine whether flavour bans would lead to less adult users moving away from combustible cigarettes, and whether selective banning of flavours could be used to reduce the appeal of e-cigarettes to younger age groups while maintaining their appeal to existing smokers in order to encourage smoking cessation.

5.11 Case Study 3: Monitoring and enforcement

Relevant findings

A recurring theme across articles was that a **lack of capacity and/or technical expertise** meant Member States were hindered from fully applying the TPD articles:

- **A lack of capacity for effective enforcement:** For example, there have been overarching issues related to product submissions and reporting through the EU-CEG system (Art. 5). This was partially related to Member State authorities lacking capacity to properly assess, process, and react to the large volume of submissions, which also hindered the application of Art. 6, 19 and 20. However, improvements could be made to the technological system itself, and an EU-wide database containing information about products could potentially increase communication and reduce workload amongst NCAs. Another example is that Member States may not have fully applied the provisions on TNCO laboratories, as they lacked resources to appoint approved labs which would be independent from industry (Art. 4).
- **A lack of expertise and technical knowledge for effective monitoring and enforcement:** Similarly, the provisions of Art. 7 (related to characterising flavours) were not fully applied, and this largely was due to a lack of Member States' technical capacity to properly identify, assess and process non-compliant products, or performing tests to verify the composition of tobacco products. Analysis of the reports on priority additives (Art. 6) was also hindered by a lack of expertise, as well as insufficient quality of the documentation submitted by the industry.

Denmark, Italy and Netherlands were selected as **examples of good practice in monitoring and enforcement** based on the evidence gathered as part of the study⁶⁹⁷.

- **Denmark:** The main success factor of the Danish approach is strong market surveillance efforts (including targeted operations to detect non-compliant menthol products and slim packages of cigarettes) linked to a dynamic case handling system which organises information and updates submitted in EU-CEG. Denmark has also implemented a new comprehensive tobacco act, demonstrating Denmark's focus and dedication to tobacco control more widely.
- **Italy:** Italy's main success factors include making use of the optional mechanisms in the Directive, which allow them to apply the most diligent approach set out in the TPD to strengthen their overall monitoring and enforcement approach; closely studying the information on EU-CEG to identify and anticipate possible incompliance; and monitoring the market continuously. (Further, when Italy implemented the TPD, they at the same time introduced provisions banning smoking in certain hospital areas and in certain situations in private cars, and they also increased fines for selling tobacco products to minors. These provisions demonstrate Italy's focus and dedication to tobacco control more widely.)
- **The Netherlands:** The Netherlands has found success in conducting in-depths technical assessments for **product emissions**, which are not required

⁶⁹⁷ These Member States are not necessarily the only countries to enact similarly strong measures, and their inclusion is meant only to illustrate some interesting and exemplary initiatives related to the enforcement and monitoring of the TPD.

by the TPD⁶⁹⁸; using a risk-based approach to ensure provisions with low compliance and high risks are prioritised for enforcement; and efficiently screening cigarettes and roll-your-own tobacco products for TNCO levels every three years.

Following the collection and analysis of the bulk of the data for the present study, the study team noted that Member States overall struggled with their obligations to monitor and review economic operators' compliance and reporting, and to produce their own product assessments – mostly due to a lack of expertise and capacity. The aim of this case study is to explore more in detail how Member States monitor and enforce product compliance, by conducting a high-level comparative analysis of Art. 23 and other articles for which effective implementation was impacted by variations in enforcement, to identify some good practice examples of Member States who seemed to face less issues in implementing the TPD requirements. It includes:

- A review of the resources made available by Member States to implement the Directive and the income generated (through fees, penalties, etc.)
- Analysis of the key challenges Member States faced in effectively implementing the Directive
- Identification of three Member States with good capacity to undertake technical assessments and a review of the mechanisms in place to undertake these, as well as good enforcement capacity, mechanisms and approaches

5.11.1 Methods

The method for this case study included an in-depth review of the responses to relevant questions in the Member State questionnaire, further analysis of the financial information requested in the latter, additional desk research and follow-up contact with the selected Member States to explore their responses in more detail.

Review of Member State questionnaires and financial information

Specific attention has been paid to Member State responses relating to the mechanisms and practices put in place that are related to Art. 23 and other articles for which effective implementation was impacted by variations in enforcement.

In addition, the financial information submitted by Member States was analysed. This included an analysis of the investment into the TPD by Member State. The **Efficiency** section (Section 4.3) provides a more detailed quantification of the costs and benefits to regulators (including fees charged by Member States).

The review of qualitative and quantitative information helped identify three Member States which appear to have good capacities and mechanisms in place, as well as sufficient resources, while experiencing relatively few compliance issues: **Denmark, Italy, and the Netherlands**.

Follow-up contact

After analysing the responses from the case study Member States, the relevant NCAs were contacted via email to clarify remaining points related to the topics covered.

NCA, CSO, and HE workshop

At the conclusion of the gap-filling stakeholder workshops, stakeholders were asked to provide an example of good practice in monitoring and enforcement in their Member States or others. We have summarised their responses here.

⁶⁹⁸ For example, the Netherlands mandates the use of ISO standards to measure TNCO levels in roll-your-own tobacco, and has also tested cigarettes using the Canadian Intense (CI) method for demonstration purposes.

5.11.2 Challenges for effective implementation

Main findings: The main challenges for effective implementation of the TPD centred around a lack capacity; and distinctly but relatedly, a lack of technical knowledge and support. These issues often affected laboratory testing and monitoring, which hindered the implementation of several articles.

We have identified certain areas which seem to pose the most challenges to effective implementation of the TPD. The following section draws on points raised in Section 3 of the present report and seeks to synthesize the main themes emerging from stakeholders related to challenges to effective implementation of the TPD.

In the consultation activities for the present study, CSOs and health experts considered the Directive as a very good example of cooperation on public health, however, a need for improved knowledge, training, and more capacity was highlighted, in particular in **smaller Member States**⁶⁹⁹; this was also reflected by a number of them.

In response to questionnaire items about Art. 23 ("Cooperation and enforcement"), a considerable number of Member States (eight Member States) reported that overall they had a **lack of human resources to carry out the inspections and analyse the data**; in some cases, **technical support** was also **lacking**. These two related but distinct themes emerge when all enforcement challenges are considered together:

- First, Member States often simply **do not have sufficient resources** in terms of staff and/or funding to conduct all the required enforcement and monitoring activities.
- Second, Member States experience **a lack of specific expertise or technical knowledge**, which hinders the extent to which they can carry out enforcement and monitoring activities effectively.

These two groupings of issues are presented in detail below.

5.11.2.1 Capacity for effective enforcement

A lack of capacity and resources in Member States has hindered the implementation of certain **monitoring or authorisation systems**, including an authorisation system for novel tobacco products (which is optional according to Art. 19(3); reported by two Member States) and a system for collecting information about all suspected adverse effects on human health of e-cigarettes (Art. 20(9); reported by one Member State). Related to Art.20(7), one Member State clarified that they had not enforced requiring manufacturers and importers to submit the market data required in this article due to a lack of capacity. Another Member State specified that they were not monitoring market developments concerning e-cigarettes and refill containers due to a lack of resources to conduct such studies. Similarly, one Member State specified that their national authorities could only take a limited number of samples of **herbal products for smoking** during controls and market **surveillance**, and therefore problems emerged as in practice there was an extremely wide range of non-compliant products on the market.

A lack of capacity has also reduced Member States' ability to assess the reports on priority additives submitted by manufacturers or importers (Art. 6(4); (reported by eleven Member States)

⁶⁹⁹ Discussed during a workshop with Member State competent authorities in December 2020.

- In addition, more in-depth discussion of articles for which the implementation was hindered by a lack of capacity is provided below.
-

TNCO laboratories (Art. 4)

As stated in the Tier 1 section on Art. 4, most Member States (17/25) **have approved laboratories for testing TNCO levels** in their country. However, some (four) use approved laboratories in **other Member States** and others (five) **do not have such laboratories** for testing at all.

The laboratories had capacity issues as well as technical and expertise issues (discussed in the subsequent section). A questionnaire of 15 regulators, part of the JATC project, found that the range of products for which emission levels could be analysed by laboratories was extremely limited, and only a few regulators reported that laboratories were capable of analysing TNCO for products other than cigarettes, with relatively few laboratories reporting the ability to analyse roll your own tobacco, cigars and pipe tobacco, tobacco for oral use, and herbal products for smoking⁷⁰⁰. These results were mirrored in the Member State questionnaire responses, as four Member States described issues with capacity for the laboratories.

Reporting of ingredients and emissions, including difficulties with EU-CEG (Art. 5)

Five Member States reported that a **large amount of data** was related to the required information in Art. 5(1), the statement of reasoning in Art. 5(2), or the toxicological data in Art. 5(3). This often puts a strain on available resources, and meant that checks on this information could not always be carried out. For example, one Member State indicated that it had not enforced the submission of the statement of reasoning due to a lack of resources and expertise. Two other Member States reported a variation in **how the information is filled out**, including incorrect or incomplete submissions, which necessitates administrative effort and follow-up from the authorities. Overall, these provisions seem to put a strain on Member States:

"The onus on competent authorities to publish such data, taking the protection of trade secrets into account, in addition the imperative to review such notifications so as to ensure that such products do not give rise to a public health risk creates an enormous administrative and technical burden on regulatory agencies given the vast number of notifications received through the EU-CEG." (Member State)

Member States in general found reviewing the information submitted to the EU-CEG system to create high **administrative and technical burdens**. Member States described issues when processing and assessing submitted products information, and problems were often related to a lack of capacity to analyse submissions (reported by eleven Member States). For example, one Member State reported limited staff members who are dedicated to processing and assessing the information, and this staff has limited time and opportunities to train others in how to carry out such checks. However, improvements could be made to the technological system itself, and an EU-wide database containing information about products could potentially increase communication and reduce workload amongst NCAs.

Note that novel tobacco products, e-cigarettes, and herbal products for smoking are also notified through the EU-CEG system, so issues with the functioning of the system have bearing on Art. 19, 20, and 21-22.

⁷⁰⁰ Joint Action on Tobacco Control (2018) Work Package 8 - Laboratory verification, collaboration and analyses. Joint Action on Tobacco Control.

Assessing ingredients in tobacco products (Art. 7)

Member States reported a lack of capacity to undertake **follow-up laboratory testing** to check if a product which had supposedly been modified to be compliant with Art. 7 had actually been modified in practice. One Member State was looking at how to support their laboratory and institute of public health to achieve this goal. Similarly, another Member State confirmed that it did not have sufficient capacity to carry out these assessments in their own laboratory, meaning that only information declared in EU-CEG was checked, as opposed to follow-up testing.

Novel tobacco products (Art. 19)

During discussion about the duration of the 6-month notification period for novel tobacco products⁷⁰¹, Member States reported a challenging amount of data to be processed and checked. Four Member States felt that this processing required significant **resources and expertise**. More collaboration across Member States was seen as sensible as not all Member States had equivalent resources or expertise (two Member States).

Assessing technical information submitted about e-cigarettes (Art. 20)

Some Member States encountered issues (similar to those described above) with **objectively assessing technical information submitted on the various product characteristics required in Art. 20(2)** due to a lack of resources or technical expertise. In one Member State, they did not have sufficient resources to adequately assess all the products on a regular basis, and therefore assessment of the technical information was made in a superficial way. This Member State clarified that most of their resources were used in the initial handling of the notification including guidance on the corrections that need to be made to the notifications and other correspondence with the notifiers.

5.11.2.2 Expertise and technical knowledge for effective enforcement

In addition to the capacity-related issues discussed above, there were some enforcement and monitoring activities which Member States were hindered from undertaking effectively due to a lack of technical expertise. For example, for Art. 4, four Member States described particular issues with capacity and expertise for the laboratories related to changes from the previous directive on tobacco products of 2001⁷⁰². Further, it seems that there were particular gaps in **scientific expertise** related to the EU-CEG system, for example three Member States struggled to analyse the quality of the submitted data on scientific grounds. In some cases they rather relied on initiatives including the JATC, as well as public laboratories in other Member States. Similarly, one Member State stated that additional technical expertise was being developed to **assess technical information** submitted about e-cigarettes (Art. 20). In addition, more in-depth discussion of articles for which the implementation was hindered by a lack of capacity is provided below.

⁷⁰¹ Discussions during a Member State workshop in December 2020.

⁷⁰² Between the first TPD in 2001 and the 2014 iteration, the phrase "Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry" (Art. 4(2)) was added. This means that while previously Member States had the option to approve and monitor laboratories which were run by economic operators, now they have to identify and approve other laboratories.

Reports on priority additives (Art. 6)

Four Member States confirmed that they had a lack of **scientific knowledge** to adequately assess the reports on priority additives. However, six Member States indicated to have used the results of the JATC, or followed the framework provided by WP9 of the JATC⁷⁰³ to assess the reports. Two further Member States supported action related to ingredients at the EU level.

Assessing ingredients in tobacco products (Art. 7)

Member States faced implementation challenges relating to Art. 7, mainly due to the overarching issue of Member States having insufficient **scientific capacity** to analyse submitted data and identify non-compliant products, for which additives produce a characterising flavour other than tobacco. Similarly, a few Member States also encountered difficulties with undertaking tests to **verify the composition of products**. The issues reported by the Member States imply that, in practice, they are not fully applying the provisions of the article.

For example, one Member State began adapting its methods for detecting caffeine and taurine in tobacco products, however the research outcomes were unreliable due to a lack of technical equipment of sufficiently high sensitivity and a low quantification threshold, and therefore the studies were stopped.

Traceability system (Art. 15)

It appears that many of the problems identified with the traceability system were the result of a lack of appropriate resources put in place at national level to implement Art. 15, giving rise to technical difficulties.

For instance, the range of controls and inspections available to the authorities regarding the verified operability of anti-tampering devices were limited, given Member States' **lack of knowledge and limited experience in this area**.

Relatedly, one Member State found that in practice it was nearly impossible to set up a "no previous contact" rule for the ID issuer, where the technical expertise had to be procured from the market, because the number of companies with the required technical expertise and knowledge was relatively small in their Member State.

Some Member States also reported on **resourcing and supervision issues**. For example, two Member States reported that the traceability and security features provisions required substantial resources and expertise.

⁷⁰³ Joint Action on Tobacco Control. (2018). WP9- D9.1 Assessment/Evaluation Framework for enhanced reporting of priority additives and guidelines for 'Good Experimental Practicing'. Available at: <https://jaotc.eu/wp-content/uploads/2019/09/WP9-D9.1-Assessment-Evaluation-Framework-for-enhanced-reporting-of-priority-additives-and-guidelines-for-%E2%80%98Good-Experimental-Practicing%E2%80%99.pdf>

5.11.3 Effective enforcement and monitoring

In contrast to the key challenges described above, reflections on good practice from NCA representatives, as well as CSO and HEs, are presented in the boxes below.

NCA reflections on good practice in monitoring and enforcement

Among NCAs, the following themes emerged as being key examples of good practice in monitoring and enforcement, either in the respondent's own Member State or another.

- **Sharing of information and experiences** was seen as valuable by several participants. This included sharing analyses of product notifications, and the Meeting of national control authorities in Denmark on 11-12 June 2019, at which NCAs shared their experiences with enforcement⁷⁰⁴.
- **EU-level cooperation** was seen as crucial and should be sustained and potentially further developed. Key examples given of such cooperation were exchanges on e-liquids containing vitamin E and regulating emerging menthol products. This cooperation was aided through various channels including the JATC, emails, Expert Group on Tobacco Policy and relevant Subgroups, and secure tools as S-CIRCABC⁷⁰⁵. The **EU-CEG** system was also seen as a tool facilitating good enforcement.
- Other examples given on good practice were:
 - Member States ensuring building **sufficient administrative capacities** in agencies focussing on tobacco control and market surveillance. Relatedly, the availability of expertise and the opinions of experts.
 - An annual monitoring plan to control tobacco products and e-cigarettes on the market.

CSO and health expert reflections on good practice in monitoring and enforcement

Among CSOs and health experts, the following similar themes emerged.

- Cooperation **between Member States** was key for good practice, e.g in the implementation and sharing of learning about standardised packaging.
- Close **cooperation between stakeholders** including NGOs, research institutes, and governmental authorities was seen as a strength in tobacco control. France was given as a strong example of cooperation and involvement of CSOs in monitoring the TPD provisions such as standardised packaging, e-cigarette requirements, and advertising restrictions.
- Work by the **JATC** is very useful for enforcement, and therefore should be promoted and disseminated more easily.

⁷⁰⁴ The meeting brought together national officials working on market surveillance and enforcement. Member States were encouraged to repeat the success of this first meeting. (European Commission, 2019. Meeting of the Group of Experts on Tobacco Policy: 15 October 2019. Available at:

https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20191015_sr_en.pdf)

⁷⁰⁵ <https://webgate.ec.europa.eu/s-circabc/faces/jsp/extension/wai/navigation/container.jsp>

The following sections discuss the experiences and initiatives of three Member States: Denmark, Italy, and the Netherlands, which were selected on the basis of the information provided in their Member State questionnaires and interviews. As previously stated, note that the inclusion of these Member States is meant only to illustrate some exemplary initiatives related to the enforcement and monitoring of the Directive.

