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Second report on e-cigarette product analyses

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JOINT ACTION ON TOBACCO CONTROL

This activity is part of the project Joint Action 761297/JATC, which has received funding from the European Union's Health Program (2014-2020)

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS (the report was prepared before Brexit) through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in October of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Below we provide an analysis for 13 EU MS that provided data: Spain, Malta, Lithuania, Netherlands, Greece, France, Denmark, Slovenia, Luxembourg, Belgium, Estonia, Latvia, Italy.

Each EU MS was provided with a detailed report for use within their own work activities.

Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Figure 1 reflects the numbers of different types of notifications across the 13 EU MS. The most common notification type was a notification for a new product EC-ID. The total number of notifications ranged from 9,576 in DK to 46079 in IT. **Figure 2** provides an indication of the % of submission types by EU MS.

Figure 1. Type of notifications within EU-CEG, 13 EU MS

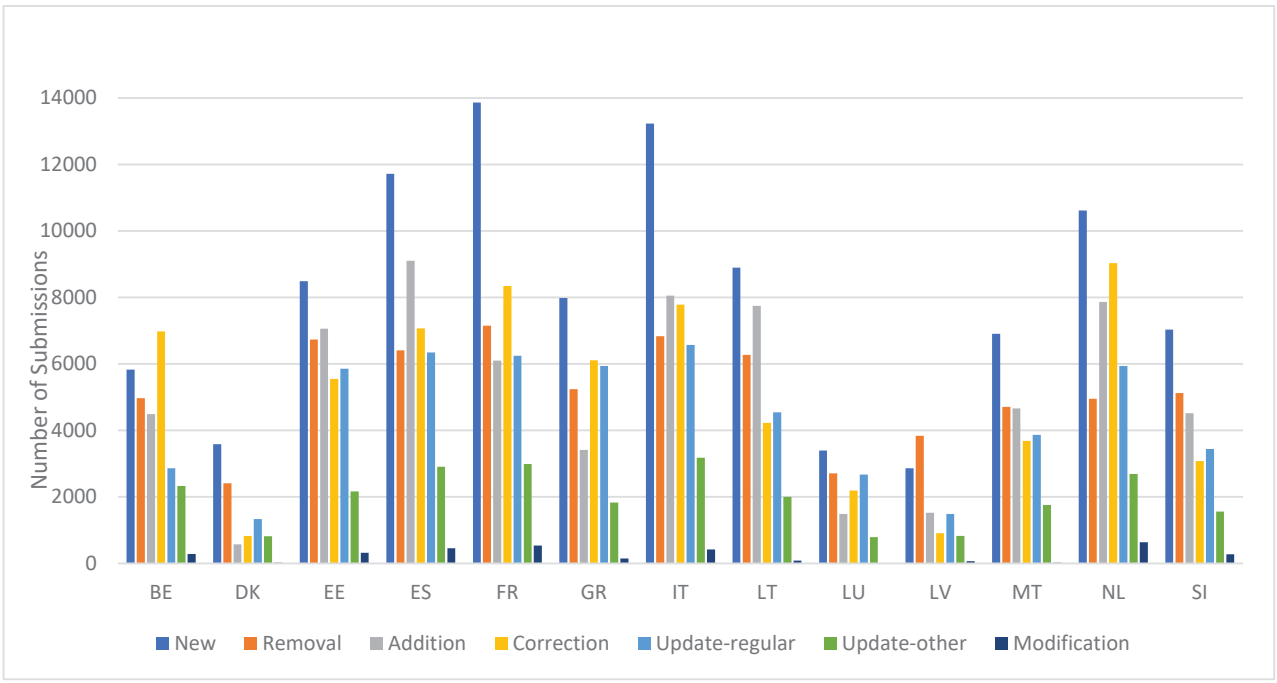
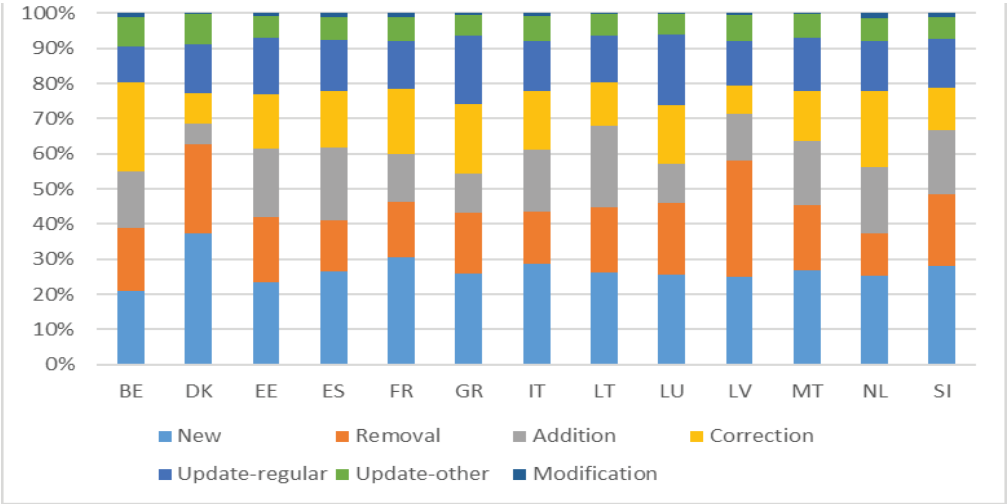


Figure 2. Percentage of submission types by EU MS



1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of October 2019, of the notifications (unique EC-IDs) submitted a percentage have been withdrawn leaving a number of unique EC-IDs active on the market. Of the total entries, proportion of withdrawn products ranged from 10.1% (IT) to 42.6% (LV). The analyses presented from here onwards are restricted to products that are currently active. **Figure 3** displays the numbers of the active products by EU MS, while **Figure 4** presents the product types currently active in EU CEG by count, and **Figure 5** presents the product types by percentage of active products in each EU MS.

Figure 3. Number of active products (not withdrawn) in EU-CEG, across 13 EU MS

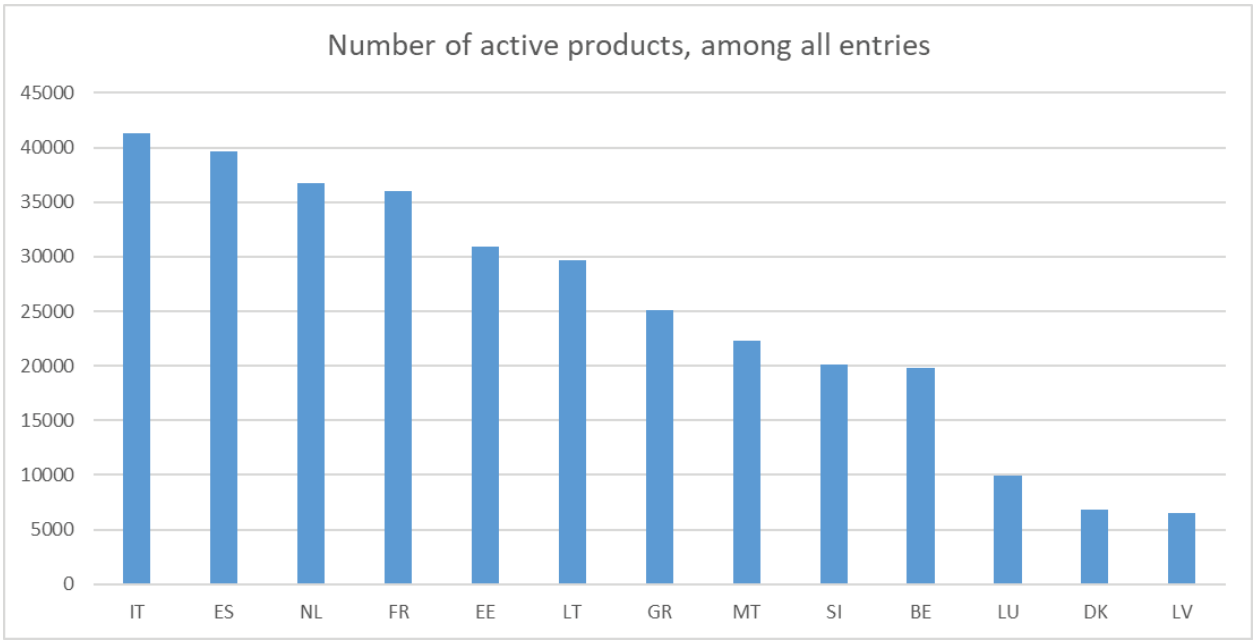


Figure 4. Product types currently active in EU CEG by count, for 13 EU MS

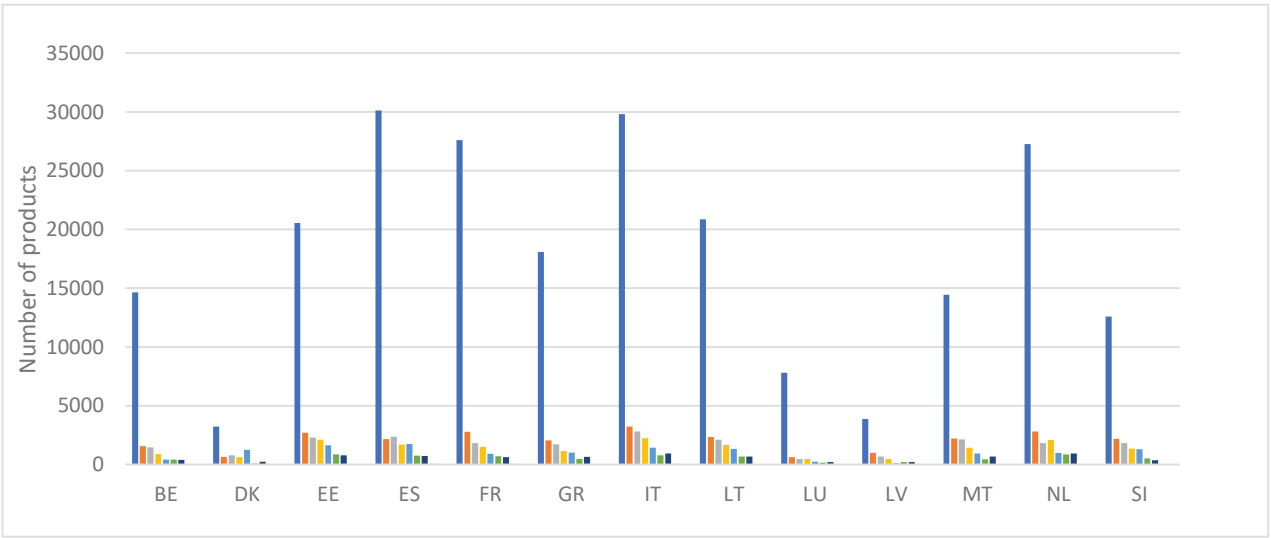
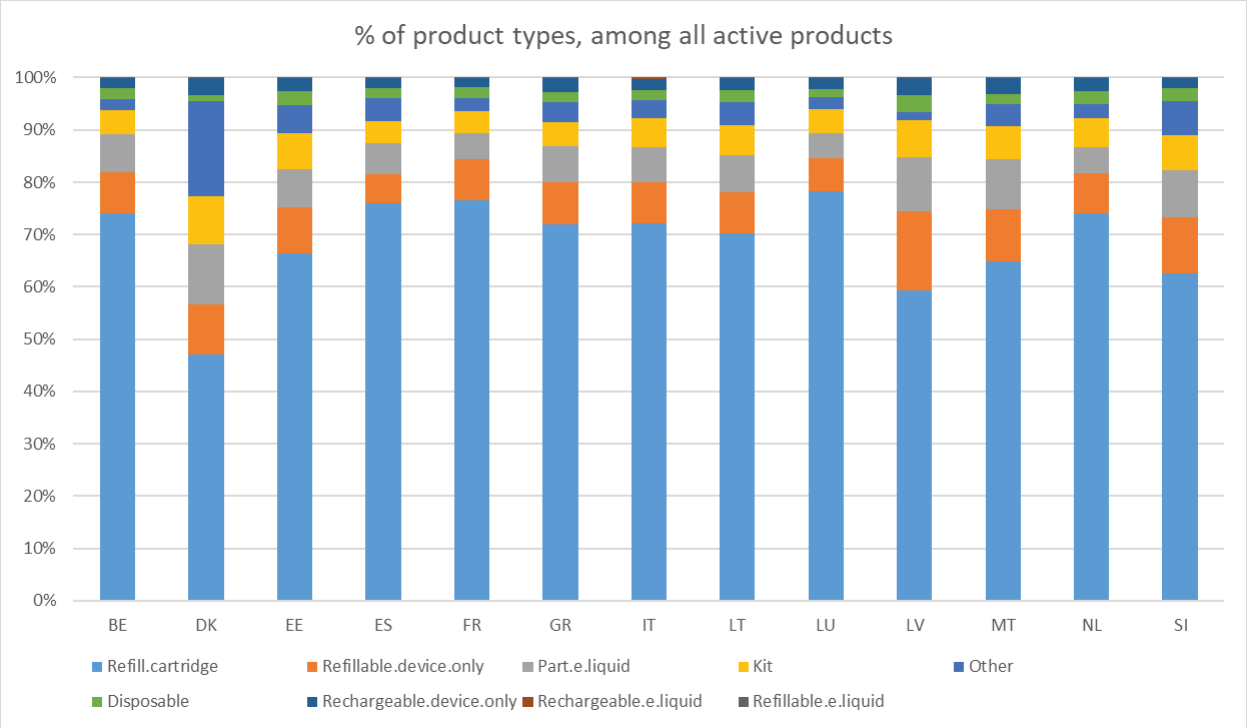


Figure 5. Product types by percentage of active products in 13 EU MS.



