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

Denmark	Contact persons:
Name(s)	Ministry of Health: Maria Larsen Danish Safety Technology Authority: Carl Christian Lange Danish Health Authority: Hanne Vibjerg Ministry of Taxation: Elisabeth Carstensen
Email(s)	Maria Larsen: mral@sum.dk Carl Christian Lange: ccl@sik.dk

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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.* Mostly regarding the tracking and tracing system, due to the complexity of the system. **Danish Safety Technology Authority**: From the point of a market surveillance authority we have faced no major issues beside what could be expected. It must be underlined that we are not responsible for transposing the Directive into national legislation. As it is with all new legislation it has taken time to familiarize retail, distributors and importers with new legislation. This has been clearer when dealing with electronic cigarettes, as the market was rather new and largely divided between many independent smaller economic operators. The final implementation of the Directive, namely track and trace, has proved very difficult for some parts of the retail sector and some distributors and manufacturers.
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.* Especially meetings in the Expert Group on Tobacco Policy and Sub-Groups have been useful. Danish authorities have participated in the available subgroups. **Danish Safety Technology Authority**: Being an enforcement authority, we would like to have seen more focus on this aspect of the TPD, like the meeting that was organized in Copenhagen in 2019.
Overall, have economic operators been compliant with the TPD in your Member State?	*Yes / No / To some extent.* *Please elaborate.* **Danish Safety Technology Authority**: The level of compliance has differed much among various parts of the sector, so the question cannot be answered in a uniform way. In general it can be said that larger operators such as retail outlets forming part of a larger cooperation has been more compliant than individual operators. In general

Question	Member State response
	compliance has been better when dealing with tobacco than with electronic cigarettes. We believe this is mainly due to the fact that electronic cigarettes today, and even more so 4 years ago, was an young and emerging market, which previously has not been heavily regulated.
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.* We believe that the TPD has improved the functioning of the internal market. We are not familiar with studies examining the Directive´s impact on smoking prevalence in Denmark, but we believe that the TPD has improved tobacco control and contributed to a strengthened focus on regulating tobacco products and electronic cigarettes.
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.* Smoking rates in Denmark have not decreased since the TPD II came into force. It is hard to determine how smoking rates would have evolved it the TPD had not been in place. However, we find it likely that the same level of regulation would not have been put in place at that time if it had not been for the TPD.
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)* We collect data through a national survey that outlines the status of the Danish smoking habits (5,017 Danish citizens in the age of 15 years and above). Data from 2019 are not published yet, but the results from 2018 can be found here: https://www.sst.dk/-/media/Udgivelser/2019/Danskernes-rygevaner---aarsrapport-2018.ashx?la=da&hash=FDCC21DAE57E7D411AC3AD4E0F781BD7D425A488 For data on prevalence of use in the age group 11-15 years, please refer to Health Behaviour in School-aged Children – Skolebørnsundersøgelsen. https://www.hbsc.dk/. Latest available data are from 2018. For data on prevalence of use in the age group 16-24 years, please refer to The Danish National Health Survey: https://www.sst.dk/-/media/Udgivelser/2018/Den-Nationale-Sundhedsprofil-2017.ashx?la=da&hash=421C482AEDC718D3B4846FC5E2B0EED2725AF517 Latest available data are from 2017.
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.* We have not seen a decline in smoking rates or tobacco consumption among young people since the Directive entered into force. We do not have knowledge of any evaluation of the effect of the TPD on tobacco use among young people. The ban on snus may have had a positive impact on snus use among young people.

Question	Member State response

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.* We recognize that ensuring that the TPD address all new market developments is challenging and that efforts have been made to ensure the continued relevance of the directive. However, some market developments have not been fully addressed by the directive, for instance heated tobacco products and non-tobacco containing nicotine products. The wording concerning novel products may result in different national regulations within the EU. Also, e-liquids containing THC etc. and shake and vape e-liquids are challenging. It has proven challenging to establish whether notified novel tobacco products were to be categorized as smokeless tobacco products or tobacco products for smoking.
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.* Please refer to the answer above. We would like the Directive to be more adaptable in order to ensure that the directive remains relevant when the market evolves. Also, we find it important that the Directive does not create unintended restrictions for countries that wish to impose further restrictions to reduce tobacco use. From a health perspective, we would like to see a continued focus on ingredients.

Question	Member State response
	Danish Safety Technology Authority: It might be useful to include heated tobacco and nicotine products in future updates of the directive. One could imagine in future updates of the directive, not to included specific standards, as these might as the years pass by prove problematic or out dated. If standards were agreed in other legislative acts, these could be easier updated.