5.11.3.1 Denmark

Denmark has spent significantly on implementing and enforcing the TPD.

In Denmark, **all costs are recovered through the fees charged**. For tobacco products, the fees are based on market shares, and for electronic cigarettes fees are based on products reported to the Danish Safety Technology Authority. At the time of the questionnaire, the fee structure for electronic cigarettes was being revised.

The analysis below shows that the main success factors of the Danish approach are:

- A dynamic **case handling system** which organises information and updates submitted in EU-CEG, and this information is combined with the results of their market surveillance efforts. The information is combined using Robotic Process Automation (RPA).
- Strong **market surveillance** efforts, including targeted operations to detect non-compliant menthol products and slim packages of cigarettes.

Denmark has also amended Act on tobacco products and Act on electronic cigarettes, and introduced plain packaging for tobacco products, herbal products for smoking and electronic cigarettes. These shall also ban flavours in e-cigarettes and refill containers, which are not restricted by the TPD itself and, among other provisions, also define and regulate tobacco substitutes. The act demonstrates Denmark's focus and dedication to tobacco control more widely.

Technical assessments

Denmark does not have a laboratory within the country for testing TNCO levels of products, and they have not received any applications for such laboratories. Therefore, they rely on the Commission's approved list of laboratories⁷⁰⁶, and specifically Denmark uses the **LNE laboratory in France** for testing.

Enforcement capacity, mechanisms and approaches

Generally, Denmark has not faced issues ensuring that manufacturers and importers provide the Commission and Member States with complete, correct and timely information requested pursuant to the Directive (Art. 23(1)). Occasionally authorities have reminded manufacturers and importers of their obligation to disclose all relevant information so they can conduct market surveillance. In some instances, the authorities have provided clarification to manufacturers or importers which were unaware of the information they had to provide, after which time the information was provided.

In response to infringements on the national provisions transposing the Directive, the Danish NCA can issue a marketing ban or an order to withdraw products from the market. They can also hand the case over to prosecuting authority in order to fine the economic operator for the infringement. Art. 23(3) states that Member States shall lay down rules on penalties for infringements of national provisions, however no detailed penalty information is available. Denmark established a **dynamic case handling**

⁷⁰⁶ https://ec.europa.eu/health/sites/health/files/tobacco/docs/approved_laboratories_en.pdf

system which processes information and updates submitted in EU-CEG, and this information is combined with the results of their market surveillance efforts. They use the information gathered by the system to update their lists of registered tobacco products⁷⁰⁷ and e-cigarettes⁷⁰⁸. The information is combined using Robotic Process Automation (RPA). The NCA provided an example of the workings of the system, described below:

Denmark's case handling system in action

- A product is submitted through EU-CEG.
- A case for the product is created in the case handling system, and the product is registered on their list of registered products.
- If market surveillance reveals that the product is not compliant, authorities use the case handling system to withdraw the product from the register.
- This process is used because submissions through EU-CEG are not always adequate to determine if a product is compliant or not, for example a submitter may not update their product notification in the system with relevant changes.

For effective enforcement, Denmark has made use of a variety of information available. When assessing cases for compliance, Denmark used classifications of tobacco products made available by **other Member States** related to Art. 5(7), for example the Swedish classification of oral tobacco has been referred when a similar product was found on the Danish market, categorized by the importer as chewing tobacco. Art. 20(3)(g) TPD requires that electronic cigarettes and refill containers be child- and tamper-proof, however the Danish NCA reported that no final standards for this have been agreed, therefore the NCA has **themselves developed guidelines** for manufacturers and importers to ensure child- and tamper-proofing⁷⁰⁹.

Market surveillance

The Danish Safety Technology Authority stated that they "believe we deliver an **overall effective market surveillance** with the funds allocated to handling the task." Denmark had conducted 4,775 inspections, placing Denmark **third out of 15 Member States** which responded to this item. Denmark had conducted 818 product tests related to the enforcement of the TPD, placing Denmark **third out of 14 Member States** which responded to this item.

In 2019, the total self-reported cost of market surveillance of tobacco products and electronic cigarettes in Denmark was approximately €1 million for tobacco, and in the questionnaire they stated they intended to increase this to €1.2 million to increase surveillance of the track and trace system. For e-cigarettes the total cost for 2019 was approximately €1.4 million. As stated above, the **annual fees** collected from importers and manufacturers cover all market surveillance, including peer reviews.

In Denmark, market developments concerning electronic cigarettes and refill containers (Art. 20(7)) are monitored through a yearly survey smoking prevalence⁷¹⁰.

⁷⁰⁷ https://www.sik.dk/en/registre/list_of_registered_tobacco_products

⁷⁰⁸ https://www.sik.dk/en/registre/list_of_registered_e_cigarette_products

⁷⁰⁹ <https://www.sik.dk/erhverv/produkter/e-cigareetter/vejledninger/krav-boernesikring-e-cigareetter-og-genopfyldningsbeholdere>; Note that Art. 20(3)(g) also requires e-cigarettes and refill containers to be protected against breakage and leakage and have a mechanism that ensures refilling without leakage, however in this instance Denmark was specifically remarking on the child- and tamper-proofing provisions.

⁷¹⁰ A recent sub-report on e-cigarettes and heated tobacco is available on the NCA website: <https://www.sst.dk/da/udgivelser/2020/danskernes-rygevaner-2019-del-2>

Not all Member States monitor these developments; see Section 3.8 for further information.

Denmark has initiated several **targeted market surveillance operations** to assess the market:

- Following the publication of the priority list of additives (Art. 6), Denmark enacted monitoring and enforcement actions for the additives **menthol and diacetyl**; not all Member States have done this. For diacetyl, the authorities located products for which the TP-ID contained the ingredient but was missing a submitted study. No products containing diacetyl were found on the Danish market. For menthol, at the time of the questionnaire Denmark had located products for which the TP-ID contained menthol, and intended to take action if necessary.
- On the basis of the Commission's explanation to the Expert Group on Tobacco Policy in 2017 regarding the minimum dimensions of cuboid packages of cigarettes and roll your own tobacco packets (Art. 9(3)), the Danish authorities launched a targeted effort to check market compliance. Following this targeted effort, they have not had reports of **slim packages**.
- As of January 2021, Denmark was enacting a targeted effort related to labelling of **smokeless tobacco products** (Art. 12 & 13). The NCA reported that so far, 35 smokeless tobacco products had been part of their testing effort.

Amendments (2020) to the Act on tobacco products, Act on a ban on tobacco advertising and the Act on electronic cigarettes

In December 2020, amendments to the Act on tobacco products, the Act on a ban on tobacco advertising and the Act on electronic cigarettes were adopted in Denmark⁷¹¹, which accomplished several tobacco control measures additional to the TPD which will come into effect during 2021 and 2022. The changes introduced include:

- Implement **plain packaging** for tobacco products, except for cigars and pipe tobacco, and for electronic cigarettes.
- **Define and regulate tobacco substitutes**, defined as products containing nicotine but are not tobacco products or e-cigarettes, and which are not approved by a marketing authorization according to law on medication or EU rules about common procedures for approval of medicinal products for human use, and equipment, that is intended for being used together with these products. The act will regulate tobacco substitutes as tobacco products related to health warnings, advertising, sponsorship, display bans, age limits, and smoke-free environments. Such tobacco substitutes are not regulated by the TPD, and therefore this measure goes beyond the mandatory requirements.
- **Ban flavours in e-cigarettes** and refill containers (both nicotine-containing and non-nicotine-containing), other than tobacco and menthol. This also goes beyond the TPD in line with Recital 47.

While not directly about monitoring and enforcement of specific TPD provisions, these amendments demonstrate a focus and dedication to tobacco control in Denmark.

⁷¹¹ <https://www.retsinformation.dk/eli/ita/2020/2071>

5.11.3.2 Italy

Italy, contrary to Denmark, does not charge fees to manufacturers and importers to cover the costs of the TPD enforcement. Italy has prepared a decree to define and impose fees for manufacturers and importers related to Art. 4, 5, 6, 7, and 20. As of January 2021, this decree was in the hand of the legal office of the two ministries involved (Health and Finance) before the respective Ministers sign it.

The analysis below shows that the main success factors of the Italian approach are:

- Making use of optional clauses in the Directive, which allows them to apply the strictest approach set out in the TPD, to strengthen their overall **monitoring** and enforcement approach. This includes the optional authorisation system in Art. 19(3). Italy is also amongst a few Member States to de facto have taken provisional measures against e-cigarettes and refill containers which present a serious risk to human health (Art. 20(11)).
- Closely studying the information on **EU-CEG** to identify and anticipate possible incompliance
- Monitoring the **market** continuously

Further, when Italy implemented the TPD, they also introduced provisions banning smoking in certain hospital areas and in certain situations in private cars, and they also increased fines for selling tobacco products to minors. These provisions demonstrate Italy's focus and dedication to tobacco control more widely.

Technical assessments

Italy **has an approved laboratory in the country** for conducting TNCO analyses: they use the laboratory of the Agency of Customs and Monopolies approved by the Decree of Minister of finance of 31 August 1994⁷¹². Not all Member States have such a laboratory; see Section 3.2 for further information.

Enforcement capacity, mechanisms and approaches

In November 2020, the Italian Ministry of Health funded a National Institute for Health project to analyse the content of the **Italian repository of EU-CEG**. One of the aims of this project was to monitor non-compliant products in order to instruct the competent authorities (Ministry of Health and Ministry of Finance) to intervene.

Art. 19(3) allows but does not require Member States to introduce a system for the authorisation of novel tobacco products. Italy is one of six Member States which has done so.

Italy is also amongst a few Member States to de facto have taken provisional measures against e-cigarettes and refill containers that comply with the requirements of Art. 20, if they **present a serious risk to human health** (Art. 20(11)). The Customs and Monopolies Agency in Italy checks EU-CEG submissions and manufacturers' declarations, and if there is reasonable reason to believe that certain products pose a risk to consumers, they are removed from the market and not authorized for sale. Also, controls to identify potential risks to human health are routinely performed by Ministry of health, National Institute of Health, and the Polizia Sanitaria, ("Police for Health").

In line with the obligation in Art. 23(3), Italy introduced several **penalties for infringements** of the national provisions transposing the TPD, and, perhaps more importantly, is actively enforcing them. Following non-compliance of economic

⁷¹²

https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=1994-10-04&atto.codiceRedazionale=094A6331&elenco30giorni=false

operators (for example incorrect submissions of information pursuant to Art. 5, and non-compliance with labelling and packaging provisions), Italy has **contacted submitters** to obtain needed information. Similarly, to ensure that provisions for combined health warning were properly implemented on packages with bevelled edges (recital 28), the Italian Ministry of Health requested that the Agency of Customs and Monopolies verify the compliance of packages with bevelled edges.

Some products have also been **removed from the market** due to non-compliance, including tobacco for oral use. The Italian Police for Health have seized e-cigarettes which are non-compliant with quality or safety requirements in Art. 20(3), as well as ingredients and health warnings (Art. 20(4)(b) and (c).

Market surveillance

Italy has undertaken a high number of product inspections (5,720 self-reported inspections at the time of the Member State questionnaire⁷¹³), indicating a focus on market surveillance. Information about some of the actions taken and products removed from the market is given below:

- Art. 17: According to the Italian NCA, two products were removed from the market which were considered **tobacco for oral use** ("General Cut Titanium" and "Thunder X" produced by Swedish Match). The producer started a suit that was still pending at the time of the questionnaire.
- Art. 20(3): Refill containers have been seized due to non-compliance with childproofing provisions.
- Art. 20(4): Refill containers have been seized due to non-compliance with information leaflets.

Italy prohibits cross-border distance sales of tobacco products, and the Customs and Monopolies Agency **constantly monitors shops of tobacco products** both in Italy and online, and has closed the websites of 433 (up to November 2019) non-compliant retailers. The website for the Agency⁷¹⁴ presents a list of closed websites, and also allows consumers to report non-compliant shops.

In Italy, market developments concerning electronic cigarettes and refill containers (Art. 20(7)) are monitored through a yearly survey on tobacco consumption conducted by the National Institute of Health, Mario Negri Institute and DOXA Agency⁷¹⁵. Not all Member States monitor these developments; see Section 3.8 for further information.

Additions to TPD implementation

When Italy implemented the TPD, they added a new article which extended their smoking ban to the external premises of some hospital wards (including Gynaecological, Paediatric, and Obstetrical), and also extended the ban to private cars when in presence of minors or pregnant women. This article also imposed fines to tobacco retailers who sell tobacco products to minors which were more severe than were previously in place. While not directly about monitoring and enforcement of the TPD, these provisions demonstrate a focus and dedication to tobacco control in Italy.

5.11.3.3 The Netherlands

In the Member State questionnaire, although the Netherlands reported a few enforcement issues, this was generally not related to a lack of capacity or technical

⁷¹³ Italy has undertaken the second-highest number of self-reported inspections of the 15 Member States which responded to this item in the cost-data template.

⁷¹⁴ <https://www.adm.gov.it/portale/siti-inibiti-tabacchi>

⁷¹⁵ A link provided in the Member State questionnaire related to this survey as is follows:
<https://www.iss.it/documents/20126/0/PACIFICI-31-maggio-2019.pdf/c5c9a560-86dd-3240-65e4-3ded6aa2b17?t=1576338071234>

ability. Overall, the Netherlands responded that it conducts "**adequate risk-based enforcement of the TPD**".

The Netherlands has **spent significantly** on implementing and enforcing the TPD. Fees are charged for notifying products in EU-CEG and for the screening of TNCO emissions in cigarettes and roll-your-own tobacco. These **fees cover partial analysis** activities of the EU-CEG data and lab analyses of TNCO screening. It was not possible for the Netherlands to determine what percentage of the total fees for analysing activities of the EU-CEG data that is not covered by the fees charged to manufacturers.

The analysis below shows that the main success factors of the Dutch approach are:

- Conducting varied technical assessments for **product emissions** which are not required by the TPD, mandating measurement of TNCO levels in roll-your-own tobacco, and testing cigarettes using the Canadian Intense (CI) method for demonstration purposes.
- Using a **risk-based approach** to ensure provisions with low compliance and high risks are prioritised for enforcement
- Effectively screening all products for TNCO levels every three years

Technical assessments

The Netherlands has an **approved laboratory** for carrying out testing of TNCO information.

The Netherlands is the only Member State to go beyond the TPD in mandating use of ISO standards to measure TNCO levels in **roll-your-own tobacco**.

For demonstration purposes, the Netherlands has tested cigarettes using the Canadian Intense (CI) method (Art. 4(4)), through which they detected systematically higher TNCO levels⁷¹⁶. The Netherlands has also tested the emissions of HTPs⁷¹⁷ and e-cigarettes. The Netherlands is unique in these tests, as few other Member States have done so.

The Netherlands also enforces limits on the presence of nicotine levels in **e-cigarettes**, based on chemical analysis of the ingredients and emissions. Data in EU-CEG can sometimes drive the choice of products for such analytical measurements.

Enforcement capacity, mechanisms and approaches

The Netherlands uses a **risk-based approach** to enforcement, whereby provisions with low compliance and high risks are prioritised for enforcement through specific projects and inspections. However, for provisions with not-perfect compliance and low risks, inspections are initiated only when there is evidence of non-compliance. New legislation may be followed up with specific projects and inspections to determine compliance and subsequent prioritisation.

The Netherlands has conducted 897 product tests, the **most of the 14 Member States** which responded to this item in the cost-data template. When economic operators in the Netherlands are not compliant, the Dutch authorities have issued fines, including 106 fines (up to 2018) for violation of the labelling provisions for cigarettes and roll-your-own tobacco, most of which concerned the incorrect placement and size of the health warnings. Four fines were also issued for non-compliant packages with bevelled edges, and eight fines were issued related to health

⁷¹⁶ <https://www.rivm.nl/en/news/rivm-measures-much-higher-levels-of-tar-nicotine-and-carbon-monoxide-in-cigarettes>

⁷¹⁷ https://www.rivm.nl/sites/default/files/2018-11/Publicatie_Nieuwsoortige_tabaksproducten_TG.pdf

warnings on slim packages. Fines were also issued for snus-like products sold as chewing tobacco. Authorities also sample e-liquids every year, and fines for violations of the TPD are given.

The Dutch NCA reported that one of their strongest examples is the system they have in place for enforcing TNCO levels for cigarettes and roll-your-own tobacco, which involves both the NVWA (the enforcement agency) and RIVM (the national institute for public health and environment). All products are screened for TNCO levels, as well as labelling and packaging requirements, every three years, and products which may not comply are inspected more thoroughly through enforcement measures. As the screening is less labour-intensive, this system makes the Netherlands more efficient.

