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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products

1. Introduction

The Tobacco Products Directive[1] ('the Directive' or 'TPD'), applicable since May 2016, aims at facilitating the smooth functioning of the internal market, protecting people's health, particularly the youth, and meeting the obligations of the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC). Under Article 28(1) of the TPD, the Commission must submit a report on the Directive's application[2] by 20 May 2021. The report must discuss, specifically, the elements of the Directive that should be reviewed given scientific and technical developments, including internationally agreed rules and standards on tobacco and related products.

The TPD has aimed to reduce tobacco consumption by 2% within five years of its transposition[3]. Based on the latest Eurobarometer[4], smoking prevalence among those aged 15+ fell from 26% in 2014 to 23% in 2020 – a drop[5] of 3 percentage points since the TPD came into force, equivalent to 12.5%. Youth smoking rates fell to 20% in 2020 from 25% in 2014, after peaking at 29% in 2017. However, the uptake of emerging products, especially e-cigarettes, is growing among young people[6]. This is worrying given the aim to protect the youth.

Significant developments since the Directive came into force have given new urgency and impetus to tobacco control work. At international level, the Sustainable Development Agenda called on all countries to implement the FCTC more robustly. At EU level, the 2021 Europe's Beating Cancer Plan places tobacco control at the spotlight of disease prevention efforts to help achieve a tobacco-free Europe by 2040. The intermediate objective is to reach the WHO target of a 30% relative reduction in tobacco use by 2025 as compared to 2010[7], translating into an EU smoking prevalence rate of around 20% by 2025 compared to 29% in 2010. To meet these ambitions, tobacco control efforts must be stepped up, including strengthening rules on tobacco products.

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[1] Directive 2014/40/EU.

[2] Despite leaving the EU and with the transition period ending on 31 December 2020, the UK is still considered and referred to as a Member State for the purposes of this report. This is done so that trends can be appropriately assessed given the targets specified in the impact assessment accompanying the TPD's revision. Moreover, the TPD will continue to apply in Northern Ireland after 2020.

[3] TPD impact assessment: https://ec.europa.eu/health/sites/health/files/tobacco/docs/com_2012_788_summary_ia_en.pdf

[4] Unless stated otherwise, all prevalence and use data were obtained from Special Eurobarometer 506 – Attitudes of Europeans towards tobacco and electronic cigarettes (Eurobarometer 2020).

[5] Mainly due to the male prevalence rate falling, from 30% to 26%, while for females this rate only fell slightly from 22% to 21%.

[6] LSE & Open Evidence, Consumer preference and perception of specific categories of tobacco and related products, 2020 (LSE 2020).

[7] The target was established under the Global action plan for the prevention and control of NCDs 2013-2020.

2. Transposition, application and enforcement (Articles 2, 23 and 24)

2.1. Compliance assessment (transposition and conformity checks)

Since the Directive entered into force, the Commission adopted 10 implementing acts[8], 2 delegated acts[9] and 2 Commission reports[10] allowing for all the Directive's provisions to be fully and timely implemented. Member States were required to bring into force the laws, regulations and administrative provisions to transpose the TPD by 20 May 2016, and provide the Commission with the text of these provisions. A large number of Member States did not transpose the Directive in time and in July 2016, the Commission launched 18 infringement proceedings based on late or incomplete notification of national transposition measures. The Member States in question subsequently communicated such measures and the Commission closed all these cases by 2020.

The Commission has been systematically assessing the conformity of national provisions with the Directive on the basis of six priority areas[11]. This conformity check is ongoing and has been completed for a first group of Member States. While scrutinising these provisions, the Commission found deficiencies and variations in the Directive's transposition, most importantly related to certain definitions[12], to provisions in the areas of ingredients and emissions, labelling and packaging, novel tobacco products, e-cigarettes and the traceability and security features systems. The Commission is holding structured bilateral dialogues with Member States to ensure conformity. As several of the Directive's provisions are complex, there is still a risk that their interpretation and practical implementation may lead to different outcomes across Member States.

2.2. Application and enforcement

In 2014, the Commission established a group of experts on tobacco policy[13] (the 'Expert Group'), composed of Member State representatives to provide expertise and help Member States and the Commission cooperate on tobacco control policies and legislation. Furthermore, in line with Article 26 of the Directive, the Commission published a list of competent authorities[14] designated by Member States to implement and enforce the Directive. Discussions in the Expert Group meetings and bilateral contacts in the context of conformity checks revealed that enforcement activities are rather limited in several Member States. The levels of enforcement, control and sanctions vary considerably across the EU. Not all Member States had the capacity or resources to ensure that only compliant products were placed on the market[15]. Moreover, despite Member

[8] Commission Implementing Decision (EU) 2015/2186; Commission Implementing Decision (EU) 2016/787; Commission Implementing Regulation (EU) 2016/779; Commission Implementing Decision (EU) 2016/786; Commission Implementing Decision (EU) 2015/1735; Commission Implementing Decision (EU) 2015/1842; Commission Implementing Regulation (EU) 2018/574; Commission Implementing Decision (EU) 2018/576; Commission Implementing Decision (EU) 2015/2183; Commission Implementing Decision (EU) 2016/586.
[9] Commission Delegated Directive 2014/109/EU; Commission Delegated Regulation (EU) 2018/573.
[10] COM/2016/0269 final; COM/2018/579 final.
[11] Ingredients, labelling and packaging, novel tobacco products, electronic cigarettes, oral tobacco (snus) and traceability and security features.
[12] Some definitions could be improved, for instance novel tobacco products, additive, flavouring/flavour, characterising flavour, nicotine, chewing, nasal and oral tobacco, herbal product for smoking, e-cigarette, cross-border distance sales. Furthermore, the following issues are important: eliminating combined categories (smokeless); creating new product categories (e.g. heated tobacco products, nicotine products); and including devices used with certain products (e.g. heated tobacco products).
[13] Commission Decision C(2014) 3509 setting up the group of experts on tobacco policy.
[14] OJ C 136, 12.4.2019, p. 13.
[15] Support Study to the report on the application of the Directive 2014/40/EU (ICF 2021).

