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REPORT FROM THE COMMISSION

on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU

1. Introduction

Article 2(28) of Directive 2014/40/EU[1] (hereinafter referred to as 'the Directive') defines the 'substantial change of circumstances' as an increase of the sales volumes by product category by at least 10 % in at least five Member States, based on sales data transmitted in accordance with Article 5(6) of the Directive or an increase of the level of prevalence of use in the under 25 years of age consumer group, by at least five percentage points in at least five Member States for the respective product category, based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies. According to the same provision, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2.5 % of total sales of tobacco products at Union level. Articles 7(12) and 11(6) of the Directive require the Commission to establish a substantial change of circumstances for a specific product category in a report.

This Report provides information on market developments, which are relevant to the assessment of a substantial change of circumstances for heated tobacco products. Heated tobacco products are novel tobacco products that are heated to produce an emission containing nicotine and other chemicals, which are then inhaled by user(s), and that, depending on their characteristics, are smokeless tobacco products within the meaning of Article 2(5) of the Directive, or tobacco products for smoking within the meaning of Article 2(9) of the Directive. The analysis presented in this Report is based on data transmitted in accordance with Article 5(6) of the Directive via the EU Common Entry Gate ('EU-CEG'), data collected from the EU tobacco traceability system established under Article 15 of the Directive and "Euromonitor International Passport Tobacco 2021" data. The latter is a commercial dataset that the Commission acquired from Euromonitor International. This Euromonitor dataset does not include data for LU, MT and CY (accounting for less than 0.5% of the EU population). Nevertheless, it was used as a representative proxy for the EU27 sales.

2. Analysis of the substantial change of circumstances for heated tobacco products

2.1 First condition for the substantial change of circumstances:

To fulfil the first condition for a substantial change of circumstances, one of the following two circumstances needs to be established.

2.1.1 Increase of the level of prevalence of use in the under 25 years consumer group by at least five percentage points in at least five Member States

The Special Eurobarometer 506 report[2] did not identify an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for heated tobacco products.

[1] 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 (OJ L 127, 29.4.2014, p. 1).

[2] Attitudes of Europeans towards tobacco and electronic cigarettes - February 2021 - - Eurobarometer survey (europa.eu)

2.1.2 Increase of the concerned products' sales volumes by at least 10% in at least five Member States

Table 1 that is based on EU-CEG data, presents the increase of the sales volumes of heated tobacco products at retail level for the period 2018 - 2020 in the Member States where the relevant increase was established to be higher than 10%.

Table 1: Sales volumes of heated tobacco products, in million sticks (2018 – 2020)

Member State	2018 sales volumes	2019 sales volumes	2020 sales volumes	2019-2018 percentage increase	2020-2019 percentage increase	2020-2018 percentage increase
CY	44.590	96.660	147.260	117%	52%	230%
CZ	0.859	1 284.094	1 744.4	Over 999%	39%	Over 999%
FR	36.796	78.215	186.009	113%	138%	406%
GR	0.007	1 159.804	1 443.958	Over 999%	25%	Over 999%
HR	0.003	219.072	289.592	Over 999%	32%	Over 999%
IT	0.042	3 571.016	5 819.033	Over 999%	63%	Over 999%
NL	28.262	43.120	71.618	53%	66%	153%
PL	0.010	1 206.171	2 466.150	Over 999%	104%	Over 999%
PT	338.022	637.649	944.977	89%	48%	180%
RO	486.239	671.053	837.587	38%	25%	72%
EU27	**934.854**	**12 332.655**	**19 716.820**	**1219%**	**60%**	**2009%**

Source: EU-CEG data

The data presented above thus confirm that the sales volumes of heated tobacco products at retail level increased by a percentage higher than 10 % in more than five Member States over the defined period of 2018 to 2020.

On this basis, the first condition for a substantial change of circumstances regarding heated tobacco products was met.

