Please note this is the end of the survey.
You should now review your responses and submit your contribution.

Below is a summary of your responses

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Welcome to the targeted survey for the **evaluation of the legislative framework for tobacco control**.

The data of this survey are treated according to the study data privacy notice (DPN). You can find the DPN below.

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2115

Important information

Please, keep in mind the following when filling in the questionnaire:
- Although multiple respondents within the same organisation can access the unique survey link provided and answer to the questions simultaneously, we advise not to fill survey at the same time in order to avoid clashes.
- It is not possible to skip questions, thus questions can only be answered in the order they appear.

Please state the following

Your organisation	European Public Health Alliance
Your role	Policy Manager for NCD prevention
Full name of the person submitting	Alessandro Gallina

Please indicate the following

Country of headquarters	Belgium
Transparency register number	18941013532-08
Number of employees	22

Please state the following

Public Health NGO

Confidentiality

You authorise for your feedback to:

(Your personal data will never be published under either option)

- (●) **Be published with attribution to your organisation or in aggregated form**
- ( ) Only be published in aggregated form

Relevance of the TPD

Which of the following definitions pose challenges (if any)?

- [ ] None of these definitions face challenges
- [ ] Tobacco
- [ ] Pipe tobacco
- [ ] Roll-your-own tobacco
- [■] **Tobacco products**
- [■] **Smokeless tobacco product**
- [ ] Chewing tobacco
- [ ] Cigarillo
- [■] **Herbal product for smoking**
- [ ] Electronic cigarette
- [ ] Refill container
- [ ] Ingredient
- [ ] Tar
- [ ] Emissions
- [■] **Toxicity**
- [ ] Combined health warning
- [ ] Cross-border distance sales
- [ ] Age verification system
- [ ] Placing on the market
- [ ] Retail outlet
- [■] **Pouch**

- [ ] Nasal tobacco
- [x] **Additive**
- [ ] Health warning
- [ ] Tobacco for oral use
- [x] **Flavouring**
- [ ] Waterpipe tobacco
- [x] **Tobacco products for smoking**
- [x] **Characterising flavour**
- [x] **Novel tobacco product**
- [ ] Cigarette
- [ ] Addictiveness
- [ ] Don’t know/ Can’t answer

Please specify the nature of the challenges for the definitions you previously indicated as posing challenges

(1000 word limit)

These definitions include uncertainties in product registration, inconsistent regulatory approaches, misleading perceptions of harm reduction, circumvention of bans on characterizing flavors, and the neglect of certain toxic aspects. To overcome these challenges and ensure robust tobacco product regulations, it is essential to establish clearer definitions, harmonize regulations across Member States, and consider a proactive approach that anticipates emerging products and industry tactics. By addressing these issues, we can better protect public health, especially among vulnerable populations, and foster a more effective and comprehensive legislative framework. In this response, we try to address the challenges posed by certain framing, offering a critical perspective on each. Definition of "novel tobacco products": The current definition of novel tobacco products, as stated in Article 2(14) and further detailed in Article 19(4) with references to smokeless tobacco or tobacco products for smoking (Article 2(5) and (9)), has proven to be unclear in practice. This lack of clarity has resulted in uncertainties among Member States when it comes to registering new tobacco products in their respective markets. Consequently, different regulatory approaches for the same products across the EU have emerged, which adversely affects the level of health protection, particularly for vulnerable groups such as minors and youth. Furthermore, these discrepancies create new obstacles to the functioning of the internal market, hindering the harmonization of tobacco product regulations. Challenges with Heated Tobacco Products (HTPs): The definition of HTPs provided by the Commission Delegated Directive (EU) 2022/2100, as "a novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s), and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking," raises concerns regarding labeling regulations. Inconsistencies arise among Member States, with some countries applying the same labeling and health warning regulations for HTPs as for cigarettes, while others only include text warnings without pictorial warnings. This disparity may lead to a perception that HTPs are "less harmful" due to the absence of prominent visual warnings. Moreover, the misleading "harm reduction" claim promoted by tobacco companies and their front groups aims to re-normalize tobacco consumption and targets youth by marketing HTPs as "smoke-free alternative products." These tactics further exacerbate the challenges associated with the regulation of HTPs. Interpretation issues regarding specific products: Delimitation issues between snus and products for chewing in Slovenia and Germany have resulted in the introduction of snus-like products and subsequent legal actions. A broader definition of "novel tobacco and nicotine products" would help regulate notification systems for emerging products like nicotine pouches and

nicotine products" would help regulate notification systems for emerging products like nicotine pouches and those introduced by the tobacco industry in the future. This proactive approach ensures that even when new products claim lower toxicity levels, their marketing and advertising strategies are not allowed to increase their attractiveness, thereby safeguarding public health and minimizing negative effects. Definition of additives: The definition of additives poses its own set of challenges. Sugars, for example, constitute the majority of added substances or extracts in cigarettes. When burned, sugars produce caramel-like substances that add a sweet flavor to the smoke, masking its bitter taste. Additionally, burning sugars releases acids that lower the smoke's pH, making it less pungent and easier to inhale. The burning process also generates acetaldehyde, which reinforces nicotine's addictive effects. To make smoking less attractive and potentially less addictive, it is crucial to regulate all sugars, including both naturally present and added sugars. By doing so, the appeal and palatability of tobacco products can be reduced. (https://www.fda.gov/tobacco-products/products-ingredients-components/chemicals-every-cigarette) Definition of flavors: The current definition of flavors lacks inclusivity, allowing the tobacco industry to find loopholes and circumvent the ban on characterizing flavors. Although the Tobacco Products Directive banned cigarettes and roll-your-own tobacco with characterizing flavors in 2014 (with implementation deadlines in 2016 and 2020 for menthol flavors), the ban does not cover additives essential for manufacturing tobacco products that do not result in characterizing flavors or significantly increase addictiveness, toxicity, or other properties. This regulatory gap has enabled the tobacco industry to introduce alternative tobacco products, such as cigarillos, pipe tobacco, heated tobacco products, and nicotine pouches, as substitutes for menthol cigarettes. To close these loopholes, a more comprehensive and robust definition of flavors is necessary to prevent industry tactics that undermine public health efforts. Neglect of cigarette butt toxicity: The current definition of toxicity within the Tobacco Products Directive overlooks the toxicity of cigarette butts, specifically those from filters. This oversight can have detrimental effects on biodiversity and human health. Existing regulations, such as the Classification Labelling and Packaging (CLP) Regulation and the Waste Framework Directive (WFD), classify cigarette butts as hazardous waste. However, the definition of toxicity in the Tobacco Products Directive fails to align with these regulations. By neglecting to account for the toxicity of cigarette butts and filters, the directive overlooks a critical aspect that affects both human health and the environment. To address this issue, it is necessary to revise the definition to include the toxicity of cigarette butts and filters, aligning it with existing regulations and fostering better protection for both biodiversity and public health.

Word count: 842

Does Art. 17 of the TPD (ban on tobacco for oral use) still meets its objectives?

Not at all	To a limited extent	To a large extent	**Yes, absolutely**	Don't Know/ Can't answer
○	○	○	●	○

Please briefly explain your response

(500 word limit)

The ban on tobacco for oral use, as outlined in Art. 17 of the Tobacco Products Directive (TPD), continues to meet its objectives in protecting public health. The tobacco industry's efforts to remove the ban through lobbying and funding studies on snus with conflicts of interest should not influence the retention of this crucial measure. Sweden's high prevalence of snus consumption poses a challenge to achieving the European Beating Cancer Plan's objective of reducing tobacco consumption. The World Health Organization (WHO) has classified smokeless tobacco, including snus, as a Group 1 carcinogen, with evidence linking it to addiction, various cancers, cardiovascular risks, and adverse pregnancy outcomes. Additionally, new products resembling snus, such as nicotine pouches, exploit regulatory loopholes. Maintaining the ban on tobacco for oral use and addressing these challenges are vital for effective tobacco control and safeguarding public health.

Word count: 140

Does the TPD effectively cover the challenges arising from the following emerging

products?