States` efforts to agree on a common approach, several of the Directive's provisions are not applied in a harmonised manner.

The Directive has a specific provision on cooperation among Member States' enforcement authorities. Feedback from discussions in the Expert Group meetings shows that Member States are willing to have a forum, which so far met once in June 2019, to exchange information and share best practices on enforcing the Directive.

2.3. Court cases[16]

Since entering into force the Directive has endured several legal challenges. In 2016, the European Court of Justice upheld its validity and that of several of its provisions, and in 2019, dismissed an action to annul delegated and implementing acts on the traceability systems and security features for tobacco products. The Court also rendered judgements on the prohibition of tobacco for oral use, the classification of chewing tobacco products and prohibition in stages of flavoured products and the relevant labelling provisions. Several court cases addressed unfounded claims about the library of pictorial health warnings. The latter have also endured national court procedures where such claims were dismissed. About half of Member States reported national court cases related to the Directive's enforcement.

2.4. Notifications (including under Articles 24(2) and 24(3))

Several Member States exercised their right under Articles 24(2) and 24(3) to maintain or introduce further requirements than those laid down in the Directive. By the time of drafting this report, eight Member States notified to the Commission national requirements on standardising the packaging of tobacco and related products justified on public health grounds, together with the grounds for introducing them. The Commission also approved national measures banning a certain category of tobacco products notified by three Member States under Article 24(3)[17]. In addition, Member States continuously notify their national laws on tobacco control to the Commission, including those covering areas not harmonised by the Directive (e.g. bans on flavours in e-cigarettes, rules on nicotine-free e-cigarettes, smoke-free environments, age limits) under the procedure established by Directive 2015/1535/EU[18]. Following the assessment, the Commission, when needed, acts to ensure the Directive is correctly implemented.

2.5. Conclusions on transposition, application and enforcement

The European Court of Justice has upheld the Directive's validity and that of several of its key provisions and addressed questions about its interpretation. The experience gained in the compliance assessments of the national transposition measures suggests that there is some variation in the transposition of the Directive's provisions into national law. Therefore, various options to streamline the legislative framework should be explored. A number of definitions may also need to be adapted. The level of enforcement varies considerably among Member States and the lack of a legal basis for EU-level audits limits the Commission's ability to get an accurate overview of Member States' implementation and enforcement activities.

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[16] https://ec.europa.eu/health/tobacco/key_documents_en#anchor3

[17] See notifications under Article 24(3) of the Directive: https://ec.europa.eu/health/tobacco/products/notifications_en

[18] For the description of the process see: https://ec.europa.eu/growth/tools-databases/tris/en/about-the-20151535/the-notification-procedure-in-brief1/

3. Ingredients and emissions (Articles 3-7)

3.1. Emissions and measurement methods (Articles 3 and 4)

The TPD sets maximum emission levels for tar, nicotine and carbon monoxide (TNCO), to be measured using ISO methods. Articles 4(3) and 4(5) empower the Commission to adapt the methods for measuring TNCO based on scientific and technical developments or internationally agreed standards, and integrate standards agreed by the FCTC or by the WHO into EU law.

Discussions on TNCO measurement methods were held in international fora, including the FCTC[19], concerning mostly ISO methods and the Canadian Intense Smoking Regime[20]. It was agreed that no current smoking regime adequately represents human smoking behaviour[21]. Since then there have been no new scientific and technical developments that warrant a change to the method prescribed.

In the EU, laboratories approved by Member States' competent authorities should monitor and verify TNCO measurements. The Commission published the list of such laboratories[22]. Except for one, no Member State has set any emission limits apart from TNCO for cigarettes, nor mandated any additional measurement methods.

3.2. Reporting of ingredients and emissions (Article 5)

The Commission developed the EU Common Entry Gate (EU-CEG) system to facilitate the reporting in electronic format of the information on ingredients and emissions required under Article 5. Overall, the EU-CEG system has operated smoothly and fulfilled its core objectives as a data repository[23], while reducing the administrative burden for manufacturers, importers and national regulators. The Commission set up a Joint Action on Tobacco Control[24] to further help Member States analyse and publish EU-CEG data on ingredients and emissions. The Joint Action helped Member States to make information publicly available online, as required under Article 5(4). The publication process was difficult, partly due to some submitters misusing the confidentiality tag.

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[19] Within the FCTC, the Working Group on Articles 9&10 (Regulation of the contents and disclosures of tobacco products) in which the EU is a key facilitator, looked at the methods. Such methods were also further developed by the WHO Tobacco Laboratory Network (TobLabNet). However, there has been no consensus among the FCTC Parties to approve any of the emission measurement methods for inclusion into the relevant FCTC guidelines.

[20] For TNCO measurement, the International Organization for Standardization (ISO 3308) smoking regime (puff volume 35 mL, puff duration 2s, puff interval 60s) and Health Canada Intense (HCI) smoking regime (puff volume 55 mL, puff duration 2s, puff interval 30s) are the two approaches usually applied. Due to the different parameters used, higher quantities of tar, nicotine and CO are systematically measured in the HCI regime (with 110ml of puff volume captured per minute) compared to the ISO method (with 35ml of puff volume captured per minute).

