RESPONDENT INFO

Name of respondent (s):

Organisation: Danish Safety Technology Authority (DSTA), Ministry of Taxation

Member state: Denmark

Date of completion:

FEES

Q1a. Do you charge any fees for any products or procedures covered by the TPD2? *Yes or No:* Yes

DSTA: please see our answers to Q1b in questionnaire

Q1b. If yes, please indicate *(mark with an X)* the procedures you charge fees by the type of product:

	Tobacco products except for novel products *(mainl Articles 5-6)*	Novel tobacco products *(Article 19)*
Receiving product reports/notifications	☐	☐
Storing and handling submitted information	☐	☐
Analysis/verification of submitted information	☐	☐

Q1c. Please indicate the amount of fees (in Euros) collected by year.

If you are unable to provide a breakdown by year, please provide the cumulative figures. If you are unable to provide a breakdown by product type, please provide the figures for the "Other" product type

	Tobacco products except for novel products *(mainl Articles 5-6)*	Novel tobacco products *(Article 19)*
2019 *(or cumulative)*	1005000	
2018	1005000	
2017	1877000	
2016	335000	

	e-cigarettes *(Article 20)*	Costs related to other procedures, other products and/or that cannot be broken down (e.g. additives, ingredients, herbal) - *please describe:*
Receiving product reports/notifications	☐	☐
Storing and handling submitted information	☐	☐
Analysis/verification of submitted information	☐	☐
2019 *(or cumulative)*	684000	
2018	844000	
2017	1491000	
2016	819000	

DSTA: the amount of fee is for e-cigarettes, novel tobacco products and herbal products

DSTA: please see our answers to Q2a in questionnaire

Q2a. Do you charge any fees to verify **measurements** (and methods) for ingredients and/or emissions related to the implementation of TPD2? *(Article 4)* *Yes or No:*

Q2b. If yes to Q2a, how much (in Euros) have you collected for these fees by year?

2019	
2018	
2017	
2016	

DSTA: please see our answers to Q3 in questionnaire

Q3. Do you charge any fees for peer reviews conducted on additives? ***(Article 6(4))*** *Yes or No:* ☐ If yes, please describe:

EU COMMON ENTRY GATE (CEG)

DSTA: we have only registered have many people were dedicated to our work concerning market surveilliance for tobacco products and e-cigaret products overall.
Tobacco products: 4.9 people / 2019
E-cigarettes: 6.3 people / 2019

Q4a. On average, about how many people (full-time equivalents) are dedicated to reviewing submissions to the EU-CEG?

Please use 2019 as your reference ear. If you are unable to provide a breakdown by product type, please provide the cumulative estimates in the last column.

	Tobacco products except for novel products *(Articles 5-6)*	Novel tobacco products *(Article 19)*	e-cigarettes *(Article 20)*	Costs related to other procedures, other products and/or that cannot be broken down (e.g. additives, ingredients, herbal) - or cumulative
Receiving product reports/notifications				
Storing and handling submitted information				
Analysis/verification of submitted information				

Q5b. What factors contribute to its variation per one submission? (e.g. type of product)

COMPLIANCE COSTS

Q6b. What costs were involved in implementing the provisions of Article 19 on novel products?
Please indicate the level of costs in 2019 by the categories listed below. If you cannot break down certain costs, please provide the estimated figures in "Other" and specify what is

IT infrastructure		*Please provide an indication of the cost to develop the necessary IT infrastructure to facilitate the authorisation of novel tobacco products. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Data assesment		*Please provide an indication of the cost to collect and store data on novel tobacco products. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Laboratory testing/assessment		*Please provide an indication of the cost to collect and store data on novel tobacco products. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Administration costs		*Please provide an indication of the administration costs involved in creating a system to authorise novel tobacco products. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Other *(including costs that cannot be broken down into the categories listed above)*	The cost to implement the necessary IT-infrastructure and so forth is part of the fee collected on the basis of market shares, please refer to relevant questions in the questionnaire, including Q 1.4.3. regarding efficiency. As the implementation of including novel tobacco products was estimated to be of minor costs, the cost has not been broken down into further detail. We do charge a fee equivalent to the fee of electronic cigarettes, for the notification of novel products. The fee is as of 2019 pr. Product notification 36.900 DKK (approx. 5.000 EURO).	*Please specify what type of costs are included in this category alongside the estimated costs / full-time equivalent). If applicable, please note how many trainings were carried out and how many people attended a training (on average)*