The Netherlands has not introduced an authorisation system for novel products (as permitted by Art. 19(3)), however they clarified that this was to prevent misperceptions by consumers of 'approval' of the products by the Dutch government. However, the Netherlands has introduced an additional specific requirement related to novel tobacco products: manufacturers must **send a specimen** of the product and, if any, the corresponding device to the relevant authority.

Market surveillance

The NCA in the Netherlands monitored market developments concerning electronic cigarettes and refill containers (Art. 20(7)) through a **signalling system** which follows developments in novel tobacco and related products⁷¹⁸. Not all Member States monitor these developments; see Section 3.8 for further information. Maastricht University, together with the NCA, has also carried out a study on the gateway effects of e-cigarettes⁷¹⁹.

In the Netherlands, after fines were issued for non-compliant products, the authorities ensured that the manufacturers developed new compliant packs through **sampling the products on the market**; they view this as the strongest approach because many products come from manufacturers outside the Netherlands.

Other tobacco control measures

In addition, the Netherlands has gone further than the TPD through introducing plain packaging (specifically permitted by Art. 24(2)) and implementing an age restriction for buying e-cigarettes of 18 years and above. While not directly about monitoring and enforcement of the TPD, these provisions illustrate that the Netherlands is dedicated to tobacco control.

⁷¹⁸ <https://publichealth.jmir.org/2018/2/e55>

⁷¹⁹ The research followed a group of adolescents temporally and asked about their use of e-cigarettes and tobacco products, including flavours. Research not yet published.

5.12 Case Study 4: Implementation of plain packaging and labelling

Key findings

- To date, eight EU Member States have introduced plain packaging policies: Belgium, Denmark, France, Hungary, Ireland, the Netherlands, Slovenia and the UK⁷²⁰. Proposals for plain packaging are currently under government consideration by an additional Member State (Finland).
- Based on the information summarised in this case study from Member States that have had plain packaging in place for a number of years (France, Ireland, and the UK), there appear to be a range of potential benefits:
 - Reduction in perceived attractiveness of cigarette packets and smoking, which was observed in all three Member States.
 - An increase in the perception of the harmfulness of smoking, as identified in France and the UK, and providing a motivating factor to stimulate smoking cessation, as found in Ireland and the UK.
 - A decrease in smoking prevalence, as found in France and Ireland, and a decline in cigarette sales, as found in the UK.
- The major impediment to introducing plain packaging highlighted by Member States that have not yet introduced plain packaging was the threat of legal action by tobacco companies and the resources this would require.
- Most countries are in support of EU-level legislation for plain packaging, which they felt would represent an important facilitator to help overcome some of the impediments to introducing plain packaging at national level, and help to harmonise regulations across the EU, which are currently fragmented.
- Key lessons for countries considering introducing plain packaging include:
 - EU-level policy on plain packaging would be considered of added value and would represent an important facilitator to introduce plain packaging at a national level.
 - Public health advocacy combined with strong political support can help to reject tobacco industry arguments and prioritise plain packaging as a public health issue.
 - A 'whole systems' approach (e.g. combining complimentary policies such as marketing controls and pricing policies alongside plain packaging legislation) is likely to be more effective than any single measure alone.
 - Scientific evidence from countries that have already implemented plain packaging, such as Australia, France and the UK, provide a strong basis for introducing plain packaging in other countries.

5.12.1 Introduction and background

Tobacco Products Directive 2014/40/EU (TPD) stipulates that all EU Member States shall require combined health warnings on tobacco products for smoking that cover 65% of both the external front and back surface of the unit packet, and any outside packaging. However, the TPD does not mandate plain packaging, and leaves the adoption of plain packaging to each Member State's discretion. Plain packaging removes from packets all branding elements, including logos and brand images, and requires that all packaging be a standardised colour (except for the pictorial health

⁷²⁰ The UK was counted as an EU Member State for the purpose of this study as the UK was governed by EU regulations for a substantial proportion of the time from implementation of the TPD until the commencement of this study.

warning) and display only a brand name in a standard font style and format⁷²¹. Although not mandated by the TPD, there is increasing evidence to suggest an impact of plain packaging measures on reducing the prevalence of smoking⁷²², and reducing its attractiveness and increasing awareness of the health risks, particularly amongst young people^{723,724,725}.

The purpose of this case study is to identify lessons learned from the examples of early adopters of this policy. This case study is focused on three EU Member States that have implemented plain packaging policies over an extended time period as examples of 'positive deviance' to be able to draw lessons: France, Ireland and the UK⁷²⁶. Given how recently the policy in Slovenia was implemented, it is likely too early to comment on any impacts of the policy. We have similarly not included Belgium or Hungary as it is likely too early to comment on any impacts of the policy in these countries.

The case study aims to answer the following questions:

2. How was plain packaging policy implemented in each country? What were the main impediments and facilitators?
3. What have been some of the legal and implementation challenges in each country?
4. What has been the impact of plain packaging policies in that country, in terms of the use, perception, sales and health consequences, particularly amongst young people?
5. What are some of the main lessons learned?

5.12.2 Methods

The methods for this case study included desk research, stakeholder consultations, and integration of data collected as part of workshops and an online survey.

5.12.2.1 Desk research

The desk research included a search of both academic and grey literature, and a review of responses from Member States, civil society organisations, and health experts to surveys undertaken for this study. Searches were conducted in Google (to identify grey literature), and Google Scholar (academic literature). The search string used is provided below. The first 50 search results were examined.

⁷²¹ Campaign for Tobacco Free Kids (2020). Standardized or plain tobacco packaging. International developments. As of 2 November 2020:
https://www.tobaccofreekids.org/assets/global/pdfs/en/standardized_packaging_developments_en.pdf

⁷²² Diethelm, P. A., Farley, T. M. (2015). Refuting tobacco-industry funded research: empirical data shows decline in smoking prevalence following introduction of plain packaging in Australia. *Tobacco Prevention & Cessation*, 1, 6.

⁷²³ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁷²⁴ Vardavas et al., (2017). Plain packaging of tobacco products in the European Union: an EU success story? *European Respiratory Journal*, 50: 1701232

⁷²⁵ Drovandi, A., Teague, P.A., Glass, B. et al. (2019) A systematic review of the perceptions of adolescents on graphic health warnings and plain packaging of cigarettes. *Systematic Reviews* 8, 25.

⁷²⁶ The UK has been included as it was a member of the European Union or operating in a transition phase until December 2020 and therefore still provides relevant information on tobacco control activities from the implementation of the TPD in 2014 until that point.

- [country] AND ("tobacco products directive" OR TPD OR tobacco) AND ("plain packaging" OR "standardized packaging" OR "standardised packaging")

The 'Consumer preference and perception of specific categories of tobacco and related products' report⁷²⁷ was also consulted, which was made available for the purposes of this study. Along with studies identified from the literature searches, 'snowballing'⁷²⁸ and forward searching⁷²⁹ were also used to identify relevant sources. Survey responses for this study were also reviewed for mention of plain packaging.

5.12.2.2 Stakeholder interviews

We conducted three interviews with individuals involved in or with knowledge of plain packaging policies in order to fill specific gaps in the evidence. Interviews were conducted using Microsoft Teams or via written responses. The interviews were semi-structured, thereby ensuring a similar set of questions were asked of all interviewees but allowing for emergent issues to be explored. The interviews covered the following topics: (1) How plain packaging policy was implemented in that country; (2) legal and implementation challenges in that country; (3) impacts of plain packaging policies in that country; and (4) any lessons learned from this example. All consultations were conducted under the principles of informed consent in line with the requirements of the EU General Data Protection Regulation requirements and the Ethical Assurance for Social Research in Government principles⁷³⁰.

5.12.2.3 Gap filling workshops

Two workshops were conducted to fill gaps in the evidence, one with CSOs and HEs, and one with representatives from NCAs responsible for tobacco control in Member States. The workshops were conducted to fill gaps in the evidence for the study as a whole and also touched on plain packaging.

5.12.2.4 Gap filling survey

An online gap filling survey was conducted to fill gaps in the evidence with representatives from NCAs responsible for tobacco control in Member States. The survey was conducted to fill gaps in the evidence for the study as a whole and also asked questions about plain packaging.

5.12.3 Results

This section summarises the data collected and synthesised for this case study. In Section 5.12.3.1 we provide an overview of the status of plain packaging in EU Member States. This is followed in Section 5.12.3.2 with a more detailed discussion of the situation in individual Member States, including the case studies of France, Ireland, and the United Kingdom (Section 0). The final section (5.12.3.3) summarises the findings relating to impediments, facilitators, and challenges for the implementation of plain packaging, drawing on the findings from the individual Member States.

⁷²⁷ European Commission (2020). Consumer preference and perception of specific categories of tobacco and related products. As of 8 October 2020: <https://open-evidence.com/project/consumer-preference-and-perception-of-specific-categories-of-tobacco-and-related-products/>

⁷²⁸ A process in which a small number of additional relevant studies are found through the quick review of the reference list of studies identified for inclusion at the end of the screening stage.

⁷²⁹ A process to identify any articles that cite the identified article.

⁷³⁰ United Kingdom Government Social Research Unit (2011) Ethical Assurance Guidance for Social Research in government. As of 6 April 2021: <https://www.gov.uk/government/publications/ethical-assurance-guidance-for-social-research-in-government>

5.12.3.1 Overview of plain packaging status in Member States

This section provides a high-level overview of the status of plain packaging in EU Member States as of April 2021, summarised in Table 1. Member States are grouped together based on the status of implementation of plain packaging legislation: (i) laws adopted or provisions applicable; (ii) plain packaging under formal consideration; (iii) no proposals under consideration. For Member States in group (i) we provide the date of introduction at the manufacturer level.

To date, eight EU countries⁷³¹ have introduced plain packaging (laws adopted or provisions applicable): Belgium (introduction at manufacturer level: 1 January 2020)^{732,733}; Denmark (1 July 2021 for tobacco products and 1 October 2021 for e-cigarettes)^{734,735}; France (20 May 2016)⁷³⁶; Hungary (currently applicable at retailer level for some products; full applicability from 1 January 2022)^{737,738}; Ireland (30 September 2017)⁷³⁹; The Netherlands (1 October 2020 for cigarettes and Roll Your Own tobacco)⁷⁴⁰; Slovenia (1 January 2020)⁷⁴¹; and the UK (21 May 2016)⁷⁴².

At the time of writing, two Member States (Finland, Lithuania) are considering proposals for plain packaging. To date, 18 EU Member States have no proposals in place regarding introducing plain packaging for tobacco products (Austria, Bulgaria, Croatia, Czechia, Estonia, Germany, Greece, Italy, Latvia, Luxembourg, Malta, Poland, Portugal, Republic of Cyprus, Romania, Slovakia, Spain, and Sweden).

⁷³¹ The UK was counted as an EU Member State for the purpose of this study as the UK was governed by EU regulations for a substantial proportion of the time from implementation of the TPD until the commencement of this study.

⁷³² Sante Publique, Securite de la Chaine Alimentaire et Environnement (2019) Arrêté royal relatif au paquet standardisé des cigarettes, du tabac à rouler et du tabac à pipe à eau. As of 23 April 2021:

<http://www.ejustice.just.fgov.be/eli/arrete/2019/04/13/2019012059/justel#LNK0012>

⁷³³ Service public federal sante publique, securite de la chaine alimentaire et environnement (2019). Arrêté royal relatif au paquet standardisé des cigarettes, du tabac à rouler et du tabac à pipe à eau. As of 31 March 2021: https://www.etaamb.be/fr/arrete-royal-du-13-avril-2019_n2019012059.html

⁷³⁴ Lov om ændring af lov om forbud mod tobaksreklame m.v., lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v. og forskellige andre love (2020) As of 23 April 2021:
<https://www.retsinformation.dk/eli/ita/2020/2071>.

⁷³⁵ von Eyben (2020). Denmark: a new era for tobacco control.

<https://blogs.bmjjournals.com/tc/2020/01/24/denmark-a-new-era-for-tobacco-control/>

⁷³⁶ Vardavas et al., (2017). Plain packaging of tobacco products in the European Union: an EU success story? European Respiratory Journal, 50: 1701232;

⁷³⁷ ENSP. (n.d.). ENSP and ERS congratulate Hungary on the finalisation of plain packaging requirements. As of 31 March 2021: <http://ensp.network/policies/resources/plain-packaging/ensp-and-ers-congratulate-hungary-on-the-finalisation-of-plain-packaging-requirements/>

⁷³⁸ Direct communication between DG SANTE and the NCA for Hungary.

⁷³⁹ Vardavas et al., (2017). Plain packaging of tobacco products in the European Union: an EU success story? European Respiratory Journal, 50: 1701232;

⁷⁴⁰ Netherlands Enterprise Agency, RVO (n.d.) Plain packaging for cigarettes and rolling tobacco. As of 6 May 2021: <https://business.gov.nl/amendment/plain-packaging-cigarettes-and-rolling-tobacco/>

⁷⁴¹ INT6

⁷⁴² Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

Table 76. Overview of implementation of plain packaging legislation (tobacco products) across EU Member States

Country	Implementation status	Date of introduction	Change in smoking prevalence since 2017 ^{743,744}
Countries that have introduced plain packaging (laws adopted/provisions applicable)			
Belgium	Provisions already applicable	1 January 2020	Increase
Denmark	Laws adopted	1 July 2021 /1 October 2021 (e-cigarettes)	Decrease
France	Provisions already applicable	20 May 2016	Decrease
Hungary	Laws adopted, some provisions already applicable	1 January 2022	Increase
Ireland	Provisions already applicable	30 September 2017	Decrease
Netherlands	Provisions in force Provisions planned	1 October 2020 – cigarettes and RYO 1 January 2022 – other products including cigars and e-cigarettes)	Decrease
Slovenia	Provisions already applicable	1 January 2020	Decrease
United Kingdom	Provisions already applicable	21 May 2016	Decrease
Countries that are formally considering or have considered plain packaging			
Lithuania	Legislation has been considered by parliament	Government proposed amendments to the tobacco control law that include provisions for plain packaging to be introduced in 2022	Decrease
Finland	Legislation being considered by parliament	27 April 2021 - Proposal published for plain packaging introduction from 2023	Decrease
Countries with no proposals in place			

⁷⁴³ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>

⁷⁴⁴ Office for National Statistics (2020) Adult smoking habits in the UK: 2019. Available as at 6 May 2021: <https://www.ons.gov.uk/releases/adultsmokinghabitsintheuk2019>

Country	Implementation status	Date of introduction	Change in smoking prevalence since 2017^{743,744}
Austria	No proposals in place	-	Decrease
Bulgaria	No proposals in place	-	Increase
Croatia	No proposals in place	-	Increase
Republic of Cyprus	No proposals in place	-	No change
Czechia	No proposals in place	-	Increase
Estonia	No proposals in place	-	Decrease
Germany	No proposals in place	-	Decrease
Greece	No proposals in place	-	Increase
Italy	No proposals in place	-	Decrease
Latvia	No proposals in place		No change
Luxembourg	No proposals in place	-	Increase
Malta	No proposals in place	-	Decrease
Poland	No proposals in place	-	Decrease
Portugal	No proposals in place	-	Decrease
Romania	No proposals in place	-	Increase
Slovakia	No proposals in place	-	Decrease
Spain	No proposals in place	-	Decrease
Sweden	No proposals in place	-	No change

5.12.3.2 Results from individual Member States

Below we present the key findings from the research relating to individual Member States. As was noted at the gap filling workshops and is shown in the summary in the previous section, plain packaging was not introduced in European countries at the time of the TPD in 2014, but this has changed in the last few years with several countries now adopting or considering plain packaging. We summarise the information for Member States currently without formal proposals in place (Section 0), those that are considering, or have considered, plain packaging (Section 0), and those that have recently adopted plain packaging (Section 0) and those that have had it in place for a number of years (Section 0).

Member States that have no proposals in place

At the time of writing, 18 Member States have no proposals in place to introduce plain packaging. Of these, ten Member States were represented at the gap filling workshops and/or responded to the gap filling survey. Available evidence from these Member States is outlined below. The evidence suggests that Member States face different impediments for not considering plain packaging.

- A representative from Member State A reported that there is no political interest to introduce plain packaging policies at national level, and so they would support EU-level plain packaging legislation.

- Member State B indicated that they are not considering plain packaging until the impact assessment of the TPD has been conducted at national level. They are currently awaiting the results of the national impact assessment.
- A representative from Member State C indicated that there might not be enough evidence to proceed with plain packaging.
- Member States D and E indicated that they might only consider introducing plain packaging if it was a requirement at EU level, suggesting that there is no political interest to introduce plain packaging at the national level.
- Member States F and G reported that although they do not have draft legislation for plain packaging in place currently, they are considering introducing it. The representative from Member State F noted that there is strong political will within their country to do so.
- A representative from Member State H mentioned that there is an issue with their constitution (regarding freedom of expression), which limits their ability to implement plain packaging. The committee overseeing implementation of the TPD recommended plain packaging to the Government, but it was found to be incompatible with existing national laws and therefore it was not introduced.