[21] One of the elements influencing the real individual exposure of smokers is filter ventilation, a technical feature designed to dilute the inhaled smoke. This is because smokers, when smoking their cigarette, usually cover some of ventilation holes. In order to improve transparency about the characteristics of products on the EU-market, manufacturers and importers are required to report a set of cigarette-specific parameters which should be considered in conjunction with emission measurements when interpreting them: the total ventilation of the filter (0-100%), the drop of pressure with closed vents (mmH_2O) and the drop of pressure with open vents (mmH_2O). These data are available to the Member States for such analysis and should provide for unbiased product assessment without a need to modify the current TPD reference to the ISO methods.

[22] https://ec.europa.eu/health/sites/health/files/tobacco/docs/approved_laboratories_en.pdf

[23] So far, over 5 500 economic operators applied for a submitter ID. Almost 2400 submitted their products (over 42 000 tobacco and 300 000 e-cigarettes are active in EU-CEG at the moment).

[24] This Joint Action (http://jaotc.eu/) brought 25 Member States together to help implement the TPD; with a cost of EUR 2.5 m (the EU contributed 80%).

The EU-CEG system hosts a lot of valuable data and information. However, despite efforts via the Joint Action, Member States have so far seldom used it for enforcement and regulatory purposes. Moreover, the data are not complete for certain mandatory variables, e.g. sales data. EU-wide analysis, to look at the single market, is hindered by national 'ownership' of data, with some Member States unwilling to share their data. The EU-CEG is costly and resource intensive for the Commission. To date, only about half of the Member States have charged fees for handling information on ingredients under Article 5(8). Reference laboratories, established in several other policy areas, do not exist. The Joint Action improved the situation somewhat. Overall, however, most resources were still used for setting up and maintaining the data repository, in detriment of data analysis, research and policy development, which would allow the data to be used for meaningful action.

The practical experience of establishing the EU-CEG showed that creating an EU database with information on ingredients and emissions from tobacco products would be technically possible. However, given the constraints on Commission and Member States' resources[15] as well as the national ownership of data, such a database might be limited in added value without a robust and fee-funded European system for assessing ingredients (as per Article 28(2)(d)). Therefore, the required resources of an agency to implement any new tobacco ingredients-related tasks should be carefully assessed[25].

3.3. Priority list of additives and enhanced reporting obligations (Article 6)

Under Article 6(1), the Commission adopted a Decision[26], establishing a priority list of 15 additives, selected on the basis of the SCENIHR scientific opinion[27]. This opinion considered available data which suggested that an additive may i) contribute to toxic, addictive or carcinogenic, mutagenic or reprotoxic properties of cigarettes and roll-your-own (RYO) tobacco, ii) may result in a characterising flavour, or iii) may facilitate inhalation or nicotine uptake.

Some 12 major manufacturers worked jointly within an ad hoc industry consortium and submitted the reports for 14 priority additives within the legal deadline. For one priority additive – diacetyl – the original deadline was not met. Several Member States have taken additional action to ensure compliance. The Joint Action peer-reviewed the reports and noted several deficiencies[28] which – as specifically requested by Member States – the Commission communicated to industry. While industry provided certain clarifications, Member States could not confirm that any chemical substance studied would not contribute to the harmful effect of tobacco use. Overall, the experience with applying Article 6 shows that the reports submitted provided little actionable information while requiring the Commission and Member States to invest considerable resources into reviewing them.

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

[25] See also Europe's Beating Cancer Plan p.9.

[26] Commission Implementing Decision (EU) 2016/787.

[27] SCENIHR: *Additives used in tobacco products*. 25 January 2016: http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en.htm

[28] These deficiencies related to specific aspects listed in Articles 6(2) and 6(3), and to the comprehensiveness, methodology and conclusions of the studies conducted (Art.6 (4)).

structured and permanent mechanism for assessing ingredients would be needed, taking into account their chemical and physical properties when both burnt and unburnt, including effects of the emissions when not burnt.

3.4. Regulation of ingredients (Article 7)

From May 2016, the TPD prohibits cigarettes and RYO tobacco with characterising flavours from being placed on the market. A four-year phase-out period had been agreed by the co-legislators for products with characterising flavours with a significant market share (i.e. menthol). So, from May 2020, there are no more exemptions. While there is no reported issue with compliance for characterising candy or fruit flavours, recent developments suggest less compliance with the menthol ban. The exemption for tobacco products other than cigarettes and RYO tobacco must be withdrawn if a 'substantial change of circumstances' can be established (see section 10).

The Commission invested substantial effort and resources into establishing and running the advisory mechanism to help decide whether or not a tobacco product has a characterising flavour. This mechanism comprises the Independent Advisory Panel (IAP) on characterising flavours in tobacco products, which has the format of a Commission expert group, and the Technical Group of Sensory and Chemical Assessors, established via public procurement. In practice, implementing the ban on characterising flavours has proven resource-intensive and cumbersome, while the Member States and the Commission have limited resources. Several Member States have also banned certain additives in line with Article 7(6).

3.5. Conclusions on ingredients and emissions

Overall, the Member States and the Commission have put a lot of effort and resources into implementing Articles 3-7. However, the effective added value for human health and the efficiency of certain provisions is negligible. While the set-ups of the main system – the EU-CEG and the Independent Advisory Panel – are fully operational and functional, they are very labour-intensive and neither the Commission nor Member States currently have sufficient resources to use them optimally. It is therefore suggested to study, how the harmonised EU level assessment of ingredients and products, including the EU-CEG information, can be improved and organised in a more robust and effective way.

The work on priority additives provided little actionable information so far and its usefulness should be reviewed. The discussion around the machine measurement methods is still inconclusive.

4. Labelling and packaging (Articles 8-14)

4.1. General warnings, information messages and combined health warnings (Articles 8-12)

The Directive introduces requirements for mandatory health warnings on tobacco and related products, including combined health warnings for tobacco products for smoking. The Commission adopted two implementing acts to specify where health warnings are to be placed on pouches of RYO tobacco[29], and to specify the layout, design and shape of the combined health warnings[30].