	Not at all	To a limited extent	To a large extent	Yes, fully	Don't Know/ Can't answer
E-cigarettes	○	○	●	○	○
Heated tobacco products	○	●	○	○	○
Nicotine pouches	●	○	○	○	○
Nicotine-free surrogates	●	○	○	○	○
Other (please specify)	○	○	○	○	●

Please specify which other product

none

Please elaborate on why the selected products hinder the ability of the TPD to remain relevant for tobacco control:

(1000 word limit)

The effectiveness of the Tobacco Products Directive (TPD) in addressing challenges from emerging tobacco and nicotine products is compromised by loopholes, inconsistencies in regulation, lack of clarity, and exclusion of certain products. To strengthen tobacco control efforts, it is crucial to close regulatory gaps, harmonize regulations across Member States, and ensure comprehensive coverage of emerging products within the TPD. These measures would contribute to safeguarding public health and maintaining the relevance of the TPD in the face of evolving tobacco and nicotine markets. Firstly, the TPD has loopholes in regulating e-cigarettes, such as the lack of comprehensive measures to address their long-term effects and the absence of clear health benefits for dual users (regular smoking and e-cigarette smoking). Additionally, the involvement of the tobacco industry in generating evidence for public health policies compromises the integrity of the TPD. Weak enforcement mechanisms in Member States further hinder effective regulation of e-cigarettes. Another emerging product that poses challenges to the TPD is nicotine pouches, which currently fall outside its scope. The regulation of nicotine pouches varies across countries, creating inconsistencies. For example, Sweden lacks regulations for smokeless nicotine products, while Estonia considers them related to tobacco. In Finland, they were initially classified as nicotine replacement therapy and are now categorized as tobacco substitutes. Norway prohibits nicotine pouches unless classified as medicinal products. This lack of uniformity in regulation undermines the TPD's ability to effectively address the challenges posed by nicotine pouches. To maintain the relevance of the TPD for tobacco control, it is crucial to revise the definition of "novel tobacco and nicotine products" and strengthen the notification system. This would encompass emerging products like nicotine pouches and anticipate future introductions by the tobacco industry, which may aim to circumvent regulations. By addressing the attractive marketing strategies of these products and potential negative health effects, the notification system can enhance the TPD's effectiveness. Furthermore, the TPD's limitations are evident in the case of heated tobacco products (HTPs). The current regulatory framework allows for differing approaches among Member States, as the industry advocates for more favorable regulations on labeling, packaging, emissions limits, health warnings, TAPS, and tax regimes. These inconsistencies undermine public health objectives and highlight the need for clearer guidelines within the TPD to prevent aggressive marketing campaigns by the tobacco industry. Lastly, the TPD's failure to include nicotine-free surrogates within its scope neglects important challenges associated with these products. This omission leaves room for potential health risks and the possibility of nicotine addiction without appropriate regulation.

Word count: 415

To what scale are the following TPD articles still relevant

To what scale are the following TPD articles still relevant…

Please provide a value from 1 (not relevant at all) to 4 (remains fully relevant) for each of the following articles and statements. Please select 0 if you don't know or can't answer

	...to tackle today's reality and address new product developments in the market?
Tobacco Products	
Definitions	2
Provisions on ingredients, measurement of emissions and reporting obligations	2
Provisions on labelling and packaging of tobacco products, including health warnings	2
Provisions on presentation of tobacco products	2
Provisions on appearance and content of unit packets	1
Provisions on traceability and security features of unit packets	2
Provisions on the ban of tobacco for oral use	2
Provisions on cross-border distance sales of tobacco products	2
Provisions on the notification of the introduction of Novel Tobacco Products on the market	2
Product regulations of herbal products for smoking and reporting of its ingredients	3
e-cigarettes	
Provisions on the notification of the introduction of electronic cigarettes and refill containers on the market	2
Provisions on ingredients and other manufacturing requirements	2
Provisions on packaging and labelling, including health warnings	2
Provisions on the prohibition of commercial communications in printed media and information society services and on commercial communications or contributions on the radio	2
Provisions on the prohibition of contribution to events, activities, or person, having cross-border effects for promotion purposes	2
Provisions on the prohibition of audio-visual commercial communications	2

	...to reach the goal of Europe's "tobacco-free generation" by 2040?

Tobacco Products	...to reach the goal of Europe's "tobacco-free generation" by 2040?
Definitions	2
Provisions on ingredients, measurement of emissions and reporting obligations	2
Provisions on labelling and packaging of tobacco products, including health warnings	2
Provisions on presentation of tobacco products	2
Provisions on appearance and content of unit packets	1
Provisions on traceability and security features of unit packets	2
Provisions on the ban of tobacco for oral use	2
Provisions on cross-border distance sales of tobacco products	2
Provisions on the notification of the introduction of Novel Tobacco Products on the market	2
Product regulations of herbal products for smoking and reporting of its ingredients	3
e-cigarettes	
Provisions on the notification of the introduction of electronic cigarettes and refill containers on the market	2
Provisions on ingredients and other manufacturing requirements	2
Provisions on packaging and labelling, including health warnings	2
Provisions on the prohibition of commercial communications in printed media and information society services and on commercial communications or contributions on the radio	2
Provisions on the prohibition of contribution to events, activities, or person, having cross-border effects for promotion purposes	2
Provisions on the prohibition of audio-visual commercial communications	2

If you replied that some of the previous <u>tobacco product</u> provisions are not pertinent, please provide examples of the loopholes and/or explain possible scope for improvement in methodologies or procedures.

(1000 word limit)

Some provisions of the Tobacco Products Directive (TPD) face challenges in terms of their relevance and effectiveness. One such provision is the tracking and tracing system established by Articles 15 and 16 of the TPD. While it aims to address illicit trade, there are several weaknesses in its implementation.

Information on the real functioning and effectiveness of the EU tracking and tracing system is lacking, and the absence of yearly reports hinders transparency and evaluation of its positive and negative results. The appointment of data repositories and auditors by the tobacco industry, with approval from the European Commission, raises concerns about the system's independence and effectiveness. The lack of public disclosure of auditor names and reports further diminishes transparency. The scope of auditing duties is limited, and improvements are needed to enhance operational impact, impartiality, and public trust. Additionally, the tracking and tracing system's application is limited to tobacco products manufactured within the EU, omitting products entering and leaving the EU under the transit regime. This omission fails to address the global context of illicit trade. Furthermore, the system does not cover raw tobacco, which is crucial for better control of the supply of raw tobacco to illegal cigarette factories within the EU. Another provision, Article 18, allows Member States to prohibit cross-border distance sales of tobacco products to consumers. However, the different approaches taken by Member States create fragmentation in the internal market and potential circumvention of TPD provisions. Cross-border online sales of tobacco products not only involve promotion but also pose risks of tax evasion, illicit trade, sales to minors, access to non-compliant products, and undermine fiscal and health policies. The TPD's measures to prevent such breaches have proven weak and insufficient, with reports highlighting the failure of age verification systems. A comprehensive EU-wide ban on cross-border sales of tobacco products and e-cigarettes would align with both internal market and health objectives. Slim cigarettes have been heavily marketed, particularly to women, as more feminine and elegant. Research indicates that misperceptions about the harmlessness of slim cigarettes are high, especially in countries where their use is prevalent among women. A ban on slim cigarettes would help counter these misperceptions and reduce their appeal. Similarly, slim packages have been shown to increase attractiveness to consumers, making a case for their prohibition under a revised Tobacco Products Directive. The provisions concerning ingredients, measurement of emissions, and reporting obligations in the TPD present challenges due to their reliance on ISO measurement methods for Tar, Nicotine, and Carbon Monoxide (TNCO). These methods have loopholes and do not accurately reflect actual exposure levels experienced by smokers due to variations in smoking behavior and other factors. Ventilated cigarette filters, for example, can artificially lower TNCO levels measured by machine smoking, leading to an underestimation of actual exposure. Moreover, the involvement of the tobacco industry in the development of ISO methods raises doubts about their validity. Member States are considering unilateral changes in TNCO measurement methodology, and it is essential to assess more reliable methods like those proposed by WHO TobLabNet, which are free from industry interference. In summary, while the TPD includes relevant provisions, there are loopholes and areas for improvement in their methodologies and procedures. Enhancements in the tracking and tracing system, addressing cross-border sales challenges, banning slim cigarettes and packages, and adopting more reliable measurement methods for emissions would strengthen the TPD's effectiveness in achieving its tobacco control objectives.

Word count: 566

If you replied that some of the previous e-cigarette provisions are not pertinent, please provide examples of the loopholes and/or explain possible scope for improvement in methodologies or procedures.