1. Assessment of volume and nicotine content in nicotine containing liquids

1.1 Volume/capacity of nicotine-containing e-cigarette liquid TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Table 1, provides an overview of the 217,920 nicotine-containing refill containers/cartridges that reported vial volumes in the 13 EU MS. Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with >99% of products (n=217,187) reporting a vial volume of 10ml or less. Only 699 non-compliant refill containers/cartridges (volume >10ml) were identified in the EU-CEG of the 13 EU MS.

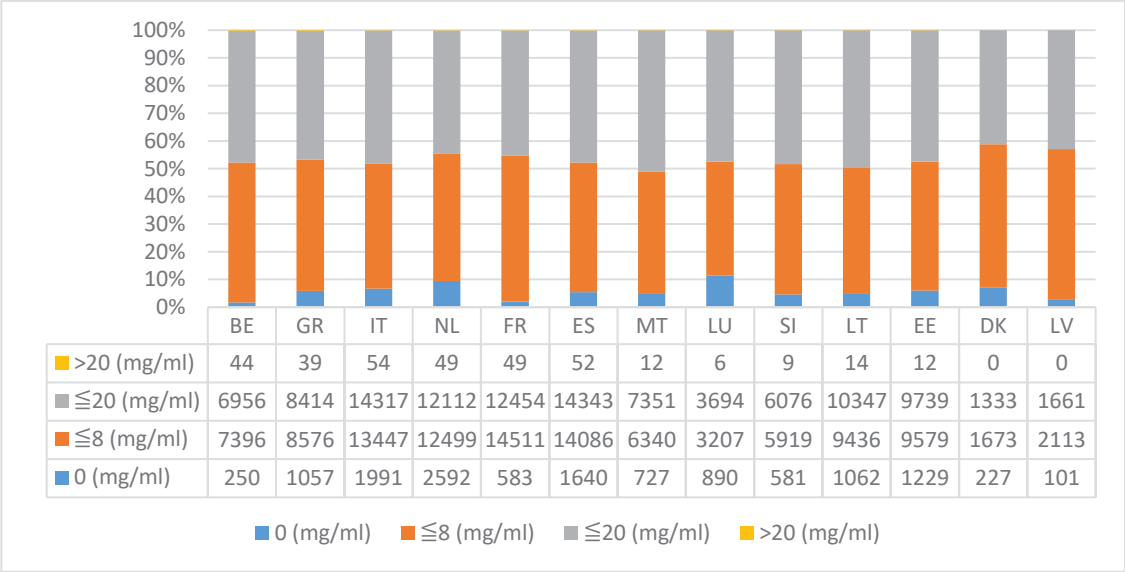
	Volume ≦10ml	Volume >10ml	Invalid (0 ml)	NAs	Volume ≦10ml	Volume >10ml
BE	14302	89	5	0	99.3%	0.6%
DK	2981	25	0	0	99.2%	0.8%
EE	19288	39	3	0	99.8%	0.2%
ES	28437	42	2	0	99.8%	0.1%
FR	26880	129	6	0	99.5%	0.5%
GR	16982	45	2	0	99.7%	0.3%
IT	27761	55	2	0	99.8%	0.2%
LT	19759	35	3	0	99.8%	0.2%
LU	6875	32	0	0	99.5%	0.5%
LV	3750	24	0	0	99.4%	0.6%
MT	13663	37	3	0	99.7%	0.3%
NL	24553	102	5	0	99.6%	0.4%
SI	11956	45	3	0	99.6%	0.4%

1.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 230,849 notifications on e-liquid products sold in refill cartridges/containers, 12,930 did not contain nicotine, 108,872 had a nicotine concentration ≦8 (mg/ml), while 340 products had a reported nicotine concentration>20 mg/ml. The distribution by EU MS is depicted below in **Table 2** and graphically in **Figure 6.**

	0 (mg/ml)	≦8 (mg/ml)	8-20 (mg/ml)	TOTAL 0-20 (mg/ml)	Non compliant >20 (mg/ml)
BE	250	7396	6956	14352	44
GR	1057	8576	8414	16990	39
IT	1991	13447	14317	27764	54
NL	2592	12499	12112	24611	49
FR	583	14511	12454	26965	49
ES	1640	14086	14343	28429	52
MT	727	6340	7351	13691	12
LU	890	3207	3694	6901	6
SI	581	5919	6076	11995	9
LT	1062	9436	10347	19783	14
EE	1229	9579	9739	19318	12
DK	227	1673	1333	3006	0
LV	101	2113	1661	3774	0

Figure 6. Nicotine concentration compliance among active refill containers/cartridges in 13 EU MS



	BE	GR	IT	NL	FR	ES	MT	LU	SI	LT	EE	DK	LV
>20 (mg/ml)	44	39	54	49	49	52	12	6	9	14	12	0	0
≦20 (mg/ml)	6956	8414	14317	12112	12454	14343	7351	3694	6076	10347	9739	1333	1661
≦8 (mg/ml)	7396	8576	13447	12499	14511	14086	6340	3207	5919	9436	9579	1673	2113
0 (mg/ml)	250	1057	1991	2592	583	1640	727	890	581	1062	1229	227	101

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* The overwhelming majority of the nicotine-containing e-liquid products in EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less.

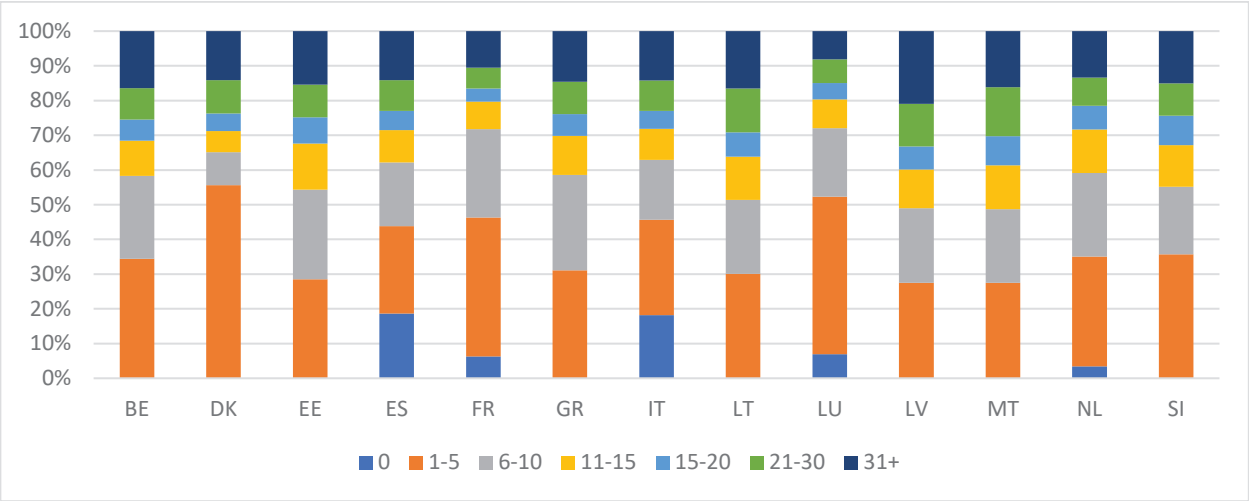
2. Ingredient Analysis

2.1 Number of ingredients contained per product [TPD Art 20(2)b]

Table 3 provides a breakdown of the number of CAS reported within one product, among all refill containers/cartridges, in the EU-CEG data for 13 EU MS.

	TOTAL CAS	0	1-5	6-10	11-15	15-20	21-30	31+
BE	1944	6	5035	3496	1485	890	1326	2408
DK	1924	0	1798	307	196	164	312	456
EE	1906	0	5867	5304	2736	1555	1922	3175
ES	1825	5608	7593	5533	2803	1674	2670	4240
FR	1709	1741	11035	7042	2165	1058	1641	2915
GR	1629	0	5622	4969	2035	1137	1678	2645
IT	1581	5422	8187	5145	2661	1544	2621	4229
LT	1440	0	6279	4436	2596	1464	2630	3454
LU	1432	538	3542	1539	643	368	535	632
LV	1286	0	1067	832	433	257	474	812
MT	1108	0	3974	3059	1824	1206	2038	2329
NL	965	944	8602	6580	3402	1872	2203	3650
SI	857	0	4499	2440	1508	1068	1171	1899

Figure 7. Graphical representation of the CAS numbers reported for each product, among refil containers/cartridges (active) in 13 EU MS.



2.2 Most frequently used ingredients [TPD Art 20(2)b]

A total of 386,818 CAS number entries were identified, only 3852 were missing a CAS indicating high compliance to CAS reporting. Among the refill containers/cartridges the top 10 most common ingredients are depicted below in Figure 8. This includes the most common function.

Continued

Table 8. Top 10 most common ingredients of e-liquids in refill containers/cartridges, in 13 EU MS.

CAS	n	%	name	function/flavour
•57-55-6	22982	5,9	propylene glycol	humectant
•56-81-5	22161	5,7	glycerine	humectant
•54-11-5	19247	5	nicotine	addictive substance
•121-33-5	8979	2,3	vanilla	vanilla
•7732-18-5	8157	2,1	water ultrapure	dilutant
•4940-11-8	7540	1,9	ethyl maltol	sweet sugar caramellic jammy strawberry
•105-54-4	6540	1,7	ethyl butyrate	fruity juicy fruit pineapple cognac
•64-17-5	5671	1,5	ethanol	alcohol
•118-71-8	5035	1,3	maltol	caramellic type odor
•141-78-6	4934	1,3	ethyl acetate	Brandy-like odor,
•3658-77-3	4592	1,2	strawberry furanone	strawberry
•121-32-4	4347	1,1	ethyl vanillin	vanilla

Recommendations

- Regulators should use the flagged EC-IDs provided to them at the EU MS level to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- Outliers remain a limitation of the current analysis of the Greece EU-CEG dataset (in particular for vial volume and nicotine concentration)- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- Missing and invalid data suggests a need to redefine or clarify product type categories and their relevant variables. For example, products missing reports for capacity, and over 50% of those reporting invalid values for capacity, were categorized as 'individual parts of e-cigarettes capable of containing an e-liquid.'
- Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume/capacity and nicotine concentration), or to change the vari-able type from "text" variables to "numeric" variables to ensure correct and consistent report-ing.
- Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report SPAIN

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This activity has received funding from the European Union's Health Program (2014-2020) under grant agreement – 761297.

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Background

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With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Below we provide an analysis for the EU MS Spain. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Spain EU-CEG dataset, there are 44,029 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type was a notification for a new product EC-ID (26.6%), followed by the addition of a product presentation to an existing product submission, for example, a national market (20.7%), and the correction of clerical/administrative errors in an existing product submission (16.1%).