[29] Commission Implementing Decision (EU) 2015/1735.
[30] Commission Implementing Decision (EU) 2015/1842.

The Commission also developed the library of picture warnings included in Annex II of the Directive[31]. Harmonising labelling and packaging rules were a key success of the TPD as it standardised packaging across the internal market.

Compulsory combined health warnings covering 65% of the front and back surfaces of tobacco packs was an important improvement of labelling measures compared to the Directive 2001/37/EC[32]. These have been effective in increasing public awareness of the harmful effects of tobacco products, and they could be associated with a decrease in tobacco consumption[15].

Complaints were received from people claiming that they or their relatives appeared in pictures without their consent, including hundreds of letters and several court proceedings[33]. All of these claims were proven to be manifestly unfounded.

Based on the information of the Commission, Member States appear to be largely applying labelling rules properly, with some exceptions as outlined below.

While harmonised labelling provisions are key example of those TPD provisions that have helped improve the internal market's functioning, a number of implementation challenges were reported[15]. Article 9(3) provisions on the minimum dimensions of lateral health warnings – which translate into a ban[34] on slim cuboid packages less than 20 mm deep – were applied variably. There were also questions about the calculation of the surface area for health warnings on bevelled or rounded packs in line with Recital 28[35], and varying degrees of compliance EU-wide. A few Member States made suggestions[15] about incorporating provisions on bevelled edges into the Directive's text, or banning packs with bevelled edges altogether.

Article 11(1) allows Member States to exempt tobacco products for smoking other than cigarettes, RYO tobacco and waterpipe tobacco from carrying the information message and the combined health warnings. They still need a label with a text warning and the general warning, and a reference to cessation services. To date, about half of Member States reported exemptions allowed through Article 11. Some criticised the exemption, pointing to industry pressure, and warned that consumers may view these exempted products as more attractive or less harmful[15]. Article 11(6) empowers the Commission to withdraw the possibility of exemptions if there is a substantial change of circumstances. However, the set of criteria for the 'substantial change of circumstances' clause laid down in Article 2(28) (see chapter 10) makes it very difficult to apply.

The Article 12 provisions on smokeless tobacco labelling were in most cases applied properly without any major issues reported.

[31] Commission Delegated Directive 2014/109/EU.

[32] Directive 2001/37/EC.

[33] See the reference under chapter 2.3.

[34] In 2017, the Commission explained to the Expert Group on Tobacco Policy, that it viewed Article 9(3) provisions as a ban on slim cuboid packages less than 20 mm deep.

[35] In 2015, DG SANTE presented a non-paper for discussion in the Expert Group on Tobacco Policy, clarifying its view of Recital 28 and of how bevelled or rounded edges should be considered in area calculations.

4.2. Product presentation, pack harmonisation and plain packaging (Articles 13, 14, 24(2))

Article 13 on product presentation provides for a broad ban on promotional elements. Many Member States had difficulties in interpreting and implementing Article 13 provisions, especially in clarifying the Article's scope, and in determining non-compliance. Product presentation is an area rife with non-compliance and attempts to circumvent the law, with legal challenges occurring in several Member States[15].

Article 14 provisions[36] on packaging are generally well understood and implemented.

Eight Member States exercised their right under Article 24(2) to go beyond the TPD's labelling provisions and introduced standardised packaging for tobacco products, i.e. **plain packaging**. These Member States notified these measures to the Commission, along with the grounds for introducing them, justified by public health considerations and they also proved that these measures are proportionate and do not constitute means of arbitrary discrimination. Based on evidence[15] from Member States, plain packaging along with pictorial warnings appear to increase awareness of tobacco related-diseases and associated illnesses, and the motivation to quit, and help to reduce smoking, including among young people. About half of Europeans are in favour of introducing 'plain packaging' for cigarettes[4]. These measures align with international developments, as plain packaging is the golden standard promoted by the WHO and the FCTC, and has been upheld as consistent with international trade law in a landmark WTO ruling[37]. Stricter regulation through plain packaging also helps with implementing product presentation provisions, namely a full ban on promotional elements. However, the introduction of plain packaging requirements only in some Member States can be an obstacle to free movement of goods. Moreover, formats of standardised packaging may differ between Member States, additionally distorting the internal market's smooth functioning.

4.3. **Conclusions on labelling and packaging**

Overall, labelling and packaging rules are applied properly across the EU. Those rules have led to – especially via enlarged combined health warnings – better awareness and understanding of the various product categories and health effects of tobacco use. Based on this success, the extent to which stronger labelling rules would work for all tobacco product categories should be examined. Some provisions on the packaging/appearance of unit packets should be further examined, particularly the size of warnings, the ban on promotional elements and on 'slim packages', and the bevelled edges.

Several Member States went beyond the TPD provisions and have successfully rolled out plain/standardised packaging. Therefore, plain packaging with larger health warnings should be also further examined.

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[36] In particular the requirement on the minimum content of unit packets of cigarettes (20 cigarettes) and roll-your-own tobacco (30 g).

[37] In June 2020, a landmark WTO ruling ended prolonged legal challenges against Australia's plain packaging law, confirming that plain packaging supports the objective of improving public health without restricting trade more than necessary, and that trademark restrictions arising from plain packaging are justified as they support the public health objective.

5. Traceability and security features (Articles 15 and 16)

Articles 15 and 16 provide for EU-wide systems of traceability and security features for tobacco products to address illicit trade. In December 2017, the Commission adopted legislation as regards technical details to establish the systems of traceability and security features for tobacco products[38]. The systems began operating in May 2019 within the deadline stipulated by the Directive. Since then, every newly manufactured or imported unit packet of cigarettes and RYO tobacco products have been marked with a unique identifier and bear a security feature. Since the stock exhaustion period ended in May 2020, non-traceable cigarettes and RYO tobacco products can no longer be traded. The systems will be expanded to cover all other tobacco products in May 2024.

