Member State Questionnaire on the Assessment of the Tobacco Products Directive

1.1 Introduction

ICF is currently undertaking a study on Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (**revised Tobacco Products Directive**) on behalf of the Directorate-General for Health and Food Safety of the European Commission (DG SANTE).

The purpose of the study is to examine the practical application of Directive 2014/40/EU (hereinafter TPD) and its specific provisions, which strengthened existing rules on how tobacco products are manufactured, produced and presented in the EU, and introduced new rules for certain tobacco-related products. The study will assess the level of implementation of the TPD by exploring both achievements and hindering factors.

In particular, the study aims to:

- Assess its implementation and levels of compliance: exploring the achievements and successes of the revised Directive, as well as obstacles and shortcomings encountered by various stakeholders (Member States, Civil Society Organisations, health experts, and economic operators);
- Generate evidence (through primary and secondary data collection) - in particular on the inputs, outputs, outcomes and impacts of the TPD, with the aim to assess its overall relevance, effectiveness, efficiency, coherence and EU-added value.

The study will be used by the Commission for the preparation of its report on the application of the TPD, required by Article 28 of the Directive.

1.2 Purpose of consultation

The purpose of the consultation is to collect information and gather views from relevant authorities of EU Member States bound by the Directive on its implementation. We encourage you to elaborate on your replies and provide references to publicly accessible studies, surveys, court cases or any other documentation that you consider relevant.

If you have any questions with regard to the study, please do not hesitate to contact the project manager of the study: Christina Dziewanska-Stringer, TPDassessment@icf.com .

1.3 Your details

Table 1.1 Respondent's details

Country	
Name(s)	
Email(s)	
Contact number	

1.4 Questions on general implementation

1.4.1 Effectiveness

This series of questions asks about your views on how successful the TPD has been in achieving or supporting progress towards its objectives, including facilitating the smooth functioning of the internal market and ensuring a high level of human health protection, since it entered into force on 19 May 2014.

Question	Member State response
Has your Member State faced any issues in transposing the TPD?	*Yes / No / To some extent.* *Please elaborate, for example, any issues with specific articles.*
Did you find the guidance received from the Commission on transposing the TPD (for example, through discussions at Expert Groups, Sub-Groups or guidance documents) clear and useful?	*Yes / No / To some extent.* *Please elaborate.*
Overall, have economic operators been compliant with the TPD in your Member State?	*Yes / No / To some extent.* *Please elaborate.*
Has the TPD achieved its objectives, i.e. improved the functioning of the internal market while reducing smoking prevalence?	*Yes / No / To some extent.* *Please elaborate.*
In your view, has the TPD improved public health in your Member State (e.g. increased awareness of the harmfulness of products; decreased smoking rates)?	*Yes / No / To some extent.* *Please elaborate, including any relevant provisions.*
Does your Member State collect national data on the level of prevalence of use in the under 25 years of age consumer group?	*Yes / No.* *If yes, please provide the most recent results (web link or attachment)*
Has the TPD changed tobacco and related product use in young people in your Member State?	*Yes: it has increased use;* *Yes: it has decreased use;* *No: it has not changed use.* *Please elaborate.*

1.4.2 Relevance

For the next set of questions, we would like to ask you about the extent to which the TPD and its objectives are still relevant and meeting needs, considering scientific, technical and epidemiological developments. We are interested in if the TPD is flexible and has the capacity to evolve to withstand developments in the sector.

Question	Member State response
In your view, has the TPD remained relevant to address new market developments in your Member State, including types of emerging products? (For example, heated tobacco products or nicotine containing products).	*Yes / No / To some extent.* *Please elaborate.*
In your view, is the TPD 'future proof', as new societal, technical and scientific developments occur in the sector?	*Yes / No / To some extent.* *Please elaborate.*

1.4.3 Efficiency

Questions in this sub-section concern your views on the administrative burdens imposed by the TPD and their magnitude in relation to the benefits generated.

Question	Member State response
Has the practical implementation of the TPD created significant additional administrative burdens in your Member State?	*Yes / No / To some extent.* *Please elaborate.*
Would you consider that the benefits the TPD brings to consumers outweigh the overall costs that are being incurred to implement the Directive? To what extent were you able to recover some of the costs incurred via fees?	*Yes / No / To some extent.* *Please elaborate.*
Has your Member State provided any specific support to small and medium enterprises affected by the TPD?	*Yes / No / To some extent.* *Please elaborate.*

1.4.4 Coherence

For the next set of questions, we are interested in your thoughts on the extent to which the TPD is still coherent and consistent internally, i.e. with its own provisions, as well as with other relevant EU and international legislation that is linked to the TPD.