Figure 1. Type of notifications within EU-CEG, Spain (N= 44,029)

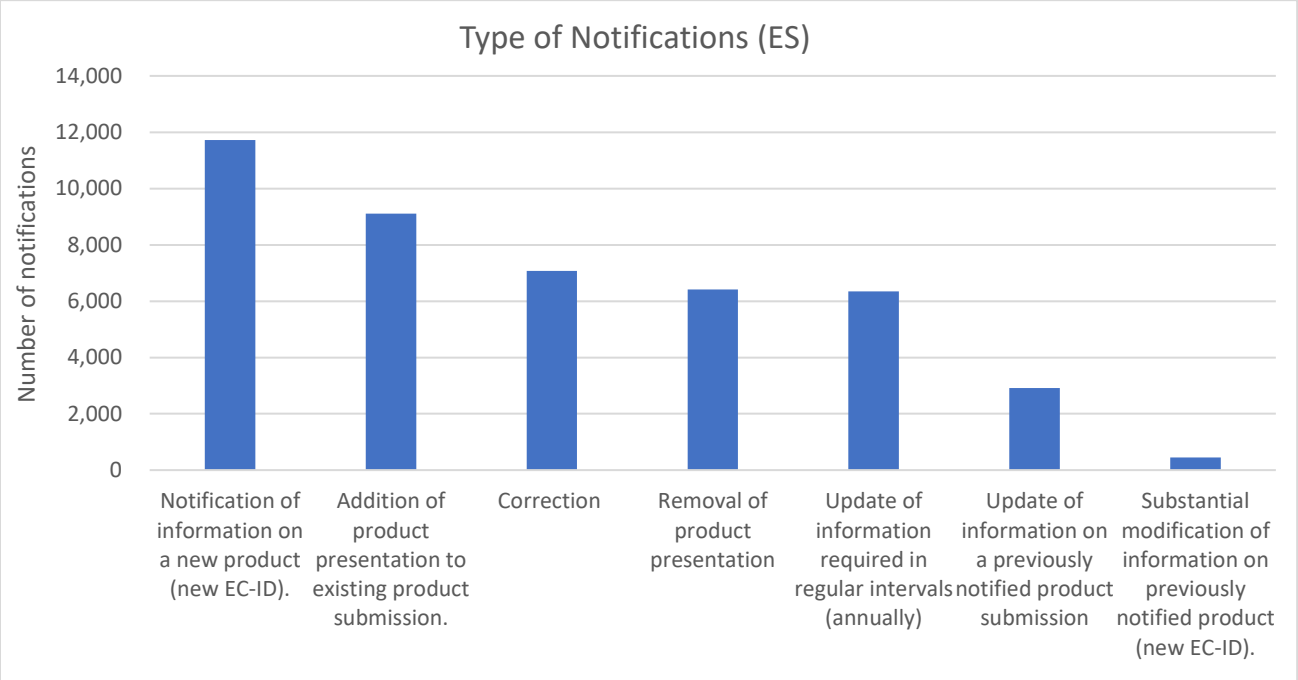


Table 1. Type of notifications within EU-CEG in Spain (N=44,029)

Notification Type	n	%
Notification of information on a new product (new EC-ID)	11,723	26.6%
Addition of product presentation (e.g. national market) to an existing product submission	9109	20.7%
Correction of clerical/administrative errors in existing product submission	7069	16.1%
Removal of product presentation, including product withdrawal, from an existing product submission	6414	14.6%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	6348	14.4%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID	2912	6.6%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID)	454	1.0%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 44,029 notifications (unique EC-IDs) submitted for Spain for the EU CEG, 2 products indicated withdrawal but did not provide a specific date and were thus excluded from the analysis. Among valid notifications, 4,426 (10.1%) have been withdrawn and 39,601 (89.9%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active.

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG in Spain is displayed in **Table 2** (below). Of the 39,601 notifications for products that are currently on the market, 71.9% (n=30,121) represented refill containers/cartridges containing an e-liquid, 8.1% (n=2,358) represented individual parts of e-cigarettes capable of containing e-liquids, and 6.9% (n=2,146) represented a refillable device (device only).

Figure 2. Product types active (not withdrawn) in EU-CEG, Spain (n=39,601)

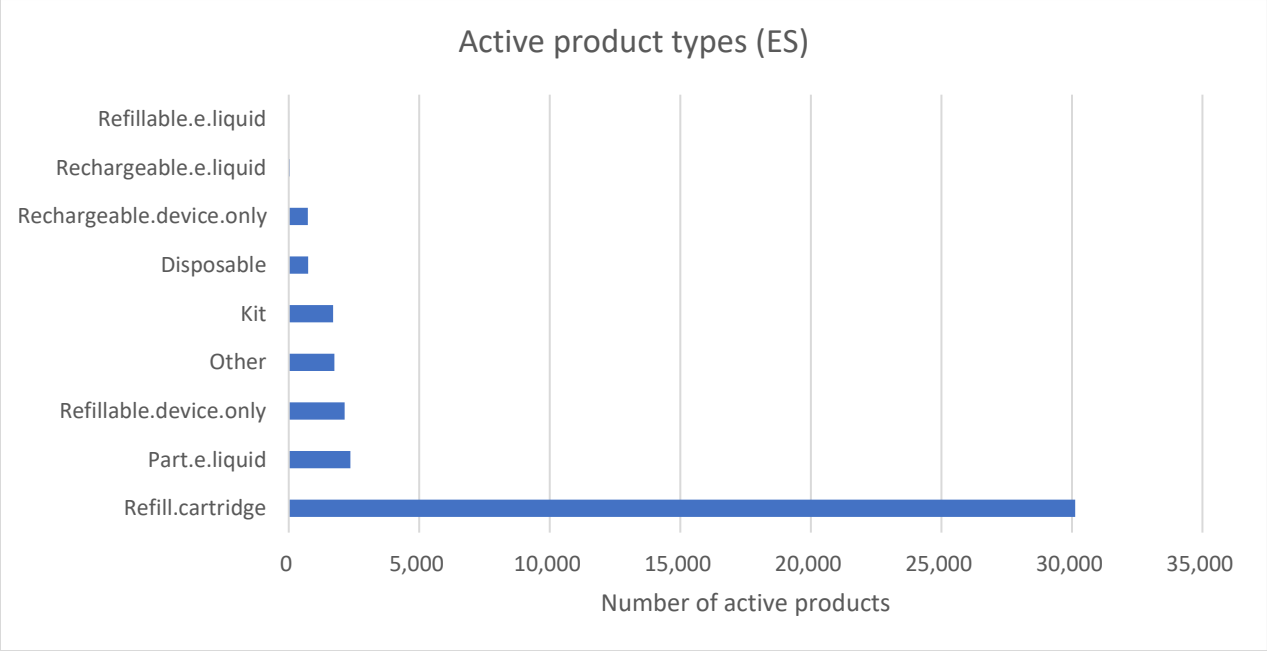


Table 2. Breakdown of product types active in EU-CEG, Spain (n=39,601)

Product type	n	%
Refill container/cartridge containing e-liquid	30121	71.9%
Individual part of e-cigarette capable of containing e-liquid	2358	8.1%
Refillable, device only	2146	6.9%
Other	1748	4.6%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	1698	4.0%
E-cigarette – Disposable	744	2.6%
E-cigarette – Rechargeable, device only	737	1.9%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	40	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	9	0.0%

2. Assessment of volume and nicotine content in nicotine containing liquids

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 30,121 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 2 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 30,119 refill containers/cartridges reporting valid vial volumes (>0 ml), 28,479 were reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 28,479 nicotine-containing refill containers/cartridges that reported valid vial volumes in Spain, the average vial volume was 10.59 ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the wide range of vial volumes reported and outliers, the SD of vial volumes among all products was 93.38ml.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml.* Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.9% of products (n=28,437) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.76ml and the middle value of the vial volumes reported (median) was 10ml. This is depicted in **Table 3**.

Only 42 non-compliant refill containers/cartridges (volume >10ml) were identified in the Spain EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with extremely large vial volumes (e.g. 11,482ml). The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Spain

	Vial volume (ml)		
	All products n=28,479	**Compliant products (≦10ml)** n= 28,437	**Non-compliant products (>10ml)** n= 42
Min.	0.67	0.67	12
Median	10	10	30
Mean	10.59	9.763	573.2
Max.	11482	10	11482
SD	93.38	1.39	2465.24

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 6,012 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 5,068 products reported a value for capacity and 944 products (15.6%) were missing reports. All of the 944 submissions missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 5,068 products which reported a value for capacity, 4,532 products (89.4%) reported valid capacity (>0 ml) and 536 products (10.6%) reported invalid values (i.e. 0 ml). Over half of the 536 products reporting invalid values for capacity (n=302) were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.'

Among the 4,532 products that reported a valid capacity (>0 ml) in Spain, the average capacity was 2.51ml (SD=2.01 ml). The middle value of the capacities reported (median) was 2ml. This distribution is presented in **Table 4** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in cartridges or tanks which do not exceed a capacity of 2 ml*. Given that cartridges or tanks placed on the market without a nicotine-containing e-liquid can still be used for the consumption of nicotine-containing vapour, compliance with Article 20.3 of the EU TPD of product types sold with, and/or capable of containing, an e-liquid was assessed in this analysis. Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 83.9% of products (n=3,801) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.80ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=731) had an average capacity of 6.22ml. The volume distribution of these non-compliant products is depicted in **Table 4**, and their EC-IDs are flagged in **Annex A.** The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there was one non-compliant nicotine-containing disposable e-cigarettes (0.1%) and one non-compliant refillable e-cigarettes sold with an e-liquid (13.9%). Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 85 products (7.6%) listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 146 (28.1%) of the rechargeable devices, and 298 (13.9%) of the refillable devices, were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Spain

	Capacity (ml) All reported (n= 5068)	All valid (>0 ml) (n= 4532)	Valid, Compliant (≦2ml) (n= 3801)	Valid, Non-compliant (>2ml) (n=731)
Min.	0	0.01	0.01	2.2
Median	2	2	2	5
Mean	2.252	2.518	1.806	6.221
Max.	30	30	2	30
SD	2.05	2.01	0.39	2.83
Invalid (=0 ml)	n= 536			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other', and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 30,121 notifications on e-liquid products sold in refill cartridges/containers, 1,640 (5.4%) did not contain nicotine. The average nicotine concentration among the remaining 28,481 nicotine-containing e-liquid products was 9.83 mg/ml and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. This distribution is depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* The overwhelming majority (99.8%) of the 28,481 nicotine-containing e-liquid products in the Spain EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 28,429 compliant products, the average nicotine concentration was 9.59 mg/ml and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. This is displayed in **Table 5**.

Only 52 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. The distribution of nicotine concentration for these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Spain

	Nicotine concentration (mg/ml) All products (n=28,481)	Compliant products (≦20 mg/ml) (n=28,429)	Non-compliant products (>20 mg/ml) (n= 52)
Min.	0.12	0.12	20.02
Median	9	9	60
Mean	9.678	9.594	55.91
Max.	180	20	180
SD	6.74	6.03	41.87

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Spain EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 461 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was lower reported capacity for disposable e-cigarettes (mode: 280mA) compared to refillable e-cigarette devices sold as ‘device only’ (mode: 1500mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 3000mA). With regards to whether the airflow is adjustable or if the wick is changeable, almost no disposable e-cigarettes were found to have the ability to alter airflow (0.0%) or change the wick (0.1%). However, among the 2,258 products listed as ‘refillable, device only’, 66.8% (n= 1509) noted the ability to adjust airflow and 41.2% (n=930) had the ability to change the wick, and among the 767 products listed as ‘rechargeable device only’, 49.9% (n=383) had the ability to adjust airflow and 19.4% (n=149) had the ability to change the wick. This suggests the plethora of product designs available on the market. A similar pattern was identified for the presence of microprocessor, which was predominately present in refillable devices sold as ‘device only’ (62.3%), rechargeable devices sold as ‘device only’ (68.8%) and kits (61.6%), whereas only 10.9% of the 763 disposable e-cigarettes had a microprocessor.

Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

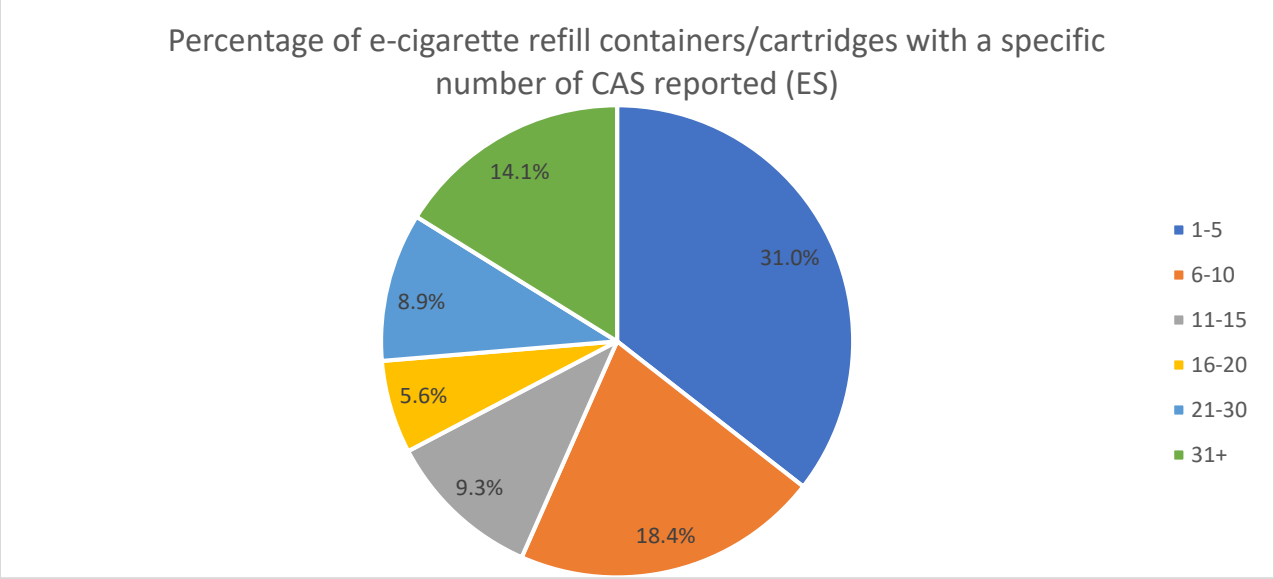
Among the 30,121 submissions for refill containers/cartridges within the Spain EU-CEG database with a "not withdrawn" status, 1,944 unique CAS numbers were submitted (Note that additional data cleaning is needed to further reduce this number).