(1000 word limit)

The relevance of certain provisions in the Tobacco Products Directive (TPD) related to e-cigarettes is debatable. Here are some examples of areas where loopholes exist or improvements can be made: Cross-border Distance Sales and Online Sales: The TPD provisions on cross-border distance sales of electronic cigarettes need to be strengthened. Currently, different approaches by Member States generate market fragmentation and potential circumvention of regulations. A comprehensive ban on cross-border distance sales and online sales of e-cigarettes would align with both internal market and health objectives. This would help prevent the promotion, tax evasion, illicit trade, and sales to minors associated with these sales channels. Disposable E-cigarettes: There is a need to prohibit or strictly regulate disposable e-cigarettes due to their accessibility and harmful environmental impact. Obligatory rules should be implemented for packaging and labeling, including authorized colors and letter types, to counter their attractiveness to young people and non-smokers. This would help mitigate the potential risks associated with disposable e-cigarettes and discourage their use. Classification and Regulation: The recommendation of the Framework Convention on Tobacco Control (FCTC)/Conference of the Parties (COP6)9 Decision encourages Parties to consider prohibiting or regulating Electronic Nicotine Delivery Systems (ENDS), including e-cigarettes,

under various categories such as tobacco products, medicinal products, or consumer products. This approach allows for a high level of protection for human health. Considering the diverse nature of e-cigarettes, their classification and regulation should be carefully assessed, ensuring appropriate safeguards for public health. Strengthening the enforcement of existing rules on advertising, promotion, and sponsorship is crucial to combat the proliferation of illegal advertising for tobacco products and e-cigarettes. Member States should consider additional restrictions on tobacco advertising, such as display bans at points of sale and explicit bans on various forms of advertising, promotion, sponsorship, and paid influencer content on social media platforms. EPHA supports extending the notification requirements for manufacturers and importers of e-cigarettes and refill containers to include a declaration or statement on any links with the tobacco industry. This aligns with the transparency requirements outlined in Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC). Full disclosure of tobacco industry funding for research on public health and environmental issues, including through third parties, should be mandated and enforced by Member States. Investing in independent scientific research is vital to ensure unbiased findings and meet the obligations outlined in Article 20 of the WHO FCTC. Governments and their institutions, such as health administrations and smoking cessation services, should inform smokers about tobacco cessation methods through inserts in tobacco product packaging. These efforts align with the guidelines of the WHO FCTC Articles 5.3 and 14 and can increase the chances of successful tobacco cessation. Regarding the notification system for e-cigarettes, the European Commission's report on the application of the TPD highlights the need for higher-quality information, particularly regarding toxicological data and consistent nicotine doses upon consumption. Standardizing assessment methods would enhance the reliability of submitted notifications. Clarification is also needed regarding labeling requirements for unit packets and outside packaging, allowable information under exemptions from promotional element bans (e.g., nicotine content and flavoring information), and limits for tank sizes.

Word count: 518

Effectiveness of the TPD

Did the fragmentation (i.e., the split into TPD, TAD, and other separate pieces of legislation) of the current EU tobacco control framework have a positive or negative effect on the achievement of the TPD legislative objectives?

Negative	**Somewhat negative**	Neither negative nor positive	Somewhat positive	Positive
○	●	○	○	○

Don’t know/Can’t answer ○

Please elaborate on which effects it had:

If applicable, please define these effects, highlighting positive and/or negative impacts on relevant stakeholders (e.g., public health, tobacco and related products users, MS public authorities, tobacco producers, manufacturers, etc.)

(750 word limit)

The fragmentation of the current EU tobacco control framework had negative effects on the achievement of the Tobacco Products Directive (TPD) legislative objectives. The use of different definitions for tobacco products across the TPD, Tobacco Advertising Directive (TAD), and Tobacco Tax Directive created incoherence and loopholes in the regulation of these products. This lack of harmonization and outdated legislation hindered the effective regulation of emerging products and market developments. The

inconsistencies in defining tobacco products result in confusion and potential gaps in the rules governing these products. For instance, the TAD defines tobacco products broadly as products intended to be smoked, sniffed, sucked, or chewed, as long as they contain any amount of tobacco. However, the TPD provides different definitions for tobacco products, smokeless tobacco products, and tobacco products for smoking. This discrepancy can lead to loopholes that the tobacco industry may exploit to circumvent regulations and promote their products. The fragmented framework also undermines the objectives of the TPD by creating an uneven playing field across Member States. Different interpretations and implementations of tobacco control measures result in varying levels of protection and regulation within the EU. This can lead to disparities in health outcomes and market dynamics, as well as potential barriers to the functioning of the internal market. To address these negative effects, a revision of the tobacco control framework should prioritize clear and comprehensive definitions that leave no room for ambiguity or exploitation. Harmonizing the definitions across directives and aligning them with current market developments would help ensure consistent and effective regulation of all tobacco products, including emerging products. Furthermore, a comprehensive and cohesive approach to tobacco control, consolidating the TPD, TAD, and other relevant legislations, would enhance the efficiency and effectiveness of tobacco control measures. This would provide a stronger foundation for achieving the legislative objectives, such as protecting public health, reducing tobacco-related harm, and preventing youth initiation.

Word count: 313

What impact did the divergencies in tobacco control policies across Member States have on the achievement of the TPD legislative objectives by Member States?

Negative	**Somewhat negative**	Neither negative nor positive	Somewhat positive	Positive
○	●	○	○	○

Don't know/Can't answer ○

Please elaborate on which effects it had:

If applicable, please define these effects, highlighting positive and/or negative impacts on relevant stakeholders (e.g., public health, tobacco and related products users, MS public authorities, tobacco producers, manufacturers, etc.)
(750 word limit)

The divergencies in tobacco control policies across Member States (MS) have had an impact on the achievement of the Tobacco Products Directive (TPD) legislative objectives. While the TPD sets minimum standards for tobacco control, it allows MS to adopt stronger measures and go beyond these minimum requirements. However, the lack of clarity and guidance on the conditions and process for implementing these stronger measures has resulted in legal uncertainty and varying approaches among MS. The provision in Article 24(2) of the TPD grants MS the flexibility to pass domestic regulatory measures that exceed the EU provisions. This has allowed certain MS to take a leadership role in implementing more robust tobacco control policies and serving as examples for others to follow. These MS have demonstrated their commitment to protecting public health by going beyond the minimum requirements of the TPD. However, the condition set in Article 24(3), which requires a specific situation in the MS seeking to prohibit certain categories of tobacco or related products, has created ambiguity and legal uncertainty. The lack of clear criteria and principles for defining these specific situations has resulted in different interpretations and applications across MS. This has hindered the effective implementation of stronger tobacco control measures and created disparities in tobacco control policies. The legal uncertainty surrounding Article 24(3) has also led to challenges for MS and civil society organizations advocating for stronger tobacco control

measures. The lack of clear guidelines on the applicability of the conditions specified in this article has made it difficult for MS to navigate the process of adopting national measures that go beyond the TPD provisions. This has limited the ability of MS to effectively pursue their public health objectives and protect the health of their citizens. To address these challenges, there is a need for the TPD to clarify the conditions and process for the application of Article 24(3). Clear guidelines should be provided to ensure that MS have a better understanding of the criteria and principles for adopting stronger tobacco control measures. This would reduce legal uncertainties and enable MS to take more decisive actions to protect public health and address health-related inequalities.

Word count: 357

Were there any unexpected or unintended consequences arising from the application of the TPD?

	No	Yes	Don't Know/ Can't answer
Unclear provisions	○	●	○
Excessive administrative burden	●	○	○
Excessively restricting provisions	●	○	○
Lack of specific approach(es) per type of product	○	●	○
Other (please specify)	○	○	●

For each positive response, which were the unintended effects?

If applicable, please define these effects, highlighting positive and/or negative impacts on relevant stakeholders (e.g., public health, tobacco and related products users, MS public authorities, tobacco producers, manufacturers, etc.)
(750 word limit)

The application of the Tobacco Products Directive (TPD) has resulted in some unexpected or unintended consequences, particularly due to unclear provisions and a lack of specific approaches per type of product. These unintended effects have created challenges and fragmentation across Member States, leading to inconsistencies in the regulation of novel tobacco products, such as heated tobacco products (HTPs). One unintended consequence is the ambiguity in the classification of HTPs as either smokeless tobacco products or tobacco products for smoking. This ambiguity has resulted in divergent approaches among Member States regarding the labelling and health warning regulations for HTPs. For example, in Belgium, the labelling and health warning regulations for HTPs are the same as for cigarettes. This lack of harmonization creates confusion and undermines the consistent regulation of HTPs across the EU. The differing views on the health effects of HTPs have also created unintended consequences. While the industry promotes HTPs as reduced-risk products that can aid smoking cessation, there are concerns about their impact on individual health and their appeal to youth. Evidence suggests that many HTP users become "dual users," continuing to use other tobacco products despite intending to reduce consumption. The effectiveness of HTPs for smoking cessation remains uncertain, as studies have not reported positive outcomes in this regard. The World Health Organization has concluded that HTPs do not help smokers end tobacco use and should not be promoted as smoking cessation tools. The application of TPD provisions to novel tobacco products like HTPs has been challenging due to the lack of flexibility to define new product categories. Existing rules developed for traditional tobacco products may not adequately address the

distinct properties of novel products. This has created difficulties in applying tobacco control measures, including advertising restrictions and smoke-free environment laws. The specific devices used for consuming HTP sticks have been widely promoted in some Member States, potentially circumventing tobacco advertising bans. Additionally, classifying HTPs as smokeless tobacco products may lead to their exemption from smoke-free environment laws, further undermining tobacco control efforts. To address these unintended consequences, enhanced harmonization and stronger rules among Member States are needed. A clearer classification system and specific approaches tailored to novel tobacco products, such as HTPs, would ensure consistency in regulation and protect human health. Efforts to clarify regulatory challenges and promote harmonization have been initiated at the international level through the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) Conference of the Parties (COP8), demonstrating the recognition of the need to address these issues.