Question	Member State response
Has your Member State faced any issues with TPD provisions being inconsistent or incoherent with each other? For example, have the requirements of one article contradicted the requirements of another?	*Yes / No / To some extent.* *Please elaborate.*
Has your Member States faced any issues with TPD provisions being inconsistent or incoherent with other EU legislation, for example: • The Tobacco Taxation Directive	

Question	Member State response
• The audio-visual media services Directive • Tobacco Advertising Directive • Smoke Free Environments recommendation • Single Use Plastics Directive • Market Surveillance Regulation • The CLP Regulation for (Classification, Labelling and Packaging) • General Product Safety Directive • REACH (Regulation (EC) No 1907/2006)	
Has your Member State faced any issues with TPD provisions being inconsistent or incoherent with FCTC guidelines, including the Protocol to Eliminate Illicit Trade in Tobacco Products?	*Yes / No / To some extent.* *Please elaborate.*

1.4.5 EU added value

The final few questions are about your views on the extent to which the TPD adds value at the EU level, in a way that may not be attainable at a national or global level.

Question	Member State response
Has the TPD added value to the regulation of tobacco and tobacco-related products across the EU?	*Yes / No / To some extent.* *Please elaborate*
Do you feel that the effects of the TPD on smoking consumption or the illicit trade could have been achieved at the level of your Member State, without EU-level involvement?	*Yes / No / To some extent.* *Please elaborate*

1.5 Questions by article of interest

1.5.1 Article 2: Definitions

Background and key considerations	Question	Member State response
The directive sets out 41 definitions to be applied. Clear definitions are indispensable to ensure that this Directive is uniformly implemented by Member States. *However, certain concepts - defined within this Directive- may remain unclear, and cause interpretation issues, and/or divergent interpretations, during implementation.* *Also, in the light of various scientific, technological and market developments, some of the current definitions may no*	Have the definitions in the TPD been clear and unambiguous enough to allow for clear interpretation and implementation? For example, definitions including (but not limited to): - Novel Tobacco Products - Electronic cigarettes - Refill containers - Roll your own tobacco - Additive - Nicotine - Chewing, nasal and oral tobacco Retail Outlet - Flavouring - Substantial change of circumstances - Flavour/flavouring - Characterising flavour - Cross border distance sales	*Yes / No / Some unclarities and ambiguities.* *Please elaborate: If you consider one or more definitions to be unclear and/or ambiguous, please describe them here and propose improvements.*
	Have you experienced any particular issues with the classification of products, based on how they are defined in the Directive (e.g. “smokeless tobacco products” versus “tobacco products for smoking”)?	*Yes / No / To some extent.* *Please elaborate.*
	Have the definitions laid out in the TPD remained relevant in view of scientific, technological and market developments?	*Yes / No / To some extent.* *Please elaborate: If you consider one or more definition to be irrelevant in view of scientific, technological and market developments, please describe them here.*

Background and key considerations	Question	Member State response
longer be relevant or appropriate. **Please refer to Article 2 of the TPD for the full list.*	Are there any other products or categories for which a definition should be included in the Directive?	*Yes / No.* *Please elaborate.*
	Are the concepts as defined in this Directive consistent with other EU legislative instruments (e.g. Tobacco Taxation Directive, Tobacco Advertising Directive, Audio-visual Media Services Directive) or other legislation at National level?	*Yes / No / To some extent.* *Please elaborate: have inconsistencies led to any implementation issues in practice?*
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 2.

1.5.2 Article 3: Maximum emission levels for tar, nicotine, carbon monoxide and other substances

Background and key considerations	Question	Member State response

The TPD sets maximum emission levels from cigarettes placed on the market or manufactured in the Member States for tar, nicotine, and carbon monoxide. *If Member States set additional maximum emission levels for cigarettes, they must inform the commission.* *In view of new technical and scientific developments, these may be no longer or less relevant.*	Are the provisions on maximum TNCO emissions (Article 3(1)) still relevant in view of scientific and technological developments?	*Yes / No / To some extent.* *Please elaborate: Is there scope or necessity for changing the TNCO limits or introducing other limits?*
	Has your Member State set limits for additional maximum emission levels for cigarettes (Article 3(3))?	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes: Please elaborate, including when the Commission was notified.*
	Has your Member State set limits for maximum emission levels for other tobacco products (Article 3(3))?	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes: Please elaborate, including when the Commission was notified.*
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 3.