Among the 30,121 submissions for refill containers/cartridges, 25.2% reported between 1 to 5 CAS, 18.4% reported between 6 to 10 CAS, and 14.1% reported more than 31 CAS. This breakdown is displayed in **Table 6**. A significant number of products (n=5,608) in the Spain EU CEG reported no CAS, thus the submissions were considered invalid and their EC-IDs are flagged in **Annex A**. **Figure 3** depicts the breakdown of the number of CAS reported within one product, excluding submissions with no CAS reported.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges (n=30,121)

Number of CAS per product	Number of products	% (total)	% (excluding invalid)
1-5	7593	25.2%	31.0%
6-10	5533	18.4%	18.4%
11-15	2803	9.3%	9.3%
16-20	1674	5.6%	5.6%
21-30	2670	8.9%	8.9%
31+	4240	14.1%	14.1%
Invalid (no CAS reported)	5608	18.6%	

Figure 3. Breakdown of the number of CAS reported within one product (among those that reported a CAS), (n=24,513)



Among valid submissions, the average number of ingredients per product was 16.18, ranging between 1 to 113 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID for all submissions and for all valid submissions is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall and among valid product submissions, Spain

	Number of CAS All refill containers/cartridges (n= 30,121)	**Valid CAS entry** (n= 24,513)
Min.	0	1
Median	7	9
Mean	13.06	16.18
Max.	113	113
SD	15.86	16.14
Invalid (i.e. no CAS reported)	n = 5608	

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges that contain an e-liquid which reported any CAS (n=24,513), a total of 1,944 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Spain (n=24,513)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	23486	95.8%
2	56-81-5	Glycerol	22762	92.9%
3	54-11-5	Nicotine	22540	92.0%
4	121-33-5	Vanillin	9487	38.7%
5	105-54-4	Ethyl butyrate	8682	35.4%
6	4940-11-8	Ethyl maltol	8182	33.4%
7	7732-18-5	Water	7893	32.2%
8	141-78-6	Ethyl acetate	6364	26.0%
9	118-71-8	Maltol	6166	25.2%
10	64-17-5	Ethyl alcohol	6111	24.9%
11	3658-77-3	Furaneol	5651	23.1%
12	928-96-1	cis-3-Hexen-1-ol	5385	22.0%
13	123-92-2	Isoamyl acetate	4986	20.3%
14	7452-79-1	Ethyl 2-methylbutyrate	4964	20.3%
15	706-14-9	γ-Decalactone	4923	20.1%
16	121-32-4	Ethyl vanillin	4907	20.0%
17	64-19-7	Acetic acid	4688	19.1%
18	100-51-6	Benzyl alcohol	4345	17.7%
19	78-70-6	Linalool	4119	16.8%
20	107-92-6	Butyric acid	3924	16.0%

21	123-66-0	Ethyl hexanoate	3845	15.7%
22	100-52-7	Benzaldehyde	3270	13.3%
23	102-76-1	Triacetin	3217	13.1%
24	142-92-7	Hexyl acetate	3201	13.1%
25	3681-71-8	cis-3-Hexenyl acetate	3190	13.0%
26	116-53-0	(±)-2-Methylbutyric acid	3059	12.5%
27	5471-51-2	Frambione	2994	12.2%
28	56038-13-2	Sucralose	2985	12.2%
29	142-62-1	Hexanoic acid	2918	11.9%
30	705-86-2	δ-Decalactone	2898	11.8%
31	120-57-0	Piperonal	2875	11.7%
32	105-37-3	Ethyl propionate	2830	11.5%
33	104-67-6	γ-Undecalactone	2792	11.4%
34	765-70-8	3-Methyl-1,2-cyclopentanedione	2781	11.3%
35	80-71-7	Methyl cyclopentenolone	2711	11.1%
36	103-26-4	Methyl cinnamate	2638	10.8%
37	659-70-1	Isoamyl isovalerate	2627	10.7%
38	123-11-5	p-Anisaldehyde	2490	10.2%
39	104-50-7	γ-Octalactone	2463	10.0%
40	108-64-5	Ethyl isovalerate	2457	10.0%
41	140-11-4	Benzyl acetate	2422	9.9%
42	2216-51-5	L-Menthol	2203	9.0%
43	713-95-1	δ-Dodecalactone	2186	8.9%
44	104-61-0	γ-Nonanoic lactone	2158	8.8%
45	5392-40-5	Citral	1985	8.1%
46	513-86-0	Acetoin	1916	7.8%
47	56-40-6	Glycine	1909	7.8%
48	127-41-3	α-Ionone	1863	7.6%
49	14901-07-6	β-Ionone	1764	7.2%
50	106-27-4	Isoamyl butyrate	1758	7.2%
51	22047-25-2	2-Acetylpyrazine	1749	7.1%
52	98-55-5	α-Terpineol	1731	7.1%
53	90-05-1	Guaiacol	1715	7.0%
54	119-84-6	Dihydrocoumarin	1640	6.7%
55	110-19-0	Isobutyl acetate	1597	6.5%
56	137-00-8	4-Methyl-5-thiazoleethanol	1583	6.5%
57	14667-55-1	2,3,5-Trimethylpyrazine	1566	6.4%
58	5989-27-5	(R)-(+)-Limonene	1550	6.3%
59	111-27-3	1-Hexanol	1509	6.2%
60	6728-26-3	trans-2-Hexen-1-al	1467	6.0%
61	23696-85-7	Damascenone	1443	5.9%
62	60-12-8	2-Phenylethanol	1439	5.9%
63	75-18-3	Dimethyl sulfide	1438	5.9%
64	105-13-5	4-Methoxybenzyl alcohol	1388	5.7%
65	695-06-7	γ-Hexalactone	1377	5.6%
66	123-51-3	Isoamyl alcohol	1377	5.6%

67	123-68-2	Allyl hexanoate	1370	5.6%
68	97-53-0	Eugenol	1345	5.5%
69	89-78-1	Menthol	1328	5.4%
70	106-24-1	Geraniol	1301	5.3%
71	79-09-4	Propionic acid	1301	5.3%
72	97-64-3	Ethyl lactate	1268	5.2%
73	134-20-3	Methyl anthranilate	1233	5.0%
74	8008-56-8	Lemon oil	1176	4.8%
75	77-92-9	Citric acid	1170	4.8%
76	104-55-2	Cinnamaldehyde	1080	4.4%
77	105-87-3	Geranyl acetate	1034	4.2%
78	8008-57-9	Orange oil	1016	4.1%
79	66-25-1	Hexanal	1006	4.1%
80	7492-70-8	Butyl butyryllactate	970	4.0%
81	123-86-4	Butyl acetate	946	3.9%
82	115-95-7	Linalyl acetate	930	3.8%
83	4180-23-8	trans-Anethole	913	3.7%
84	77-93-0	Triethyl citrate	900	3.7%
85	470-82-6	Eucalyptol	899	3.7%
86	124-07-2	Octanoic acid	861	3.5%
87	138-86-3	Dipentene	842	3.4%
88	109-21-7	Butyl butyrate	823	3.4%
89	93-92-5	Styralyl acetate	793	3.2%
90	2305-05-7	γ-dodecalactone	790	3.2%
91	16491-36-4	cis-3-Hexenyl butyrate	788	3.2%
92	141-97-9	Ethyl acetoacetate	779	3.2%
93	620-02-0	5-Methylfurfural	769	3.1%
94	106-32-1	Ethyl octanoate	757	3.1%
95	51115-67-4	2-Isopropyl-N,2,3-trimethylbutyramide	752	3.1%
96	928-95-0	trans-2-Hexen-1-ol	746	3.0%
97	39711-79-0	N-Ethyl-p-menthane-3-carboxamide	722	2.9%
98	120-51-4	Benzyl benzoate	714	2.9%
99	1124-11-4	2,3,5,6-Tetramethylpyrazine	703	2.9%
100	8008-26-2	Lime oil	701	2.9%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=24,513)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity, concentration, and major function are presented below in **Table 9**. Besides the carriers (propylene glycol and glycerol), nicotine was listed as the most common ingredient, primarily functioning as an addictive enhancer. All other ingredients in the top 20 were mainly reported to be used as flavor/taste enhancers.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Spain

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4576.00	3828.00	464.96	397.24	Carrier	-
2	56-81-5	Glycerol	5171.00	12049.00	524.00	1220.00	Carrier	-
3	54-11-5	Nicotine	40.35	70.72	5.70	7.53	Addictive Enhancer	-
4	121-33-5	Vanillin	7.33	27.94	0.793	2.91	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
5	105-54-4	Ethyl butyrate	4.00	98.90	0.41	9.91	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
6	4940-11-8	Ethyl maltol	9.05	24.60	0.962	2.53	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	7732-18-5	Water	145.77	343.42	15.08	34.93	Flavour and/or Taste Enhancer	-
8	141-78-6	Ethyl acetate	2.00	10.07	0.200	1.02	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
9	118-71-8	Maltol	2.43	9.81	0.259	1.02	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
10	64-17-5	Ethyl alcohol	30.00	108.73	3.26	11.13	Flavour and/or Taste Enhancer	-
11	3658-77-3	Furaneol	3.00	10.47	0.303	1.08	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
12	928-96-1	cis-3-Hexen-1-ol	2.07	6.66	0.210	0.681	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
13	123-92-2	Isoamyl acetate	2.50	17.84	0.250	1.84	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
14	7452-79-1	Ethyl 2-methylbutyrate	2.90	14.17	0.300	1.43	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
15	706-14-9	γ-Decalactone	0.81	3.72	0.088	0.378	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
16	121-32-4	Ethyl vanillin	9.90	30.51	1.00	3.11	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
17	64-19-7	Acetic acid	1.82	7.35	0.187	0.755	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
18	100-51-6	Benzyl alcohol	3.75	22.86	0.426	2.34	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste
19	78-70-6	Linalool	0.55	3.62	0.056	0.366	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste
20	107-92-6	Butyric acid	1.00	5.95	0.102	0.597	Flavour and/or Taste Enhancer	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Spain EU CEG.

**Flavour descriptions* are according to a desk literature review.

Conclusions

Summary of Results

Within the current Spain EU-CEG dataset, there were 44,027 notifications (unique EC-IDs), of which 4,426 were indicated to be withdrawn from the market. The most common notification type was a notification for a new product leading to a new EC ID (n=11,723), followed by the addition of a product presentation to an existing product submission (n=9,109), and the most common active product type in the Spain EU CEG was refill containers/cartridges containing e-liquids (n=30,121).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.9% of products reporting a vial volume of 10ml or less. Non-compliant products (n=42) included outliers reporting a maximum vial volume of 11,482ml. Two invalid values (=0ml) were reported for vial volumes. Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the capacity, with 83.9% reporting a capacity of 2ml or less. Non-compliant products (n=731) included outliers which reported a maximum capacity of 30ml. A significant number of invalid values (=0ml) were reported for capacity (n=536), more than half of which were characterized as 'individual part of electronic cigarette capable of containing e-liquid.'

With regards to the nicotine concentration, the overwhelming majority (99.8%) of e-liquid refill cartridges/containers were compliant, with a nicotine concentration of 20 mg/ml or less. Non-compliant products (n=52) included outliers reporting a maximum nicotine concentration of 180mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,944 unique CAS numbers reported in the Spain EU CEG. The average number of ingredients per product, among products reporting CAS, was 16.18, ranging between 1 and 113 different CAS per product. A significant proportion of products (18.6%) reported no CAS. The most common ingredients in frequency were the humectants propylene glycol and glycerol, and nicotine. The most frequently reported flavorings were vanilla, ethyl butyrate, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non-compliant products or to improve the quality of their EU CEG submission, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Outliers remain a limitation of the current analysis of the Spain EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers (or, in the case that submissions truly reflect product properties, notifying manufacturers of non-compliance) would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Spain EU CEG (e.g. vial volumes, capacity, CAS) suggest a need to redefine or clarify product type categories and the relevant variables. For example, all products

missing reports for capacity, and over 50% of those reporting invalid values for capacity, were categorized as 'individual parts of e-cigarettes capable of containing an e-liquid.'

- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume/capacity and nicotine concentration) to limit outliers, or to change the variable type from "text" variables to "numeric" variables to ensure correct and consistent reporting.
- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ A mechanism should be in place within EU CEG to ensure that all products sold with e-liquids enter CAS information, given that 18.6% of refill cartridge/containers in the Spain EU CEG reported no CAS.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report MALTA

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and results by research question

Below we provide an analysis for the EU MS Malta. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Malta EU-CEG dataset, there are 25,606 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type, among products with valid notifications, was a notification on a new product (27.0%), followed by the removal of a product presentation, including product withdrawal (18.4%), and the addition of a product presentation to an existing product submission (18.2%).