Word count: 417

Has the extension in the use of standardised (plain) packaging across different Member States affected the effectiveness of the TPD in facilitating the smooth functioning of the internal market?

Not at all	**To a limited extent**	To a large extent	To a full extent	Don't Know/ Can't answer
○	●	○	○	○

Please explain in which way it affected the effectiveness of the TPD:

If applicable, please define these effects, highlighting positive and/or negative impacts on relevant stakeholders (e.g., public health, tobacco and related products users, MS public authorities, tobacco producers, manufacturers, etc.)

(500 word limit)

The extension of standardised (plain) packaging across different Member States (MS) has had an impact on the effectiveness of the Tobacco Products Directive (TPD) in facilitating the smooth functioning of the internal market. While plain packaging is an effective public health measure to discourage tobacco use, its implementation at the national level by some MS has resulted in different levels of public health protection for EU citizens and potential fragmentation of the internal market. Currently, Article 24(2) of the TPD allows MS to implement plain standardised packaging, and seven MS have already done so, while others are in the process of discussing, adopting, or implementing similar measures. This variation in the adoption of plain packaging creates disparities in public health protection among EU countries and can lead to health inequalities. Additionally, it can disrupt the functioning of the internal market, as different packaging regulations exist across MS. In the previous revision of the TPD, the fragmentation caused by differences in the implementation of graphic health warnings across MS was recognized, leading to the adoption of common rules for mandatory pictorial warnings. However, a similar fragmentation now exists with the adoption of plain packaging only by some MS, necessitating EU action to address this issue. The lack of harmonized standards for plain packaging at the EU level further exacerbates the disruption to public health protection and the internal market. Reports from MS indicate that sales arrangements and displays of tobacco products have been adapted to undermine the visibility and effectiveness of plain packaging. For example, some packs are positioned in a way that minimizes the visibility of health warnings or changes in pack design are made to make tobacco products more attractive. These heterogeneous developments in MS contribute to the fragmentation of the internal market and the level of health protection. To address these challenges and improve the functioning of the internal market, there is a need to establish a common set of rules for the implementation of plain standardised packaging at the EU level. This would ensure consistency in public health measures and reduce disparities among MS. By adopting harmonized standards for plain packaging, the EU can facilitate the smooth functioning of the internal market and promote a higher level of health protection for all EU citizens.

Word count: 377

Does the exception provided by TPD article 11 undermine the achievement of facilitating the smooth functioning of the internal market while ensuring a high level of human health protection?

Not at all	To a limited extent	To a large extent	**To a full extent**	Don't Know/ Can't answer
○	○	○	●	○

Please explain how:

If applicable, please define these effects, highlighting positive and/or negative impacts on relevant stakeholders (e.g., public health, tobacco and related products users, MS public authorities, tobacco producers, manufacturers, etc.)

(500 word limit)

The exception provided by Article 11 of the Tobacco Products Directive (TPD) undermines the achievement of facilitating the smooth functioning of the internal market while ensuring a high level of human health protection. This exception allows Member States to exempt tobacco products for smoking, other than cigarettes, roll-your-own tobacco, and waterpipe tobacco, from certain labelling requirements and combined health warnings. The provision has particular implications for Heated Tobacco Products (HTPs). HTPs can be regulated either as tobacco products for smoking or as smokeless tobacco products, creating ambiguity and fragmentation across the EU. The lack of clarity in the regulation of HTPs hinders the achievement of a harmonized approach to tobacco control. The World Health Organization (WHO) has expressed concerns about the claims of reduced harm associated with HTPs. Insufficient evidence exists to support the notion that HTPs are less harmful than conventional cigarettes, and further independent studies are needed to substantiate any claims of reduced risk or harm. Regulating HTPs as tobacco products for smoking would subject them to the same regulations as cigarettes, including advertising and promotion bans, labelling requirements, bans on flavors, and restrictions on their use in public places. This approach would ensure a consistent and high level of human health protection across the EU. The exception provided by Article 11 undermines the harmonization of regulations for HTPs, as it allows for variations in the labelling requirements and health warnings applicable to these products. This lack of uniformity can create market distortions and hinder the smooth functioning of the internal market. It also leads to confusion among consumers and undermines the goal of providing clear and consistent information about the risks associated with tobacco products. To ensure a high level of human health protection and facilitate the smooth functioning of the internal market, it is necessary to regulate HTPs as tobacco products for smoking. This would align their regulation with other tobacco products and prevent the fragmentation and inconsistencies that arise from different approaches across Member States.

Word count: 330

Did the TPD adequately address the issue of tobacco initiation, particularly among the <25 years old age group?

Not at all	**To a limited extent**	To a large extent	Yes, completely	Don't know/Can't answer
○	●	○	○	○

Considering the rise of emerging products, does the TPD effectively regulate the current

Considering the rise of emerging products, does the TPD effectively regulate the current landscape?

Not at all	**To a limited extent**	To a large extent	To a full extent	Don't know/Can't answer
○	●	○	○	○

Efficiency of the TPD

Is the extent of compliance costs for each of the following main actors acceptable, considering the inherent conflict of interest between public health and the tobacco industry?

	Not at all	To a limited extent	To a large extent	To a full extent	Don't Know/ Can't answer
Public authorities	○	●	○	○	○
Economic operators in the tobacco industry	●	○	○	○	○
Consumers	○	○	●	○	○

How can a more adequate distribution be ensured?

(500 word limit)

To ensure a more adequate distribution of compliance costs, the following measures can be taken: Public Authorities: Public authorities should allocate sufficient funding for the implementation of national tobacco control strategies and plans. This includes funding for enforcement activities, monitoring and evaluation, research, and public awareness campaigns. By increasing their financial commitment to tobacco control, public authorities can alleviate the burden on other actors, such as consumers and economic operators, and ensure that necessary measures are effectively implemented. Economic Operators in the Tobacco Industry: Economic operators in the tobacco industry have a responsibility to bear the compliance costs associated with tobacco control regulations. They should be required to allocate a portion of their resources towards meeting these obligations. This includes investments in product labeling, packaging, advertising restrictions, and compliance with health warnings. Implementing stricter regulations and imposing fines or penalties for non-compliance can serve as incentives for economic operators to prioritize public health over their commercial interests. Consumers: While consumers may experience some indirect compliance costs, such as potential price increases due to taxes and regulations, their overall burden should be minimized. Public authorities can implement measures to ensure that affordable tobacco cessation products, services, and resources are available to help consumers quit smoking. This includes providing access to smoking cessation programs, support services, and nicotine replacement therapies. By prioritizing public health interventions and support for tobacco users, public authorities can alleviate the financial burden on consumers while promoting positive health outcomes. Additionally, public awareness campaigns should focus on educating consumers about the long-term health and financial benefits of quitting smoking. By highlighting the costs associated with tobacco use and the potential savings from quitting, consumers may be more motivated to seek assistance and make positive behavior changes. To implement these measures, it is crucial for public authorities to secure sustainable funding for tobacco control efforts. This can be achieved through budget allocations, earmarked taxes on tobacco products, or alternative sources such as fines imposed on the tobacco industry for non-compliance. By ensuring a stable and sufficient funding stream, public authorities can effectively distribute compliance costs and prioritize public health over the tobacco industry's interests.

Word count: 355

Coherence of the TPD

Are all of the TPD provisions internally coherent with each other?

Not at all	To a limited extent	To a large extent	Yes, absolutely	**Don't Know/ Can't answer**
○	○	○	○	●

To what extent is the TPD coherent with other applicable EU legislation relevant for tobacco control?