1.5.3 Article 4: Measurement methods

Background and key considerations	Question	Member State response
The TPD sets the measurement methods using ISO standards for tar, nicotine, and carbon monoxide for cigarettes placed on the market or manufactured in the Member States. *The measurements must be verified by independent approved laboratories.* *In view of new technical and scientific developments, these measurement methods may be no longer relevant, in which case delegated acts are foreseen by this directive.*	Are provisions on measurement methods (Article 4(1)) still relevant in view of scientific and technological developments?	*Yes / No / To some extent.* *Please elaborate.*
	Would there be necessity or scope for changing the measurement methods for emissions from the ISO method to e.g. the Canadian Intense (CI) method?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues with regard to the appointment and monitoring of laboratories (Article 4(2))? For example, in ensuring these are fully independent from the tobacco industry?	*Yes / No / To some extent.* *Please elaborate.* *How many laboratories have you approved to date? If none, what laboratories do you use for verification?*
	Has your Member State used any measurement methods for emissions for cigarettes other than the three specified in Article 4(1) (Article 4(4))?	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes: Please elaborate, including when the Commission was notified.*
	Has your Member State used any measurement methods for emissions for other tobacco products (Article 4(4))?	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes: Please elaborate, including when the Commission was notified.*
	Has your Member State charged manufacturers and importers of tobacco products proportionate fees for the verification of these measurement methods (Article 4(6))?	*Yes / No.* *If no: are you considering it? Why or why not?*

Background and key considerations	Question	Member State response
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 4.

1.5.4 Article 5: Reporting of ingredients and emissions

Background and key considerations	Question	Member State response
The Directive requires manufacturers and importers of tobacco	Has your Member State faced any issues in requiring manufacturers and importers to	*Yes / No / To some extent.* *Please elaborate, including if there have been any issues with manufacturers or importers informing about modifications of the composition of a product.*

products to submit to competent authorities certain information concerning the ingredients and emissions of tobacco products. There is an overall lack of evidence of how this provision is being implemented by different Member States.	submit the required information in Article 5(1), the statement of reasoning in Article 5(2), or the toxicological data in Article 5(3)?	
	Has your Member State faced any issues in making submitted information publicly available on a website (Article 5(4))? E.g. have there been issues with economic operators requesting information not be published due to trade secrets?	*Yes / No / To some extent.* *Please elaborate.* *Please provide a link to the publicly available list.*
	Do you know if consumers make use of the public information? In what ways / for what purpose?	*Yes / No.* *Please elaborate.*
	Has your Member State faced any issues with processing and assessment of submitted product information?	*Yes / No / To some extent.* *Please elaborate, for example any difficulties with scientific capacity to understand and assess data.*
	How has your Member State reacted to incorrect or insufficient submissions, including insufficient data?	*Please elaborate, including the actions and follow-up undertaken*
	Has your Member State faced any issues in requiring and assessing manufacturers and importers to submit the studies required by Article 5(6)?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in ensuring that the Commission and other Member States have access to this information (Article 5(7))?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State used information made available by	*Yes / No.* *If no: are you considering it? Why or why not?*

other Member States for the purposes of applying this Directive (Article 5(7))?	
Do you consider that the EU-CEG system works effectively? Would any further developments be required to improve its functioning?	*Yes / No / To some extent.* *Please elaborate.*
What would be the effects on your work of a possible European Union database containing information on tobacco products, including ingredients?	*Please elaborate, including possible benefits and difficulties with an EU-wide system.*
Since the Directive came into force, how many times has your Member State taken actions (such as product modification, product withdrawal, fines, or other punitive measures) against manufacturers or importers due to non-compliance related to reporting of ingredients and emissions?	*Please elaborate.*
Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 5.