Figure 1. Type of valid notifications within EU-CEG, Malta (N= 25,606)

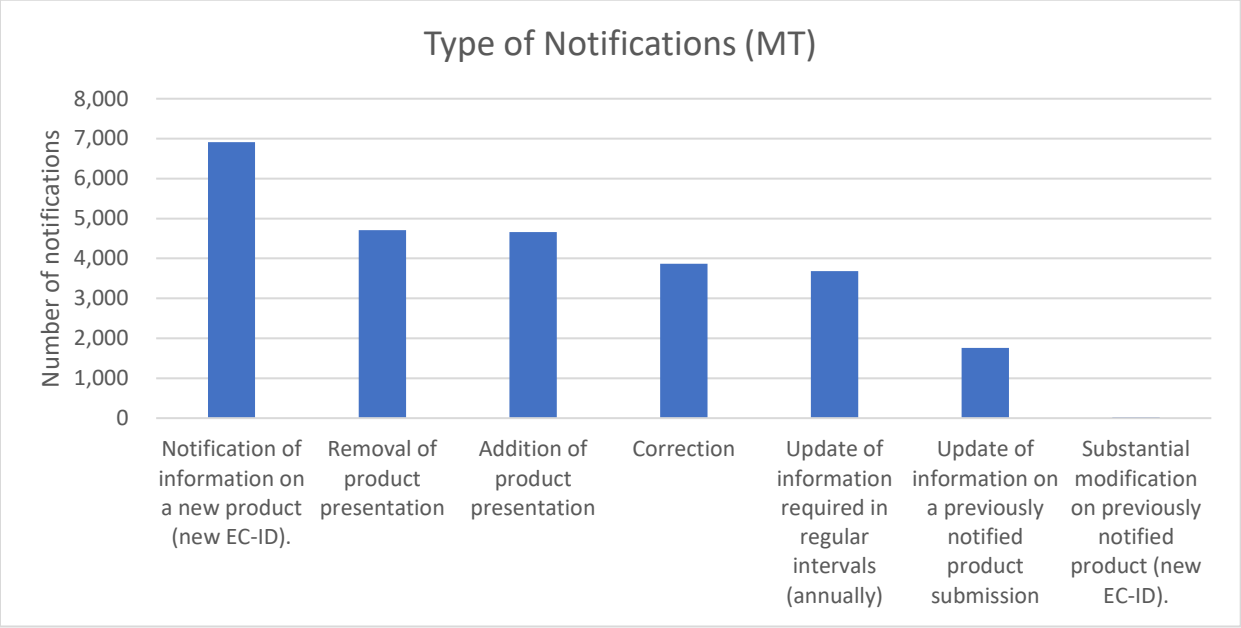


Table 1. Type of notifications within EU-CEG in Malta (N=25,606)

Type	n	% (valid)
Notification of information on a new product (new EC-ID).	6,911	27.0%
Removal of product presentation, including product withdrawal, from an existing product submission.	4,705	18.4%
Addition of product presentation (e.g. national market) to an existing product submission.	4,661	18.2%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	3,864	15.1%
Correction of clerical/administrative errors in existing product submission.	3,683	14.4%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	1,756	6.9%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	26	0.1%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 25,606 notifications (unique EC-IDs) submitted for Malta in the EU CEG, 3,264 (12.7%) products have been withdrawn and 75 (0.3%) products indicated withdrawal but did not provide a specific date at the time of analysis, while 22,267 (87.0%) unique EC-IDs remain active on the market. This analysis is restricted to products that are currently active (n=22,267).

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG for Malta is displayed in **Table 2** (below). Of the 22,267 notifications for products that are currently on the market, 64.8% (n=14,430) represented refill containers/cartridges containing an e-liquid, 9.9% (n=2,214) represented a refillable device (device only), and 9.6% (n=2,128) represented individual parts of e-cigarettes capable of containing e-liquids.

Figure 2. Product types active (not withdrawn) in EU-CEG, Malta (n=22,267)

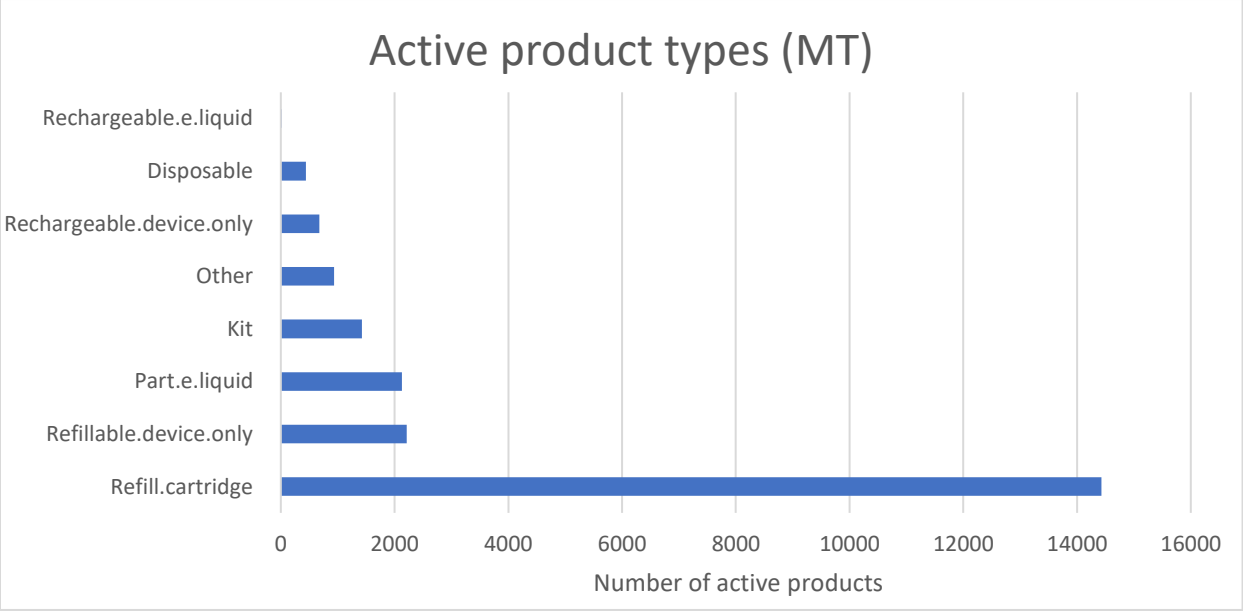


Table 2. Breakdown of product types active in EU-CEG types, Malta (n=22,267)

Product type	n	%
Refill container/cartridge containing e-liquid	14430	64.8%
Refillable, device only	2214	9.9%
Individual part of e-cigarette capable of containing e-liquid	2128	9.6%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	1423	6.4%
Other	936	4.2%
E-cigarette – Rechargeable, device only	676	3.0%
E-cigarette – Disposable	441	2.0%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	15	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	4	0.0%

2. Assessment of volume (capacity) and nicotine content

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 14,430 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 4 products reported an invalid vial (container/cartridge) volume (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 14,426 refill containers/cartridges reporting valid vial volumes (>0 ml), 13,700 were reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 13,700 nicotine-containing refill containers/cartridges that reported valid vial volumes in Malta, the average vial volume was 19.32ml. The middle value of all vial volumes reported (median) was 10ml and the SD was 311.36ml. This distribution is presented in **Table 3** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml.* Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.7% of products (n=13,663) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.69ml and the middle value of the vial volume data set (median) was 10ml. This is depicted in **Table 3**.

There were 37 refill containers/cartridges identified as non-compliant (volume >10ml) in the Malta EU-CEG, reporting a maximum volume of 11,482ml. The volume distribution of these non-compliant products is depicted in **Table 3** below, andthe non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Malta

	Vial volume (ml)		
	All products n=13,700	**Compliant products (≦10ml)** n= 13,663	**Non-compliant products (>10ml)** n=37
Min.	0.67	0.67	12
Median	10	10	30
Mean	19.32	9.698	3572
Max.	11482	10	11482
SD	311.36	1.57	4887.16

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 5,457 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 4,574 products reported a value for capacity and 883 products (16.2%) were missing reports. All of the 883 submissions that were missing reports were listed as ‘individual parts of e-cigarettes capable of containing an e-liquid.’ Of the

4,574 products which reported a value for capacity, 4,119 products (90.1%) reported a valid capacity (>0 ml) and 455 products (9.9%) reported invalid values for capacity (i.e. 0 ml). Over half of the 455 products reporting invalid values for capacity (n=248) were 'individual parts of e-cigarettes capable of containing an e-liquid,' and the majority of the remaining products reporting invalid values (n=192) were characterized as rechargeable e-cigarettes (device only).

Among the 4,119 products that reported a valid capacity (>0 ml) in Malta, the average capacity was 2.41ml, and the middle value of the capacities reported (median) was 2ml. The SD of capacity among all products was 1.75ml. This distribution is presented in **Table 4** below.

Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 80.5% of products (n=3,314) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.82ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=805) had an average capacity of 4.84ml, a middle value (median) of 4ml, and a maximum value of 60ml. The SD for products reporting non-compliant capacities was 2.77ml. The volume distribution of these non-compliant products is depicted in **Table 4**, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there were 24 non-compliant nicotine-containing disposable e-cigarettes (5.7%). Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 86 products (8.6%) listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 147 rechargeable e-cigarette devices (30.4%), and 548 refillable devices (24.9%), were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Malta

	Capacity (ml)			
	All reported (n= 4574)	**All valid (>0 ml)** (n= 4119)	**Valid, Compliant (≦2ml)** (n=3314)	**Valid, Non-compliant (>2ml)** (n=805)
Min.	0	0.01	0.01	2.2
Median	2	2	2	4
Mean	2.168	2.408	1.816	4.843
Max.	60	60	2	60
SD	1.81	1.75	0.38	2.77
Invalid (=0 ml)	n= 455			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other', and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 14,430 notifications on e-liquid products sold in refill cartridges/containers, 727 (5.0%) did not contain nicotine. The average nicotine concentration among the remaining 13,703 nicotine-containing e-liquid products was 10.18 mg/ml and the middle value of the reported nicotine concentrations (median) was 10 mg/ml. This distribution is depicted below in **Table 5**.

The overwhelming majority (99.9%) of the 13,703 nicotine-containing e-liquid products in the Lithuania EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 13,691 compliant products, the average nicotine concentration was 10.13 mg/ml and the middle value of the reported nicotine concentrations (median) was 10 mg/ml. This is displayed in **Table 5**.

Only 12 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. The distribution of nicotine concentration for these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Lithuania

	Nicotine concentration (mg/ml)		
	All products (n=13,703)	**Compliant products (≦20 mg/ml)** (n=13,691	**Non-compliant products (>20 mg/ml)** (n= 12)
Min.	0.3	0.3	20.02
Median	10	10	20.6
Mean	10.18	10.13	66.88
Max.	180	20	180
SD	6.55	6.01	69.83

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Malta EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 167 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was a wide range of capacities reported among different product types, for example disposable e-cigarettes (mode: 280mA), refillable e-cigarette devices sold as ‘device only’ (mode: 3000mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 3000mA). With regards to whether the airflow is adjustable or if the wick is changeable, none of the 441 disposable e-cigarettes were found to have the ability to alter airflow or to change the wick. However, among the 2,214 products listed as ‘refillable, device only’, 70.4% (n= 1,559) noted the ability to adjust airflow and 35.9% (n=795) had the ability to change the wick, and among the 676 products listed as ‘rechargeable device only’, 52.4% (n=354) had the ability to adjust airflow and 17.2% (n=116) had the ability to change the wick. This suggests the plethora of product designs available on the market. Microprocessors were present in the majority of rechargeable devices sold as ‘device only’ (71.3%), kits (66.7%), and refillable devices sold as ‘device only’ (66.5%) had a microprocessor, whereas only 14.7% of the 441 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

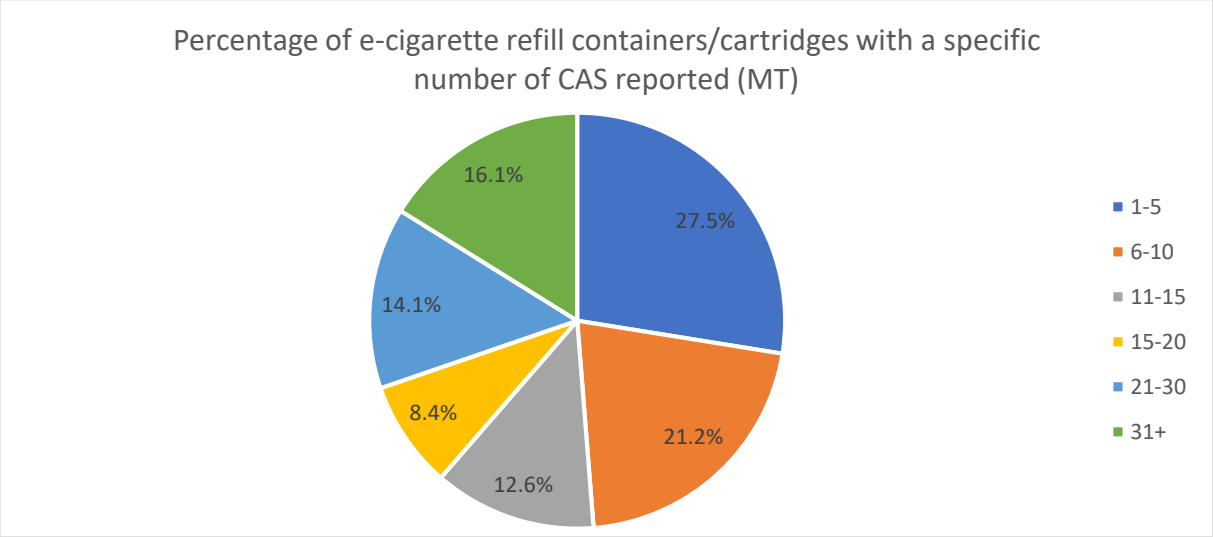
Among the 14,430 submissions for refill containers/cartridges within the Malta EU-CEG database with a "not withdrawn" status, 1,431 unique CAS numbers were submitted.