	Not at all	To a limited extent	To a large extent	To a full extent	Don't Know/ Can't answer
The Tobacco Advertisement Directive (TAD)	○	●	○	○	○
The Council Recommendation on Smoke-Free Environments	○	○	○	●	○
The Tobacco Taxation Directive	○	●	○	○	○
The Single-Use plastics Directive	●	○	○	○	○
The Audio-visual Media Services Directive	○	●	○	○	○
The Digital Services Act	○	●	○	○	○
The Common Agricultural Policy	●	○	○	○	○
Other (please specify)	○	○	○	○	●

In which regards? Please elaborate.

(750 word limit)

The coherence of the Tobacco Products Directive (TPD) with other applicable EU legislation relevant for tobacco control can be assessed in several regards: Single Use Plastics (SUP) Directive: The TPD is not fully coherent with the SUP Directive, particularly regarding the treatment of cigarette filters. While the SUP Directive bans certain single-use plastics, it does not include a ban on filters in tobacco products. This lack of alignment is due to the decision that reducing cigarette consumption or filter use falls beyond the scope of tackling marine litter. However, filters containing plastic have a significant detrimental environmental impact, and their ban could have been justified based on environmental grounds. The TPD should include provisions to address this issue and support the reduction of cigarette filters as outlined in the SUP Directive's reduction targets. Environmental Impact and Tobacco Cultivation: Tobacco cultivation has significant environmental consequences, including pollution of ground water due to the use of pesticides, fertilizers, and growth regulators. The TPD does not directly address these environmental issues associated with tobacco farming. Soil degradation, deforestation, and erosion caused by tobacco cultivation have detrimental effects on ecosystems and contribute to environmental degradation. The TPD should

incorporate measures to promote sustainable agricultural practices and mitigate the environmental impact of tobacco cultivation, aligning with broader EU goals for sustainable food production and environmental protection. Common Agricultural Policy (CAP) Subsidies: The TPD lacks coherence with the EU's Common Agricultural Policy (CAP) subsidies for tobacco farming. Despite the EU's commitment to promoting sustainable food production and public health, tobacco farming continues to receive subsidies through the CAP. These subsidies, estimated at a significant amount, contradict the goals and values of other European policies, such as the European Beating Cancer Plan and the Farm to Fork strategy. To ensure coherence, the revised TPD should address the issue of tobacco farming subsidies and advocate for their discontinuation to align with broader EU objectives.

Word count: 316

To what extent is the TPD coherent with other policies relevant for tobacco control adopted nationally by Member States?

Not at all	**To a limited extent**	To a large extent	To a full extent	Don't Know/ Can't answer
○	●	○	○	○

EU Added Value of the TPD

Is there any misalignment between EU and national regulations?

Not at all	To a limited extent	**To a large extent**	Completely	Don't Know/ Can't answer
○	○	●	○	○

On which matters?

Different overall approaches (e.g., Member States going beyond TPD regulations)		
☐		
Labelling and packaging (e.g., plain packaging)	Points of sale regulations	Other (please specify)
■	☐	☐

Sustainability of the TPD

What are the most concerning impacts, for your organisation, regarding the environmental consequences from tobacco and related products?

(750 word limit)

As the European Public Health Alliance (EPHA), the most concerning impacts regarding the environmental

consequences from tobacco and related products are similar to those highlighted by one of our members, the Smoke Free Partnership (SPF). We share their concerns regarding cigarette filters and disposable electronic devices. Cigarette filters, with their plastic composition, contribute significantly to plastic pollution. Billions of cigarette filters are discarded each year, making them one of the most prevalent forms of single-use plastic waste found in the environment, including beaches and water bodies. These filters take a long time to break down, releasing harmful chemicals and microplastics into the environment. The negative impact on terrestrial and aquatic ecosystems is alarming, threatening wildlife and polluting ecosystems. Furthermore, the use of filters has no proven health benefits and may even be linked to a more aggressive form of cancer. Banning cigarette filters would not only help address environmental concerns but also protect public health. Disposable electronic devices, such as heated tobacco products, pose additional environmental challenges. These devices contain batteries and electronic components that require mining for raw materials and energy consumption during their production and use. Improper disposal of these devices leads to electronic waste, which often contains hazardous substances and contributes to pollution of soil, water, and air. The agricultural practices associated with tobacco production for these devices, including the use of water, pesticides, and fertilizers, also have significant environmental impacts. The increasing popularity of these products raises concerns about the potential escalation of their environmental footprint if not properly addressed. To address these concerns, it is crucial to adopt comprehensive measures at the EU level. This includes banning cigarette filters and implementing strict regulations on the disposal and management of electronic waste from tobacco-related products. Additionally, promoting sustainable alternatives to conventional tobacco products and encouraging the reduction of overall tobacco consumption would have positive environmental and public health outcomes. The EU should also consider aligning its policies and subsidies, such as the Common Agricultural Policy, with sustainable food production and public health objectives, ensuring coherence across different areas of legislation. EPHA advocates for the adoption of evidence-based policies and measures that prioritize public health and environmental protection. By addressing the environmental consequences of tobacco and related products, we can contribute to a healthier and more sustainable future for European citizens and ecosystems.

Word count: 386

Which type of measures have been taken (or will be taken) by the European Commission or/and Member States?

(750 word limit)

Cigarette filters: Efforts have been made by several European countries to address the environmental impact of cigarette filters. In the Netherlands, the State Secretary of I&W commissioned an independent report to explore ways to achieve a 70% reduction in littered cigarette filters as part of the national circular economy plan. The report concluded that a ban on cigarette filters is the most effective approach to reach this target. Currently, the Netherlands is actively investigating the legal possibilities for implementing such a ban. This initiative demonstrates a proactive step towards reducing the environmental harm caused by cigarette filters. Additionally, Belgium's Superior Health Council recently issued an advisory report highlighting the impact of cigarette filters on public health and the environment, recommending a ban. This recognition from a national health authority further strengthens the case for action against cigarette filters. It is crucial for Member States to consider these recommendations and take concrete measures to address the environmental consequences of cigarette filters. Disposable vaping products: In line with circular economy objectives, disposable vaping products are also being subject to unilateral regulations across the EU. France, for instance, is contemplating a ban on disposable vapes by the end of 2023. The French government acknowledges the environmental impact of these products, as well as the potential health risks associated with their use. This proposed ban aligns with broader efforts to reduce waste and promote a circular economy. Germany is also taking steps to address the issue of disposable e-cigarettes. The Bundesrat is preparing to vote on Bavaria's call to outlaw single-use vapes. Various committees, including the Committee for Environment, Nature Conservation and Nuclear Safety, the Committee on European Union Questions, and the Economic Committee, have recommended a ban on the marketing of single-use vapes at both national and EU levels. These recommendations demonstrate a growing consensus on the need for effective measures to restrict the use of disposable vaping products. EU-level action is also underway to ban single-use disposable devices, including vaping products. The draft Battery Regulation, specifically Article 11, emphasizes the importance of portable batteries being readily removable and replaceable. While the proposed regulation indicates progress, further secondary regulations and guidance

will be developed in the coming years to provide more detailed instructions on the removability and replaceability of portable batteries.

Word count: 378

What is the level of concern, for your organisation, regarding the environmental impact of single-use (disposable) e-cigarettes (e.g., incorrect disposal of the product, content of critical raw material, etc.)?

Not concerned	Somehow concerned	Concerned	**Very concerned**	Don't know/Can't answer
○	○	○	●	○

Complementarity of the TPD

Are there considerable divergencies in the effective implementation of any of the TPD provisions across the different Member States?

Not at all	**To a limited extent**	To a large extent	Yes, completely	Don't know/Can't answer
○	●	○	○	○

Which divergencies are more noticeable?

Please explain the divergencies in detail (article with divergences, Member States involved, its impact, etc.).

(750 word limit)

Divergences in the effective implementation of TPD provisions can be observed across different Member States, particularly in areas such as plain standardised packaging, distance sales of tobacco products, and regulations on new products and flavors. Plain standardised packaging: Article 24(2) of the TPD allows Member States to implement plain standardised packaging, and currently, seven Member States have taken steps to adopt this measure. However, other Member States are in the process of considering or implementing similar measures. The divergence lies in the pace and extent of implementation, with some countries being more proactive in adopting plain packaging regulations, while others are still in the early stages of the process. This variation creates inconsistencies in the appearance and branding of tobacco products across different countries. Distance sales of tobacco products: Across the European Union, 17 Member States have implemented bans on local and/or cross-border distance sales of tobacco products. In addition, seven Member State authorities have imposed registration requirements for distance sellers. However, there are still Member States that have not implemented such measures, leading to divergences in the regulation of online tobacco sales. This can create challenges in enforcing consistent regulations and protecting public health across borders. Regulations on new products and flavors: Member States are taking different approaches to regulate certain new tobacco products and flavors. For example, the Netherlands has announced a ban on nicotine pouches starting from January 2023. This diverges from the approach taken by other countries, which may have different regulations or no specific regulations on these products. The varying regulations on new products and flavors can create inconsistencies in the availability and marketing of these products, potentially impacting consumer behavior and public health outcomes. These divergences in the effective implementation of TPD provisions highlight the challenges in achieving harmonization and consistency across the European Union. While the TPD provides a framework for tobacco control measures, Member States have some flexibility in implementing these measures, which can lead to differences in regulatory approaches. It is important to address these divergences through increased collaboration and coordination among Member States, sharing best practices, and working

towards a more harmonized approach to tobacco control.