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1.5.5 Article 6: Priority list of additives and enhanced reporting obligations

Background and key considerations	Question	Member State response
The Directive requires enhanced reporting obligations for certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list. *In addition, Member States shall require manufacturers and importers to carry out comprehensive studies*	Has your Member State faced any issues in requiring manufacturers and importers to carry out the comprehensive studies required in Article 6(2)?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State assessed reports submitted by manufacturers or importers to create the reports required in Article 6(4)?	*Yes / No / To some extent.* *Please elaborate, including on possible peer-review by a scientific body* *If no: are you considering it? Why or why not?*
	Since the publication of the priority list of additives, has your Member State taken regulatory action on any of the ingredients identified? Is your Member	*Yes / No / Considered.* *Please elaborate*

and to establish a report on the results of these studies. *Evidence is needed to understand whether this provision is being implemented and how MS are implementing it.*	State **intending** on taking regulatory actions of this type?	
	Has your Member State charged manufactures and importers proportionate fees for peer reviews of their reports (Article 6(4))?	*Yes / No.* *If no: are you considering it? Why or why not?*
	Since the Directive came into force, how many times has your Member State taken actions (such as product modification, product withdrawal, fines, or other punitive measures) against manufacturers or importers due to non-compliance related to additives and reporting?	*Please elaborate.*
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 6.

1.5.6 Article 7: Regulation of ingredients

Background and key considerations	Question	Member State response
The Directive requires that tobacco product with characterising flavours be prohibited. It also requires independent advisory panels to assist the Commission with determining the characterising flavours requirements. *Tobacco products with certain additives are also prohibited.* *These provisions only apply to certain products, and it is important to understand how these bans operate differently in Member States.*	Has your Member State faced any issues in prohibiting the placing on the market tobacco products with a characterising flavour (Article 7(1))?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in prohibiting the placing on the market tobacco products containing the additives listed in Article 7(6) (vitamins, caffeine, taurine, etc)?	*Yes / No / To some extent.* *Please elaborate on the practical implementation.* *Have you further detailed additives covered by this article?*
	Has your Member State prohibited any products following scientific evidence of their containing additives in quantities that increase the toxic or addictive effect, or the CMR properties at the stage of consumption to a significant or measurable degree (Article 7(9))?	*Yes / No/Under consideration* *Please list the products, if yes.* *If yes, did you notify the Commission of all products?*
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 7.

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 7.
*For example, does the current system of listing **prohibited** additives work well, or would you prefer a list with **permitted** products or additives?*

1.5.7 Articles 8-14: Labelling and Packaging

Article 8: General provisions
Article 9: General warnings and information messages on tobacco products for smoking
Article 10: Combined health warnings for tobacco products for smoking
Article 11: Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco
Article 12: Labelling of smokeless tobacco products
Article 13: Product presentation
Article 14: Appearance and content of unit packets

Background and key considerations	Question	Member State response
This Directive includes requirements for mandatory health warning labels and packaging of tobacco and related products. These requirements refer to the use of combined health warnings consisting of a picture and a text, information on cessation	Has your Member State faced any issues in implementing the provisions concerning general warnings and information messages on tobacco products for smoking (Articles 8 & 9)?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in implementing the provisions concerning combined health warnings for tobacco products for smoking (Article 10), including the minimum	*Yes / No / To some extent.* *Please elaborate.*

Background and key considerations	Question	Member State response
services and promotional elements in and on unit packets. *We want to understand to what extent are general provisions on labelling and packaging being implemented and if Member States are facing any issues implementing any of the provisions outlined in this section.*	dimension of warnings (Art. 10(1))?	
	Has your Member State ensured that the provisions for combined health warning were properly implemented on packages with bevelled edges (see recital 28)? Which action was taken if not?	*Yes / No / To some extent.* *Please describe how you have addressed the issue.*
	Has your Member States received any claims/complaints concerning the content or persons depicted on health warnings?	*Yes / No.* *Please elaborate on the type of those claims and how you addressed them.*
	Has your Member State faced any issues in implementing the provisions of Article 9(3) concerning the minimum dimensions of health warnings on the lateral surfaces of cuboid packets such as slim/flat/shoulder-hinged lid-packs (taking into account the guidance provided by the Commission).	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State exempted any tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message 'Tobacco smoke contains over 70 substances known to cause cancer' (Article 11(1))?	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes, please elaborate on the exempt products and any benefits or disadvantages.*