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.* **Danish Safety Technology Authority**: For 2019 the total cost of market surveillance of tobacco and electronic cigarettes was approximately 7.5 million DKK (1 million EURO) for Tobacco, which we intend to increase to 8.9 million DKK (1.2 million EURO) in order to increase our surveillance of the track and trace system. For electronic cigarettes the total cost for 2019 was approximately 10.8 million DKK (1.4 million EURO). Please refer to the cost data template also provided.
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.* **Danish Safety Technology Authority**: All costs are sought recovered through fees. For tobacco the fees are based on market shares and for electronic cigarettes fees are based on products reported to the DSTA. The fee structure for electronic cigarettes are currently being revised, as it has proven difficult to recover all costs through fees on individual products.
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	*Yes / No / To some extent.* *Please elaborate.*

Question	Member State response
incoherent with each other? For example, have the requirements of one article contradicted the requirements of another?	
Has your Member States faced any issues with TPD provisions being inconsistent or incoherent with other EU legislation, for example: • The Tobacco Taxation Directive • 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)	The definition of tobacco products is different from the definition in the Tobacco Advertising Directive. We find it important that the directive ensures a high degree of protection of human health and that it is made more clear that the Member States retain the power to impose further requirements in order to protect public health. We believe that restrictions introduced by Member States should be assessed in light of the need to take precautionary actions due to the particular harmfulness of tobacco and other nicotine products.
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.* We have not ratified the FCTC Protocol.

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* For instance with regards to ingredients, e-cigarettes, labelling and packaging. **Danish Safety Technology Authority**: From a market surveillance perspective, we believe it is beneficial to have a common legislation across the EU.
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* We do not have data on the impact of the TPD on tobacco consumption but find it likely that this level of regulation would not have been achieved at the national level in the same period. One of the reasons being that the TPD regulates numerous technical issues that we as a Member State do not have the means to examine to the same degree. **Danish Safety Technology Authority**: We believe it is beneficial that the track and trace system has been implemented across the EU, with one common system, instead of numerous local versions.

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.*	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.* The definition of smokeless tobacco has proven challenging with regards to the classification of novel tobacco products. The Danish Health Authority notes that there is no joint specific or accepted level for addictiveness, toxicity or CMR (art. 7, 9). **Danish Safety Technology Authority**: (6) + (8) The definition of chewing tobacco and oral tobacco is unclear. Both products are presented in sachet portions or porous sachets. We have experienced that the consumer is confused whether the product is chewing tobacco or oral tobacco. Furthermore we have experienced that the rules are circumvented by means of the unclear definition and the similarities between the products (16) The definition of an electronic cigarette have not been clear to the manufacturers, importers and retailers. The expression “the device without cartridge or tank” has been a subject to discussion several times. The submitters, think that the rules are unclear and can be interpreted. In Denmark we have made a scheme with an overview of the specific components to verify whether the product need to be notified or not. (30) The definition of ’unit packet’ regarding refill containers containing nicotine. It has been unclear whether the unit package was related to the bottle or the package surrounding the bottle.
Also, in the light of various scientific, technological and market developments, some of the current	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.* Please refer to the answer to the question above.

Background and key considerations	Question	Member State response
definitions may no longer be relevant or appropriate. **Please refer to Article 2 of the TPD for the full list.*		The Danish Health Authority finds that the differences between snus and chewing tobacco are in practice very small, and the Health Authority experiences that people do not see or know the difference between the products, because the products are very similar. They would like TPD to define the differences more clearly and technically to make it easier to regulate and control the products.
	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.* Please refer to the answers above. From a health perspective it might be relevant to look into the definition of cigars/cigarillos, taking into account the existence of for instance "little cigars".
	Are there any other products or categories for which a definition should be included in the Directive?	*Yes / No.* *Please elaborate.* It could be considered to define heated tobacco products and nicotine products not containing tobacco. From a health perspective, if it is unclear how a new product should be classified, it would be preferable if the product had to be treated as the more harmful product category by default. . Danish Safety Technology Authority finds that it could be relevant to include definitions of tobacco containing products as blunts, wraps etc. They have had difficulties in categorising these products.
	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?* The TPDII and the Tobacco Advertising Directive are not consistent. The definition of tobacco products in the TPD is different from the definition in the Tobacco Advertising Directive.
	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.*

Background and key considerations	Question	Member State response
		See answers above.