Word count: 356

Did the divergencies in tobacco control policies across Member States have a positive or negative effect on the achievement of the TPD legislative objectives?

Negative	Somewhat negative	Neither negative nor positive	**Somewhat positive**	Positive
○	○	○	●	○

Don't know/Can't answer ○

Please elaborate on which effects it had:

(750 word limit)

Divergencies in the effective implementation of TPD provisions can also be observed in the interpretation and application of Article 24, which allows Member States to set more ambitious goals and provisions in tobacco control. Lack of clarity in conditions and process: The conditions and process for the application of Article 24(3) need to be clarified to reduce uncertainties around the adoption of national measures. The current lack of clarity has resulted in legal uncertainty and differing interpretations among Member States, leading to inconsistencies in the implementation of more ambitious tobacco control measures. Clear guidelines and criteria are necessary to ensure a transparent and standardized approach across the European Union. Legal uncertainty and challenges: The flexibility provided by Article 24(3) has led to legal challenges and uncertainties. Member States and civil society advocacy groups have faced difficulties in navigating the specific situation and conditions required to prohibit certain categories of tobacco or related products. The lack of clear guidance and uniform interpretation hinders the effective pursuit of public health objectives and may result in delays or inconsistencies in implementing necessary measures. Harmonization and coordination: The divergencies in the application of Article 24 can create challenges in achieving harmonization and coordination among Member States. While the provision allows for more ambitious measures, it is important to strike a balance between national circumstances and the need for a consistent approach to tobacco control. Clear guidelines and a coordinated framework will help ensure that public health objectives are effectively pursued while minimizing discrepancies between Member States. To address these issues, it is essential for the TPD to provide clear and comprehensive guidelines on the conditions and process for the application of Article 24(3). This will help reduce legal uncertainties, promote harmonization, and facilitate the adoption of more ambitious tobacco control measures by Member States. The guidelines should consider the specific situations and national circumstances of Member States, while also ensuring that public health objectives and health-related inequalities are effectively addressed.

Word count: 326

To what extent have Member States implemented national tobacco control policies which support the following objectives of the WHO FCTC (beyond TPD requirements)?

	Not at all	To a limited extent	To a large extent	National policies perfectly fit the FCTC's objectives	Don't know/Can't answer
Regulating sales arrangements including tobacco vending	○	●	○	○	○

	Not at all	To a limited extent	To a large extent	National policies perfectly fit the FCTC's objectives	Don't know/Can't answer
machines, points of sale and cross-border distance sale of tobacco	○	●	○	○	○
Promoting and strengthening public awareness of tobacco control issues by adopting and implementing appropriate measures	○	●	○	○	○
Developing and disseminating guidelines based on scientific evidence and best practices and taking measures to promote cessation of tobacco use and adequate treatment for tobacco dependence	○	●	○	○	○
Protecting the environment and the health of the persons in relation to the environment with respect to tobacco cultivation and manufacture	●	○	○	○	○
Developing and promoting national research and coordinating research programmes in the field of tobacco control	○	●	○	○	○
Other (please specify)	○	○	○	○	●

To what extent did the TPD miss any opportunity to achieve further economic, environmental and/or social benefits?

Not at all	To a limited extent	**To a large extent**	To a full extent	Don't know/Can't answer
○	○	●	○	○

Which were these missed opportunities?

(750 word limit)

The TPD missed certain opportunities to achieve further economic, environmental, and social benefits. Two key missed opportunities are: Ban on the sale and delivery of tobacco products to people born on or after 1 January 2012: The introduction of a ban on the sale and delivery of tobacco products to individuals born after a certain date would have significant benefits for public health and the reduction of tobacco use among young people. Countries like New Zealand have already implemented similar measures, which aim to create a smoke-free generation. By including such a ban in the revised TPD, the EU could lead by example

and demonstrate its commitment to protecting the health of young people. Targeting and preventing young people from taking up smoking is crucial to reducing the overall number of smokers in Europe. This measure would align with the EU's initiatives to enhance public health protection and contribute to the implementation of the Europe's Beating Cancer Plan, which aims for a tobacco-free Europe and a tobacco-free generation. Ban on tobacco filters: Cigarette filters, made of non-biodegradable materials like cellulose acetate, contribute significantly to environmental pollution. They are among the most commonly found single-use plastic items on beaches and contain harmful microplastics that can take decades to decompose. Additionally, cigarette filters have no proven health benefits and may even lead to a more aggressive form of cancer. Despite their negative environmental and health impacts, tobacco product filters have not been subject to market restrictions under the Single-Use Plastics (SUP) Directive. A missed opportunity lies in the failure to address the environmental consequences of cigarette filters and include a ban on filters in the TPD. A ban on filters would not only contribute to environmental sustainability but also align with the EU's efforts to combat plastic pollution and promote a circular economy. It would also dispel the misconception that filters make cigarettes safer and reinforce the harmful nature of smoking. By seizing these missed opportunities, the revised TPD could have a more comprehensive and impactful approach to tobacco control, leading to positive economic, environmental, and social outcomes. A ban on the sale and delivery of tobacco products to young individuals and a ban on tobacco filters would demonstrate the EU's commitment to protecting public health, reducing tobacco-related harm, and addressing environmental concerns associated with tobacco use.

Word count: 385

Coordination of the TPD

To what extent have coordination efforts among Member States been sufficient following the adoption of the TPD?

Not at all	**To a limited extent**	To a large extent	To a full extent	Don’t Know/ Can’t answer
○	●	○	○	○

To what extent have coordination efforts between Member States and the European Commission been sufficient following the adoption of the TPD?

Not at all	To a limited extent	To a large extent	To a full extent	**Don’t Know/ Can’t answer**
○	○	○	○	●

Which were the missed opportunities to improve coordination at the Member State-Member State and European Commission-Member State levels?

(750 word limit)

There were missed opportunities to improve coordination at the Member States-Member States (MS-MS) and EC-MS levels, particularly in relation to the implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC). This article requires Parties to protect their public health policies from commercial and other vested interests of the tobacco industry. The EU and its Member States are Parties to the FCTC, and therefore have an obligation to take steps to prevent interference by the tobacco industry in tobacco control policies. At the MS-MS level, there is a need for better coordination and implementation of measures to prevent tobacco industry interference. This can be achieved by following the guidelines for the implementation of Article 5.3 of the FCTC, which provide recommendations for preventing tobacco industry interference in all branches of government that may affect public health policies related to

tobacco control. Strengthening coordination among Member States in implementing these guidelines would ensure a consistent and unified approach in protecting public health from the influence of the tobacco industry. At the EC-MS level, there have been concerns regarding the European Commission's failure to adequately implement the obligations of Article 5.3. The EU Ombudsman has found instances of maladministration on the part of the Commission, including its refusal to apply proactive transparency policies across the entire Commission and its approach to meeting with tobacco lobbyists. To address these concerns and improve coordination, it is important to reference the obligations of Article 5.3 in the recitals of the TPD, reaffirming the commitment to safeguard public health policies from undue influence and providing a clearer legal basis for implementing Article 5.3 at both EU and Member State levels. Another missed opportunity for coordination relates to the Illicit Trade Protocol, which was not in force and ratified by the EU at the time of adopting the TPD. However, the Protocol is a binding treaty to which the EU is a key Party, and it sets obligations for combatting illicit trade in tobacco products. Conducting a thorough legal and operational review of the compatibility of the TPD with the Illicit Trade Protocol and including it in considerations for the directive would strengthen the political and legal value of the Protocol within the EU tobacco control framework. This would also highlight the importance of consistency and cooperation in addressing illicit trade in tobacco products. Improving coordination at both the MS-MS and EC-MS levels regarding the implementation of Article 5.3 and the integration of the Illicit Trade Protocol would enhance the effectiveness of tobacco control measures, ensure a consistent approach across Member States, and protect public health policies from undue influence by the tobacco industry.