Background and key considerations	Question	Member State response
	Has your Member State exempted any tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry combined health warnings (Article 11(1))?	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes, please elaborate on the exempted products and any benefits or disadvantages.*
	If your Member State has exempted products in this way, has it faced any issues in implementing the alternative labels described in Article 11?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in implementing the provisions concerning labelling of smokeless tobacco products (Article 12)?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in interpreting and implementing the provisions concerning product presentation (Article 13), e.g. on promotional elements?	*Yes / No / To some extent.* *Please elaborate and provide examples of promotional elements you have dealt with.*
	Has your Member State faced any issues regarding the minimum number of sticks per pack or any of the other provisions listed in Article 14 (e.g. for RYO, material/opening of pack, etc.)	*Yes / No / To some extent.* *Please elaborate, including on possible further rules on pack sizes.*
	Since the Directive came into force, how many times has your Member State taken actions	*Please indicate the number of actions taken per Article and elaborate on the issue(s) encountered*

Background and key considerations	Question	Member State response
	(such as product modification, product withdrawal, fines, or other punitive measures) against manufacturers or importers due to non-compliance related to labelling and packaging?	
	Should there be stricter/clearer labelling provisions overall? Or on any specific products specifically?	*Yes / No.* *Please elaborate.*
	Has your Member State encountered any other difficulties in the practical application of the provisions of Articles 8-14?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Articles 8-14.

1.5.8 Articles 15-16: Traceability and security features

Background and key considerations	Question	Member State response
This Directive introduced an interoperable system on traceability and security features at Union level. *The system on traceability and security features requires a unique identifier be placed on unit packs, cartons, master cases and shipping cases that are either manufactured in the EU or imported into the EU market. All economic operators from manufacturing to the first retail outlet need to track all packs by recording the entry, intermediate movements, and final exit of the packs in their possession. We would like to gather your preliminary experiences with this system.*	Has your Member State faced any issues in implementing the traceability system required by Article 15 in relation to its provisions further specified in Commission Implementing Regulation (EU) 2018/574, for example in relation to appointment of an ID issuer and full access to the records created by anti-tampering devices?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in implementing the traceability system required by Article 15 in relation to its provisions not reflected in Commission Implementing Regulation (EU) 2018/574, in particular paragraphs 6 (maintenance of records of all relevant transactions) and 7 (provision of equipment)?	*Yes / No / To some extent.* *Please elaborate.*
	To what extent is the traceability system (Article 15) helping to fight the illicit trade of tobacco products?	*Please elaborate.*
	Has your Member State faced any issues in implementing the security features system required by Article 16, for	*Yes / No / To some extent.* *Please elaborate.*

Background and key considerations	Question	Member State response
	example in relation to the tamper proof marker?	
	To what extent is the security features system (Article 16) helping to fight the illicit trade of tobacco products?	*Please elaborate.*
	To what extent do you expect the procedures governing the appointment and monitoring of ID issuers, providers of repository services and providers of anti-tampering devices to provide for a sufficient level of independence from the tobacco industry?	*Please elaborate.*
	Has your Member State encountered any other difficulties in the practical application of the provisions of these Articles?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Articles 15 & 16.

1.5.9 Article 17: Tobacco for oral use

Background and key considerations	Question	Member State response

Background and key considerations	Question	Member State response
The Directive prohibits placing tobacco for oral use on the market, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.	Has your Member State encountered any difficulties in implementing the ban on tobacco for oral use?	*Yes / No / To some extent.* *Please elaborate.*
	Are you aware of any efforts to circumvent the ban on tobacco for oral use in your Member State?	*Yes / No.* *Please elaborate.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 17.

1.5.10 Article 18: Cross-border distance sales of tobacco products

Background and key considerations	Question	Member State response
The Directive allows Member States to prohibit cross-border distance sales of tobacco products to consumers. In Member States where this is not prohibited, retail outlets intending to sell products across borders must	Has your Member State prohibited cross-border distance sales to consumers (Article 18(1))?	*Yes / No.* *If no: are you considering it? Why or why not?*
	For countries where cross-border distance sales are permitted, which retail outlets have been registered in your Member States (Article 18(1))?	*How many retail outlets located in your Member State have registered with your competent authority?* *How many retail outlets located in another Member State with consumers in your Member State have registered with your competent authority?* *How many retail outlets located outside the EU with consumers in your Member State have registered with your competent authority?*