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?* We consider it relevant to maintain provisions on maximum TNCO-levels, but also to assess the current maximum emission levels.
	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.* We are not currently considering setting limits for maximum emissions levels for cigarettes. To ensure uniform regulation of the emission levels and due to the technical aspects we believe there are advantages in handling this at the EU-level.
	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.* We are not currently considering setting limits for maximum emission levels for other tobacco products. Again, we find that this matter is better addressed at the EU-level.
	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.* We believe that there is a need to investigate and assess the measurement methods, also taking into account the issue of filter ventilation. We find it important that the emission levels being measured to the greatest extent possible reflect actual levels of emissions that smokers are exposed to. As part of this work it might be relevant to consider the maximum emission levels as well. **Danish Safety Technology Authority**: The DSTA notes that the ISO standard reads lower levels of TNCO than other methods, and furthermore that the ISO method is developed by the tobacco industry. On this basis it is the view of the DSTA that the Commission should initiate a thorough investigation into measurements methods of TNCO. This being said, we do not at this time possess the necessary professional insight to say if the Canadian Intense method is more correct than the currently used ISO standards.
	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.* Please refer to the answers above.
	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?* **Danish Safety Technology Authority**: We have not approved any laboratories, and we have not had any applications. We use LNE located in France for testing.
	Has your Member State used any measurement methods for emissions for cigarettes other than	*Yes / No.* *If no: are you considering it? Why or why not?* *If yes: Please elaborate, including when the Commission was notified.*

Background and key considerations	Question	Member State response
	the three specified in Article 4(1) (Article 4(4))?	
	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?* **Danish Safety Technology Authority**: The annual fee collected from importers and manufacturers based on market shares, covers all market surveillance, including peer reviews.
	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.* **Danish Safety Technology Authority**: The number of notified products in EUCEG does not reflect the number of products on the Danish market. Manufacturers and importers seem to notify their products all over the EU. This issue makes it difficult to selects products for a control. The submitters have no obligation to keep their submissions updated in the EUCEG system. As a member state we have no punitive measures to ensure that our part of EUCEG only reflects the products that is actually marketed in our country.

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 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.	Has your Member State faced any issues in requiring manufacturers and importers to submit the required information in Article 5(1), the statement of reasoning in Article 5(2), or the toxicological data in Article 5(3)?	*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.* **Danish Safety Technology Authority**: We have experienced that submitters do not submit any technical documentation setting out a general description of the additives used and their properties for cigarettes and roll-your-own tobacco. The submitters who does not comply with this are often confused of what the content of these documents should be.
	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.* **Danish Safety Technology Authority**: Our currently available public list can be find here: https://www.sik.dk/registre/tobaksregister Economic operators have marked almost all information in EU-CEG as confidential. The DSTA is currently awaiting the publication from Joint Action on Tobacco Control, deliverable 5.1 *"Report on the principles to distinguish what data is public on confidential"*, including a list of public and confidential information submitted into EU-CEG and also a final clarification if the Commission will provide a publication tool of this information, or if this will have to be done on a national level.
	Do you know if consumers make use of the public information? In what ways / for what purpose?	*Yes / No.* *Please elaborate.* **Danish Safety Technology Authority**: To some extent consumers uses the public information in order to verify whether the products are legal in Denmark.
	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* **Danish Safety Technology Authority_** If the manufacturers or importers have notified insufficient submissions, including insufficient data, we: - Request further information (insufficient submissions)

	- Inform the submitter about the incorrect / non-compliant data (hearing of parties) - Prohibit marketing of the product if the product notification is not updated with correct / compliant data - Ultimately the case can be handed over to the prosecuting authority in order to fine the submitter
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.* **Danish Safety Technology Authority**: - Sales volume: the manufacturers and importers are mostly capable of submitting the correct information. When we face issues they are often caused by the following: - There is no overall consistency in the reported sales volume. Some manufacturers / importers report the sales volume out of the factory and some the sales volume from the national retailers. There is also a difference in which kind of data we receive depending om whether it is a manufacturer or an importer that submit the data - Some of the annual sales volumes are reported as a zero sale. This is when either the manufacturers / importers have submitted their products in Denmark, but they are not marketing the products in Denmark or if the marketing of the product is not started yet. Some submit a zero sale when the product is on the market in retail, but the manufactor has not produced any new products. Market surveys, internal and external studies: To this day no useful studies have been submitted.
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.* **Danish Safety Technology Authority**: The information on sales volumes are stored in our case handling system.
Has your Member State used information made available by other Member States for the purposes of applying this Directive (Article 5(7))?	*Yes / No.* *If no: are you considering it? Why or why not?* **Danish Safety Technology Authority**: Yes, we have used the classification of tobacco products from other countries, when we assess a case, for instance the Swedish classification of oral tobacco has been used when we have found similar products on the Danish market, categorized by the importer as chewing tobacco.
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.* **Danish Safety Technology Authority**: We would firstly refer to the Joint Action on Tobacco control, in which this point as been discussed and worked with in great detail. Specifically we refer to deliverable 5.6 Report for M1-18 on the potential improvements/alterations identified through Task 3.1, already available here: https://jaotc.eu/wp-content/uploads/2019/09/WP5-D5.6-Report-for-M1-18-on-the-potential-improvementsalterations-identified-through.pdf. To this report DSTA has contributed both as WP5 leader and with actual input to the report. Furthermore we would refer to deliverable 5.7 within the JATC which is a follow up report on the 5.6 report.