Word count: 440

Acceptability of the TPD

To what extent can the TPD be considered acceptable, considering public health interests?

Not at all	To a limited extent	**To a large extent**	To a full extent	Don't Know/ Can't answer
○	○	●	○	○

Relevance of the TAD

Which of the following products pose challenges to the ability of the TAD to remain relevant?

Choose as many as apply

E-cigarettes	**Heated Tobacco Products**	**Nicotine pouches**	**Nicotine-free surrogates**
■	■	■	■

Other (please specify)	None	Don't know/Can't answer
☐	☐	☐

To what extent does the TAD remain pertinent to address the following developments?

	Not at all	To a limited extent	To a large extent	To a full extent	Don't Know/ Can't answer

	Not at all	To a limited extent	To a large extent	To a full extent	Don't Know/ Can't answer
The expansion of novel tobacco products	●	○	○	○	○
The development of emerging products (non-tobacco)	●	○	○	○	○
The use of social media	●	○	○	○	○
The portrayal of some products as a quitting tool	●	○	○	○	○

Are any of the definitions from the TAD irrelevant nowadays?

Yes	No	Don't know/ Can't answer
●	○	○

If so, which one(s) and why?

(750 word limit)

One of the definitions from the Tobacco Advertising Directive (TAD) that may be considered irrelevant nowadays is the definition of 'tobacco products'. The TAD defines tobacco products as all products intended to be smoked, sniffed, sucked, or chewed inasmuch as they are made, even partly, of tobacco. This definition is inconsistent with the definition of tobacco products in other EU legislation, such as the Tobacco Products Directive (TPD), and may not reflect market developments. The TPD defines tobacco products as products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not. It also provides specific definitions for smokeless tobacco products, tobacco products for smoking, and novel tobacco products. However, the TAD does not clearly cover novel tobacco products, such as heated tobacco products and nicotine pouches. As a result, the tobacco advertising and sponsorship restrictions do not apply to these products. This legislative gap is similar to the one that existed for the marketing of electronic cigarettes before it was addressed in the TPD. The TPD extended the advertising and sponsorship restrictions to electronic cigarettes, which are not tobacco products. However, no similar extension exists for devices used for heated tobacco products, despite the fact that the tobacco products themselves are covered by the ban on tobacco advertising and sponsorship. This creates a loophole that allows the tobacco industry to concentrate their marketing efforts on heated tobacco products, which are largely unrestricted by the bans on traditional tobacco products. This undermines the effectiveness of tobacco control measures and jeopardizes public health goals. To address this issue, it is necessary to align the definitions of tobacco products across relevant legislation and ensure that the TAD applies to all tobacco products, including novel tobacco products and devices used exclusively for their consumption. By closing this legislative gap, the advertising and sponsorship restrictions can be effectively extended to cover all tobacco products, promoting consistent and comprehensive tobacco control measures and protecting public health

Word count: 325

Do new corporate social responsibly schemes (including the creation of foundations) undermine the policy objectives of the TAD?

Not at all	To a limited extent	To a large extent	**To a full extent**	Don't Know/ Can't answer
○	○	○	●	○

Please elaborate how and if the TAD could have prevented this

(750 word limit)

New corporate social responsibility (CSR) schemes, including the creation of foundations, undermine the policy objectives of the Tobacco Advertising Directive (TAD). The tobacco industry utilizes CSR as a means to reduce support for regulatory change and to influence public opinion in favor of their own agenda. These CSR activities serve as a covert form of lobbying and can fracture opposition by creating a divide among stakeholders. The tobacco industry's CSR activities violate the provisions of the World Health Organization's Framework Convention on Tobacco Control (FCTC), particularly Articles 13 on advertising and 5.3 on tobacco industry interference. The FCTC Guidelines for implementation state that tobacco industry CSR should be banned. However, the TAD currently does not cover all forms of advertising and promotion, including CSR activities, allowing the tobacco industry to exploit this gap. To prevent the tobacco industry's CSR activities from undermining tobacco control efforts, the revision of the TAD should consider the following measures: 1) Expanding the definition of advertising: The definition of advertising should be broadened to include a wider range of activities, including CSR activities. This would ensure that any activity that could be construed as CSR, such as donations or funding for public projects, would be considered advertising and subject to regulation. 2) Banning tobacco industry CSR activities: The TAD should explicitly prohibit tobacco industry CSR activities. This would make any form of CSR by tobacco companies illegal, preventing them from using these activities as a means of promoting their products or improving their public image. 3) Mandatory disclosure of tobacco industry CSR activities: Requiring tobacco companies to disclose their CSR activities would provide transparency and allow regulators and the public to understand the extent of their involvement in such initiatives. This would enable better monitoring and evaluation of their impact on public health. 4) Strict regulation of branding in CSR activities: The use of brand names or logos in CSR activities should be strictly regulated to minimize the promotional impact of these activities. This would prevent tobacco companies from using their branding to gain positive recognition or influence public opinion. 5) Implementation of strict penalties for non-compliance: The TAD should establish stringent penalties for non-compliance with regulations related to CSR activities. This would serve as a strong deterrent for the tobacco industry, discouraging them from engaging in CSR initiatives that undermine tobacco control efforts. 6) Third-party verification of compliance: Requiring third-party verification of compliance with CSR regulations would help ensure transparency and limit the tobacco industry's ability to misinterpret or misreport their activities. Independent verification would enhance credibility and accountability in assessing the true nature and impact of CSR initiatives. These measures, if carefully crafted and accompanied by strong enforcement mechanisms, would help address the undermining effect of tobacco industry CSR on the policy objectives of the TAD. They would also contribute to the successful implementation of Article 12 of the FCTC, which emphasizes the promotion and strengthening of public awareness of tobacco control issues. By shedding light on tobacco industry CSR activities, these measures would increase public awareness of the industry's tactics and their negative impact on public health.

Word count: 515

To what scale are the following TAD articles still relevant…

Please provide a value from 1 (not relevant at all) to 4 (remains fully relevant) for each of the following articles and statements. Please select 0 if you don't know or can't answer

	...to tackle today's reality and address new product developments in the market?	...to reach the goal of Europe's "tobacco-free generation" by 2040?
Definition of tobacco products	2	2
Definition of advertising	2	2
Definition of		

	...to tackle today's reality and address new product developments in the market?	...to reach the goal of Europe's "tobacco-free generation" by 2040?
sponsorship	2	2
Definition of information society services	2	2
Ban on the advertising of tobacco products in press and on all other non-professional printed publications	4	3
Ban on all radio advertisement of tobacco products	4	3
Ban on the sponsorship of radio programmes by tobacco sellers or manufacturers	4	3
Ban on the sponsorship of tobacco products in events taking place in several member states	4	3
Ban on the sponsorship of tobacco products in events having cross-border effects	4	3
Ban on the free distribution of tobacco products at events	4	3
Ban on the advertisement of e-cigarettes and refill containers in the press and on all other non-professional printed publications	4	3

Effectiveness of the TAD

To what extent were the following objectives set by the TAD effectively achieved?

	Not at all	To a limited extent	To a large extent	To a full extent	Don't Know/ Can't answer
Ban on the advertising of tobacco products in press and on all other non-professional printed publications	○	○	●	○	○
Ban on all radio advertisement of tobacco products	○	○	●	○	○
Ban on the sponsorship of radio programmes by tobacco sellers or manufacturers	○	○	●	○	○
Ban on the sponsorship of tobacco products in events taking place in several member states	○	○	●	○	○
Ban on the sponsorship of tobacco products in events having cross-border effects	○	●	○	○	○
Ban on the free distribution of tobacco	○	○	●	○	○

products at events

To a limited | To a large | To a full | Don't Know/

Did the fragmentation (i.e., the split into TPD, TAD, and other separate pieces of legislation) of the current EU tobacco control framework have a positive or negative effect on the achievement of the TAD legislative objectives?

Negative | **Somewhat negative** | Neither negative nor positive | Somewhat positive | Positive

Don't know/Can't answer

Please elaborate on which effects it had:

If applicable, please define these effects, highlighting positive and/or negative impacts on relevant stakeholders (e.g., public health, tobacco and related products users, MS public authorities, tobacco producers, manufacturers, etc.)