Member States that are considering introducing plain packaging

Two Member States (Finland and Lithuania) have considered introducing plain packaging or have taken steps in the legislation process. Of these, one Member State was represented at the gap filling workshops (Finland). Available findings from the gap filling workshop and case study desk research are outlined below.

Finland has published a government proposal on plain packaging^{745,746}. In the gap-filling workshop, Finland indicated that one reason for not implementing the measure has been the threat of court proceedings because of the resources this would use⁷⁴⁷. For this reason, Finland supports plain packaging at an EU level. The workshop representative indicated that it would be good if EU-level plain packaging measures took into account other nicotine-containing products in addition to tobacco products.

There are no data from Lithuania from the gap filling data sources, but amendments to the Lithuanian Law on the Control of Tobacco, Tobacco Products and Related Products have been discussed that would introduce plain cigarette packaging in 2022⁷⁴⁸.

Member States that have recently adopted plain packaging measures

In this section we summarise findings from five Member States (Belgium, Denmark, Hungary, the Netherlands, and Slovenia) that have recently adopted plain packaging measures. Broader findings for our case study countries that have had plain packaging in place for several years (France, Ireland, and the UK), follows in Section 1.3.2.4.

⁷⁴⁵ European Commission (2021) Notification Detail: Government proposal to Parliament on amending the Tobacco Act. 2021/248/FIN (Finland). As of 7 May 2021: <https://ec.europa.eu/growth/tools-databases/tris/index.cfm/en/search/?trisaction=search.detail&year=2021&num=248&mLang=EN>

⁷⁴⁶ Medical Xpress (2021) Finland plans stricter smoking rules, unbranded cigarettes. As of 7 May 2021: <https://medicalxpress.com/news/2021-04-finland-stricter-unbranded-cigarettes.html>

⁷⁴⁷ Gap-filling workshops, November 2020.

⁷⁴⁸ New proposals in Lithuania: plain cigarette packaging, outdoor café, balcony smoking ban (2018) The Lithuania Tribune. As of 24 April 2021: <https://lithuanatribune.com/new-proposals-in-lithuania-plain-cigarette-packaging-outdoor-cafe-balcony-smoking-ban/>

Belgium

- Belgium has implemented plain packaging for cigarettes, roll-your-own tobacco and waterpipe tobacco. Legislation came into force on 1 January 2020^{749,750}.
- To support the policy, Belgium used evidence from Australia⁷⁵¹ and Member States that had already implemented plain packaging (e.g. the UK and France), as well as studies from Belgium that corroborated this evidence⁷⁵². The survey respondent confirmed that there is currently no data on the effect of plain packaging on smoking behaviour since it has been implemented recently; however, plain packaging was supported by the population based on preliminary surveys. It may also have reduced circumvention of packaging and labelling requirements.
- In terms of implementation challenges, the survey respondent reported that since plain packaging is not mandated for all types of tobacco products, shops are taking advantage of this loophole to display other types of tobacco products (i.e. cigars, cigarillos) that still have regular packaging with only a text warning.

Denmark

- Denmark indicated that the introduction of plain packaging in Denmark is a part of the action plan “the National Action Plan against Smoking among Children and Youth.” Plain packaging will come into force from 1 July 2021 for all tobacco products, with the exception of pipe tobacco and cigars, and from 1 October 2021 for e-cigarettes.^{753,754} Moreover, plain packaging will also apply to herbal products for smoking.
- In terms of evidence to support the policy, evidence from Australia and support from the WHO have been helpful, including the appeal from the World Trade Organisation that was in favour of Australia.
- The arguments that the tobacco industry uses against the introduction of plain packaging in Denmark are very similar to the arguments that have been used in other countries that have already introduced plain packaging.

⁷⁴⁹ Sante Publique, Securite de la Chaine Alimentaire et Environnement (2019) Arrêté royal relatif au paquet standardisé des cigarettes, du tabac à rouler et du tabac à pipe à eau. As of 23 April 2021:

<http://www.ejustice.just.fgov.be/eli/arrete/2019/04/13/2019012059/justel#LNK0012>

⁷⁵⁰ Service public federal sante publique, securite de la chaine alimentaire et environnement (2019). Arrêté royal relatif au paquet standardisé des cigarettes, du tabac à rouler et du tabac à pipe à eau. As of 31 March 2021: https://www.etaamb.be/fr/arrete-royal-du-13-avril-2019_n2019012059.html

⁷⁵¹ Australia was the first country to introduce plain packaging, introduced at the manufacturer level on 1 October 2012 and at the retail level on 1 December 2012. In June 2020 the final remaining legal challenge to Australia’s tobacco plain packaging laws was decided in favour of Australia: World Trade Organization’s Appellate Body report as of 6 May 2021:

https://www.wto.org/english/news_e/news20_e/435_441abr_e.htm

⁷⁵² Van Hal G, Van Roosbroeck S, Vriesacker B, et al. Flemish adolescents’ perceptions of cigarette plain packaging: a qualitative study with focus group discussions. BMJ Open 2012;2:e001424.

⁷⁵³ Lov om ændring af lov om forbud mod tobaksreklame m.v., lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v. og forskellige andre love (2020) As of 23 April 2021:

<https://www.retsinformation.dk/eli/ita/2020/2071>

⁷⁵⁴ von Eyben (2020). Denmark: a new era for tobacco control.

<https://blogs.bmj.com/tc/2020/01/24/denmark-a-new-era-for-tobacco-control/>

Their arguments against plain packaging are primarily on trademarks, illegal trade and harm reductions.

Hungary

- Hungary is in the process of implementing plain packaging; as of 20 May 2018, plain packaging requirements are being gradually applicable, but from 1 January 2022 all cigarettes and roll-your-own tobacco can only be packaged in a plain package⁷⁵⁵. The findings from the gap filling survey indicate that prior to the introduction of plain packaging, public opinion polls and consultations with healthcare professionals and industry representatives took place in Hungary. The process was supported by national healthcare authorities, NGOs and the WHO. These groups used evidence and counter arguments from authorities and NGOs in other countries, including Australia, the UK, Canada, the European Commission, and the appeal from the World Trade Organisation that was in favour of Australia.
- There is currently no data on the effect of plain packaging since it has been implemented recently; however, plain packaging was supported by the population based on preliminary surveys.
- The representative for Hungary attending the gap filling workshop expressed the view that there is scope for the EU to introduce EU level plain packaging.

The Netherlands

- Plain packaging for cigarettes and roll-your-own tobacco is implemented from 1st October 2020 in the Netherlands⁷⁵⁶. Plain packaging for other products, such as cigars and e-cigarettes, is planned to be required by 1 January 2022⁷⁵⁷.
- The Netherlands indicated that they used evidence from the Cochrane Institute to support their plain packaging law⁷⁵⁸. In terms of challenges from the tobacco industry, a participant in the gap filling survey indicated that one international tobacco company filed a lawsuit against the Dutch government to discuss the studies that were used for introducing plain packaging.
- The Netherlands indicated that they would welcome EU-level plain packaging measures in the gap filling data collection.

Slovenia

- Plain packaging for cigarettes and roll-your-own tobacco was implemented on 1 January 2020 in Slovenia⁷⁵⁹.
- Plain packaging measures were proposed by public health experts, public health expert institutions and public health-oriented NGOs and accepted by

⁷⁵⁵ ENSP. (n.d.). ENSP and ERS congratulate Hungary on the finalisation of plain packaging requirements. As of 31 March 2021: <http://ensp.network/policies/resources/plain-packaging/ensp-and-ers-congratulate-hungary-on-the-finalisation-of-plain-packaging-requirements/>

⁷⁵⁶ FCTC (2020). The Netherlands: Implementation of plain packaging from 01/10/2020. As of 29 January 2021: <https://untobaccocontrol.org/impldb/the-netherlands-implementation-of-plain-packaging-from-01-10-2020/>

⁷⁵⁷ Netherlands Enterprise Agency, RVO (n.d.) Plain packaging for cigarettes and rolling tobacco. As of 6 May 2021: <https://business.gov.nl/amendment/plain-packaging-cigarettes-and-rolling-tobacco/>

⁷⁵⁸ Cochrane: McNeill, A., Gravely, S., Hitchman, S. C., Bauld, L., Hammond, D., & Hartmann-Boyce, J. (2017). Tobacco packaging design for reducing tobacco use

⁷⁵⁹ INT6

the Ministry of Health, which is responsible for preparation of the tobacco control act. The measure was supported by numerous organizations such as: the Ministry of Health of the Republic of Slovenia, National Institute of Public Health (NIPH), other public health expert institutions, public health-oriented NGOs and civil society. Strong support was also provided by the World Health Organization, experts from Australia, the United Kingdom, Ireland and France⁷⁶⁰. Implementation of plain packaging for cigarettes and roll-your-own tobacco was part of comprehensive package of provisions implemented in line with the TPD and in line with the WHO FCTC. The provisions were prepared on the basis of FCTC guidelines and evidence from Australia, the UK, France and Ireland⁷⁶¹.

- The main impediment was the opposition of the tobacco industry, related organizations and associations. The tobacco industry tried to prevent the adoption of plain packaging in 2016 during the public consultation process and then again in 2019 before implementation⁷⁶².
- There is currently a lack of evidence on the impacts of plain packaging in Slovenia due to the short period of implementation and the postponement of planned studies amongst young people due to COVID-19 and the closure of schools⁷⁶³.

Case studies: France, Ireland and the UK

This section presents broader evidence on three countries that have implemented plain packaging policies for some time to help draw lessons for countries considering implementing plain packaging in the future.

France

How was plain packaging policy implemented? What were the main impediments and facilitators?

- France introduced plain packaging of tobacco products on 20 May 2016⁷⁶⁴. In France, plain packaging applies only to cigarettes and roll-your-own tobacco, and not to other tobacco products (e.g. cigars, waterpipe tobacco)⁷⁶⁵.
- The main facilitators to implementing plain packaging policy have been the FCTC and the TPD, which provide a strong legal basis to support EU Member States⁷⁶⁶.
- The main impediment to implementing plain packaging policy has been the opposition of tobacco companies⁷⁶⁷.

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⁷⁶¹ INT6

⁷⁶² INT6

⁷⁶³ INT6

⁷⁶⁴ Khoury & Melchior (2018). Smoking-related perceptions after plain tobacco packaging in France: DePICT a representative study. European Journal of Public Health, 28.

⁷⁶⁵ Moodie et al., (2019). Plain packaging: legislative differences in Australia, France, the UK, New Zealand and Norway, and options for strengthening regulations. Tobacco Control, 28:485-492.

⁷⁶⁶ Vardavas et al., (2017). Plain packaging of tobacco products in the European Union: an EU success story? European Respiratory Journal, 50: 1701232.

⁷⁶⁷ Crosbie et al., (2019). Containing diffusion: the tobacco industry's multipronged trade strategy to block tobacco standardised packaging. Tobacco Control, 28:195-205; INT5

What has been the impact of plain packaging, in terms of the use, perception, sales and health consequences, particularly amongst youth?

- Research examining changes in smoking-related perceptions and behaviours one year after the implementation of plain packaging in France found that the perception of the harmfulness of smoking has increased in both adolescents and adults⁷⁶⁸. Additionally, the social acceptance of smoking has decreased among adolescents⁷⁶⁹. In 2017, as compared with 2016, smoking rates decreased in France⁷⁷⁰. This is supported by Eurobarometer data, which shows that the highest drop in the smoking prevalence occurred in France⁷⁷¹.
- Similarly, the appeal of cigarette packaging following plain packing implementation was found to reduce substantially, with the percentage of smokers reporting they enjoyed the appearance dropping from 53% to 16%⁷⁷². Another study found that participants in France reported that plain packaging was less “attractive” or “fun” and more “austere”, whereas other products that had not been regulated in the same manner due to their novelty were as a result implicitly positively highlighted⁷⁷³.
- The introduction of new anti-smoking measures (including plain packaging) did not increase the likelihood of smokers purchasing tobacco from abroad⁷⁷⁴.
- Emerging evidence suggests that in France plain packaging (in combination with increased size of combined health warnings as required by the TPD) contributes to changes in smoking norms, resulting in lower levels of tobacco use in the population, including amongst adolescents⁷⁷⁵.

Ireland

How was plain packaging policy implemented? What were the main impediments and facilitators?

- The policy process for plain packaging involved the following: In 2013, the Department of Health launched a “Tobacco Free Ireland” policy, which set out 60 recommendations and measures, including introducing plain packaging. Public health groups approached policymakers and the media, and consistently explained plain packaging as a health and protection of

⁷⁶⁸ Khoury & Melchior (2018). Smoking-related perceptions after plain tobacco packaging in France: DePICT a representative study. European Journal of Public Health, 28.

⁷⁶⁹ Khoury & Melchior (2018). Smoking-related perceptions after plain tobacco packaging in France: DePICT a representative study. European Journal of Public Health, 28.

⁷⁷⁰ El-Khoury Lesueur et al., (2019). Plain tobacco packaging, increased graphic health warnings and adolescents’ perceptions and initiation of smoking: DePICT, a French nationwide study. Tobacco Control, 28:e31–e36.

⁷⁷¹ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>

⁷⁷² A Pasquereau, R Andler, R Guignard, J B Richard, V Nguyen-Thanh, (2020) Smokers’ perception of cigarette packaging in France before and after the plain packaging, European Journal of Public Health, 30,S5, ckaa166.290.

⁷⁷³ European Commission (2020). Consumer preference and perception of specific categories of tobacco and related products. As of 8 October 2020: <https://open-evidence.com/project/consumer-preference-and-perception-of-specific-categories-of-tobacco-and-related-products/>.

⁷⁷⁴ Gomajee et al., (2020). Decrease in cross-border tobacco purchases despite intensification of antitobacco policies in France. Tobacco Control.

⁷⁷⁵ El-Khoury Lesueur et al., (2019). Plain tobacco packaging, increased graphic health warnings and adolescents’ perceptions and initiation of smoking: DePICT, a French nationwide study. Tobacco Control, 28:e31–e36.

children issue. This helped to build a strong policy consensus amongst the public and policymakers to protect the health of the public⁷⁷⁶. Plain packaging requirements were introduced on 30 September 2017⁷⁷⁷.

- The main facilitators to implementing plain packaging policy in Ireland were supporting policy frameworks: the World Health Organization's FCTC implementation guidelines recommend that governments adopt plain packaging along with pictorial health warning labels covering 50% or more of the tobacco package; the TPD requirement for combined health warnings to cover 65% of the external front and back surface of a packet, and TPD's support for the EU Member States to introduce plain packaging.
- The main impediment to implementing plain packaging policy in Ireland was the opposition of tobacco companies⁷⁷⁸. The main opposing stakeholders to the plain packaging Bill in Ireland that submitted comments to the government included tobacco companies, business groups, trademark associations, intellectual property organizations, retailer groups and individual smokers⁷⁷⁹.

What has been the impact of plain packaging, in terms of the use, perception, sales and health consequences, particularly amongst youth?

Emerging findings from the Healthy Ireland Survey 2019, an annual survey commissioned by the Department of Health and conducted by Ipsos MRBI, found that 44% of smokers in the latest wave rate the appeal of their cigarette packaging lower compared to one year previously, and 50% of smokers disagree with the statement "I like the look of my regular cigarette package", which has increased slightly from 45% in the previous survey wave⁷⁸⁰. The survey also found that smoking prevalence in Ireland dropped from 23% in 2015 to 20% in 2018 and that plain packaging legislation was cited by 23% of smokers as a good motivation to quit⁷⁸¹.

United Kingdom

How was plain packaging policy implemented? What were the main impediments and facilitators?

The policy process for plain packaging spanned 2008-2016, and involved the following: the UK government first tabled plain packaging in 2008 in a report "Consultation on the Future of Tobacco Control"⁷⁸². In 2011, the government produced the report "Tobacco Control Plan for England", in which they presented options for reducing the promotional impact of tobacco packaging. In 2013, standardised packaging was debated in the House of Commons. In 2014, the House of Commons supported an amendment to include enabling legislation for plain packaging in the

⁷⁷⁶ Crosbie, E. (2019). Removing the last billboard for the tobacco industry: Tobacco standardized packaging in Ireland. *Health Policy*, 123(10): 932-935.

⁷⁷⁷ Department of Health (2018) The future of cigarette packets is here and it's plain. As of 25 April 2021: <https://www.gov.ie/en/press-release/d613ab-the-future-of-cigarette-packets-is-here-and-its-plain/>

⁷⁷⁸ Crosbie et al., (2019). Containing diffusion: the tobacco industry's multipronged trade strategy to block tobacco standardised packaging. *Tobacco Control*, 28:195-205.