	The EU-CEG system is working functionally to us, however there is room for improvements. Some examples are mentioned below: - As we have experienced a lot of frustrated submitters, that cannot see the submitted data after loading it into the system, it would be a place for improvement, if they had a view access to their own submissions after submitting them. We have had a lot of request from the submitters to control whether or not a specific submission has been completed correctly or submitted to Denmark at all. They would not have made the request if they were able to see their own submitted data. - In order to ensure more correct data in the submissions, it would be approvable if limit values was predefined for certain fields e.g. emissions. - In order to digitalize our processing of the submission data, it would be valuable if the digital access to the EU-CEG database could be smoother. - The Member States should be able to flag submitted products that need to be removed from the national part of EU-CEG.
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.* **Danish Safety Technology Authority**: We would not have to make an extension for our present lists of registered products.
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.* **Danish Safety Technology Authority**: Based on our updated information in our case handling system from days date, we have taken action 2 times against manufacturers or importers due to non-compliance related to reporting of ingredients and emissions. Please notice that our system is dynamic and reflects the actual updates submitted in the EU-CEG.
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.

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 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.*	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.* **Danish Safety Technology Authority**: It is difficult to distinguish the technical reports from Article 5 (3) and the studies required for Article 6(2). The Danish Health Authority did not receive any reports on diacetyl, but as we don't have any products containing this additive, it's OK.
	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?* **Danish Safety Technology Authority:** We have yet to assess any reports.
	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 State **intending** on taking regulatory actions of this type?	*Yes / No / Considered.* *Please elaborate* The Danish Health Authority are waiting for the conclusions and recommendations of the peer review panel. **Danish Safety Technology Authority**: We have taken action on the ingredients Menthol and Diacetyl for the CAS numbers mentioned on the priority list. For Diacetyl we located which TP-ID's contained the ingredient and was missing a submitted study. The result of this was that no product contained Diacetyl on the Dffanish market For Menthol we have located which TP-ID's contains this ingredient. This ingredient will no longer be permitted in products intended for sale in Denmark as of 20-05-2020. We will take actions towards these TP-ID's if they still contains the ingredient(s) after this date. New products containing the CAS numbers mentioned on the priority list will not be allowed to market their products in Denmark after this date.
	Has your Member State charged manufactures and	*Yes / No.* *If no: are you considering it? Why or why not?*

importers proportionate fees for peer reviews of their reports (Article 6(4))?	**Danish Safety Technology Authority**: The annual fee collected from importers and manufacturers based on market shares, covers all market surveillance, including peer reviews.
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.* **Danish Safety Technology Authority**: Since the Directive came into force, we have not taken any actions against manufacturers or importers due to non-compliance related to additives and reporting.
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.

At the moment the expert panel is finalising the peer reviews of the enhanced reporting information submitted by the industry. The Danish Health Authority are waiting for the final report, the conclusions and recommendations from the peer review panel before taking any action. The Danish Health Authority looks forward to see the report from the peer review panel. The Danish Health Authority is cautious when it comes to reports from the industry, and they always suggest that regulatory actions are based on independent reports analysing the effects of the additives and not reports from the industry. That said The Danish Health Authority believes the peer review panel base their conclusions and recommendations on independent literature. In the future The Danish Health Authority suggests that report about effects of the additives are composed by independents experts and not the industry.

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.* **Danish Safety Technology Authority**: We have not had any cigarettes or RYO tobacco products with a characterizing flavor notified in Denmark, except for menthol which is legal until 20th of May 2020.
	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?* **Danish Safety Technology Authority**: According to the submitted data in EU-CEG we have not had any tobacco products containing the additives listed in Article 7(6) (vitamins, caffeine, taurine, etc.) notified in Denmark.
	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.
*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,	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	*Yes / No / To some extent.* *Please elaborate.*

Background and key considerations	Question	Member State response
information on cessation 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.*	provisions concerning combined health warnings for tobacco products for smoking (Article 10), including the minimum 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.* **Danish Safety Technology Authority**: We have based our market surveillance on *"Bevelled and Rounded Edges – Non-paper for discussion by the Tobacco Products Committee and the Expert Group on Tobacco Policy",* from 15th of October 2015. We continues to monitor tobacco products and their compliance with the TPD provisions regarding health warnings.
	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.* **Danish Safety Technology Authority**: On basis of the Commission official guidance issued on September 2017, regarding the minimum dimensions of cuboid packages of cigarettes and roll your own, the DSTA launched a targeted effort in order to see that the market was compliant. In general the market quickly adopted to the legislation when stakeholders was confronted with the requirements. One manufacturer disagreed but eventually agreed to change their packages in order to accommodate the minimum dimensions. We have since this targeted effort not had reports of slim packages etc.