2.2 Second condition for the substantial change of circumstances: sales' volume of the concerned products at retail level exceed 2.5% of total sales of tobacco products at Union level

The market share of heated tobacco products at retail level was calculated by dividing their annual sales volume by the overall sales volume of all tobacco products at Union level. Alternative data sources were explored to ensure the robustness of such calculation.

2.2.1 Sales volume of heated tobacco products at retail level

Table 2 shows the EU27 sales volume of heated tobacco products in 2020 from two different, mutually independent data sources.

Table 2: Sales volumes of heated tobacco products in EU27 in million sticks (2020)

Data source	Sales volume 2020
EU-CEG	19 717
Euromonitor	20 766

As shown in the table, the sales volume reported by Euromonitor is slightly higher than the EU-CEG sales volume. In line with the conservative approach chosen for this Report, the lowest sales volume (i.e. the EU-CEG volume) was used as the numerator for the calculation of the heated tobacco products' market share. The numerator expresses their annual market volume in 2020 which is to be compared with the total volume of tobacco products sold in EU27 in 2020 at retail level.

2.2.2 Total sales of tobacco products at Union level

Table 3 is based on the Euromonitor data. It shows the total sales of tobacco products, including the total sales of cigarettes, cigars, cigarillos, roll-your-own tobacco, pipe and chewing tobacco and heated tobacco products in 2020.

Table 3: Total sales volumes of tobacco products (in 2020)

Cigarettes (in million sticks)	**Cigars (in million units)**	**Cigarillos (in million units)**	**Roll-your-own tobacco (in million sticks)***	**Pipe and chewing tobacco** (adjustment)**	**Heated tobacco (in million sticks)**	**Total sales of tobacco products (in million sticks equivalent)**
408 279	1 006	8 459	108 059	3 908	20 766	550 478

* Euromonitor report: Roll-your-own tobacco products weigh 75 641 tons. The analysis calculates the equivalent in roll-your-own tobacco sticks by considering that 0.7 grams equals to one stick.
** Due to the fact that pipe and chewing tobacco sales volume cannot be quantified in sticks in a standardised manner, the analysis adjusts the total sales volume of tobacco products by adding the corresponding share of market value of EU27, which 0.71% in 2020 (thus equivalent to 550 478 * 0.71% = 3 908 million sticks equivalent).
Source: Euromonitor International Passport Tobacco 2021

As of May 2019, the EU tobacco traceability system allows Member States to follow the market flow of cigarettes and roll-your-own tobacco. Table 4 shows the sale volumes of cigarettes and roll-your-own tobacco for 2020, calculated from data based on the tobacco traceability system, taking into consideration two alternative approaches, each capturing slightly different time periods, reflecting the time required for products to move down the distribution chain. As the data are recorded at the level of manufacturer, one-month delay is assumed until the product reaches the retail level ("time-adjusted production figures").

As the traceability database does not include the pack size, the analysis cross-checked the traceability data with the EU-CEG database using the unique product identifier (TP-ID) to ascertain the number of cigarettes per unit package declared for each tobacco products' identifier in the EU-CEG report.

Table 4: Production of cigarettes and roll-your-own tobacco in 2020[3]

Cigarettes		**Roll-your-own tobacco**	
Time-adjusted production figures (in million of sticks)	**Non-time-adjusted production figures** (in million of sticks)	**Time-adjusted production figures** (in million sticks equivalent)	**Non-time-adjusted production figures** (in million sticks equivalent)
436 123	434 164	121 239	122 341

Time-adjusted production figures refer to period: Dec 2019 - Nov 2020.
Non-time-adjusted production figures refer to period: Jan 2020 - Dec 2020.
Source: EU tobacco traceability system

For the purpose of the adopted conservative calculation, the Report considers the higher of the two values for the respective categories (i.e. the time-adjusted production figures for cigarettes and the non-time-adjusted production figures for roll-your-own tobacco).