⁷⁷⁹ Crosbie et al., (2019). Containing diffusion: the tobacco industry's multipronged trade strategy to block tobacco standardised packaging. *Tobacco Control*, 28:195-205.

⁷⁸⁰ Department of Health (2019). Post-Enactment Report. As of 8 October 2020: https://ptfs-oireachtas.s3.amazonaws.com/DriveH/AWData/Library3/Documents%20Laid/pdf/DOHdoclaid121219_121219_121444.pdf.

⁷⁸¹ Crosbie, E. (2019). Removing the last billboard for the tobacco industry: Tobacco standardized packaging in Ireland. *Health Policy*, 123(10): 932-935.

⁷⁸² Hatchard et al., (2016). Corporate Conflict Expansion and Adaptation, Supplementary File 1: Policy timeline 2008-2016.

Children and Families Bill and an independent review of the evidence supported implementation. The House of Commons voted to introduce plain packaging from May 2016. During this time, the Department of Health conducted three impact assessments and held two public consultations. Plain packaging requirements were introduced on 21 May 2016⁷⁸³.

The main impediment to implementing plain packaging policy in the UK was the opposition of tobacco companies through legal challenges and various tactics to exploit loopholes in the legislation to delay and undermine the policy⁷⁸⁴. There have been several implementation challenges to plain packaging both before and after introduction of plain packaging. One challenge related to exploitation by tobacco companies of the transition period, which in the UK was longer (12 months) than for other countries, e.g. France (9 months)⁷⁸⁵. Tobacco companies delayed the introduction of standardised products and removal of fully branded packaging during the transition period, which may have mitigated some of the immediate intended effects of the legislation by desensitising consumers to plain packaging⁷⁸⁶. In addition, tobacco companies also exploited the transition period by introducing new pack, brand and product aspects⁷⁸⁷. Post-implementation, although compliance was generally high, market surveillance and commercial sales data revealed that there were cases of non-compliance with the legislation; with tobacco companies made adaptations and introduced innovations to tobacco products to enable brand differentiation (e.g. slim packets were on sale and changes to variant name) after plain packaging was fully implemented^{788,789,790}. Tobacco companies have also capitalised on gaps in the legislation, for example by introducing new menthol-flavoured cigarillos, which are exempt from plain packaging legislation regarding controls on branding, price marking, and packet sizing; minimum excise tax; and the characterising flavour ban⁷⁹¹.

⁷⁸³ Critchlow et al., (2018). Introduction of Standardized Tobacco Packaging During a 12-Month Transition Period: Findings From Small Retailers in the United Kingdom. *Nicotine & Tobacco Research*, 21(7):871-878.

⁷⁸⁴ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁷⁸⁵ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁷⁸⁶ Critchlow et al., (2018). Introduction of Standardized Tobacco Packaging During a 12-Month Transition Period: Findings From Small Retailers in the United Kingdom. *Nicotine & Tobacco Research*, 21(7):871-878.

⁷⁸⁷ Moodie C et al (2018). How tobacco companies in the United Kingdom prepared for, and responded to, standardised packaging of cigarettes and rolling tobacco. *Tobacco Control*, 27:e85-e92.

⁷⁸⁸ Moodie C et al (2018). How tobacco companies in the United Kingdom prepared for, and responded to, standardised packaging of cigarettes and rolling tobacco. *Tobacco Control*, 27:e85-e92

⁷⁸⁹ Evans-Reeves et al., (2019). Prospective longitudinal study of tobacco company adaptation to standardised packaging in the UK: identifying circumventions and closing loopholes. *BMJ Open*, 9:e028506

⁷⁹⁰ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁷⁹¹ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

What has been the impact of plain packaging, in terms of the use, perception, sales and health consequences, particularly amongst youth?

A longitudinal online survey of smokers found that approval for plain packaging in the UK increased, and disapproval decreased, post implementation⁷⁹².

The introduction of plain packaging and minimum excise tax in the UK was associated with a significant decline in sales and in tobacco industry revenues⁷⁹³. It was also associated with a plateau in the previous growth of cheap cigarette brands that appeal to young and price conscious smokers⁷⁹⁴. The introduction of plain packaging also saw an increase in the price of leading cigarettes by almost 5%⁷⁹⁵, particularly for the cheapest brands⁷⁹⁶. Plain packaging and minimum pack size was associated with tobacco users switching from tobacco cigarettes to e-cigarettes, and choosing cheaper version of products they currently used⁷⁹⁷. This appears to contradict claims made by tobacco companies that plain packaging would lead to a reduction in prices (and consequently increase smoking rates)⁷⁹⁸.

A study in Scotland suggests that the introduction of plain packaging, including combined health warnings, has reduced the perceived attractiveness of cigarette packets amongst young people in the United Kingdom who smoke or are at elevated risk of becoming smokers⁷⁹⁹. Plain packaging appears to be disrupting positive brand imagery, increasing the salience of health warnings and contributing to de-normalising smoking.

A systematic review of the evidence from the UK found that although plain packaging appears to have increased the salience of health warnings which depict tobacco disease and harms, there is currently limited evidence of the impacts on smoking behaviour⁸⁰⁰. Three studies examining the impact of plain packaging on this outcome

⁷⁹² Moodie C et al., (2020). Increased support for standardised packaging in the UK: a longitudinal online survey

Tobacco Control.

⁷⁹³ Hiscock et al., (2020). Longitudinal evaluation of the impact of standardised packaging and minimum excise tax on tobacco sales and industry revenue in the UK. *Tobacco Control*; Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁷⁹⁴ Hiscock et al., (2020). Longitudinal evaluation of the impact of standardised packaging and minimum excise tax on tobacco sales and industry revenue in the UK. *Tobacco Control*

⁷⁹⁵ Critchlow & Mitchell (2018). Plain packaging for tobacco: what other countries can learn from the UK's experience. *The Conversation*. As of 30 October 2020:

<https://www.storre.stir.ac.uk/bitstream/1893/28503/1/Critchlow-Mitchell-Conversation-2018.pdf>

⁷⁹⁶ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁷⁹⁷ Opazo Breton et al., (2020). Effect of UK plain tobacco packaging and minimum pack size legislation on tobacco and nicotine product switching behaviour. *Addiction*, 115(10):1913-1923.

⁷⁹⁸ Critchlow & Mitchell (2018). Plain packaging for tobacco: what other countries can learn from the UK's experience. *The Conversation*. As of 30 October 2020:

<https://www.storre.stir.ac.uk/bitstream/1893/28503/1/Critchlow-Mitchell-Conversation-2018.pdf>; Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁷⁹⁹ MacGregor et al., (2020). 'It's like sludge green': young people's perceptions of standardized tobacco packaging in the UK. *Addiction*, 115(9):1736-1744.

⁸⁰⁰ Moodie et al., (2019). A systematic review of research exploring the response of consumers, retailers and tobacco companies to standardised packaging in the United Kingdom. As of 29

were identified.^{801,802,803} All three found that smokers would be less likely to use cigarettes in plain packages: one study reported that smokers would likely reduce consumption (60%) or to quit (46%); another found that plain packets encouraged more thoughts of quitting; and one study found that plain packaging might encourage switching from cigarettes to other tobacco products or to e-cigarettes. However, a caveat of these studies is that they were conducted during the transition period and not after full implementation.

5.12.3.3 Impediments, facilitators and challenges for plain packaging implementation

Across the desk research, scoping consultations, workshops and survey, Member States highlighted several facilitators that could help to introduce plain packaging:

- **Political support both at the national and EU level.** Most countries were in support of EU-level legislation, which they felt would represent an important facilitator to help overcome some of these impediments to introducing plain packaging at national level, particularly legal challenges by tobacco companies. For example, two Member States indicated that there is strong political support for plain packaging.
- **Strong scientific evidence.** Emerging evidence from countries that have already implemented plain packaging, such as Australia, France and the UK, provided a strong basis for introducing plain packaging in other countries⁸⁰⁴.
- **Advocacy to provide support for measures.** Strong advocacy networks can help to promote anti-tobacco measures including plain packaging. For example, in France the National Institute of Cancer was very active in promoting anti-tobacco measures⁸⁰⁵. Similarly, in Ireland public health groups were effective in rejecting tobacco industry trade and investment framing diversions. A review of the evidence also found that reframing the issue as one of children's rights has been an effective strategy⁸⁰⁶.
-

The key impediment highlighted by Member States was the **threat of legal action by tobacco companies**. Several Member States highlighted that they were reluctant to introduce plain packaging due to the threat of court proceedings by tobacco companies and the high resources this would require.

What have been some of the legal and implementation challenges?

October 2020: https://dspace.stir.ac.uk/retrieve/327483ea-7f8b-4a6c-82d2-0f6e24b125ec/Standardised%20packaging%20PHRC_Final.pdf

⁸⁰¹ Moodie C, Brose LS, Hyun L, et al. (2020) How did smokers respond to standardised cigarette packaging with new, larger health warnings in the United Kingdom during the transition period? A cross-sectional online survey. Addiction Res Theory, 28(1):53-61.

⁸⁰² Poundall T, Bogdanovica I, Langley T. (2018) A cross-sectional study of the impact of standardised tobacco packaging legislation on university students. J Child Adolescent Subst Abuse, 27:165- 73.

⁸⁰³ Retzler C, Shiraj N, Retzler J. (2019) Eye movement data reveal increased attention to combined health warnings on cigarette packs. Drug Alc Depend, 194:336-40.

⁸⁰⁴ Institute for Global Tobacco Control (2020) Advancing Tobacco Plain and Standardized Packaging in Low and Middle-Income Countries: Advice from Experts. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. As at 6 May 2021:
https://www.globaltobaccocontrol.org/sites/default/files/plain_packaging_report_0.pdf

⁸⁰⁵ INT6

⁸⁰⁶ IVO (2020). Tobacco control advocacy and countering the tobacco industry: Results from international expert interviews. As of 29 January 2021: <https://ivo.nl/publicaties/factsheet-pleiten-voor-meer-tabaksontmoediging-en-tegenwicht-bieden-aan-de-tabaksindustrie/>

The major legal and implementation challenges to the introduction of plain packaging relate to industry opposition. Evidence on this comes primarily from academic research⁸⁰⁷; the main findings of this research are:

- Tobacco companies have opposed plain packaging using four main arguments, claiming that plain packaging:
 - lacks sufficient evidence to demonstrate that it will work;
 - would increase illicit tobacco trade because plain packages will be easier to counterfeit;
 - would create unnecessary problems for retailers;
 - would violate domestic laws and international treaties governing trade, intellectual property (e.g. trademarks, patents, copyright) and investment⁸⁰⁸.
- The tobacco industry has attempted to reframe plain packaging as an issue relating to trade and investment, and human rights, rather than public health. A review of internal tobacco industry documents, government documents and media sources indicates that, in all Member States, industry has employed a multipronged strategy throughout the progression of plain packaging policy⁸⁰⁹. Although this strategy is tailored towards each domestic context, the overall tobacco industry's strategy remains consistently focused on shifting the attention away from public health, and framing plain packaging as an attack on trade and investment⁸¹⁰. In addition, tobacco companies have argued that plain packaging is a dispute about human rights, EU law or investment law⁸¹¹. For example, in the UK, tobacco company claimants raised arguments involving the law of evidence, domestic and European constitutional law, human rights law, European and international intellectual property rules and the rules of the internal market⁸¹². None of the challenges to the legislation advanced by the industry were successful; the High Court ruled that intellectual property rights must always be subject to implicit normative limitations in the public interest⁸¹³. However, the ruling by the World Trade Organization's (WTO) Appellate Body in June 2020 regarding plain packaging requirements in Australia⁸¹⁴, the conclusion of the final remaining legal challenge to Australia's tobacco plain

⁸⁰⁷ For a comprehensive factsheet of tobacco tactics see: IVO (2020). Factsheet: Literature review of tobacco industry responses to tobacco control measures. As of 29 January 2021: <https://ivo.nl/publicaties/factsheet-literature-review-of-tobacco-industry-responses-to-tobacco-control-measures/>

⁸⁰⁸ Crosbie et al., (2019). Containing diffusion: the tobacco industry's multipronged trade strategy to block tobacco standardised packaging. *Tobacco Control*, 28:195-205; IVO (2020). Tobacco Industry arguments and strategies against policy measures: results from international expert interviews As of 29 January 2021: <https://ivo.nl/publicaties/argumenten-en-strategieen-van-de-tabaksindustrie-tegen-3-beleidsmaatregelen/>

⁸⁰⁹ Hawkins et al., (2018). A multi-level, multi-jurisdictional strategy: Transnational tobacco companies' attempts to obstruct tobacco packaging restrictions. *Global Public Health*, 14:4, 570-583.

⁸¹⁰ Crosbie et al., (2019). Containing diffusion: the tobacco industry's multipronged trade strategy to block tobacco standardised packaging. *Tobacco Control*, 28:195-205.

⁸¹¹ Nanopoulos & Yotova (2016). *Journal of International Economic Law*, 19(1):175-210.

⁸¹² Griffiths, J. (2017). The tobacco industry's challenge to the United Kingdom's standardised packaging legislation – global lessons for tobacco control policy? *QUT Law Review*.

⁸¹³ Griffiths, J. (2017). The tobacco industry's challenge to the United Kingdom's standardised packaging legislation – global lessons for tobacco control policy? *QUT Law Review*.

⁸¹⁴ Cases brought by Honduras and the Dominican Republic in "Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging" (DS435 and DS441). As of 6 May 2021: https://www.wto.org/english/news_e/news20_e/435_441abr_e.htm

packaging laws, should end the use of challenges under trade or intellectual property law to stop or delay the implementation of plain packaging in other countries, given the status of WTO Appellate Body as a final appeal mechanism⁸¹⁵.

- The tobacco industry has attempted to slow down the progression of plain packaging legislation through litigation, lobbying, threatening plant closures, and the use of third parties (i.e. mobilising the support of businesses and allies in other industries to for example 'flood' government consultations)^{816,817}. Processing multiple submissions can be burdensome to policymakers, taking up time and resources, which can delay the adoption of tobacco control policies. Tobacco companies have also been reported to be involved in direct lobbying of legislators and officials; public relations campaigns to mobilise the support of other businesses and the general public; attempts to frame the issue away from health and onto trade and intellectual property, as well as the alleged negative consequences of the policy, such as increased smuggling and associated criminality; providing responses to government consultations; legal threats and action; garnering international opposition; and misrepresentation of scientific evidence in the media⁸¹⁸.

5.12.4 Overall findings: What are some of the main lessons learned?

- **Relevant changes have been observed in Member States where plain packaging has been in place for a number of years** in terms of: reduction in perceived attractiveness of cigarette packets and smoking; increase in perceptions of harmfulness of smoking and motivation to quit; decrease in smoking prevalence and cigarette sales.
- **Member States are generally supportive of introducing EU-level legislation on plain packaging.** In their view, this would help to overcome some of the impediments to introducing plain packaging at a national level, as Member States do not all have the same level of resources to support its implementation. This has contributed to the variation in the adoption of this policy by Member States as described in this report, and thus an EU-level policy would also help to harmonise plain packaging regulations across the EU. **From the perspective of Member States, an EU-level policy to support harmonisation of plain packaging would also provide added-value**, and would facilitate introduction of plain packaging at a national level.
- **Countries seeking to introduce plain packaging should consider the length of the transition period.** The 12-month period in the United Kingdom appeared longer than needed to transition stockholding. Evidence suggests that tobacco companies took advantage of the longer transition period to delay the removal of fully branded products and delay the

⁸¹⁵ Cohen, J. E., Zhou, S., Goodchild, M., Allwright, S. (2020). Plain packaging of tobacco products: Lessons for the next round of implementing countries. *Tobacco Induced Diseases*, 18(November), 94.

⁸¹⁶ Hawkins et al., (2018). A multi-level, multi-jurisdictional strategy: Transnational tobacco companies' attempts to obstruct tobacco packaging restrictions. *Global Public Health*, 14:4, 570-583.

⁸¹⁷ Lie et al., (2018). Can't see the woods for the trees: exploring the range and connection of tobacco industry argumentation in the 2012 UK standardised packaging consultation. *Tobacco Control*, 27:448-454.

⁸¹⁸ Tobacco Tactics (2020). Plain Packaging Opposition in Ireland. As of 8 October 2020: <https://tobaccotactics.org/wiki/plain-packaging-opposition-in-ireland/>.

introduction of products in plain packaging in a gradual manner⁸¹⁹. The staggered introduction of plain packaging in the UK may have desensitised consumers to the new designs and mitigated immediate intended effects of plain packaging⁸²⁰. Tobacco companies also used the delay to inform customers and retailers about the changes; and introduce new product innovations such as changes to the structure of the pack or filter innovation⁸²¹.