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 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.* All other tobacco products for smoking are exempted from the obligation. They must carry a general warning and a text warning. The general warning must include a reference to the cessation services - Stoplinien: 80 31 31 31 www.stoplinien.dk.
	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.* All other tobacco products for smoking. Please refer to the answer above.
	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.* **Danish Safety Technology Authority**: We have mainly focused on the labelling of cigarettes and roll your own so far. In the upcoming year a targeted effort has been planned for smokeless tobacco.

Background and key considerations	Question	Member State response
	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.* There have been challenges, but after a targeted effort by the Danish Safety Technology Authority, compliance has increased. **Danish Safety Technology Authority**: On the basis of national legislation and the TPD the DSTA has issued a guidance document, regarding the presentation of tobacco products. It is available here: https://www.sik.dk/sites/default/files/2019-06/praesentation_af_tobaksvarer_-_vejledning_27062019.pdf, unfortunately only in Danish. In general we have had quite a few disputes over this matter, both in the regard as to which words / and graphic elements could refer to taste, but also to strength, social status etc. There is on ongoing court case regarding the use of the word “Royal” on a tobacco product.
	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 (such as product modification, product withdrawal, fines, or other punitive measures) against manufacturers or importers due to non-compliance related to labelling and packaging?	*Please indicate the number of actions taken per Article and elaborate on the issue(s) encountered* **Danish Safety Technology Authority**: We have not taken action against manufacturers or importers due to non-compliance related to labelling and packaging

Background and key considerations	Question	Member State response
	Should there be stricter/clearer labelling provisions overall? Or on any specific products specifically?	*Yes / No.* *Please elaborate.* - Labelling of non-tobacco containing nicotine products. - Plain packaging **Danish Safety Technology Authority**: From the perspective of a market surveillance unit, the DSTA believe that the rules should be as clear and well defined as possible.
	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.* **Danish Safety Technology Authority**: According to the submissions in the EU-CEG, we have had some difficulties in distinguishing between the product types of pipe tobacco and RYOT. We have experienced that some submitters have changed their product type from pipe tobacco to RYOT or the other way around.
	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.
The current provisions regarding smokeless tobacco products have in practice meant that manufacturers of for instance chewing tobacco have often placed health warnings on the side and bottom of the products, meaning that the health warming is not visible when the tobacco products are displayed in the shops.

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.* **Danish Safety Technology Authority**: From an authority point of view we faced no major issues in implementing track and trace in regards of appointment of ID-issuer etc. It is still early stages of the track and trace system, as it has not yet been running one full year, so further experiences is needed, in order to test if everything works as planned. The EO's have struggled with the implementation of the track and trace system.
	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.* **DSTA**: A target effort focused on track and trace was planned to take place from mid-February and forward. The effort has been halted by COVID-19, and thus at this point we are still missing adequate data in order to fully say if all relevant transactions are being recorded correctly. As far as equipment goes, it follows from our national legislation that the DSTA has the authority is fully try the decisions of tobacco manufacturers when it comes to compensation. So far we have received no formal complaints to this matter.
	To what extent is the traceability system (Article 15) helping to fight the illicit trade of tobacco products?	*Please elaborate.* **Danish Safety Technology Authority**: We merely ensure that the track and trace system is working and that economic operators are reporting correctly, whether it will have an impact on illicit trade, time will tell.
	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?	The Ministry of Taxation has not had any issues implementing the tamper proof marks, as tax stamps were already used on some tobacco products (e.g. cigarettes and fine cut tobacco), and these stamps met the set criteria for tamper proof marks.
	To what extent is the security features system (Article 16) helping to fight the illicit trade of tobacco products?	*Please elaborate.* The Ministry of Taxation notes that the security feature system is helping to fight the illicit trade of tobacco products to the same extent as our tax stamps did before, as we already used tax stamps on some tobacco products (e.g. cigarettes and fine cut tobacco), and these stamps met the set criteria for tamper proof marks.
	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.* **Danish Safety Technology Authority**: As previously mentioned, that system has been running for less than 1 year, at this time, the DSTA believe it is too early to say anything for certain regarding the independence from the tobacco industry. For now no issues with independence has been found by the DSTA or brought to the attention of the DSTA.
	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
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.* **Danish Safety Technology Authority**: We have encountered difficulties. Retailers in Sweden illegally market oral tobacco products to Danish consumers from their website. According to our legislation we only have the possibility to sanction the retailer. Not the consumer. Oral tobacco products are marketed from social medias, online and physical retailers. The Danish Health Authority notes that the TPD states that: "For other smokeless tobacco products that are not produced for the mass market, strict provisions on labelling and certain provisions relating to their ingredients are considered sufficient to contain their expansion in the market beyond their traditional use". In Denmark, we experience that chewing tobacco is now popular among young people, which indicate that the strict provisions on labelling etc. are not sufficient to contain their expansion in the market beyond their traditional use.
	Are you aware of any efforts to circumvent the ban on tobacco for oral use in your Member State?	*Yes / No.* *Please elaborate.* **Danish Safety Technology Authority**: The definition of chewing tobacco and oral tobacco is unclear. Both products are presented in sachet portions or porous sachets. We have experienced that the rules are circumvented by means of the unclear definition and the similarities between the products.