5.1. Traceability

By the end of 2020, the EU traceability system collected information on 795 000 companies and 1 520 000 facilities handling tobacco products. The manufacturers and importers of cigarettes and RYO tobacco products received and applied 45 billion unique identifiers, generated by the ID issuers appointed by Member States. The system's central components, the secondary repository and the router, operated by Dentsu Aegis Network under a concession contract with the Commission, handled billions of messages on logistics and transactions in the supply chain.[39]

The EU traceability system was implemented with due regard to the WHO FCTC Protocol on Illicit Trade (ITP), in particular Article 8 thereof. The system's design fully complies with the ITP provisions. None of the ITP Party's formal obligations was delegated to the tobacco industry. Member States and the Commission control the system through a series of mutually reinforcing measures[40].

Altogether, Member States appointed 22 different entities to act as ID issuers, 17 being state-controlled entities, including national printing houses. There are also five private IT companies contracted by eight Member States. Both public and private entities have been fully integrated into the system and their different statuses have not affected its day-to-day operations.

By the end of 2020, the Commission had approved 46 data storage contracts for providing primary repositories, which were concluded by the manufacturers and the importers of tobacco products with 10 different providers, although four of them are in the same corporate group. The contracts were, among other things, verified against the key contractual elements laid down in Regulation (EU) 2018/573, while the providers were screened in view of the independence requirements under Article 35 of Regulation (EU) 2018/574. The Commission also rejected one data storage contract along with one proposed provider.

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[38] Commission Implementing Regulation (EU) 2018/574, Commission Delegated Regulation (EU) 2018/573, Commission Implementing Decision (EU) 2018/576.

[39] If needed, the traceability system's design and adopted technical solutions can be expanded to other areas requiring stricter regulatory controls of supply chain.

[40] These measures include: (a) the independent ID issuers, (b) the installation of anti-tampering devices on the production lines, (c) the general exclusion of the industry from consulting the traceability data, (d) the verification of the providers of primary repositories and their auditors by the Commission, (e) pre-defined independence criteria applying to all key third-party providers of IT solutions, (f) a copy of all data stored at the secondary repository and (g) real-time data access by the competent authorities.

For the first annual cycle of primary-repository audits, the Commission approved 15 auditors proposed and paid by the tobacco manufacturers. The Commission collected declarations concerning anti-tampering devices from the providers who installed them on the production lines for which 10 manufacturers and importers of tobacco products were responsible.

All Member States' competent authorities and DG OLAF are connected to the interfaces provided by the secondary repository operator, and many of them started using the traceability data to help with enforcement. Those activities are further facilitated with a mobile inspection application supplied by Dentsu Aegis Network under a separate agreement with the Commission. Several Member States use or intend to use the EU system[41] to supply data to their own enforcement systems.

Although the system works and represents a major step in the fight against illicit trade, Member States and the Commission had considerable problems with the quality of traceability data, e.g. in relation to VAT numbers, information on production machines or on last movements of products to retail outlets. While data quality has gradually improved, it remains critical for enforcement and for fully attaining the system's objectives.

5.2. Security features

To comply with the security feature provisions, 22 Member States decided to rely on and, if necessary, adapt their pre-existing tax stamp and fiscal marking programmes. The remaining five Member States introduced new authentication labels. In this sense, the system of security features allowed a largely similar security standard to be established EU-wide.

5.3. **Conclusions on traceability and security features**

Despite the issues affecting data quality, the traceability system is fully functional and well established. The Commission will examine whether the system's long-term performance can be improved with stronger audits in terms of their scope, operational impact and safeguards guaranteeing their impartiality and public trust.

6. Cross-border distance sales (Article 18)

More than half of the Member States banned cross-border distance sales of tobacco and/or related products to consumers in their countries. The vast majority of the Member States allowing cross-border distance sales published lists of the retailers registered in their country on their competent authorities' websites[15].

Monitoring and enforcing cross-border distance sales bans or restrictions have proven challenging. Member States found unregistered retailers operating in their countries or retailers selling non-compliant or banned products. Also, cross-border distance sales occurred in Member States where they were banned. Only a few Member States claimed to monitor unregistered retailers' activity and admitted difficulties in closing their websites especially when the servers were located

[41] These developments are a big improvement compared to the earlier systems developed by the industry as a part of the anti-fraud agreements concluded between the Commission and the major tobacco manufacturers in 2004-2010.

outside the EU. In addition, age verification systems do not seem to be effective, with Member States calling for improved age verification systems[42].

Member States had difficulties controlling cross-border distance sales, with many signalling the need for strong enforcement cooperation. Some Member States acted against non-compliant retailers. Moreover, Member States highlighted problems with the TPD definition of 'cross-border distance sales'.

6.1. Conclusions on cross-border distance sales

Generally, there is insufficient monitoring and enforcement of cross-border distance sales restrictions or bans under the TPD. Age verification systems seem to be ineffective, vary between Member States and are poorly enforced. Not all Member States have published lists of registered retailers as required. There are difficulties in dealing with retailers/websites located outside the EU. The clarity of certain provisions, especially the definition of 'cross-border distance sales' may be improved. Given the persistent disparities between Member States and concerns over cross-border distance sales of non-compliant products, there is scope for developing further the current regime, or as an alternative consider banning cross-border distance sales of tobacco and related products, as many Member States have already done.