-
- **Countries should consider closing existing or potential loopholes and standardising all aspects of pack design prior to implementing plain packaging.** Following the introduction of plain packaging in the UK, tobacco companies sought to undermine plain packaging legislation through loopholes. They introduced packaging innovations such as adding bevelled edges and slim designs (which do not appear to meet the minimum size needed for health information on the side of packets), novel filter designs and new pack seals⁸²². In the UK, tobacco companies also sought to exploit loopholes such as marketing menthol flavoured cigarillos which were exempt from plain packaging legislation⁸²³.
-
- **Countries seeking to implement plain packaging should be prepared for resistance by the tobacco industry.** Across all MSs, tobacco companies have employed multiple strategies to delay or prevent implementation, including trade diversions, disputes regarding industry legal and reputational claims, and garnering third-party support from businesses and allies in other industries⁸²⁴.
-
- **Public health advocacy combined with strong political support can produce progressive and highly effective public health policy solutions to reduce tobacco consumption.** In Ireland, public health groups were effective in rejecting tobacco industry trade and investment framing diversions and instead consistently explained plain packaging as a public health issue. Gaining policy consensus amongst the public helped Ireland's political leaders reject industry arguments and prioritise plain packaging as a public health issue⁸²⁵. Existing research and scientific

⁸¹⁹ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁸²⁰ Critchlow et al., (2018). Introduction of Standardized Tobacco Packaging During a 12-Month Transition Period: Findings From Small Retailers in the United Kingdom. *Nicotine & Tobacco Research*, 21(7):871-878.

⁸²¹ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁸²² Critchlow & Mitchell (2018). Plain packaging for tobacco: what other countries can learn from the UK's experience. *The Conversation*. As of 30 October 2020:

<https://www.storre.stir.ac.uk/bitstream/1893/28503/1/Critchlow-Mitchell-Conversation-2018.pdf>

⁸²³ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:

https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

⁸²⁴ Crosbie et al., (2019). Containing diffusion: the tobacco industry's multipronged trade strategy to block tobacco standardised packaging. *Tobacco Control*, 28:195-205.

⁸²⁵ Crosbie, E. (2019). Removing the last billboard for the tobacco industry: Tobacco standardized packaging in Ireland. *Health Policy*, 123(10): 932-935.

evidence from countries that have already implemented plain packaging can be leveraged to provide support⁸²⁶.

- **A 'whole systems' approach is likely to be more effective than any single measure alone.** From the success seen in the UK and France, policymakers should consider implementing complimentary policies (such as marketing controls and pricing policies) alongside plain packaging legislation to disincentivise tobacco sales and consumption⁸²⁷.

⁸²⁶ Institute for Global Tobacco Control (2020) Advancing Tobacco Plain and Standardized Packaging in Low and Middle-Income Countries: Advice from Experts. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. As at 6 May 2021:
https://www.globaltobaccocontrol.org/sites/default/files/plain_packaging_report_0.pdf

⁸²⁷ Hiscock et al. (2020). Market and tobacco industry response to standardised tobacco packaging in the UK. As of 8 December 2020:
https://www.cancerresearchuk.org/sites/default/files/cruk_summary_paper_-_market_and_industry_response_to_standard_tobacco_packaging_uk_-_december_2020.pdf

Annex 10: Mystery shopping task

5.13 Aim

The main purpose of this mystery shopping exercise was to understand if online retailers from different MS comply with the provisions of Article 18 of the TPD.

Objective: To determine if there is an age-verification system in place and what form that system takes, when purchasing tobacco and e-cigarettes cross-border online.

5.14 Methodological approach

In this study, multiple researchers acted as shoppers using online retailers of tobacco products and E-cigarettes under a range of different scenarios. A set of retailers were selected from 11 Member States (see below) and a set of 46 scenarios developed in which the shopper was based in an EU country other than that of the retailer. The scenarios varied in terms of whether they shopper posed as someone above or below the legal age for purchasing tobacco or E-cigarette products. In all cases, the shopper selected an item for purchase and in a subset of the scenarios, completed the purchase (including payment and delivery) to determine what, if any, age verification checks were in place throughout the full purchasing process. The approach is summarised below, with the questionnaire used by researchers presented following the conclusions.

5.14.1 Member States included

Nine Member States (CZ, DE, DK, IE, MT, NL, SE, SK, UK) allow CBDS of tobacco products and twelve overlapping but not exactly the same Member States (HR, CZ, DK, DE, EL, FR, IE, NL, SE, MT, SK, UK) allow CBDS of e-cigarettes. We included 11 Member States in the present exercise. However, at the time of the mystery shopping exercise, the study team did not have full access to the comprehensive set of rules on CBDS in Member States. Therefore this mystery shopping exercise does not include tobacco sales from Malta, or e-cigarette sales from France, all of which are permitted.

We conducted the exercises from Member States which allowed cross-border distances sales where ICF staff members or colleagues were located. This was necessary as we could not use a VPN for all the exercises because the purchased products had to be shipped to the researchers. Purchases based in more Member States could be an opportunity for future research.

5.14.2 The shopping exercises

- There are several variables which the exercises varied on (see Table 77):

Underage/legal age:

In half the exercises, the researcher used their real (legal) age and ID information.

In half of the exercises, the researcher acted as if they were underage, to test the age verification systems.

The underage/legal age exercises were distributed between purchases and non-purchases, and tobacco products and e-cigarettes.

Tobacco/e-cigarette:

- In half of the exercises, the target product was a tobacco product. This corresponded to the *cheapest available quantity of traditional cigarettes*.
- In half of the exercises, the target product was an e-cigarette.
 - Option A: *cheapest available disposable nicotine e-cigarette*
 - Option B (if A not available): *cheapest available "starter kit"*

- **Purchase/non-purchase:**
- In 19 of the 46 exercises, the product was actually purchased by the researcher.
- In 27 of the 46 exercises, the researcher went through the steps to purchase (adding the product to a basket and proceeding until the point of payment), but not actually purchasing the item.

Table 77. High-level summary of shopping scenarios

Exercise		Underage	Legal age	Total
Tobacco	Purchase	5	4	9
	Non-purchase	5	7	12
	Total	10	11	21
E-cigarette	Purchase	5	5	10
	Non-purchase	8	7	15
	Total	13	12	25
Total		23	23	46

Table 78 below gives more detailed information about what exercises that were undertaken in the selected Member States. Note that fewer exercises were planned for Croatia and Greece as Croatia only permits CBDS of e-cigarettes and not tobacco products, and Greece only permits exports of e-cigarettes. While it appears that Malta officially allows cross-border sales of tobacco products, no online retailers were found which did so.

Table 78. Detailed summary of shopping scenarios by location of retailer

Location of retailer	Purchases				Non-purchases				Total	
	Tobacco		E-cigarette		Tobacco		E-cigarette			
	Under age	Legal age	Under age	Legal age	Under age	Legal age	Under age	Legal age		
Croatia				1			1		2	
Czechia	1	1			2		1		5	
Denmark	2		1		1	1			5	
Germany	1	1	1		2		1		6	
Greece				1			1		2	
Ireland	1	1			1		1		4	
Malta				1			1		2	
Netherlands		1		1			2		4	
Slovakia	1	1			2		2		6	
Sweden	1				2	2			5	
UK	1		1		1	2			5	
Total	5	5	5	5	7	8	8	7	46	

The detailed protocol for the exercises is given in the box below:

Protocol for ordering products

Retailers

- The study team have provided the researcher doing the exercise with information about the target retailer.
- For most MS, we selected EU retailers from the **lists of approved online retailers** published by the MS.
- We made use of the list of approved retailers and of a random number generator to select the retailers to target (e.g. if there were 50 retailers, we generated a random number between 1-50 to select the first retailer, and then repeated the procedure).
- However, as Some MSs did not complete the MS questionnaire or provide a link to their lists of retailers prior to undertaking the mystery shopping exercise. We were unable to find lists of registered retailers online in Germany, Greece and Slovakia. Sweden does not publish a list of retailers. We attempted to locate the online list for Malta, but did not find any registered retailers.
- Therefore, in these MS, we googled for example "buy cigarettes online Germany" or "buy e-cigarettes online Germany". We googled these terms in the official language of the MS.
- Then we used a random number generator for the first 20 google results to select our target retailers (e.g. if the number 8 was produced, we selected the eighth google result). If the number selected was not an online retailer, we repeated the process until we obtained a retailer.
- We attempted to use a different retailer for each of the exercises. However, this was not possible in Member States in which the number of registered retailers was lower than number of exercises we planned.
- The lists of approved online retailers in each Member State are given below (all links were functional at the time of the Mystery Shopping exercise):
 - Croatia
 - [E-cigarette retailers](#)
 - Czechia
 - [Tobacco retailers](#)
 - [E-cigarette retailers](#)
 - Denmark
 - [E-cigarette retailers](#)
 - [Tobacco retailers](#)
 - Germany
 - [Google results: cigarettes](#)
 - [Google results: e-cigarettes](#)
 - Greece
 - [Google results: e-cigarettes](#)
 - Ireland
 - [Tobacco retailers \(both in and out of IE\)](#)

- [E-cigarette retailers \(both in and out of IE\)](#)
- Malta
 - [Google results: cigarettes](#)
 - [Google results: e-cigarettes](#)
- Netherlands
 - [Retailers \(both in and out of NL\)](#)
- Slovakia
 - [Google results: cigarettes](#)
 - [Google results: e-cigarettes](#)
- Sweden
 - [Google results: cigarettes](#)
 - [Google results: e-cigarettes](#)
- UK
 - [Retailers \(both in and out of UK\)](#)
- We confirmed that all retailer sites were active, sold cigarettes either by money order or credit card, and were not part of buyer clubs.

Privacy concerns

- For exercises in which the researchers are overage, their real ID and/or date of birth was used. If an ID was requested by mail, this was not be provided and the exercise was terminated. For exercises in which the researchers were "underage" the date of birth **01 January 2003** was used.
- The following email address was used: TPDassessment@icf.com
- If a telephone number was requested, researchers used their own numbers to allow for communication related to the delivery of the product.
- The products were sent to the researchers' **homes** in the relevant Member State. This was necessary to verify if age verification was required on delivery, as this would not be possible to assess if the products were shipped to an office. Further, Covid-19 restricted access to offices during the period when the mystery shopping was conducted.
- Researchers paid for the items themselves and were reimbursed by ICF.

Product disposal

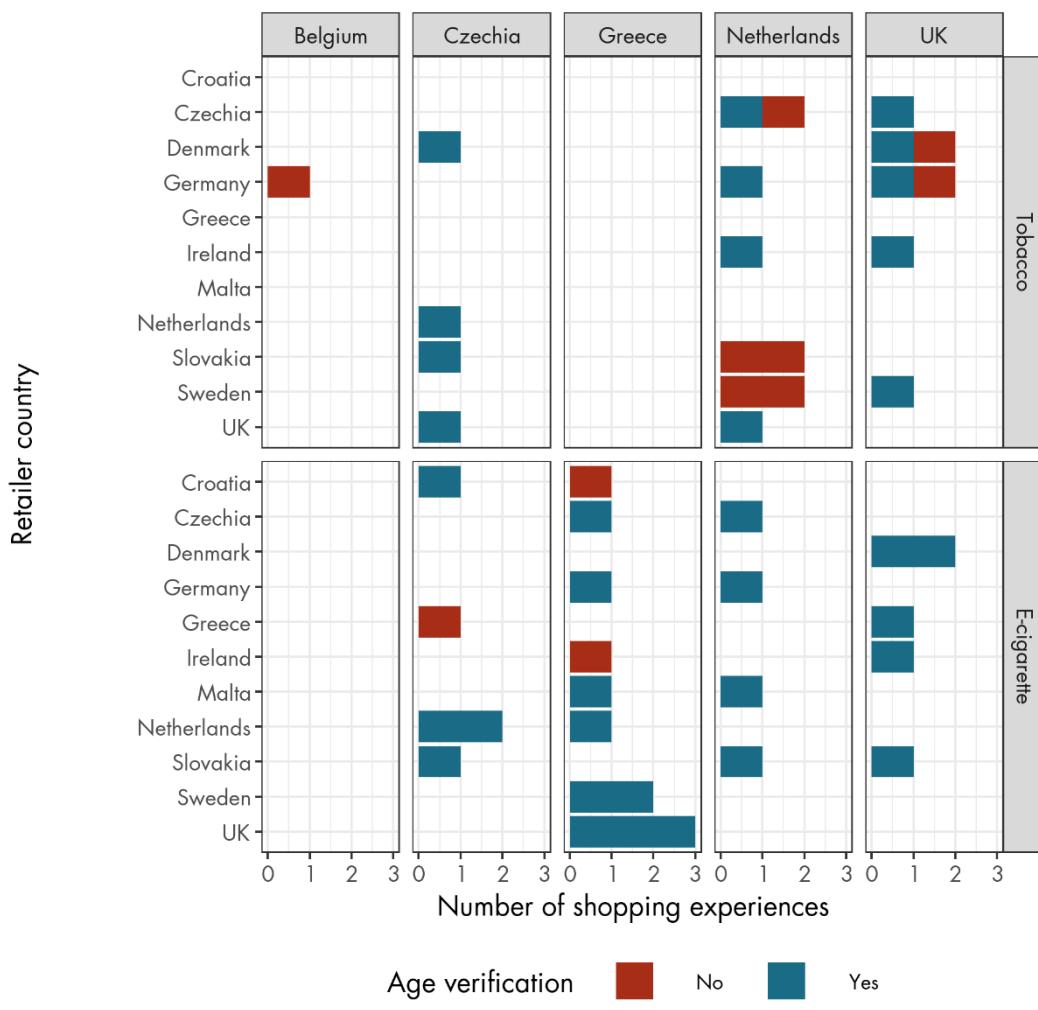
- After the product was received and information about the delivery and product had been recorded, the product was destroyed.
- This was done by removing any lithium batteries and disposing of them in local recycling centres, and disposing of the other product components in domestic bins.

5.15 Results

5.15.1 Presence of age verification system

Overall, some form of age verification was encountered in 76% of shopping experiences (35 out of 46 experiences). As shown in Figure 57, the presence of age verification checks varied by retailer/purchaser combination.

Figure 57. Age verification across the retailer/purchaser combinations analysed in this study



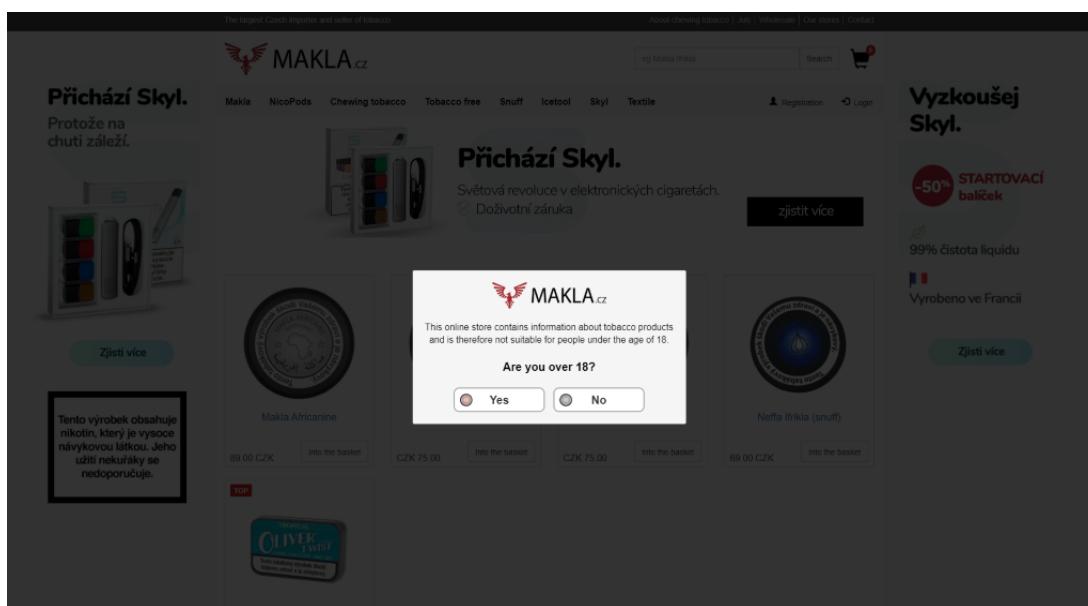
Source: RAND Europe analysis

All retailers based in Malta and Netherlands had age verification checks in place. For 9 of the 11 countries retailers were based in, there were some retailers without age verification, although this was slightly more common amongst in retailers based in Sweden, Slovakia, and Germany. Lack of age verification systems also appeared to be more common for tobacco retailers rather than E-cigarette retailers.

5.15.2 Types of age verification systems in place

The two most commonly encountered age verification systems were self-reported age verification by the user by ticking a check-box ($n = 23$; 66%) or a warning on the retailer website page regarding age restrictions ($n = 20$; 57%; see Figure 58 for example). One or both approaches were used on 31 of the 35 (89%) retailer sites that had some form of age verification system in place.