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.

The Danish Health Authority notes that it can be an issue for tobacco control on snus that it is possible for Danish consumers to buy snus in Sweden and have it shipped to Denmark.

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 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.*	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?* We are not currently considering banning cross-border distance sales.
	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?* 5 retail outlets located in our Member State. *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?* 9 retail outlets located in another Member State or outside the EU.
	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.* **Danish Safety Technology Authority**: The lists are published on our website www.sik.dk List of cross-border distance sales of tobacco products out of Denmark List of cross-border distance sales of tobacco products into Denmark
	Has the pattern of cross-border distance sales in your Member State changed in any significant	*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.*

Background and key considerations	Question	Member State response
	way since the TPD was introduced?	We do not have data regarding this. It is the Ministry of Taxation´s assessment that there has not been any change in cross-border distance sales following the implementation of the TPD.
	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)?* **Danish Safety Technology Authority**: If we receive information regarding illegal sale of tobacco products we check if the website is registered for cross-border distance sales into Denmark. So far we have primarily focused on the marketing of oral tobacco into Denmark.
	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.9* *Please elaborate.* *How do you monitor whether they work? What issues have you encountered?* **Danish Safety Technology Authority**: The age verification system set up is, is a system that will ask the user if the user has reached the minimum age (18) for buying tobacco. Please refer to the answer below regarding the effectiveness of the age verification systems.
	Is further action needed regarding regulating cross-border sales?	*Yes / No / To some extent.* *Please elaborate.* - Ensuring that retailers who sell products across borders use effective age verification systems, thus avoiding that tobacco products are sold to minors. - Cross-border sales of snus to Danish consumers. **Danish Safety Technology Authority**: The DSTA believe that a common developed, adopted and effective age verification system could increase the effectiveness of cross border market surveillance. Furthermore a further increase in the focus on market surveillance and sharing of best practices across EU member states could also help increase the effectiveness of the market surveillance of cross border sales.

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.*
	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-compliance related to cross-border distance sales?	*Please elaborate* **Danish Safety Technology Authority**: We have taken action **1** time against retailers due to non-compliance related to cross-border distance sales. We have taken actions several times against retailers selling illegal products to Denmark. If the retailers sell illegal products, for instance snus, that cannot be legally placed on the Danish market, we do not pursue the matter of a age verification system.
	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.* **Danish Safety Technology Authority**: Heat sticks for IQOS and for NEO. The products have not yet been classified as smokeless tobacco or tobacco for smoking.
	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	*Yes / No.* *If yes: how many times and for which novel products?*

Background and key considerations	Question	Member State response
	importers of novel tobacco products to carry out additional tests or submit additional/updated information (Article 19(2))?	*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 system for novel products (Article 19(3))?	*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?* We are not currently considering introducing an authorisation system (article 19(3)). **Danish Safety Technology Authority**: Novel tobacco products are only allowed to be marketed in Denmark if they have been notified to the Danish Safety Technology Authority. Each manufacturer and importer who wants to market a novel tobacco product must give notification no later than six months before marketing begins. Notification of a new category of tobacco product costs DKK 36,900 (approx. 5.000 EURO) for each product.
	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	*Yes / No / To some extent.* *Please elaborate.* New market developments: Tobacco free nicotine containing products. Heated tobacco products.

Background and key considerations	Question	Member State response
	consider that the TPD appropriately addresses all types and all aspects of products (e.g. heat stick/devices)?	
	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.* The novel tobacco products that have been notified in Denmark have not been categorized as smokeless tobacco products or tobacco products for smoking. Which rules apply depends on this categorization.
	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 notification of novel tobacco products?	*Please elaborate.* Neither the Danish Safety Technology Authority nor the Danish Health Authority have taken action against manufacturers or importers due to non-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 Danish Health Authority notes that the TPDII does not clarify when a novel tobacco products stops being a novel tobacco product.