Background and key considerations	Question	Member State response
register with the competent authorities of the Member State where the retail outlet is established and the Member State where the consumers are located *Retailers who sell products across borders are required to have an age verification system at sale.*	Where do you publish the lists of the retail outlets registered in your Member State (Article 18(2))?	*Please describe where the list is published.* *Please provide the list of registered retail outlets.*
	Has the pattern of cross-border distance sales in your Member State changed in any significant way since the TPD was introduced?	*Yes; there have been increased cross-border distance sales / Yes; there have been reduced cross-border distance sales / No; there has been no change.* *Please elaborate.*
	Are you aware of any unregistered retail outlets operating (selling tobacco products) in your Member State?	*Yes / No.* *How do you monitor whether unauthorised retail outlets are active in your Member State?* *If yes, do you know the origins of these retail outlets (e.g. other Member States; outside the Union)?*
	What type of age verification systems are being used in your Member State? Do these age verification systems (Article 18(4)) work?	*Yes / No / To some extent.* *Please elaborate.* *How do you monitor whether they work? What issues have you encountered?*
	Is further action needed regarding regulating cross-border sales?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*
	Since the Directive came into force, how many times has your Member State taken actions (such as product modification, product withdrawal, fines, or other punitive measures) against retailers due to non-	*Please elaborate*

Background and key considerations	Question	Member State response
	compliance related to cross-border distance sales?	
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 18.

1.5.11 Article 19: Notification of novel tobacco products

Background and key considerations	Question	Member State response
Manufacturers and importers are required to notify Member States about novel tobacco products, including certain pieces of information in their notification. Member States may also require updates or additional information, and may also create systems for authorising novel products, as well as charging manufacturers and importers fees. *These provisions are intended to monitor novel products and protect consumers' health, however there may have been issues with implementation of these requirements, and they may no longer be relevant following recent market or scientific developments.*	Have there been any issues in your Member State with manufacturers and importers submitting notifications about novel tobacco products (Article 19(1))?	*Yes / No / To some extent.* *Please elaborate. If there are any examples of incorrect notification, please give them here.*
	What types of novel products have been notified to your competent authority (Article 19(1))? How have these been classified (smokeless / for smoking)?	*Please list examples of the main families/systems of notified products and their classification, for example IQOS and Heets sticks.*
	Have there been any issues in your Member State with manufacturers and importers submitting the information required under Article 19(1) when notifying a novel tobacco product?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State confirmed or authorised products sooner than 6 months before they were placed on the market?	*Yes / No.* *Please elaborate with details of the type of product.*
	Has your Member State required manufacturers or importers of novel tobacco products to carry out additional tests or submit additional/updated information (Article 19(2))?	*Yes / No.* *If yes: how many times and for which novel products?* *If no: are you considering it? Why or why not?* *Please specify any issues with regards to such submissions.*
	Has your Member State introduced an authorisation	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes: how does it work? Within what delay do you provide authorisations?*

Background and key considerations	Question	Member State response
	system for novel products (Article 19(3))?	
	Has your Member State prevented any submitted product entering the market (through refusal or withdrawal of application)?	*Yes / No.* *Please elaborate, describing any barred products.*
	Has your Member State introduced any other specific requirements related to novel tobacco products (in addition to the transposition of this TPD article)?	*Yes / No.* *Please elaborate why, their purpose, etc.*
	Have TPD provisions concerning novel tobacco products accounted for new market developments? Do you consider that the TPD appropriately addresses all types and all aspects of products (e.g. heat stick/devices)?	*Yes / No / To some extent.* *Please elaborate.*
	Which of the provisions of this Directive apply to novel tobacco products placed on the market in your Member State? (Article 19(4))?	*Smokeless tobacco product provisions / tobacco products for smoking provisions / combination of both.* *Please elaborate.*
	Since the Directive came into force, how many times has your Member State taken actions (such as product modification, product withdrawal, fines, or other punitive measures) against manufacturers or importers due to non-	*Please elaborate.*

Background and key considerations	Question	Member State response
	compliance related to notification of novel tobacco products?	
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 19.
Please elaborate, including specifying the provisions of difficulty/ challenges in the practical application of this Article

1.5.12 Article 20: Electronic cigarettes

Background and key considerations	Question	Member State response
Manufacturers and importers of electronic cigarettes and refill containers must notify Member States before	Have there been any issues with manufacturers and importers submitting notifications about electronic	*Yes / No / To some extent.* *Please elaborate. If there are any examples of incorrect notification, please give them here.*