Figure 58. Example of self-reported age verification check-box



An actual date of birth was only requested from the shopper in a small number of shopping experiences ($n = 6$; 17% of retailers with age verification) and in only two of those (both tobacco retailers) was identification requested to verify this (Figure 59; see Figure 60 for example of verification using identification). In one instance it was stated that age would be verified on delivery, but this could not be confirmed because the purchase could not be completed without first setting up an account with the retailer.

Figure 59. Types of age verification checks across the retailer locations analysed, by type of product purchased (note that retailers may have employed more than one type of age verification check).

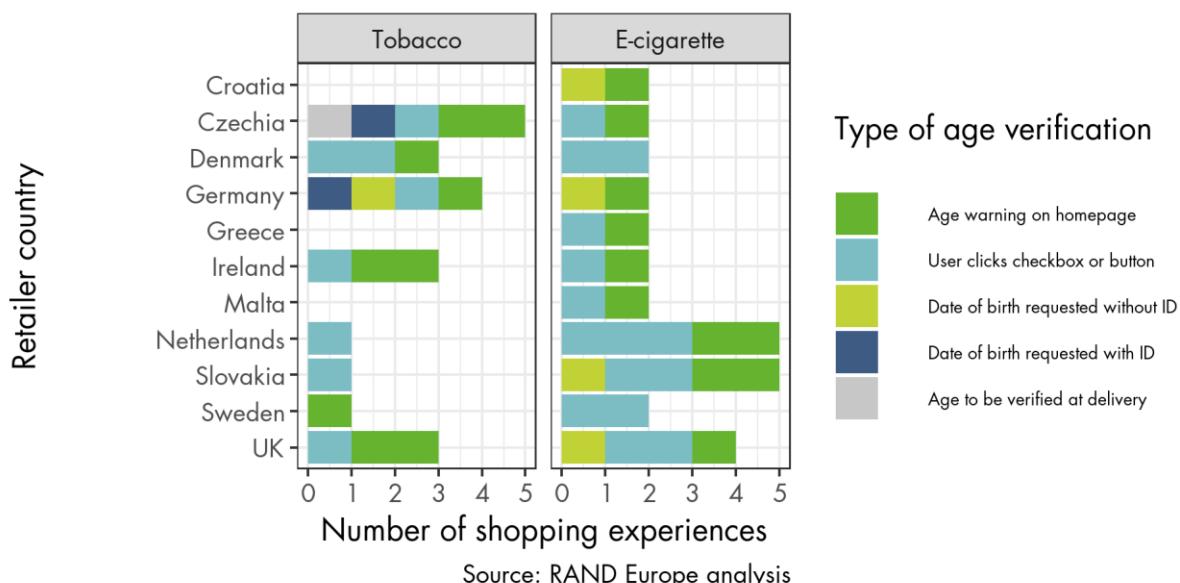


Figure 60. Example of age-verification with identification

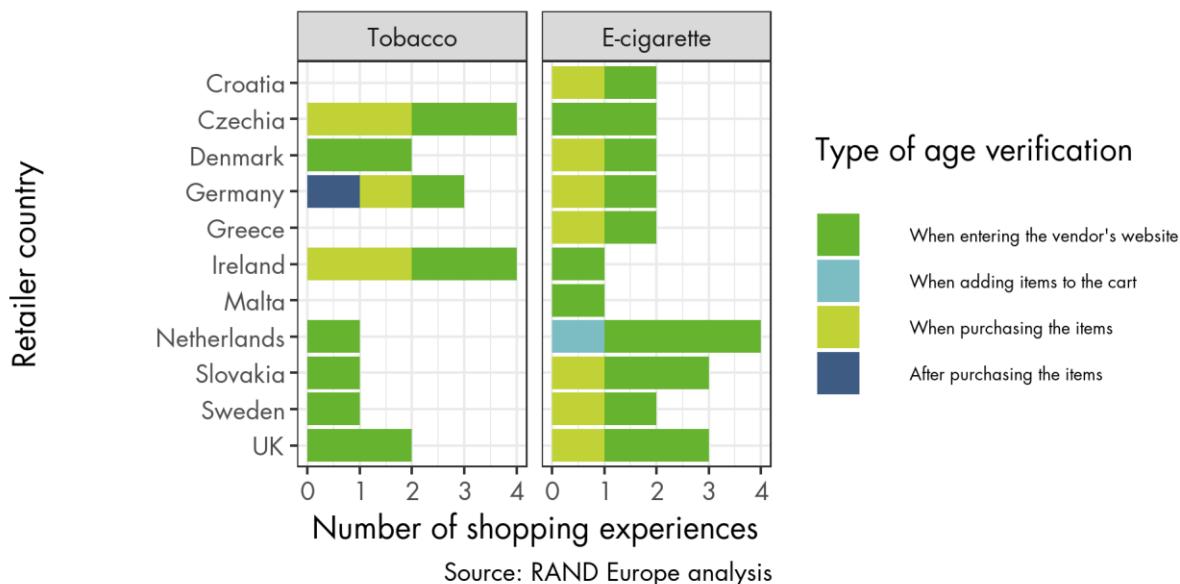
The screenshot shows a web interface for Tabak24.shop. At the top, there's a navigation bar with links like CIGARETTES, TOBACCO, CIGARILLOS, PIPES, SMOKING ACCESSORIES, WHISKEY LOUNGE, VAPE, IQOS, and GLO. On the right side of the header are icons for account, shopping cart (with a notification of 1), and cashbox.

The main content area shows a flow of steps: 1. Select shipping method (highlighted in green), 2. Select the payment method, 3. Confirm, and 4. Done. Below this, there's a section for Shipping options and Age verification. It includes information about the Youth Protection Act, instructions to select 'New ID' or 'Old ID', and contact details for non-German customers. Two German identity cards are shown: a 'New identity card' and an 'Old identity card', both with specific fields highlighted with red boxes and labeled Feld 1 through Feld 4.

Below the cards, there are four input fields labeled Field 1, Field 2, Field 3, and Field 4, each with a small asterisk indicating it's required. To the left, a section for choosing delivery method shows DHL selected with a note of '3.99 EUR'. To the right, there's a 'delivery address' field with a 'Change Address' button. Navigation buttons '< Back' and 'Further >' are located at the bottom of the form.

When retailers did have age verification systems in place, this most commonly occurred when entering the website ($n = 28$; 80%), followed by the point at which the shopper attempted to purchase an item ($n = 12$; 34%; see Figure 61). There did not appear to have any substantial differences between retailers selling tobacco products *versus* E-cigarettes regarding stage of age verification.

Figure 61. Stages of age verification checks across the retailer locations analysed, by type of product purchased (note that retailers may have employed more than one type of age verification check; data missing for one shopping experience with retailer based in Malta).



5.15.3 Completing purchases

For 19 of the 46 shopping experiences, we attempted to complete the purchase of the selected tobacco products or e-cigarette. The purchase could not be completed for 9 of these experiences (47%). In one instance this was because the minimum order cost had not been reached, but in all others instances the purchase was prevented because the retailer reported that they could not ship products to the shopper's apparent country of residence. One retailer, based in Czechia, also stated that products could not be shipped outside Czechia to individuals without a registered account because their age must be verified first. The retailers who refused to ship cross-border sales were based in Czechia, Germany, Sweden, Denmark and Netherlands.

The remaining 10 purchases were completed, although 1 was subsequently cancelled (by the retailer). Retailers through which purchases were completed were based in Slovakia, Ireland, the UK, Croatia, Greece, Denmark, and Malta. The purchases were shipped to Czechia, the UK, and Greece. Products arrived between 3 and 10 days after purchase, with an average delivery time of 5.5 days. In all instances the product received was the same as the one purchased online, although for 5 of the 9 purchases the sender name was different from the original vendor name. Recipients did not report age verification checks for any of the 9 delivered purchases (2 were not delivered face-to-face, being posted through a mail delivery slot or delivered to a post office box).

5.15.4 Under-aged shoppers

In the 23 shopping experiences where shoppers pretended to be under-age, age verification systems were in place for 16 experiences (70%). In 7 of the shopping experiences, the shopper attempted to purchase tobacco products and e-cigarettes to determine whether it was possible to complete the purchase when providing information that identified them as under-age. In 3 of these 7 experiences, the shopper pretended to be underage but was able to complete the purchase. For these 3 cases, the age verification in place only consisted of age-restriction warnings on the website and ticking a check-box or a warning on the retailer website page regarding age restrictions. As mentioned previously, no age verification took place at delivery for any completed sales,

including these purchases by shoppers pretending to be under-age. For the remaining 4 experiences, it was not possible to finalise the purchase but the information on the websites stated that this was due to issues related to cross-border distance sales in 3 cases and minimum order values in 1 case, rather than any problems with the shopper's age.

5.16 Conclusions and limitations

We found that there was **some form of age verification system in place for just over three quarters of online retailers** selling tobacco products and E-cigarettes from 11 Member States (Croatia, Czechia, Denmark, Germany, Greece, Ireland, Malta, Netherlands, Slovakia, Sweden and the UK). However, the majority of retailers with age verification systems in place (80%; n = 29) only used relatively 'weak' systems that rely on the shopper being honest about their age and ticking a check-box to confirm they can legally purchase the products. Only **two of the 46 online retailers (4%) included in this study requested a shopper's date of birth and verified this using a form of identification** such as a passport.

Self-reported age verification is unlikely to prevent under-age shoppers from browsing online retailer websites, and in this mystery shopping experiment, it did not prevent purchases from being completed for shoppers pretending to be underage. In other cases where purchasers pretended to be underage and it was not possible to finalise purchases, this was due to cross-border sales issues or minimum order costs, and not because of age verification issues. We did not identify any substantial differences between online retailers selling tobacco products or e-cigarettes with regards to age verification.

The findings from this research cannot be generalised to all online retailers across the EU, or to those within a particular country as the sample size is too small and cannot be considered to be representative of all retailers. However, these findings do demonstrate the variability in whether age verification systems are implemented by retailers across the EU, and where they are implemented, the form they take and how effective they are in preventing under-aged shoppers from accessing retailer websites and making purchases.

These results echo the findings from the Member States survey (<insert X-ref>) relating to age verification systems not functioning properly in many Member States. In this context, Czechia, Denmark, Ireland, and the UK all called for improvements to strengthen age verification systems within the EU. The findings here regarding the use of weak age verification systems and demonstrated capacity for under-age shoppers to circumvent these to purchase products from some online retailers lend support to the suggestion that enhanced systems are needed.

5.17 Observation questionnaire

In each exercise, the buyer recorded details of the purchase. See the observation questionnaire below.

The instruction email had the following text:

Thank you for participating in our mystery shopping exercise. This exercise will have the following conditions:

- Your purchase attempt number is: X
- You will be making your purchase/purchase attempt from the following retailer: XXX.
-
- **Purchase information:**
 - You will not be completing the purchase; you will put the item in the cart and proceed with the purchase until the stage of entering payment information.
 - You will be completing the purchase.
- If asked for a contact email, please use the following email address:
TPDassessment@icf.com
- Please use your own payment details; you will be reimbursed for the purchase.
- Please have the product shipped to your address and use your real name / other information
-
- **Age information:**
 - You will be doing this exercise as someone who is of age. Please use your real date of birth if requested.
 - You will be doing this exercise pretending to be underage. Please use the following date of birth if requested: 01 January 2003.
-
- **Product information:**
 - This exercise will be for a **tobacco product**: please attempt to purchase the cheapest available quantity of traditional cigarettes. If no cigarettes
 - This exercise will be for an **e-cigarette**: please attempt to purchase:
 - Option A: cheapest available disposable nicotine e-cigarette
 - Option B (if A not available): cheapest available "starter kit"
-
- **Please take screenshots of all pages and notices you encounter. If you are completing a purchase, please take pictures of all packaging and the product.**

Q.	Question	Response options
Section A: Background questions		
	<ul style="list-style-type: none"> Please insert the date and time at which the mystery shopping task was performed 	<ul style="list-style-type: none"> •
	<ul style="list-style-type: none"> Section B: Age verification • • We are interested in determining if there is an age-verification system in place when purchasing tobacco or related products online. Age-verification is mandatory by law (TPD article 18(4)). • • All researchers: please refer to the instruction email as to which product your purchase attempt should be for. • • If you were asked to purchase a tobacco product, please attempt to purchase the cheapest available quantity of traditional cigarettes. • • If you were asked to purchase an e-cigarette, please attempt to purchase: <ul style="list-style-type: none"> - Option A: cheapest available disposable nicotine e-cigarette - Option B (if A not available): cheapest available "starter kit" • • Please find the required item and attempt the purchase (put the item in the cart and proceed with the purchase until the stage of entering payment information) • • Please take screenshots of all age verification notices or tick boxes you are presented with. 	
	<ul style="list-style-type: none"> Did you encounter any age verification checks during your exercise? 	<ul style="list-style-type: none"> • <input type="checkbox"/> Yes • <input type="checkbox"/> No •
	<ul style="list-style-type: none"> If yes, what were the age verification check(s)? Please select all that you encountered. 	<ul style="list-style-type: none"> • <input type="checkbox"/> Age warning on home page • <input type="checkbox"/> User clicks check box or button e.g. "I am over 18 years old" • <input type="checkbox"/> Date of birth requested without ID • <input type="checkbox"/> Date of birth requested with ID • <input type="checkbox"/> Driver's license number requested • <input type="checkbox"/> Site claims that age will be verified at delivery • <input type="checkbox"/> Site claims that age will be verified at delivery • <input type="checkbox"/> Other (please elaborate)

	<ul style="list-style-type: none"> If yes, at what stage of the process was the age verification conducted? 	<ul style="list-style-type: none"> <input type="checkbox"/> When entering the vendor's website <input type="checkbox"/> When adding items to the cart <input type="checkbox"/> When purchasing the items <input type="checkbox"/> After purchasing the items, for example by email <input type="checkbox"/> Other (please elaborate)
<p>If you are doing this exercise pretending to be underage, please select the date of birth 01 January 2003 (of requested)</p>		
	<ul style="list-style-type: none"> When you acted as if you are underage, what happened? 	<ul style="list-style-type: none"> <input type="checkbox"/> Prevented from using website <input type="checkbox"/> Allowed to continue using website but prevented from the purchase attempt <input type="checkbox"/> Allowed to continue using website and allowed to do purchase attempt <input type="checkbox"/> Other Please elaborate
<ul style="list-style-type: none"> Section C: Purchase <i>If in the instruction email you were asked to actually purchase an item, please do so.</i> <i>This section asks about if there were any issues encountered in actually making the purchase.</i> Please take screenshots of all pages encountered while purchasing. 		
	<ul style="list-style-type: none"> Were you able to finalise the purchase? 	<ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A: not purchasing
	<ul style="list-style-type: none"> Did you encounter any additional problems during this stage? 	<ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A: not purchasing Please elaborate.
<ul style="list-style-type: none"> Section D: Post-purchase and delivery of products <i>This section asks about what happened after you purchased the products.</i> 		
	<ul style="list-style-type: none"> After the purchase was made, did you receive any follow up email asking for any additional type of information? 	<ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No Please elaborate.
	<ul style="list-style-type: none"> Did you receive the goods? 	<ul style="list-style-type: none"> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not yet, but I have received a confirmation

	<ul style="list-style-type: none"> • How long did it take the goods to arrive (in days) after you purchased them? 	<ul style="list-style-type: none"> •
	<ul style="list-style-type: none"> • What delivery company did it arrive from? 	<ul style="list-style-type: none"> •
	<ul style="list-style-type: none"> • Who received the package? 	<ul style="list-style-type: none"> • <input type="checkbox"/> Me • <input type="checkbox"/> Someone else, who is over 18 years old • <input type="checkbox"/> Someone else, who is under 18 years old • <input type="checkbox"/> Other (please elaborate)
	<ul style="list-style-type: none"> • Please enter the address and name the package was sent from (return address). Does this match the vendor you purchased the product from? 	<ul style="list-style-type: none"> • Please enter the name and address. • • <input type="checkbox"/> Yes: This matches the vendor. • <input type="checkbox"/> No: This does not match the vendor. •
14	<ul style="list-style-type: none"> • When packages were delivered, did you experience any age-verification attempts? 	<ul style="list-style-type: none"> • <input type="checkbox"/> Yes • <input type="checkbox"/> No • Please elaborate.
15	<ul style="list-style-type: none"> • Did the item that arrived match the product you ordered? 	<ul style="list-style-type: none"> • <input type="checkbox"/> Yes • <input type="checkbox"/> No (please elaborate) •
<p><i>After you have received the product and documented all of the above information, please destroy the product by removing any lithium batteries and disposing of them in local recycling centres, and disposing of the other product components in domestic bins.</i></p>		
16	<ul style="list-style-type: none"> • Please tick here to verify that the product was destroyed, as stated above 	<ul style="list-style-type: none"> • <input type="checkbox"/> I destroyed the product by removing any lithium batteries and disposing of them in local recycling centres, and disposing of the other product components in domestic bins.
<p>• Section E: Consumer perception</p> <p><i>This section will focus on your final thoughts and experiences as a consumer.</i></p>		
17	<p>Please provide any additional information you may deem necessary in order to qualify this mystery shopping test.</p>	<ul style="list-style-type: none"> •
	<p>Please upload all relevant screenshots.</p>	<ul style="list-style-type: none"> •

Annex 11 Market developments, public health and perception information of HTPs

This annex presents more detailed information on market developments, health effects and perception of HTPs, which has not been included in the main body of the report. Also see Annexes 3 and 6 for further information on market developments, public health, and perception information on HTPs.