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 placing them on the market, and the notification must contain certain information.	Have there been any issues with manufacturers and importers submitting notifications about electronic cigarettes and refill containers (Article 20(2))?	*Yes / No / To some extent.* *Please elaborate. If there are any examples of incorrect notification, please give them here.* **Danish Safety Technology Authority**: We have experienced issues as: - Submitters are not consistent in choosing product type and / or submission type - Documentation are not sufficiently uploaded, e.g. emission reports - Not unique identification of products regarding product names and / or description of the product
Member States are required to ensure that certain requirements are met around these products, including that nicotine-containing liquid does not contain nicotine	Has your Member State requested completion of notification information following incorrect submission (Article 20(2))?	*Yes / No / under consideration* *Please elaborate.* **Danish Safety Technology Authority**: To some extent. If the manufacturers or importers have notified insufficient submissions, including insufficient data, we request further information.

Background and key considerations	Question	Member State response
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.	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.* **Danish Safety Technology Authority**: To some extent. We have experienced lack of e.g. emission reports.
	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.* **Danish Safety Technology Authority**: Barred products: - Electronic cigarettes which can be activated by drawing. - Sqounk MODS
	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.* The Danish Health Authority notes that Initially, the manufactures claimed difficulties in providing a full list of ingredients on a leaflet and argued that putting the word “aroma” instead of the full list of ingredients leading to the aroma was in compliance with the TPDII.

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.* **Danish Safety Technology Authority**: The definition of 'unit packet' regarding refill containers containing nicotine. It has been unclear whether the unit package was related to the bottle or the package surrounding the bottle.
	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.* The Consumer Ombudsman – the authority responsible for enforcing Article 20(5) – notes that as an enforcement authority, it can be challenging to assess when an activity is covered by the far-reaching advertising ban and when the activity is purely legal product information. The Consumer Ombudsman has interpreted the prohibition on advertising so that it is covered by the advertising definition itself if a company that sells e-cigarettes uses a name that includes e-cigarettes or associates with e-cigarettes, since the use of the name in our opinion will be aimed at promoting the sale of e-cigarettes or have the direct or indirect effect. The same applies to such companies' use of profiles on social media, such as Facebook, YouTube and Instagram and the distribution of newsletters. The Consumer Ombudsman has also found that there is not enough understanding in the industry that it is not allowed to promote e-cigarettes when it is legal to sell the products.
	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.* **Danish Safety Technology Authority**: Retail outlets located in another Member State or outside the EU that are registered at the Danish Safety Technology Authority for cross-border distance sales often market non-compliant products to the Danish consumers.
	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.* The quality of the submitted information is a challenge. **Danish Safety Technology Authority**: To some extent some submitters have been confused of what the requirements has been for Article 7 (ii), (iii) and (iv)

Background and key considerations	Question	Member State response
	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.* The prevalence on e-cigarette use is part of the yearly survey "The survey on smoking prevalence in Denmark" (Danskernes Rygevaneundersøgelse). A larger proportion of non-smokers among children and adolescents have tried electronic cigarettes than among adult non-smokers (source: Danish Health Authority. E-cigarettes and Health, 2019).
	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.* **Danish Safety Technology Authority**: Our currently available public list can be find here: https://www.sik.dk/registre/register_over_e_cigaretter Economic operators has marked almost all information in EU-CEG as confidential. The DSTA is currently awaiting the publication from Joint Action on Tobacco Control, deliverable 5.1 *"Report on the principles to distinguish what data is public on confidential"*, including a list of public and confidential information submitted into EU-CEG and also a final clarification if the Commission will provide a publication tool of this information, or if this will have to be done on a national level.
	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	*Yes / No / To some extent.* *Please elaborate.* **Danish Safety Technology Authority**: The manufacturers and importers are confused on how to builtd up a functional system. A joint EU system could possibly be preferable.

Background and key considerations	Question	Member State response
	health of these products (Article 20(9))?	
	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 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))?	*Yes / No.* *Please elaborate, including when and how the Commission was notified.*
	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? It could be relevant to address e-liquids containing THC and CBD-oils.

Background and key considerations	Question	Member State response
		The Danish Health Authority notes that the TPDII does not include all products, as it only covers products containing nicotine, and therefore not products that the consumer can mix with nicotine and use as intended by the manufacturer after purchase.
	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.* **Danish Safety Technology Authority**: We have taken action **220** times against manufacturers or importers due to non-compliance related to e-cigarettes and refill containers.
	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.* The provisions regarding smoke free environments apply to both nicotine containing e-cigarettes and non-nicotine containing e-cigarettes. The ban on sales to minors also applies to non-nicotine containing electronic cigarettes. In December 2019, the Danish Government and a majority of the political parties in Parliament agreed on a national action plan targeting the use of tobacco products and similar products among children and young people. The Bill implementing the national action plan will we introduced in 2020. As a part of this Bill, manufacturers and importers of non-nicotine containing electronic cigarettes will be required to register and submit a notification to the competent authority, the Danish Safety Technology Authority. As a result of the action plan, display ban and plain packaging will be introduced for both nicotine containing electronic cigarettes and non-nicotine containing e-cigarettes. Finally, the planned restrictions on the use of flavorings will apply to both nicotine containing electronic cigarettes and non-nicotine containing e-cigarettes
	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.* **Danish Safety Technology Authority**: We have experienced difficulties regarding the definition of child resistance of an electronic cigarette. Manufactures and importers primarily / solely focus on the risk of contact with the nicotine-containing e-liquid.