7. Novel tobacco products (Article 19) and other emerging products

The TPD provisions for 'novel tobacco products' were designed to provide a wide regulatory net for new tobacco product categories rapidly entering the EU market. However, the date-based definition[43] means that provisions are not specific to the unique characteristics of certain new products. Moreover, the TPD does not fully capture certain new products not containing tobacco, such as oral nicotine pouches. These are non-pharmaceutical in nature and are sold as consumer products, resembling tobacco for oral use, which the TPD bans under Article 17[44].

Also challenging is the use of flavours, which particularly appeal to young people. Novel tobacco products are exempted from the ban on characterising flavours (Article 7 (12)). The TPD gives scope for withdrawing this exemption, but there is a significant regulatory barrier – the Commission has to demonstrate a 'substantial change of circumstances' (see chapter 10).

Heated tobacco products (HTPs), the prominent type of novel tobacco products, have increased their presence in the EU market[45], with EUR 2.92 billion in sales in 2019[46] (2% of the tobacco market). In 2020, 7% of Europeans aged 15-24 had (at least) tried HTPs and 2% were current users.

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[42] ICF 2021. A mystery shopping exercise showed that many retailers across different Member States use relatively weak checks that can be easily circumvented by under-age shoppers: 80% of retailers reviewed use self-reporting as age verification, and age is not verified at the point of delivery.

[43] The TPD defines this category as products placed on the market after 19 May 2014, which do not fall into any other product category (i.e. cigarettes, RYO tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use) under the Directive.

[44] Article 151 of the Act of Accession of Austria, Finland and Sweden grants Sweden a derogation from the ban.

[45] EU-CEG Data. Cumulatively, by September 2020 almost 1 000 active unique TP-IDs were registered in EU-CEG. Data also shows a steady EU-wide increase in product launches being registered in EU-CEG, peaking at almost 500 new launches in 2020 only. These numbers include unique-IDs launched in EU countries. If the same product is launched in several countries, it is only counted once.

[46] Euromonitor Passport.

Views differ over the extent to which novel tobacco products, especially HTPs, negatively affect the individual user's health. While the industry often presents HTPs as reduced-risk products compared to conventional tobacco products, claiming they help smokers quit, worrying trends of popularity exist among youths[47]. Evidence also shows that many users[48] become 'dual users'[49] despite intending to reduce consumption of another tobacco product. As other tobacco products, HTPs contain nicotine, an addictive substance, and evidence shows that HTPs emit chemical substances, including several toxicants[50].

The application of TPD provisions to novel tobacco products depends on whether these products are defined as a smokeless tobacco product or a tobacco product for smoking (Article 19(4)). A smokeless tobacco product is defined as lacking a combustion process. This is a challenge for regulators as the principle of combustion is ambiguous, leading to Member States classifying certain products in a divergent manner, as also addressed at international (WCO) level[51].

Moreover, without flexibility to define new product categories, it is challenging to apply rules developed for existing categories to novel tobacco products, as they do not necessarily respond to the distinct properties of the new products.

These novel tobacco products also pose challenges for applying tobacco control measures overall, including on advertising and smoke-free environments. The device specifically designed for consuming such products is widely promoted in some Member States, thus circumventing the tobacco advertising bans. Classifying a product as smokeless may also lead to smoke-free environment laws, historically focused on tobacco products for smoking, being circumvented. To clarify the issues above and address the regulatory challenges posed by these products, the EU initiated and supported a mandate at the WHO FCTC COP8[52].

7.1. Conclusions on novel tobacco and emerging products

The EU regulatory framework does not currently address all novel tobacco and emerging products, nor provide flexibility to address rapid product developments. HTPs should be monitored closely as they pose specific regulatory challenges, including health warnings, use of flavours and interaction with devices. There are also legal loopholes with respect to emerging nicotine or similar products (excluding those authorised for medical purposes and/or for smoking cessation under medical authorisation).

8. Electronic cigarettes and refill containers (Article 20)

E-cigarettes, containing nicotine but no tobacco, are a specific diverse product category, accounting for up to 7% of the national EU markets, in terms of value, for tobacco and related

[47] LSE 2020. Research within a specific sample across 12 Member States showed that 31% of young respondents (aged 18-25) had some experience with HTPs, among which 8% were current users. Interestingly, this figure was lower for people over 26, with only 27% having tried HTPs. Among current HTP users, almost 60% were daily users in both age groups.
[48] LSE 2020. In terms of product perception, 44% of respondents among both age groups felt HTPs were 'unhealthy' and a further 77% felt that young people underestimated the risks of using them.
[49] LSE 2020. 85% of respondents in the product perception study claimed to use other products in addition to HTPs.
[50] WHO 2020. Heated tobacco products: a brief.
[51] Customs Co-operation Council International Convention on the Harmonized Commodity Description and Coding System.
[52] Conference of the Parties to the FCTC, Eighth session, 1-6 October 2018.

products[53]. The EU-CEG contains over 300 000 active e-cigarettes, compared to over 42 000 active tobacco products[54]. In recent years, big tobacco companies have increased investments in e-cigarettes.

The EU was the first regional jurisdiction to regulate them, including advertising. To capture a wide net of diverse products, the TPD broadly defines this category to encompass both the device, including its parts, and refill containers with nicotine containing e-liquid. This has provided legal clarity, particularly when compared to provisions on novel tobacco products, where the device is not specifically captured. The Commission adopted two implementing acts and a report on risks associated with refillable e-cigarettes[55].