Among the 14,430 submissions for refill containers/cartridges, 27.5% reported between 1 to 5 CAS, 21.2% reported between 6-10 CAS, and 16.1% reported more than 30 CAS. This breakdown is displayed in **Table 6** and in **Figure 3**.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Malta (n=14,430)

Number of CAS per product	Number of products	% (total)
1-5	3974	27.5%
6-10	3059	21.2%
11-15	1824	12.6%
16-20	1206	8.4%
21-30	2038	14.1%
31+	2329	16.1%
Invalid (no CAS reported)	-	

Figure 3. Breakdown of the number of CAS reported within one product Malta (n=14,430)



The average number of ingredients per product was 16.29, ranging between 1 to 98 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall, Malta (n=14,430)

Number of CAS All refill containers/cartridges	
Min.	1
Median	11
Mean	16.29
Max.	98
SD	14.72

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges that contain an e-liquid), a total of 1,431 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Malta (n=14,430)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	13930	96.5%
2	56-81-5	Glycerol	13607	94.3%
3	54-11-5	Nicotine	12891	89.3%
4	121-33-5	Vanillin	6120	42.4%
5	105-54-4	Ethyl butyrate	5923	41.0%
6	0004940.11.8	Ethyl maltol	4917	34.1%
7	141-78-6	Ethyl acetate	4037	28.0%
8	118-71-8	Maltol	3701	25.6%
9	928-96-1	cis-3-Hexen-1-ol	3309	22.9%
10	3658-77-3	Furaneol	3250	22.5%
11	123-92-2	Isoamyl acetate	3160	21.9%
12	706-14-9	γ-Decalactone	3148	21.8%
13	64-17-5	Ethyl alcohol	3147	21.8%
14	7732-18-5	Water	3109	21.5%
15	7452-79-1	Ethyl methylbutyrate	3078	21.3%
16	121-32-4	Ethyl vanillin	3076	21.3%
17	100-51-6	Benzyl alcohol	3011	20.9%
18	64-19-7	Acetic acid	2908	20.2%
19	78-70-6	Linalool	2686	18.6%
20	123-66-0	Ethyl hexanoate	2447	17.0%
21	100-52-7	Benzaldehyde	2290	15.9%
22	107-92-6	Butyric acid	2233	15.5%
23	5471-51-2	Frambione	1928	13.4%
24	3681-71-8	cis-3-Hexenyl acetate	1909	13.2%
25	80-71-7	Methyl cyclopentenolone	1867	12.9%
26	104-67-6	γ-Undecalactone	1866	12.9%
27	142-92-7	Hexyl acetate	1842	12.8%
28	705-86-2	δ-Decalactone	1734	12.0%

29	102-76-1	Triacetin	1647	11.4%
30	140-11-4	Benzyl acetate	1641	11.4%
31	105-37-3	Ethyl propionate	1617	11.2%
32	120-57-0	Piperonal	1584	11.0%
33	104-50-7	γ-Octalactone	1575	10.9%
34	108-64-5	Ethyl isovalerate	1573	10.9%
35	116-53-0	(±)-2-Methylbutyric acid	1556	10.8%
36	103-26-4	Methyl cinnamate	1547	10.7%
37	659-70-1	Isoamyl isovalerate	1544	10.7%
38	123-11-5	p-Anisaldehyde	1521	10.5%
39	142-62-1	3-Methyl-1,2-cyclopentanedione	1427	9.9%
40	765-70-8	3-Methylcyclopentane-1,2-dione	1385	9.6%
41	104-61-0	γ-Nonanoic lactone	1356	9.4%
42	127-41-3	α-Ionone	1331	9.2%
43	2216-51-5	L-Menthol	1331	9.2%
44	56038-13-2	Sucralose	1209	8.4%
45	106-27-4	Isoamyl butyrate	1158	8.0%
46	713-95-1	δ-Dodecalactone	1158	8.0%
47	513-86-0	Acetoin	1150	8.0%
48	14901-07-6	β-Ionone	1143	7.9%
49	5392-40-5	Citral	1142	7.9%
50	22047-25-2	2-Acetylpyrazine	1094	7.6%
51	90-05-1	Guaiacol	1064	7.4%
52	98-55-5	α-Terpineol	1060	7.3%
53	5989-27-5	(R)-(+)-Limonene	1057	7.3%
54	111-27-3	1-Hexanol	1022	7.1%
55	137-00-8	4-Methyl-5-thiazoleethanol	973	6.7%
56	60-12-8	2-Phenylethanol	945	6.5%
57	123-51-3	Isoamyl alcohol	943	6.5%
58	119-84-6	Dihydrocoumarin	921	6.4%
59	14667-55-1	2,3,5-Trimethylpyrazine	911	6.3%
60	97-53-0	Eugenol	890	6.2%
61	134-20-3	Methyl anthranilate	867	6.0%
62	123-68-2	Allyl hexanoate	845	5.9%
63	6728-26-3	trans-2-Hexen-1-al	833	5.8%
64	56-40-6	Glycine	815	5.6%
65	106-24-1	Geraniol	800	5.5%
66	97-64-3	Ethyl lactate	795	5.5%
67	105-13-5	4-Methoxybenzyl alcohol	787	5.5%
68	110-19-0	Isobutyl acetate	780	5.4%
69	23696-85-7	Damascenone	774	5.4%
70	79-09-4	Propionic acid	759	5.3%
71	695-06-7	γ-Hexalactone	748	5.2%
72	89-78-1	Menthol	745	5.2%
73	104-55-2	Cinnamaldehyde	731	5.1%
74	75-18-3	Dimethyl sulfide	702	4.9%
75	105-87-3	Geranyl acetate	676	4.7%

76	7492-70-8	Butyl butyryllactate	669	4.6%
77	66-25-1	Hexanal	629	4.4%
78	8008-56-8	Lemon oil	592	4.1%
79	84929-31-7	Lemon oil	581	4.0%
80	8008-57-9	Orange oil	565	3.9%
81	93-92-5	1-Phenylethyl acetate	557	3.9%
82	470-82-6	Eucalyptol	556	3.9%
83	77-93-0	Triethyl citrate	555	3.8%
84	115-95-7	Linalyl acetate	531	3.7%
85	23726-92-3	(Z)-β-Damascone	524	3.6%
86	106-32-1	Ethyl octanoate	522	3.6%
87	123-86-4	Butyl acetate	517	3.6%
88	2305-05-7	4,5,6,7-Tetrahydroindazole	504	3.5%
89	138-86-3	Dipentene	503	3.5%
90	4180-23-8	trans-Anethole	500	3.5%
91	109-21-7	Butyl butyrate	496	3.4%
92	1122-62-9	2-Acetylpyridine	489	3.4%
93	77-83-8	Ethyl methylphenylglycidate	476	3.3%
94	124-07-2	Octanoic acid	464	3.2%
95	8006-90-4	Peppermint oil	453	3.1%
96	8008-26-2	Lime oil	451	3.1%
97	77-92-9	Citric acid	446	3.1%
98	620-02-0	5-Methylfurfural	440	3.0%
99	39711-79-0	N-Ethyl-p-menthane-3-carboxamide	433	3.0%
100	928-95-0	2-Hexen-1-OL	424	2.9%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=14,430)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity, concentration, and major function are presented below in **Table 9**. The carriers propylene glycol and glycerol, in addition to nicotine (primarily functioning as an addictive enhancer) were listed as the most common ingredients. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers, except for water, which was reported as a water-wetting agent.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Malta

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4648.90	3915.98	475.50	397.83	Carrier	-
2	56-81-5	Glycerol	5000.00	4517.21	500.00	455.46	Carrier	-
3	54-11-5	Nicotine	60.00	70.58	6.00	7.27	Addictive Enhancer	-
4	121-33-5	Vanillin	6.00	25.32	0.63	2.52	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
5	105-54-4	Ethyl butyrate	3.58	14.49	0.36	1.46	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
6	0004940. 11.8	Ethyl maltol	8.50	27.57	0.90	2.68	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	141-78-6	Ethyl acetate	2.00	8.61	0.20	0.86	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
8	118-71-8	Maltol	2.16	9.77	0.22	0.97	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
9	928-96-1	cis-3-Hexen-1-ol	1.97	5.83	0.20	0.59	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
10	3658-77-3	Furaneol	2.49	8.00	0.27	0.80	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
11	123-92-2	Isoamyl acetate	2.20	14.42	0.22	1.50	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
12	706-14-9	γ-Decalactone	1.00	3.61	0.10	0.37	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
13	64-17-5	Ethyl alcohol	24.32	97.93	2.59	9.60	Flavour and/or Taste Enhancer	-
14	7732-18-5	Water	113.00	345.00	11.49	35.35	Water-Wetting Agents	-
15	7452-79-1	Ethyl methylbutyrate	2.29	13.00	0.24	1.30	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
16	121-32-4	Ethyl vanillin	7.31	27.49	0.73	2.73	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
17	100-51-6	Benzyl alcohol	3.60	19.77	0.40	2.01	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste
18	64-19-7	Acetic acid	2.24	7.90	0.22	0.82	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
19	78-70-6	Linalool	0.50	4.29	0.05	0.43	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste
20	123-66-0	Ethyl hexanoate	1.00	5.35	0.10	0.53	Flavour and/or Taste Enhancer	Strong, fruity, pineapple, banana with strawberry, pear & tropical notes

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Malta EU CEG.

**Flavour descriptions* are according to a desk literature review, where available.

Conclusions

Summary of Results

Within the current Malta EU-CEG dataset, there are 25,606notifications (unique EC-IDs), of which 3,264 were indicated to be withdrawn from the market and 75 indicated withdrawal but did not provide a specific date. The most common type of product active in the Malta EU CEG was refill containers/cartridges containing e-liquids (n=14,430).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.7% of products reporting a vial volume of 10ml or less. Non-compliant products (n=37) included outliers reporting a maximum vial volume of 11,482ml. Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the capacity, with 80.5% reporting a volume capacity of 2ml or less. Non-compliant products (n=805) reported a maximum capacity of 60ml. A significant number of invalid values (=0ml) were reported for capacity (n=455).

With regards to the nicotine concentration, the overwhelming majority (99.9%) of e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less. Non-compliant products (n=12) included outliers reporting a maximum nicotine concentration of 180 mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,431 unique CAS numbers reported in the Malta EU CEG. The average number of ingredients per product, was 16.29, ranging between 1 and 98 different CAS per product. The most common ingredient in frequency were the humectants propylene glycol and glycerol, and nicotine. The most frequently reported flavorings were vanilla, ethyl butyrate, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Outliers remain a limitation of the current analysis of the Malta EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Malta EU CEG (specifically for vial volumes and capacity) suggests a need to redefine or clarify product type categories and their relevant variables. For example, all products missing reports for volume capacity were categorized as ‘individual parts of e-cigarettes capable of containing an e-liquid,’ suggesting a need to clarify the categorical definition.
- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume capacity and nicotine concentration), or to change the variable type from “text” variables to “numeric” variables to ensure correct and consistent reporting (e.g. in battery type reporting).

- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report LITHUANIA

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Below we provide an analysis for the EU MS Lithuania. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Lithuania EU-CEG dataset, there are 33,783 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type was a notification for a new product EC-ID (26.3%), followed by the addition of product presentation to an existing product submission (22.9%), and the removal of a product presentation from an existing product submission (18.6%).