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.
Please elaborate, including specifying the provisions of difficulty/ challenges in the practical application of this Article Danish Health Authority notes that it is primarily a challenge that the TPDII only applies to nicotine containing products. There is no clear definition on Art. 20, no. 3, e): except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form and how this is to interpreted or checked.

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.* **Danish Safety Technology Authority**: Based on our updated information in our case handling system, we have not registered any herbal products on the Danish list of registered products at the moment.
	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	*Yes / No / To some extent.* *Please elaborate.* **Danish Safety Technology Authority**:

Background and key considerations	Question	Member State response
	information not be published due to trade secrets?	To some extent we have made the information regarding the herbal products for smoking public – when herbal products were on the market. We have not made information regarding ingredients public. *Please provide a link to the publicly available list.* Currently we have no herbal products for smoking on the Danish market, but herbal products for smoking can be found at the same list as tobacco product are listed on: list of registered tobacco products
	What types of products are on the market in your Member State which are considered herbal products for smoking?	*Please list the products.* **Danish Safety Technology Authority**: Based on our updated information in our case handling system, we have not registered any herbal products on the Danish list of registered products at the moment.
	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?* No herbal products for smoking are registered and thus placed legally placed on the market.
	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.* **Danish Safety Technology Authority**: We have taken action In 1 case against manufacturers or importers due to non-compliance related to herbal products for smoking
	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.* **Danish Safety Technology Authority**: In general no, at times manufacturers and importers have been reminded of their obligation to disclose all relevant information to the DSTA, in order for us to carry out our market surveillance. Sometimes the manufacturers or importers have been unaware of the information they had to provide, but after clarification from the DSTA, the information has been provided. Beside this we have not had to resolve to hand the case over to the prosecuting authority in order to take further action.
	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.* **Danish Safety Technology Authority**: If the manufacturers / importers do not submit all relevant information to the DSTA they will: - not be registered at the DSTA to market their products in Denmark. - receive a marketing ban for the relevant product
	Has your Member State faced any issues in ensuring that tobacco and related products	*Yes / No / To some extent.* *Please elaborate, including any follow up actions you have taken in this regard.*

Background and key considerations	Question	Member State response
	which do not comply with the Directive and its implementing and delegated acts are not placed on the market?	**Danish Safety Technology Authority**: It has proved difficult to enforce the requirements of the TPD on websites, especially those not located in the Union. The import of oral tobacco has also proven difficult to stop.
	What is your overall experience with the enforcement of the Directive? Do you have adequate staffing for enforcement activities such as inspections?	*Please elaborate.* **Danish Safety Technology Authority**: The DSTA believe we deliver an overall effective market surveillance with the funds allocated to handling the task.
	Has your Member State faced any court cases related to enforcing the Directive?	*Yes / No.* *Please elaborate, provide references when available.* **Danish Safety Technology Authority**: We have a current court case regarding the use of the term “royal” on a tobacco product.
	What measures has your Member State taken to ensure that penalties for infringements on the national provisions transposing the Directive are enforced?	*Please elaborate.* **Danish Safety Technology Authority**: Depending on the infringement the DSTA can issue and marketing ban, an order to withdraw products from the market, including from consumers or we can hand the case over to prosecuting authority in order to fine the economic operator for the infringement.
	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.* **Danish Safety Technology Authority**: The enforcement of the directive and the overall sharing of best practises hand been greatly helped by the Expert Group on Tobacco Policy and the subsequent subgroups and the network developed through this. An subgroup purely focused on enforcement and better cooperation between enforcement authorities we believe could further assist the enforcement of the TPD.

Background and key considerations	Question	Member State response
	Do you consider that the Directive is applied in a conform way across Member States?	*Yes/No/* *Please elaborate, providing examples.* **Danish Safety Technology Authority**: Our understanding is that the Directive in an overall manner has been applied in a conform manner across member states. The implementation of track and trace is still too recent to assess whether this is also true for this part of the TPD.

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*	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.* In December 2019, the Danish Government and a majority of the political parties in Parliament agreed on a national action plan targeting tobacco use among children and young people. As a part of this action plan, plain packaging will be introduced to tobacco products - apart from pipe tobacco and cigars – electronic cigarettes and herbal products for smoking.
	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?*

Background and key considerations	Question	Member State response
grounds for human health protection.	**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).* Not in our current legislation. Reference is made to notification number 2020-228-DK.

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