Background and key considerations	Question	Member State response
placing them on the market, and the notification must contain certain information. *Member States are required to ensure that certain requirements are met around these products, including that nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml and that electronic cigarettes and refill containers are child- and tamper-proof. Unit packets of electronic cigarettes and refill containers also must contain leaflets with certain information.*	cigarettes and refill containers (Article 20(2))?	
	Has your Member State requested completion of notification information following incorrect submission (Article 20(2))?	*Yes / No / under consideration* *Please elaborate.*
	Has your Member State faced any issues in objectively assessing technical information submitted on the various product characteristics required in Article 20(2)? For example, information on nicotine doses and uptake (Art 20(2)d)?	*Yes / No.* *Please elaborate, providing examples of issues with such requirements and measurement methods accepted.*
	Has your Member State confirmed or authorised products sooner than 6 months before they were placed on the market?	*Yes / No.* *Please elaborate with details of the type of product/procedure.*
	Has your Member State prevented any submitted products from entering the market (through refusal or withdrawal of application)?	*Yes / No.* *Please elaborate, describing any barred products.*
	Has your Member State faced any issues with quality/safety requirements in Article 20(3)?	*Yes / No / To some extent.* *Please elaborate. Is its application consistent with Article 7(6)?*
	Has your Member State faced any issues in implementing the provisions concerning leaflets in unit packets of electronic cigarettes (Article 20(4a))?	*Yes / No / To some extent.* *Please elaborate.*

Background and key considerations	Question	Member State response
	Has your Member State faced any issues in implementing the provisions concerning unit packets and outside packaging of electronic cigarettes, including ingredients and health warnings (Article 20(4b and c))?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in interpreting and implementing provisions of Article 20(5), which prohibits commercial communications and advertising about e-cigarettes?	*Yes / No / To some extent.* *Please elaborate, describing challenges e.g. promotion on social media, cross border sporting events or magazines, online publications.*
	Has your Member State faced any issues in implementing provisions concerning cross-border distance sales (Article 18) specifically related to e-cigarettes (Article 20(6))?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in requiring manufacturers and importers to submit the market data required in Article 20(7)?	*Yes / No / To some extent.* *Please elaborate.*
	How has your Member State monitored market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers (Article 20(7)?	*Yes / No / To some extent.* *Please elaborate.*

Background and key considerations	Question	Member State response
	Has your Member State faced any issues in making submitted information publicly available on a website (Article 20(8))? E.g. have there been issues with economic operators requesting information not be published due to trade secrets?	*Yes / No / To some extent.* *Please elaborate.* *Please provide a link to the publicly available list.*
	Has your Member State faced any issues in requiring manufacturers, importers and distributers of electronic cigarettes and refill containers to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products (Article 20(9))?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State used Safety Gate (formerly known as RAPEX) or the Information and Communication System on Market Surveillance (ICSMS) to report on adverse effects?	*Safety Gate / ICSMS / both / none.* *Please elaborate.*
	Have there been any instances in your Member State of economic operators withdrawing or recalling unsafe or non-compliant products, or taking corrective action to bring the product into conformity with the Directive Article 20(9))?	*Yes / No.* *Please elaborate, describing the products.*
	Has your Member State competent authority taken any provisional measures against	*Yes / No.* *Please elaborate, including when and how the Commission was notified.*

Background and key considerations	Question	Member State response
	manufacturers/importers of e-cigarettes or refill containers that comply with the requirements of Article 20 but could present a serious risk to human health (Article 20(11))?	
	Do the TPD provisions sufficiently cover all aspects of emerging e-cigarette products?	*Yes / No / To some extent.* *Please elaborate.* What relevant changes have occurred in the e-cigarette market since the Directive was implemented?
	Since the Directive came into force, how many times has your Member State taken actions (such as product modification, product withdrawal, fines, or other punitive measures) against manufacturers or importers due to non-compliance related to e-cigarettes and refill containers?	*Please elaborate.*
	Has your Member State applied similar provisions for non-nicotine containing e-cigarettes?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 20.