Overall, Member States had a fairly good experience with implementing certain provisions on e-cigarettes, with scope for improvement in other specific areas. While manufacturers and importers submit notifications to the competent authorities, in line with Article 20(2), more could be done to provide higher quality information, particularly on toxicological data and consistent nicotine doses upon consumption, e.g. by standardising assessment methods. Certain provisions have proven challenging to implement in practice, e.g. health warnings under Article 20(4)(b)(iii) not only apply to refill containers or pre-filled devices but also to the e-cigarette device itself. Further specification and more differentiated warnings would help, in particular when a product is marketed without a nicotine-containing liquid. Also, questions over interpretation were raised over i) labelling requirements for unit packets and outside packaging, ii) the information allowed under the exemption from the bans of promotional elements (e.g. nicotine content and information on flavourings), and iii) the limits for the tank size.

Applying Article 20(5) – banning commercial communications and sponsorship activities to promote e-cigarettes - continues to be challenging, especially in information society services and on social media where young people are particularly exposed/targeted.

Regarding reporting market surveillance activities, Member States have a legal obligation to report dangerous e-cigarettes, chargers supplied with them and refill containers in the Safety Gate/RAPEX, as well as, measures taken against them. The Information and Communication System for Market Surveillance (ICSMS) is also available to authorities to exchange information on non-compliant products. However, the use of these tools by Member States is uneven.

Safety concerns related to e-cigarettes spiralled worldwide in 2019 with 'EVALI' (E-cigarette or Vaping Associated Lung Injury) cases rising sharply in the USA[56]. These cases have since been linked to cannabis extract and/or vitamin E acetate containing e-liquids. EU countries have not observed this trend, possibly due in part to the specificities of e-cigarette regulation under the TPD, notably additive restrictions, e.g. a ban of vitamins in nicotine-containing liquids. These events show that the toxicological effects of the heated and inhaled forms of ingredients of both

[53] Euromonitor Passport. E-cigarettes' market presence is substantial, with 2019 data showing the UK as the largest market (EUR 2 417 m), followed by France (EUR 847 m), and Germany (EUR 673 m) and Poland.

[54] Open systems with refillable tanks are the most popular, followed by rechargeable devices with replaceable cartridges. While closed systems restrict device manipulation and reduce malpractice, open systems allow independent dosing and tailored interoperability, which can act as a gateway for user negligence.

[55] Commission Implementing Decision (EU) 2015/2183, Commission Implementing Decision (EU) 2016/586, COM/2016/0269 final.

[56] CDC. Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping. Feb 2020 https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

nicotine-containing and (thus far unregulated) nicotine-free e-cigarettes should be highlighted. The TPD also sets a maximum nicotine concentration of 20 mg/ml and overall this has been implemented, although industry use of technical features can increase nicotine uptake per puff.

The industry presents e-cigarettes as reduced-risk products and claims that they help smokers to quit. However, worrying trends of popularity[57] exist among youths. There is strong evidence that flavours in e-liquids are attractive to youths and adults. Significantly, young people use non-traditional flavours in particular, such as candy and fruit[458]. These flavours strongly influence young people by decreasing harm perception and increasing the will to try[59]. Member States are increasingly banning flavours for e-cigarettes.

Views on the actual health effects of e-cigarettes are divided, ranging from harmful to harm-reducing for the individual, compared to conventional tobacco products for smoking. As scientific consensus has yet to be reached, the precautionary principle prevails and the TPD takes a careful approach in regulating these products[60]. The WHO further concluded that no firm evidence exists on the safety of e-cigarettes, but there is increasing evidence of harm[61]. Also, there is concern over increased indoor use[62] and potential related harm.

To better understand the health effects and the public health dimension of e-cigarettes, the Commission has tasked the Scientific Committee on Health and Environmental Risks (SCHEER) to study the health effects of e-cigarette use, and their role in encouraging people to start or quit smoking. For users of electronic cigarettes, they found moderate weight of evidence for risks of local irritative damage to the respiratory 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, they found 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 concluded that weight of evidence for risk of poisoning and injuries due to burns and explosion is strong. They also found 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[59].

8.1. Conclusions on e-cigarettes and refill containers

E-cigarettes contain nicotine, a toxic substance. The Commission will base its risk management decisions on e-cigarettes on the SCHEER scientific opinion. The SCHEER opinion underlined

[57] LSE 2020. The two main reasons for using e-cigarettes were ‘enjoyment’ and ‘trying to quit or reduce consumption of a tobacco product’. Yet quitting or reducing consumption was more pronounced for those aged over 26 (54%), compared to young people aged 18-25 (33%).
[58] 75% of 15-24 year olds are using fruit flavoured and 30% candy flavoured e-liquids.
[59] SCHEER 2021. Opinion on electronic cigarettes.
[60] This approach was validated in the ECJ Case 477/14.
[61] WHO 2015. A systematic review of health effects of electronic cigarettes.
[62] 19-28% of Europeans report exposure to e-cigarettes or HTPs in public spaces where people do not usually smoke (e.g. shopping malls, airports), and in drinking or eating establishments.

their health consequences and the important role they play in smoking initiation. This opinion supports the careful and precautionary approach taken so far.

However, it should be explored whether some provisions could be further developed or clarified, such as tank size or labelling requirements; use of flavours; use of nicotine-free liquids; and advertising provisions.

Insofar as e-cigarettes are smoking cessation aids, their regulation should follow the pharmaceutical legislation.

9. Herbal products for smoking (Articles 21 and 22)

Herbal products for smoking were newly added to the TPD. These include products based on plants, fruits or flowers, which can be consumed via combustion without tobacco. The TPD provisions complement other relevant legislative frameworks and do not regulate as such the types of plants, herbs or fruits contained in herbal products for smoking. Over 1 600 product presentations are active in EU-CEG, most of which could be linked to cannabis products for smoking. There are concerns over the finding that some cannabidiol (CBD) products may also contain tetrahydrocannabinol (THC)[63], which is controlled under the 1971 UN Convention on Psychotropic Substances, of which all Member States are Parties to[64]. The 2020 Eurobarometer survey identified that 8% of Europeans have used products containing cannabis in the last 12 months, most frequently by smoking it with tobacco[4]. With certain types of cannabis being decriminalised in a few EU countries and some other countries worldwide, interest in these products has increased.