Q7a. What activities do you carry out on a regular basis (not enforcement - see next section) to support the implementation of the TPD2 in relation to **tobacco products**? For each activity, please note approximately the current annual resources allocated

DSTA: we have only registered have many people were dedicated to our work concerning market surveilliance for tobacco products overall.
Tobacco products: 4.9 people / 2019

Monitoring of ingredients, additives, and emissions of tobacco products *(Articles 3-7)*		*Please provide an indication of the costs involved in the monitoring of ingredients, additives, and emissions of tobacco products. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Monitoring of labelling and packaging standards for tobacco products *(Articles 8-13)*		*Please provide an indication of the costs involved in the monitoring and labelling of packaging standards. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Facilitating the function of track and tracing systems for tobaco products *(Articles 15-16)*	The implementation of the security features in article 16 have been done through the existing tobacco tax stamps. New security stamps have been made for the tax-free tobacco products, and the production costs to the supplier of these are approximately 150.000 DKK on a yearly basis.	*Please provide an indication of the costs involved in facilitating the function of tracking and tracing systems. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Monitoring of cross-border sales for tobacco products *(Article 18)*		*Please provide an indication of the costs involved to monitor cross-border sales. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Other costs for tobacco products, please describe:		*Please provide an indication of the other costs involved in supporting the implementation of the TPD2. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*

Q7b. What activities do you carry out on a regular basis (not enforcement - see next section) to support the implementation of the TPD2 in relation to **e-cigarettes and other products**? For each activity, please note approximately the current annual resources allocated

DSTA: we have only registered have many people were dedicated to our work concerning market surveilliance for e-cigaret products overall.
E-cigarettes: 6.3 people / 2019

Monitoring of ingredients, emissions and quality		*Please provide an indication of the costs involved in the monitoring of ingredients, emissions and quality of e-cigarettes. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Monitoring of labelling and packaging standards		*Please provide an indication of the costs involved in the monitoring and labelling of packaging standards. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*
Monitoring of cross-border sales for e-cigarettes *(Article 18) - please include in Q7a above if this cannot be split*		*Please provide an indication of the costs involved in implementing Article 18 of the TPD. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*

Other costs for e-cigarettes and other products, please describe:		*Please provide an indication of the costs involved in implementing Article 20 of the TPD. If there was a labour cost, please provide a rough indication of the number of employees (full-time equivalent), the time period of the work and the level of the employee*

ENFORCEMENT COSTS

	Product tests?	*Inspections?*
Q8a. Have you carried out **tests and/or inspections** related to the enforcement of the TPD2? Yes/No	Yes	Yes

Q8b. If yes, how many were conducted in each of the following years?

2019 *(or cumulative)*	274	1653
2018	198	1473
2017	346	1649
2016		

	Annual cost for maintenance of equipment *(Fixed cost)*	Cost of running a test *(Variable cost)*		
Q9a. On average, on much did a product test cost?		800 EURO	*Please explain your response:*	DSTA: The estimated cost is an average of test cost of tobacco products and e-cigarettes. The most expensive costs is test of RYOT
Q9b. On average, how much did an inspection cost?	160 EURO		*Please explain your response:*	

	Yes or No:
Q10a. Have you laid down rules on penalties applicable to infringements of the national provisions adopted pursuant to the TPD2? *(Article 23)*	Yes

Q10b. For how many products did you take administrative action since the application of TPD2?	Tobacco products	91
	Novel tobacco products	0
	E-cigarettes	220
	Other (e.g herbal)	1

		Please specify the number of products:		
Q10c. What was the outcome of the administrative action for these products?	Manufacturer withdrew product		*Please explain your response:*	DSTA: Our case management system is not updated with informations regarding the actions of the manufacturer and importor as an outcome of our action. As a part of our market surveillance we check if the manufacturers and importers market non-compliant products.
	Manufacturer modified product	We do not have statistics on this	*Please explain your response:*	DSTA: the products are either withdrawn by manufacturers or modified. We do not keep statistics on this.

Q10d. What kind of penalties were applied?	DSTA: 670-2010 EURO per non-compliant / illegal product

Q10e. How much did you collect in penalties per year?	2019 *(or cumulative)*	
If you cannot provide a breakdown by year please provide the cumulative figures	2018	
DSTA answer: the penalties are not collected by the DSTA but by the prosecuting authority, and we do not keep track of the total amount of fines.	2017	
	2016	