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Please elaborate, including specifying the provisions of difficulty/ challenges in the practical application of this Article

1.5.13 Article 21 & 22: Herbal products for smoking / Reporting of ingredients of herbal products for smoking

Background and key considerations	Question	Member State response
The directive provides provisions on herbal products for smoking, including about health warnings and reporting of ingredients and emissions. *There may be issues faced in implementing these requirements, however.*	Has your Member State faced any issues in placing health warnings on packets for herbal products for smoking; e.g. are there any herbal products for smoking which do not carry the warning (Article 21)?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in requiring manufacturers and importers to report the ingredients of herbal products for smoking (Article 22(1))?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in making submitted information publicly available on a website (Article 22(2))? E.g. have there been issues with economic operators requesting information not be published due to trade secrets?	*Yes / No / To some extent.* *Please elaborate.* *Please provide a link to the publicly available list.*
	What types of products are on the market in your Member	*Please list the products.*

Background and key considerations	Question	Member State response
	State which are considered herbal products for smoking?	
	Does your Member State apply TPD provisions for herbal products for smoking for certain cannabis or marijuana products placed legally on the market?	*Yes / No.* *If yes: What additional rules and provisions apply for them beyond the TPD requirements?*
	Since the Directive came into force, how many times has your Member State taken actions (such as product modification, product withdrawal, fines, or other punitive measures) against manufacturers or importers due to non-compliance related to herbal products for smoking?	*Please elaborate.*
	Has your Member State encountered any other difficulties in the practical application of the provisions of this Article?	*Yes / No / To some extent.* *Please elaborate, including specifying the provisions of difficulty.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Articles 21 & 22.
Please elaborate, including specifying the provisions of difficulty/ challenges in the practical application of these Articles

1.5.14 Article 23: Cooperation and enforcement

Questions related to this Article should be addressed in parallel together with the costs-data template shared.

Background and key considerations	Question	Member State response
The Directive describes how it should be implemented and enforced. There may be issues with compliance or enforcement.	Has your Member State faced any difficulties in ensuring that manufacturers and importers provide the Commission and Member States with complete, correct and timely information requested pursuant to the Directive (Article 23(1))?	*Yes / No / To some extent.* *Please elaborate, including any actions your Member State has taken to enforce this obligation.*
	Has your Member State faced any difficulties in enforcing the responsibility of the manufacturer, importer or joint responsibility of manufacturer and importer pursuant to Art. 23(1)?	*Yes / No / To some extent.* *Please elaborate.*
	Has your Member State faced any issues in ensuring that tobacco and related products which do not comply with the Directive and its implementing and delegated acts are not placed on the market?	*Yes / No / To some extent.* *Please elaborate, including any follow up actions you have taken in this regard.*
	What is your overall experience with the enforcement of the Directive? Do you have adequate staffing for enforcement activities such as inspections?	*Please elaborate.*
	Has your Member State faced any court cases related to enforcing the Directive?	*Yes / No.* *Please elaborate, provide references when available.*

Background and key considerations	Question	Member State response
	What measures has your Member State taken to ensure that penalties for infringements on the national provisions transposing the Directive are enforced?	*Please elaborate.*
	What has been the experience of your Member State in cooperating with other Member States? Have there been any helpful mechanisms to applying the Directive in a harmonised way?	*Please elaborate, for example correct application, matters of interpretation, or enforcement of the Directive.*
	Do you consider that the Directive is applied in a conform way across Member States?	*Yes/No/* *Please elaborate, providing examples.*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 23.
Please elaborate, including specifying the provisions of difficulty/ challenges in the practical application of this Article

1.5.15 Article 24: Free movement

Background and key considerations	Question	Member State response
Member States can but are not required to implement plain/standardised packaging of tobacco products. *The directive also allows Member States to prohibit certain categories of tobacco or related products, if they justify the grounds for human health protection.*	Has your Member State implemented plain or standardised packaging for any products (Article 24(2))?	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes: Please describe when and for which products you have done this.*
	If yes: Please describe any challenges you faced when introducing and implementing plain packaging.	*Please elaborate on e.g. industry reaction, public support etc.* *Possible issues with e.g. removing older packs from shelves immediately?*
	If yes: Were you able to observe/measure any impact of plain packaging introduction?	*Please elaborate on* your observations concerning prevalence/awareness/youth uptake etc. levels or possible economic impacts? Provide references when available.
	Are any categories of tobacco or related products prohibited in your Member State (Article 24(3))?	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes: Please describe which products are prohibited, and from when (also if these bans pre-dated the Directive).*

Please use this space for further explanation of any of the responses above, AND / OR any other observations you would like to share related to Article 24.
Please elaborate, including specifying the provisions of difficulty/ challenges in the practical application of this Article