Figure 1. Type of notifications within EU-CEG, Lithuania (N= 33,783)

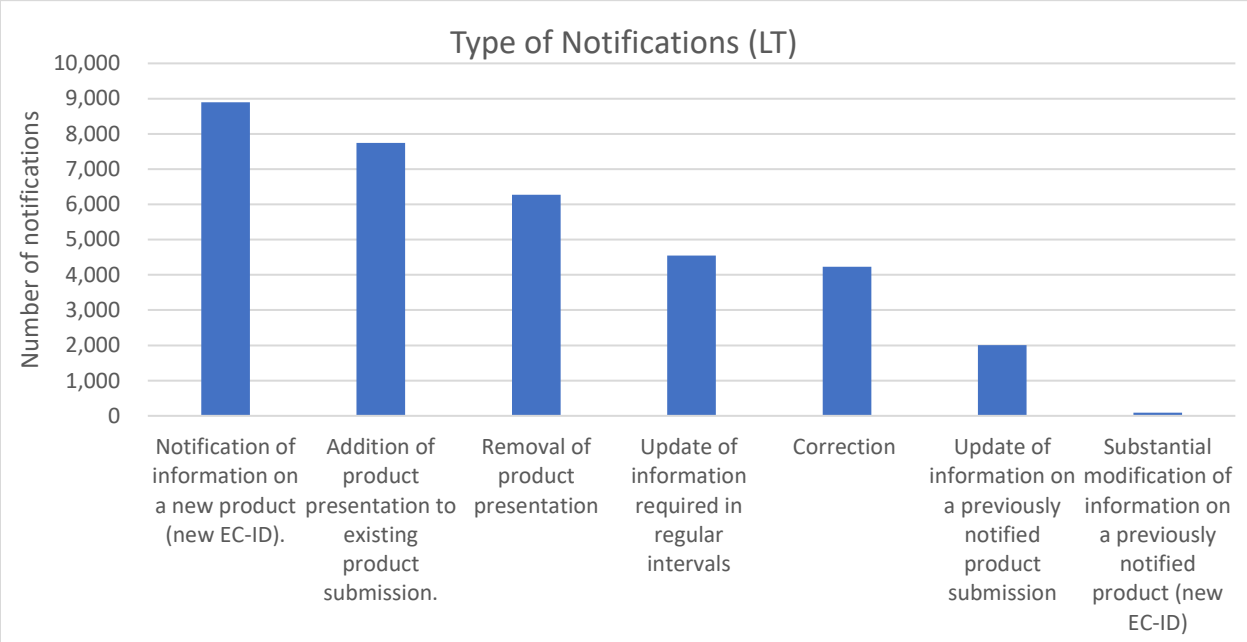


Table 1. Type of notifications within EU-CEG in Lithuania (N=33,783)

Notification Type	n	%
Notification of information on a new product (new EC-ID).	8,897	26.3%
Addition of product presentation (e.g. national market) to an existing product submission.	7,746	22.9%
Removal of product presentation, including product withdrawal, from an existing product submission.	6,275	18.6%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	4,544	13.5%
Correction of clerical/administrative errors in existing product submission.	4,226	12.5%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	2,007	5.9%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	88	0.3%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 33,783 notifications (unique EC-IDs) submitted for Lithuania for the EU CEG, 4,087 (12.1%) have been withdrawn while 29,696 (87.9%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active.

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG in Lithuania is displayed in **Table 2** (below). Of the 29,696 notifications for products that are currently on the market, 70.2% (n=20,859) represented refill containers/cartridges containing an e-liquid, 7.9% (n=2,340) represented a refillable device (device only), and 7.1% (n=2,111) represented an individual part of e-cigarette capable of containing e-liquid.

Figure 2. Product types active (not withdrawn) in EU-CEG, Lithuania (n=29,696)

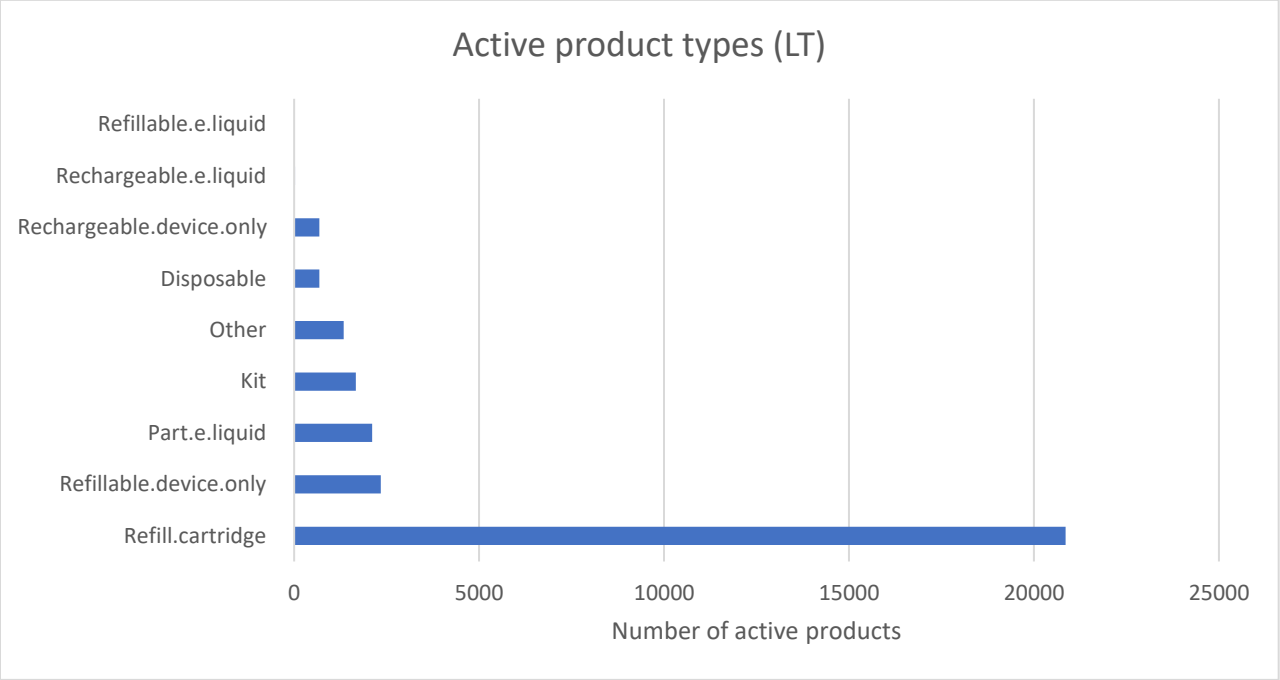


Table 2. Breakdown of product types active in EU-CEG, Lithuania (n=29,696)

Product type	n	%
Refill container/cartridge containing e-liquid	20859	70.2%
Refillable, device only	2340	7.9%
Individual part of e-cigarette capable of containing e-liquid	2111	7.1%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	1668	5.6%
Other	1337	4.5%
E-cigarette – Disposable	678	2.3%
E-cigarette – Rechargeable, device only	678	2.3%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	21	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	4	0.0%

2. Assessment of volume and nicotine content in nicotine containing liquids

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 20,859 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 4 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 20,855 refill containers/cartridges reporting valid vial volumes (> 0 ml), 19,794 are reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 19,794 nicotine-containing refill containers/cartridges that that reported valid vial volumes in Lithuania, the average vial volume was 11.01 ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the wide range of vial volumes reported and outliers, the SD of vial volumes among all products was 115.16ml.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml.* Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.8% of products (n=19,759) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.82ml and the middle value of the vial volumes reported (median) was 10ml. This is depicted in **Table 3**.

Only 35 non-compliant refill containers/cartridges (volume >10ml) were identified in the Lithuania EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with extremely large vial volumes (e.g. 11,482ml). The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Lithuania

	Vial volume (ml)		
	All products n=19,794	**Compliant products (≦10ml)** n= 19,759	**Non-compliant products (>10ml)** n= 5
Min.	0.6	0.6	12
Median	10	10	30
Mean	11.01	9.82	684.1
Max.	11482	10	11482
SD	115.16	1.22	2693.08

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 5,811 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as

these single-use products are not subject to the same volume regulations), 4,957 products reported a value for capacity and 854 products (14.7%) were missing reports. All of the 854 submissions missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 4,957 products which reported a value for capacity, 4,483 products (90.4%) reported a valid capacity (>0 ml) and 474 products (9.6%) reported invalid values (i.e. 0 ml). Over half of the 474 products reporting invalid values for capacity (n=272) were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.'

Among the 4,483 products that reported a valid capacity in Lithuania, the average capacity was 2.76ml (SD=2.16 ml). The middle value of the capacities reported (median) was 2ml. This distribution is presented in **Table 4** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in cartridges or tanks which do not exceed a capacity of 2 ml*. Given that cartridges or tanks placed on the market without a nicotine-containing e-liquid can still be used for the consumption of nicotine-containing vapour, compliance with Article 20.3 of the EU TPD of product types sold with, and/or capable of containing, an e-liquid was assessed in this analysis. Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 76.0% of products (n=3,407) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.81ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=1,076) had an average capacity of 5.77ml. The volume distribution of these non-compliant products is depicted in **Table 4** below, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there were 239 non-compliant nicotine-containing disposable e-cigarettes (36.4%). Rechargeable and refillable e-cigarettes sold with e-liquids all reported compliant capacities. Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 72 (7.3%) of valid submissions of 'individual parts of e-cigarettes capable of containing an e-liquid', 144 (29.3%) of the rechargeable devices, and 621 (26.7%) of the refillable devices, were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Lithuania

	Capacity (ml)			
	All reported (n= 49757	**All valid (>0 ml)** (n= 4483)	**Valid, Compliant (≦2ml)** (n= 3407)	**Valid, Non-compliant (>2ml)** (n=1076)
Min.	0	0.01	0.01	2.2
Median	2	2	2	4.5
Mean	2.498	2.763	1.813	5.77
Max.	30	30	2	30
SD	2.21	2.16	0.38	2.67
Invalid (=0 ml)	n= 474			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other', and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing liquids [TPD Art 20(3)b]

Among the 20,859 notifications on e-liquid products (refill cartridges/containers), 1,062 (5.1%) did not contain nicotine. The average nicotine concentration among the remaining 19,797 nicotine-containing e-liquid products was 10.01 mg/ml, and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. These distributions are depicted below in **Table 5**.

The overwhelming majority (99.9%) of the 19,797 nicotine-containing e-liquid products in the Lithuania EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 19,783 compliant products, the average nicotine concentration was 9.97 mg/ml and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. This is displayed in **Table 5**.

Only 14 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. The distribution of nicotine concentration for these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Lithuania

	Nicotine concentration (mg/ml)		
	All products (n=19,797)	**Compliant products (≦20 mg/ml)** (n=19,783)	**Non-compliant products (>20 mg/ml)** (n= 14)
Min.	0.25	0.25	20.02
Median	9	9	35.48
Mean	10.01	9.971	69.13
Max.	180	20	180
SD	6.47	6.05	65.72

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Lithuania EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 391 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was lower reported capacity for disposable e-cigarettes (mode: 280mA) compared to refillable e-cigarette devices sold as ‘device only’ (mode: 3000mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 3000mA). With regards to whether the airflow is adjustable or if the wick is changeable, no disposable e-cigarettes were found to have the ability to alter airflow or to change the wick. However, among the 2,340 products listed as ‘refillable, device only’, 71.6% (n=1,675) noted the ability to adjust airflow and 37.6% (n=879) had the ability to change the wick, and among the 678 products listed as ‘rechargeable device only’, 50.4% (n=342) had the ability to adjust airflow and 16.4% (n=111) had the ability to change the wick. This suggests plethora of product designs available on the market. A similar pattern was identified for the presence of a microprocessor, which was predominately present in refillable devices sold as ‘device only’ (61.8%), rechargeable devices sold as ‘device only’ (67.9%) and kits (62.8%), whereas only 9.4% of the 678 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

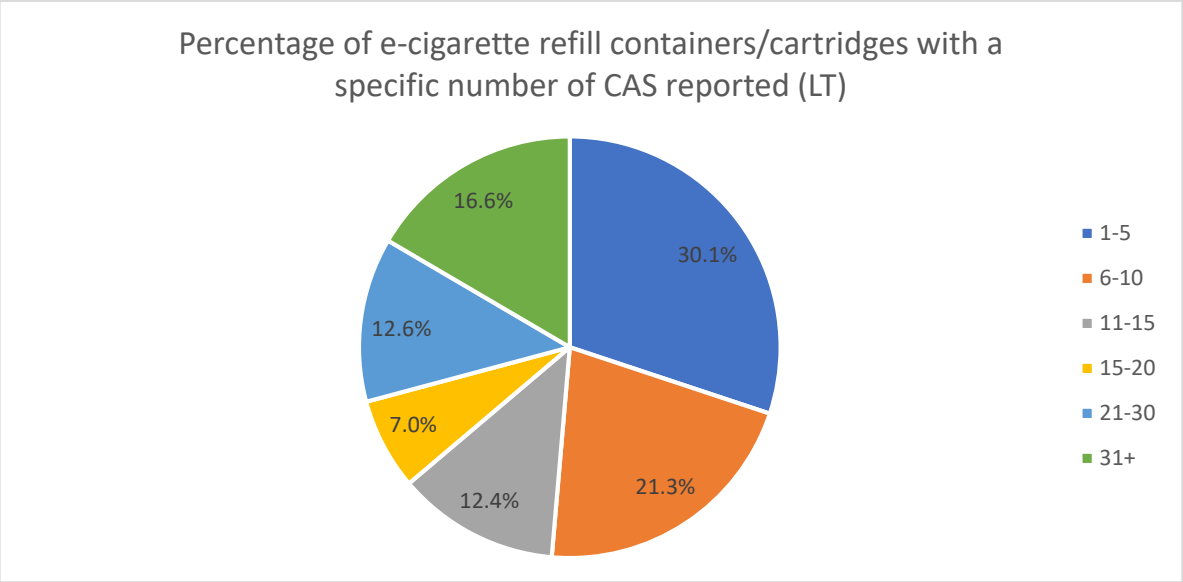
Among the 20,859 submissions for refill containers/cartridges within the Lithuania EU-CEG database with a "not withdrawn" status, 1,439 unique CAS numbers were submitted (Note that additional data cleaning is needed to further reduce this number).