There is some evidence in the literature reviewed that there has been a consolidation of the HTPs market, favouring larger players in the tobacco landscape. For example, in 2016-2017, large tobacco companies acquired smaller companies specialising in HTPs and launched new lines of HTPs⁸²⁸. This market consolidation had been anticipated by some private industry stakeholders as a potential impact of TPD measures around e-cigarettes and HTPs as they hypothesised that the TPD would increase manufacturing and importing costs and this would cause smaller businesses to leave the market⁸²⁹.

However, it is unclear whether the actual consolidation occurred as a result of the TPD. In addition, the TPD may not have been fully contributing to facilitation of the internal market of HTPs, primarily due to the ambiguity in the classification of HTPs.

Market development of HTPs share and trends including their usage

Academic literature and grey literature were reviewed to assess market shares and trends of novel tobacco products, assessment of implementation of related provisions, and their impact on the internal market. Most novel tobacco products referenced in the literature and the consultation activities were HTPs.

HTPs have a particular significance in the EU. Phillip Morris's IQOs system was launched in Italy in 2014. The study on consumer preference and perception⁸³⁰ reported from expert interviews that HTP appeal to tobacco users because the product is associated with cleanliness, exclusivity and high-tech appearance.

By 2017, one brand of HTPs was commercially available in 30 countries with launches planned in additional countries⁸³¹. In 2018, HTPs were available in 39 countries, including 29 from the WHO European region. Within the EU, this brand of HTP is the market leader and it is present in 19 Member States^{832,833}. As of February 2020, the product was available in 20 MS including the relatively large market of IT, RO, EL, ES, PT, SK, PL⁸³⁴. For example, in Italy, sales grew rapidly between 2015-2017, and sales of heated tobacco sticks intended for use with the HTP also increased⁸³⁵.

Furthermore, data from Euromonitor suggests that between 2017 and 2019, the market size of HTPs in the EU increased from €0.5 billion to €2.7 billion, as HTPs became available in a wider selection of countries. Between 2017-18 the market grew by 208%, and by 77% between 2018-19. This indicates that although the market for HTPs is still growing at the EU level, the rate of growth is slowing down.

⁸²⁸ Mathers, A., Hawkins, B., & Lee, K. (2019). Transnational Tobacco Companies and New Nicotine Delivery Systems. *American Journal of Public Health*: 109(2).

⁸²⁹ IFF Research. (2016). Understanding the Online E-cigarette market. HM Revenue and Customs.

⁸³⁰ European Commission (2020) Consumer preference and perception of specific categories of tobacco and related products.

⁸³¹ Simonavicius, E., McNeill, A., Shahab, L., et al. (2019). Heat-not-burn tobacco products: a systematic literature review. *Tobacco Control*: 28, 582-594.

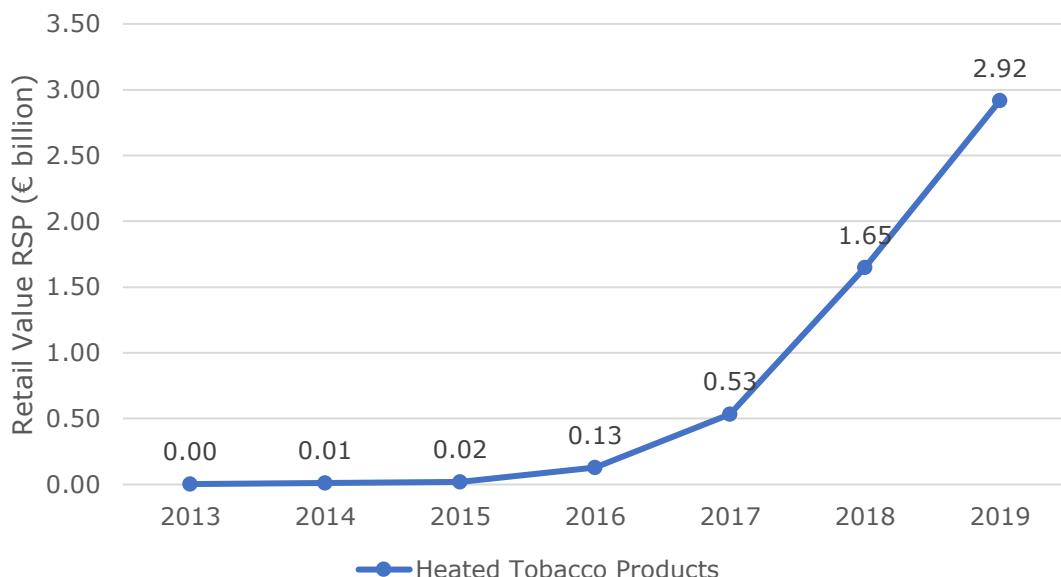
⁸³² ENSP. (2018b). ENSP Fact Sheet: On heated tobacco products. ENSP.

⁸³³ 19 Member States: BG, HR, CY, CZ, DK, FR, DE, EL, IT, LV, LT, NL, PL, PT, RO, SK, SI, ES, UK.

⁸³⁴ Phillip Morris International (2020) <https://www.pmi.com/smoke-free-products/iQOS-our-tobacco-heating-system>, as of February 2020 as cited in European Commission (2020) Consumer preference and perception of specific categories of tobacco and related products.

⁸³⁵ ENSP. (2018b). ENSP Fact Sheet: On heated tobacco products. ENSP.

Figure 62. Market size for heated tobacco products 2013-19 (€ billion)



Source: Euromonitor International; Tobacco Industry Edition, 2021 (ICF calculations)

In 2019, Italy had the largest market for heated tobacco⁸³⁶, recording a retail volume of over 3 billion sticks⁸³⁷.

According to Euromonitor data, between 2013 and 2019 the only products to experience increases in the market size in retail volume⁸³⁸ were HTPs (heated tobacco, tobacco heated devices)⁸³⁹.

In the most recent (2020) wave of the Eurobarometer survey⁸⁴⁰, 6% of respondents had at least tried HTPs. Respondents in Czechia (15%) and Latvia (14%) are the most likely to have at least tried HTPs.

Health effects

The most recent systematic review of HTPs, conducted in 2019, found that such products **expose users and bystanders to substantially fewer harmful and potentially harmful compounds than traditional cigarettes**, although there was a **lack of**

⁸³⁶ This comment refers to heated tobacco, which is a category of product under the umbrella of heated tobacco products. Heated tobacco products consist of heated tobacco and tobacco heating devices. Heated tobacco is the consumable element of tobacco vapour products. Tobacco Heating Devices refer to the any piece of technology or equipment which allow the consumer to heat rather than combust a tobacco product.

⁸³⁷ Italy was followed by Romania (1.8 billion sticks), Poland (1.1 billion sticks), and Czechia (1.1 billion sticks). Between 2017-19, the highest growth in the retail volume of heated tobacco was observed in Germany (increase from 26.7 million sticks in 2017 to 901 million in 2019), Slovenia (5 million sticks in 2017 to 111 million in 2019) and Poland (83.4 million sticks in 2017 to 1.2 billion in 2019). Within the countries for which data was available (see. Annex 6), between 2017 and 2019 the prevalence of use of HTPs increased from 0.2% to 0.72% of the adult population.

⁸³⁸ Measured as the sale of tobacco and related products by unit volume in 25 EU MS (excluding MT, LU, CY). More information about the units used to determine the retail volume of different products is available in Annex 7.

⁸³⁹ No data on retail volumes were available for e-cigarettes

⁸⁴⁰ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240> ; see Annex 3 for further information.

evidence on the long-term health effects of HTPs⁸⁴¹. In this review, 20 of the 31 included studies were affiliated with tobacco industry funding, although findings were similar across industry-funded and independent studies⁸⁴². The findings echo those of a previously published 2018 Public Health England review of both e-cigarettes and HTPs which found that HTPs were most likely **less harmful than cigarettes, but more harmful than e-cigarettes**, although more than half of the 20 studies included were funded by manufacturing companies of tobacco products⁸⁴³.

There is increasing concern that the tobacco industry is appropriating public health harm minimisation approaches to promote the use of HTPs, along with e-cigarettes, by marketing them as a less harmful and a safer alternative to conventional tobacco products without sufficient evidence^{844,845,846}.

Although HTPs do appear to produce lower levels of some toxicants compared to cigarette smoke⁸⁴⁷, research on whether HTPs use results in a lower or higher level of adverse health effects compared to smoking cigarettes is currently inconclusive, requiring longer-term studies in human subjects than conducted to date and assessment of impacts on smoking cessation, morbidity and mortality^{848,849,850}.

The World Health Organisation has recommended that given available evidence that HTPs do produce side-stream emissions that may have irritating effects for bystanders and contain harmful toxicants and particles, no exposure to 'second-hand' HTP emissions be regarded as safe⁸⁵¹. Additionally, the WHO FCTC strongly argued that the World Customs Organization's 2022 Harmonized System should classify HTPs (and electronic non-nicotine delivery systems, or ENNDS) as tobacco products to facilitate application of tobacco control laws, but should allocate them to a category separate from nicotine replacement therapies that are used only in a medicinal context⁸⁵².

The European Respiratory Society has highlighted in a position paper the potentially harmful effects of HTPs, particularly in light of the influence of industry over research in this area and their promotion of HTPs as potentially safer than traditional cigarettes

⁸⁴¹ Simonavicius, E., McNeill, A., Shahab, L., Brose, L.S. (2019). Heat-not-burn tobacco products: a systematic literature review. *Tobacco Control*: 28, 582-594

⁸⁴² Simonavicius, E., McNeill, A., Shahab, L., Brose, L.S. (2019). Heat-not-burn tobacco products: a systematic literature review. *Tobacco Control*: 28, 582-594

⁸⁴³ McNeill, A., Brose, L.S., Calder, R., Bauld, L., Robson, D. (2018). Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England. London: Public Health England.

⁸⁴⁴ Dewhirst T. (2020) Co-optation of harm reduction by Big Tobacco. *Tobacco Control*. (online ahead of print; doi:10.1136/tobaccocontrol-2020-056059).

⁸⁴⁵ Hendlin YH, Vora M, Elias J, Ling PM. (2019) Financial conflicts of interest and stance on tobacco harm reduction: A systematic review. *Am J Public Health*, 109(7):E1–8.

⁸⁴⁶ Gruszczynski, L., Melillo, M. (2020) The FCTC dilemma on heated tobacco products. *Global Health* 16:81.

⁸⁴⁷ World Health Organisation (2020) Heated Tobacco Products: A Brief. Copenhagen: World Health Organisation.

⁸⁴⁸ Mallock N, Pieper E, Hutzler C, Henkler-Stephani F, Luch A. (2019) Heated Tobacco Products: A Review of Current Knowledge and Initial Assessments. *Frontiers in Public Health*. 7(October):1–8.

⁸⁴⁹ Jankowski M, Brożek GM, Lawson J, Skoczyński S, Majek P, Zejda JE. (2019) New ideas, old problems? Heated tobacco products – A systematic review. *International Journal of Occupational Medicine and Environmental Health*, 32(5):595–634.

⁸⁵⁰ Gruszczynski, L., Melillo, M. (2020) The FCTC dilemma on heated tobacco products. *Global Health* 16:81.

⁸⁵¹ World Health Organisation (2020) Heated Tobacco Products: A Brief. Copenhagen: World Health Organisation.

⁸⁵² Secretariat of the WHO Framework Convention on Tobacco Control (2019) Information note on classification of novel and emerging tobacco products. Geneva: WHO FCTC.

without adequate impartial evidence to suggest this⁸⁵³. The European Respiratory Society has also written a related position paper about tobacco harm reduction which claims that alternative nicotine delivery products are not effective as a tool for reducing smoking, as they are based on "incorrect assumptions" and "undocumented claims" about their safety and effectiveness⁸⁵⁴. This position was determined based on the high level of harmful or potentially harmful substances emitted by HTPs as compared to traditional cigarettes^{855,856}, as well as lack of longitudinal evidence that they are an effective smoking cessation aid and some evidence that there is no improved lung function and that there are similar biomarkers of potential harm in those that switch from smoking to HTPs⁸⁵⁷.

Attractiveness

Some evidence suggests that novel tobacco products may attract those who would otherwise not initiate smoking. For example, in Italy a survey found that in absolute numbers, there are a similar number of never smokers and smokers that have tried IQOS's HTPs⁸⁵⁸, although the study did not include a measure of whether these never smokers would have taken up smoking in the absence of IQOS. The perception study provided data on why young consumers (18-25) started smoking HTPs. According to this study 20% of this population started smoking HTPs, because it was trendy to socialize. Also 20% of the group started smoking HTPs because of tobacco advertising. Those percentages drop to 17 and 18% respectively⁸⁵⁹.

Similarly, in the recent consumer preference and perception study also highlighted the **reasons for initiation** in of using HTPs among young people. In the 18-25 age group the main reasons were 'enjoyment' at 33%, 'trying to quit or reduce consumption of another tobacco product' 29%, with 'to socialise/it was trendy' and 'tobacco advertisements' both 20%. Among the 26+ age group 'trying to quit or reduce consumption of another tobacco product' at 41% was the dominant reason, followed by 'enjoyment' 34%, 'tobacco advertisements' 18% and 'to socialise/it was trendy' 17%. This study showed that while HTPs have been advertised as a tool to reduce or quit other tobacco products, it was clear from the survey that the actual use of the product did not reflect this purpose, with extensive parallel use of HTPs with other tobacco and related products across all consumer groups⁸⁶⁰.

The same study showed that 70% of respondents form the 18-25 group and 66% from the 26+ group reported that the HTP are attractive to young people. Additionally, 77%

⁸⁵³ Pisinger, C. et al. on behalf of the ERS Tobacco Control Committee. (n.d.) ERS position paper on heated tobacco products. European Respiratory Society.

⁸⁵⁴ The ERS Tobacco Control Committee. (2019). ERS Position Paper on Tobacco Harm Reduction. European Respiratory Society.

⁸⁵⁵ St Helen G, Jacob III P, Nardone N, et al. (2018). IQOS: examination of Philip Morris International's claim of reduced exposure. *Tob Control* 2018;27(Suppl 1):s30-s36. doi: 10.1136/tobaccocontrol-2018-054321

⁸⁵⁶ Auer R, Concha-Lozano N, Jacot-Sadowski I, et al. (2017). Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name. *JAMA internal medicine* 2017;177(7):1050-52. doi: 10.1001/jamainternmed.2017.1419

⁸⁵⁷ Glantz SA. (2018). PMI's own in vivo clinical data on biomarkers of potential harm in Americans show that IQOS is not detectably different from conventional cigarettes. *Tob Control* 2018 doi: 10.1136/tobaccocontrol-2018-054413

⁸⁵⁸ Liu X., Lugo A., Spizzichino L., et al. (2018). Heat-not-burn tobacco products: concerns from the Italian experience. *Tobacco Control*: 28, 113-114

⁸⁵⁹ European Commission (2020) Consumer preference and perception of specific categories of tobacco and related products

⁸⁶⁰ EU Commission (2020) Consumer preference and perception of specific categories of tobacco and related products.

from the 18-25 and 76% from the 26+ age groups considered that young people might underestimate the risk of consuming HTPs⁸⁶¹.

According to the WHO, tobacco companies have employed non-traditional marketing and product distribution strategies to the latest generation of HTPs to attract customers and increase sales, for example attempts to reduce consumer health concerns through claims that HTPs are reduced-risk products. In addition, tobacco companies pursued advertising by acknowledging the health risks of traditional cigarettes and describing the new products as cleaner alternatives, shifting the tobacco companies' corporate image towards promoting alternative tobacco products⁸⁶². HTPs may be considered only to less than half of young consumers to be harmful to health⁸⁶³.

In the most recent (2020) wave of the Eurobarometer survey⁸⁶⁴, among those with no or hardly no experience with them, only **7%** said they find HTPs appealing. Of all Eurobarometer respondents, 61% said they think that they are **think that they are harmful to the health** of those who use them. However, **41%** of the HTP users started using it because they believed they are **less harmful than smoking tobacco products.**

⁸⁶¹ Ibid.

⁸⁶² https://www.who.int/tobacco/publications/prod_regulation/htps-marketing-monitoring/en/

⁸⁶³ European Commission (2020) Consumer preference and perception of specific categories of tobacco and related products

⁸⁶⁴ DG SANTE. (2021). Special Eurobarometer 506: Attitudes of Europeans towards tobacco and electronic cigarettes. Available at: <https://europa.eu/eurobarometer/surveys/detail/2240>

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