(750 word limit)

The fragmentation of the current EU tobacco control framework, with separate pieces of legislation such as the Tobacco Products Directive (TPD) and the Tobacco Advertising Directive (TAD), has had a negative effect on the achievement of the TAD legislative objectives. One of the main challenges resulting from this fragmentation is the difficulty in addressing new market developments and emerging forms of tobacco advertising. The TAD has not been revised since 2003, which prevents EU institutions from effectively addressing new advertising channels, such as social media platforms, which have become increasingly popular in recent years. The lack of harmonized legislation hampers a coherent and speedy revision process, limiting the ability to adapt to new advertising strategies used by the tobacco industry. The rise of social media advertising of tobacco products poses a significant challenge to the implementation of the advertising ban. Tobacco companies often employ covert and indirect advertising tactics on social media, using influencers to subtly promote their products. The fragmented EU tobacco control framework makes it difficult to identify and monitor these covert forms of advertising, enforce regulations, and hold responsible entities accountable. The inherently cross-border nature of online platforms further complicates the enforcement process. Although many social media platforms have internal policies that prohibit paid advertising for tobacco products, these rules are not consistently enforced, and they often do not cover paid influencer content. The existing EU provisions on tobacco advertising in information society services are outdated and lack appropriate enforcement mechanisms, making it challenging to respond effectively to the evolving virtual environment. Another area affected by the fragmentation is the depiction of tobacco use in films and television. While the TAD prohibits tobacco sponsorship in films and television, the presence of tobacco use and imagery in media content is still prevalent. Proving potential arrangements between tobacco companies and film producers or actors can be difficult. To address this, the full implementation of Article 13 of the FCTC, along with its Guidelines, is crucial. This would introduce obligations for producers and streaming platforms to certify that no benefits have been received for tobacco depictions, prohibit the use of identifiable brands or imagery, require anti-tobacco advertisements, and implement a rating system that considers tobacco depictions.

Word count: 366

To what extent did the application of the provisions of the TAD caused unexpected and/or unintended effects?

Not at | To a limited | To a large extent | To a full | **Don't Know/ Can't**

Not at all	To a limited extent	To a large extent	To a full extent	Don't Know/ Can't answer
○	○	○	○	●

Efficiency of the TAD

Did public health benefits outweigh the costs related to the implementation of the TAD?

Not at all	To a limited extent	To a large extent	**To a full extent**	Don't Know/ Can't answer
○	○	○	●	○

Coherence of the TAD

To what extent is the TAD consistent with other applicable EU legislation relevant for tobacco control?

	Not at all	To a limited extent	To a large extent	To a full extent	Don't Know/ Can't answer
The Tobacco Products Directive (TPD)	○	○	●	○	○
The Council Recommendation on Smoke-Free Environments	○	○	●	○	○
The Tobacco Taxation Directive	○	○	●	○	○
The Single-Use plastics Directive	○	●	○	○	○
The Audio-visual Media Services Directive	○	●	○	○	○
The Digital Services Act	○	●	○	○	○
The Common Agricultural Policy	○	●	○	○	○
Other (please specify)	○	○	○	○	●

To what extent did the TAD miss any opportunity to supplement Member States' policies?

Not at all	To a limited extent	**To a large extent**	To a full extent	Don't Know/ Can't answer
○	○	●	○	○

To what extent are there differences amongst Member States as far as the following

provisions of the TAD are concerned?

	Not at all	To a limited extent	To a large extent	To a full extent	Don't Know/ Can't answer
Article 2: Definitions	○	○	●	○	○
Articles 3-5: Advertisement bans	○	○	●	○	○
Article 7: Penalties and enforcement	○	○	●	○	○

EU Added Value of the TAD

To what extent have EU-wide advertisement bans supported Member States in the development of tobacco control policies compared to what could have reasonably been achieved by Member States acting alone?

	Not at all	To a limited extent	To a large extent	To a full extent	Don't know/Can't answer
Advertising in printed media and information society services	○	○	●	○	○
Radio advertising and sponsorship	○	○	●	○	○
Sponsorship of events	○	○	●	○	○

To what extent is EU level action in the area of tobacco advertisement essential to ensure that public health objectives are met?

Not at all	To a limited extent	To a large extent	**To a full extent**	Don't Know/ Can't answer
○	○	○	●	○

Which are the main challenges faced by your country for reaching the objectives of Europe's Beating Cancer plan to achieve a tobacco-free generation by 2040?

(1000 word limit)

The main challenges faced in reaching the objectives of Europe's Beating Cancer Plan to achieve a tobacco-free generation by 2040 include the need to ban all flavors, flavor accessories, and additives, strengthen advertising bans, implement a ban on the sale and delivery of tobacco products to individuals born after a certain date, and enforce display bans of tobacco products at points of sale. 1) Ban all flavors, flavor accessories, additives, and strengthen advertising bans: While the Tobacco Products Directive (TPD) banned characterizing flavors in cigarettes and roll-your-own tobacco, there are loopholes that allow the tobacco industry to continue using additives that do not result in a characterizing flavor. Flavor accessories, such as menthol filter tips, have been introduced to circumvent the ban. The tobacco industry also uses advertising to insinuate flavor-like qualities, undermining the effectiveness of the ban. Strengthening the

ban on flavors, flavor accessories, and additives would prevent tobacco companies from using them as tools to attract new users, especially inexperienced individuals. 2) Ban the sale and delivery of tobacco products to individuals born after a certain date: The TPD does not include a comprehensive ban on the sale and delivery of tobacco products to individuals born after a specific date. This loophole allows tobacco products to be sold and delivered to young people, undermining efforts to prevent youth initiation and reduce tobacco use among the younger population. Implementing a ban on the sale and delivery of tobacco products to individuals born after a certain date, such as January 1, 2012, would help protect young people and contribute to the goal of a tobacco-free generation. 3) Display ban of tobacco products at points of sale: The Tobacco Advertising Directive (TAD) does not explicitly address the display of tobacco products at points of sale (POS). Display bans at POS are considered a form of tobacco advertising, promotion, and sponsorship, which are not allowed under the World Health Organization Framework Convention on Tobacco Control (WHO FCTC). While some countries have implemented display bans, there is incoherence in the legislation among member states, leading to health inequalities. Implementing a total ban on the display and visibility of tobacco products at POS, as advised by the WHO FCTC, would help reduce tobacco use and its associated negative health impacts, particularly among adolescents. The evidence supports the effectiveness of display bans in reducing smoking rates, especially among young people. Studies have shown that countries with display bans experienced a decrease in smoking rates among adolescents. The phased-in ban on the open display of tobacco products in the UK led to a reduction in smoking susceptibility among adolescents. Global research also indicates that countries with display bans had lower overall smoking rates. Therefore, implementing display bans consistently across all member states is essential for achieving the objectives of Europe's Beating Cancer Plan.

Word count: 467

Which are the major areas of divergencies among national and EU regulations on tobacco control?

(1000 word limit)

The major areas of divergence among national and EU regulations on tobacco control include advertising, nicotine pouches, and sustainability. 1) Advertising: Regulations on tobacco advertising vary significantly across Member States. While the Tobacco Advertising Directive (TAD) provides a framework for advertising restrictions, there is a wide margin of discretion for Member States in implementing and enforcing these rules. This has resulted in differences in the interpretation and application of the advertising bans. For example, in Germany, there is still promotion for tobacco and e-cigarettes at festivals, which can have cross-border effects when promoted on the internet. Additionally, there is often confusion regarding the concrete responsibilities of national authorities and the role of civil society in enforcing the rules. The Digital Services Act should aim to address the gaps in current tobacco advertising legislation, particularly in relation to online advertising. Furthermore, the ongoing development of supplementary guidelines to Article 13 of the WHO Framework Convention on Tobacco Control (FCTC) by the Conference of the Parties (COP) specifically focused on tobacco advertising and promotion in entertainment media should be considered in future legislative reviews. 2) Nicotine pouches: Nicotine pouches, which are not covered by the Tobacco Products Directive (TPD), are regulated in different ways across Member States. The lack of harmonization in the regulation of these products creates inconsistencies and challenges in ensuring their safety and appropriate labeling. Introducing a new definition of "novel tobacco and nicotine products" would help regulate products such as nicotine pouches and provide a framework for a notification system. It is important to address the advertising and attractiveness of these products, as even if they have lower levels of toxicity, their marketing strategies can still have negative health effects. A comprehensive regulatory approach is needed to address these emerging products. 3) Sustainability: Sustainability is another area where national and EU regulations on tobacco control diverge. Novel and emerging tobacco products pose obstacles to the realization of circular economy goals. National circular economy legislative frameworks tend to be more ambitious in regulating tobacco and related products to promote sustainability. Harmonizing regulations and incorporating sustainability principles at the EU level would help ensure a more consistent and effective approach to tobacco control.

Word count: 363

Is there is any further evidence you would like to upload supporting any of your answers?

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