The current definition of herbal products for smoking does not capture certain new products entering the market, such as CBD containing cannabis extracts and oils, used particularly in e-cigarettes (with or without nicotine). In the context of the TPD, there is lack of clarity of the regulation of cannabis extracts or synthetic CBD in e-liquids.

9.1. Conclusions on herbal products for smoking

Overall, Articles 21 and 22 of the TPD have been implemented EU-wide, with Member States reporting some issues around labelling requirements[15]. They also reported good compliance with reporting obligations on ingredients. However, a significant challenge lies in competent authorities ensuring that all relevant products are submitted to the EU-CEG. Nonetheless, cannabis extracts are currently regulated at national level.

10. Specific consideration for other product types and categories, including market developments and substantial change of circumstances

10.1. Waterpipe tobacco, slim cigarettes and other product categories

Article 28 of the TPD tasked the Commission to also specifically look at waterpipe tobacco and slim cigarettes, for which it mandated a specific study[6]. On implementing provisions on slim cigarettes, waterpipe tobacco, and cigarillos, different experiences have been reported. Most Member States do not mandate pictorial warnings for cigarillos, often targeted at cigarette users

[63] EMCDDA 2019. Developments in the European cannabis market, EMCDDA Papers.
[64] https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-16&chapter=6#3

with their lower price or features banned in cigarettes, e.g. flavour capsules. Waterpipe tobacco use frequently takes place in specific premises, e.g. shisha lounges, where consumers do not see health warning labels and pictorials. Another concern over waterpipe tobacco, as for cigarillos, is the use of flavours and their attractiveness to youths.

The EU waterpipe market is significant[65], and some EU countries have one of the highest prevalence of waterpipe tobacco use among youths[66]. The slim cigarette market has been declining since 2000, but retail volume has increased in several Eastern European Member States[6]. More women smoke slim cigarettes (10%) than men (2%).

Evidence shows that the risks associated with waterpipe tobacco are underestimated[67]. Flavour use is strongly linked to waterpipe tobacco, and 'nice flavours' was the term most frequently associated with these products[6]. Some people may also underestimate the risks associated with slim cigarette use[68]. Eurobarometer 2017 stated that 18% of respondents identified slim cigarettes as attractive. However, connotations of femininity are less deep-rooted[6].

During the reporting period, the snus ban was clearly circumvented as, outside of Sweden, many snus-like products were presented as chewing tobacco to gain a legal status. Legal loopholes related to chewing bags and emerging nicotine pouches became apparent.

10.2. Substantial change of circumstance clause (Articles 2(28), 7(12), 11(6))

The TPD sets out criteria for a 'substantial change of circumstances'[69] and calls for the Commission to withdraw certain regulatory exemptions once those conditions are met (a flavour ban for product categories other than cigarettes and RYO tobacco, labelling exemptions). The Commission followed the market shares closely and no product category reached the threshold that would mandate the Commission to trigger this clause in the reporting period. The closest to the threshold are HTPs[70]. Therefore, assessing the current criteria should be considered.

10.3. Other considerations

The TPD enabled some tobacco control actions to be financed by fees, and some Member States started to use such options. Further exploration of how to fully finance tobacco control actions through fees is merited. The Directive does not contain provisions on the tobacco industry's liability for the health effects and health costs of tobacco and related product use. However, in line with Article 19 of the FCTC[71], the EU could, for the next TPD review, examine options to increasing tobacco manufacturers' liability.

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[65] LSE 2020. Germany alone accounts over half of the EU pipe tobacco market, with a retail volume worth EUR 368 m for waterpipe and pipe tobacco in 2017.
[66] Jawad et. al., The prevalence and trends of waterpipe tobacco smoking : A systematic review, PLoS One, 2018.
[67] LSE 2020. Despite users being exposed to both tobacco and charcoal, waterpipe tobacco was perceived as less harmful than cigarettes and HTPs.
[68] 7% of Eurobarometer 458 (2017) respondents identified slim cigarettes as less harmful than normal cigarettes.
[69] Article 2(28) provides for a set of objective criteria defining 'substantial change of circumstances'.
[70] Euromonitor Passport. HTPs' market share was approaching 2% in 2019.
[71] Article 19(1) FCTC stipulates that 'for the purpose of tobacco control, the Parties shall consider taking legislative action or promoting their existing laws, where necessary, to deal with criminal and civil liability, including compensation where appropriate.'

11. Conclusions

The TPD has enhanced tobacco control and its validity was upheld in courts. It strengthened rules, e.g. enlarged combined health warnings, the track and trace system, banning characterising flavours, the ingredients database, the regulation of electronic cigarettes, all of which have established their position as part of a comprehensive EU tobacco control policy. The TPD achieved the 2% reduction target of the impact assessment with decreased smoking prevalence among youths. The Directive also implemented relevant WHO FCTC provisions.

The study that gathered evidence for this report concluded that the TPD has contributed to the improvement of public health. The TPD provides added value and Member States could not have accomplished the same objectives alone. In general, the TPD was considered to be consistent internally, but due to market developments there is scope for improvement in certain essential areas. Compliance of national laws with the TPD and their harmonised application varies. Many Member States lack adequate enforcement resources. The new functional systems (EU-CEG, IAP, traceability) are relatively resource-intensive.

Persistently high smoking rates, high numbers of youths taking up smoking, the WHO target of a 30% relative reduction in tobacco use by 2025 as compared to 2010[7], as well as the Europe's Beating Cancer Plan's objective to achieve a tobacco-free generation by 2040, should be duly taken into consideration when assessing the EU framework on tobacco and related products.