As the Directive defers the traceability of other tobacco product categories until 2024, table 5 combines the tobacco traceability system's data obtained for cigarettes and roll-your-own tobacco with the relevant Euromonitor data for other tobacco products' categories:

Table 5: Total sales of tobacco products (in 2020)

Tobacco traceability system data		**Euromonitor data**			**Adjustment**	**Tobacco traceability system + Euromonitor data**
Cigarettes (million units)	**Roll-your-own tobacco** (1 Unique identifier = 50 grams) (million sticks equivalent)	**Cigars** (million units)	**Cigarillos** (million units)	**HTP** (million sticks)	**Pipe and Chewing Tobacco*** (adjustment)	**All tobacco products** (in million sticks equivalent)
436 123	122 341	1 006	8 459	20 766	4 210	**592 904**

*Due to the fact that pipe and chewing tobacco sales volume cannot be quantified in sticks, the analysis adjusts the total sales volume of tobacco products by adding the corresponding share of market value of EU27, which is 0.71% in 2020 (thus 592 904 * 0.71% = 4 210 million sticks equivalent).
Source: EU tobacco traceability system, Euromonitor International Passport Tobacco 2021

[3] To estimate the sales volume of roll-your-own tobacco products, a packet of roll-your-own tobacco, as registered in the tobacco traceability system, was considered to contain 50 grams of tobacco, i.e. the equivalent of around 71 sticks (assuming 0.7 gram of tobacco per stick).

To calculate the exact proportion of the EU total sales of tobacco products that corresponds to the sales volume of heated tobacco products at retail level, the analysis used the highest sales volume (i.e. the combination of the tobacco traceability system and Euromonitor data on sales volume) as the denominator.

2.2.3 Sales volumes of heated tobacco products at retail level in relation to total sales of tobacco products at Union level

As explained above, to calculate the exact proportion of the EU total sales of tobacco products that corresponds to the sales volume of heated tobacco products at retail level, the lowest numerator - EU-CEG sales volume (i.e. 19 717 million sticks) was used in combination with the highest denominator based on the tobacco traceability and Euromonitor volume (i.e. 592 904 million sticks equivalent).

This conservative approach indicated that the sales volume of heated tobacco products at retail level corresponded to **3.33 %** of the total sales volume of all tobacco products at Union level for the year 2020.

As this value exceeds the threshold of 2.5%, the second condition for a substantial change of circumstances regarding heated tobacco products is also met.

2.2.4 Sales value of heated tobacco products at retail level in relation to total sales of tobacco products at Union level

The analysis of the sales value provides an alternative measurement of the heated tobacco products' market share in 2020 and allows for consideration of the remaining minor categories of tobacco products which cannot be measured in sticks: pipe and chewing tobacco (used for adjustments on the principal sales volume analysis).

The table below shows the total sales value on each product category for all Member States in EU27 in billion of euros:

Table 6: Sales value on each product category (in 2020)

Product Categories	Retail value EUR billion	Market share (%) of total sales at Union level
Cigarettes	109.88	81.38%
Cigarillos	2.33	1.73%
Cigars	2.05	1.52%
Fine Cut Tobacco (RYO)	15.06	11.15%
Pipe Tobacco	0.93	0.69%
Chewing Tobacco	0.02	0.02%
Heated Tobacco	4.74	**3.51%**
All tobacco products	135.01	100.00%

Source: Euromonitor International Passport Tobacco 2021

These data thus indicate that the sales value of heated tobacco products at retail level correspond to **3.51 %** of the total sales volume of all tobacco products at Union level for the year 2020. This further confirms the principal analysis based on the sales volume.

3. Conclusion

Considering that the sales volumes of heated tobacco products:

- have increased by at least 10% in at least five Member States, and
- the sales volumes of heated tobacco products at retail level exceed 2.5% of total sales of tobacco products at Union level,

the present Report establishes the substantial change of circumstances for heated tobacco products.