All products listed as refill containers/cartridges in the Lithuania EU CEG reported at least one CAS. Among the 20,859 submissions for refill containers/cartridges, 30.1% reported between 1 to 5 CAS, 21.3% reported between 6 to 10 CAS, and 16.6% reported more than 31 CAS. This breakdown is displayed in **Table 6** and depicted in **Figure 3**.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Lithuania (n=20,859)

Number of CAS per product	n	% (total)
1-5	6279	30.1%
6-10	4436	21.3%
11-15	2596	12.4%
16-20	1464	7.0%
21-30	2630	12.6%
31+	3454	16.6%
Invalid (no CAS reported)	0	0.0%

Figure 3. Breakdown of the number of CAS reported within one product (among all refill containers/cartridges), Lithuania (n=20,859)



The average number of ingredients per product was 16.16, ranging between 1 to 105 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall, Lithuania (n=20,859)

	Number of CAS **All refill containers/cartridges** (n= 20,859)
Min.	1
Median	10
Mean	16.16
Max.	105
SD	15.46
# Invalid (no CAS reported)	n=0

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges (n=20,859) a total of 1,439 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed below in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Lithuania (n=20,859)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	20381	97.7%
2	54-11-5	Nicotine	19265	92.4%
3	56-81-5	Glycerol	17990	86.2%
4	105-54-4	Ethyl butyrate	8111	38.9%
5	121-33-5	Vanillin	8070	38.7%
6	4940-11-8	Ethyl maltol	7296	35.0%
7	141-78-6	Ethyl acetate	5995	28.7%
8	118-71-8	Maltol	5411	25.9%
9	7732-18-5	Water	5119	24.5%
10	121-32-4	Ethyl vanillin	4930	23.6%
11	3658-77-3	Furaneol	4927	23.6%
12	64-17-5	Ethyl alcohol	4771	22.9%
13	928-96-1	cis-3-Hexen-1-ol	4709	22.6%
14	123-92-2	Isoamyl acetate	4500	21.6%
15	7452-79-1	Ethyl 2-methylbutyrate	4427	21.2%
16	706-14-9	γ-Decalactone	4346	20.8%
17	64-19-7	Acetic acid	4193	20.1%
18	100-51-6	Benzyl alcohol	3938	18.9%
19	78-70-6	Linalool	3683	17.7%
20	107-92-6	Butyric acid	3605	17.3%
21	123-66-0	Ethyl hexanoate	3350	16.1%
22	56-40-6	Glycine	3271	15.7%
23	100-52-7	Benzaldehyde	2907	13.9%
24	120-57-0	Piperonal	2774	13.3%
25	5471-51-2	Frambione	2772	13.3%

26	3681-71-8	cis-3-Hexenyl acetate	2725	13.1%
27	705-86-2	δ-Decalactone	2683	12.9%
28	102-76-1	Triacetin	2612	12.5%
29	142-92-7	Hexyl acetate	2559	12.3%
30	104-67-6	γ-Undecalactone	2544	12.2%
31	765-70-8	3-Methylcyclopentane-1,2-dione	2512	12.0%
32	105-37-3	Ethyl propionate	2458	11.8%
33	659-70-1	Isoamyl isovalerate	2447	11.7%
34	116-53-0	(±)-2-Methylbutyric acid	2403	11.5%
35	80-71-7	Methyl cyclopentenolone	2366	11.3%
36	142-62-1	3-Methyl-1,2-cyclopentanedione	2286	11.0%
37	123-11-5	p-Anisaldehyde	2278	10.9%
38	104-50-7	γ-Octalactone	2266	10.9%
39	56038-13-2	Sucralose	2190	10.5%
40	140-11-4	Benzyl acetate	2181	10.5%
41	108-64-5	Ethyl isovalerate	2170	10.4%
42	103-26-4	Methyl cinnamate	2119	10.2%
43	104-61-0	γ-Nonanoic lactone	2072	9.9%
44	2216-51-5	L-Menthol	1950	9.3%
45	713-95-1	δ-Dodecalactone	1880	9.0%
46	5392-40-5	Citral	1713	8.2%
47	513-86-0	Acetoin	1692	8.1%
48	127-41-3	α-Ionone	1662	8.0%
49	137-00-8	4-Methyl-5-thiazoleethanol	1647	7.9%
50	90-05-1	Guaiacol	1552	7.4%
51	22047-25-2	2-Acetylpyrazine	1537	7.4%
52	106-27-4	Isoamyl butyrate	1504	7.2%
53	14901-07-6	β-Ionone	1504	7.2%
54	98-55-5	α-Terpineol	1436	6.9%
55	5989-27-5	(R)-(+)-Limonene	1405	6.7%
56	105-13-5	4-Methoxybenzyl alcohol	1386	6.6%
57	97-53-0	Eugenol	1339	6.4%
58	111-27-3	1-Hexanol	1310	6.3%
59	695-06-7	γ-Hexalactone	1288	6.2%
60	119-84-6	Dihydrocoumarin	1285	6.2%
61	110-19-0	Isobutyl acetate	1279	6.1%
62	123-68-2	Allyl hexanoate	1255	6.0%
63	75-18-3	Dimethyl sulfide	1217	5.8%
64	123-51-3	Isoamyl alcohol	1186	5.7%
65	60-12-8	2-Phenylethanol	1170	5.6%
66	23696-85-7	Damascenone	1153	5.5%
67	6728-26-3	trans-2-Hexen-1-al	1152	5.5%
68	104-55-2	Cinnamaldehyde	1149	5.5%
69	14667-55-1	2,3,5-Trimethylpyrazine	1141	5.5%
70	134-20-3	Methyl anthranilate	1136	5.4%
71	106-24-1	Geraniol	1125	5.4%
72	97-64-3	Ethyl lactate	1103	5.3%

73	89-78-1	Menthol	1079	5.2%
74	105-87-3	Geranyl acetate	1020	4.9%
75	79-09-4	Propionic acid	995	4.8%
76	8008-56-8	Lemon oil	988	4.7%
77	7492-70-8	Butyl butyryllactate	975	4.7%
78	66-25-1	Hexanal	879	4.2%
79	115-95-7	Linalyl acetate	861	4.1%
80	77-93-0	Triethyl citrate	859	4.1%
81	124-07-2	Octanoic acid	852	4.1%
82	77-92-9	Citric acid	794	3.8%
83	8008-57-9	Orange oil	762	3.7%
84	120-51-4	Benzyl benzoate	760	3.6%
85	109-21-7	Butyl butyrate	739	3.5%
86	470-82-6	Eucalyptol	730	3.5%
87	106-32-1	Ethyl octanoate	712	3.4%
88	4180-23-8	trans-Anethole	710	3.4%
89	93-92-5	1-Phenylethyl acetate	706	3.4%
90	138-86-3	Dipentene	699	3.4%
91	39711-79-0	N-Ethyl-p-menthane-3-carboxamide	693	3.3%
92	2305-05-7	4,5,6,7-Tetrahydroindazole	686	3.3%
93	77-83-8	Ethyl methylphenylglycidate	678	3.3%
94	150-78-7	1,4-Dimethoxybenzene	659	3.2%
95	50-21-5	DL-Lactic acid	654	3.1%
96	928-95-0	2-Hexen-1-OL	614	2.9%
97	8008-26-2	Lime oil	609	2.9%
98	620-02-0	5-Methylfurfural	604	2.9%
99	123-86-4	Butyl acetate	590	2.8%
100	1122-62-9	2-Acetylpyridine	582	2.8%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=20,859)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity (mg per product), concentration, and major function are presented below in **Table 9**. Besides the carriers (propylene glycol and glycerol), nicotine was the most common ingredient, primarily functioning as an addictive enhancer. All other ingredients in the top 20 were mainly reported to be used as flavor/taste enhancers.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Lithuania

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4595.00	9789.00	463.88	397.57	Carrier	-
2	54-11-5	Nicotine	30.00	67.98	3.02	7.08	Addictive Enhancer	-
3	56-81-5	Glycerol	5566.00	19275.00	561.00	487.68	Carrier	-
4	105-54-4	Ethyl butyrate	4.37	18.70	0.44	1.87	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
5	121-33-5	Vanillin	7.98	27.33	0.80	2.80	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
6	4940-11-8	Ethyl maltol	10.00	25.50	1.00	2.59	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	141-78-6	Ethyl acetate	2.20	12.43	0.23	1.25	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
8	118-71-8	Maltol	2.42	10.17	0.25	1.05	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
9	7732-18-5	Water	100.00	3143.00	10.00	27.16	Flavour and/or Taste Enhancer	-
10	121-32-4	Ethyl vanillin	10.18	31.25	1.05	3.13	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
11	3658-77-3	Furaneol	3.00	10.55	0.30	1.08	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
12	64-17-5	Ethyl alcohol	30.00	96.64	3.05	9.90	Flavour and/or Taste Enhancer	-
13	928-96-1	cis-3-Hexen-1-ol	2.07	7.58	0.21	0.76	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
14	123-92-2	Isoamyl acetate	2.60	16.50	0.26	1.72	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
15	7452-79-1	Ethyl 2-methylbutyrate	3.07	14.54	0.31	1.45	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
16	706-14-9	γ-Decalactone	0.80	4.33	0.09	0.44	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
17	64-19-7	Acetic acid	2.24	8.65	0.22	0.89	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
18	100-51-6	Benzyl alcohol	3.60	26.31	0.37	2.66	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste
19	78-70-6	Linalool	0.65	4.06	0.07	0.41	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste
20	107-92-6	Butyric acid	1.55	7.53	0.16	0.75	Flavour and/or Taste Enhancer	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Lithuania EU CEG.

**Flavour descriptions* are according to a desk literature review.

Conclusions

Summary of Results

Within the current Lithuania EU-CEG dataset, there are 33,783 notifications (unique EC-IDs), of which 4,087 were indicated to be withdrawn from the market. The most common type of product active in the Lithuania EU CEG was refill containers/cartridges containing e-liquids (n=20,859).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.8% of products reporting a vial volume of 10ml or less. Non-compliant products (n=35) included outliers reporting a maximum vial volume of 11,482ml. Four invalid values (=0ml) were reported for vial volumes The majority of cartridges/containers capable of carrying an e-liquid were compliant with regards to the capacity, although the compliance rate was less than that for other categories, with only 76% of products reporting a capacity of 2ml or less. Non-compliant products (n=1076) included outliers reporting a maximum capacity of 30ml. A significant number of invalid values (=0ml) were reported for capacity (n=474), more than half of which were characterized as 'individual part of electronic cigarette capable of containing e-liquid.'

With regards to the nicotine concentration, the overwhelming majority (99.9%) of e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less. Non-compliant products (n=14) included outliers reporting a maximum nicotine concentration of 180 mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, presence of a changeable wick and airflow) when compared to disposable products.

There were 1,439 unique CAS numbers reported in the Lithuania EU CEG. The average number of ingredients per product was 16.2, ranging between 1 and 105 different CAS per product. The most common ingredients in frequency were the carriers propylene glycol and glycerol, and nicotine. The most frequently reported flavorings were ethyl butyrate, vanillin, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions in the case of missing data or outliers which are a result of reporting errors.
- ✓ Outliers are a limitation of the current analysis of the Lithuania EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Lithuania EU CEG (e.g. capacity) suggests a need to redefine or clarify product type categories and their relevant variables. For example, all products missing reports for capacity, and over 50% of those reporting invalid values for capacity, were categorized as 'individual parts of e-cigarettes capable of containing an e-liquid.'

- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting vial volumes and nicotine concentration), or to change the variable type from “text” variables to “numeric” variables to ensure correct and consistent reporting.
- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report NETHERLANDS

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Below we provide an analysis for the EU MS Netherlands. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Netherlands EU-CEG dataset, there are 41,732 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type, among products with valid notifications, was a notification for a new product EC-ID (25.4%), followed by the correction of clerical/administrative errors in an existing product submission (21.6%), and the addition of a product presentation to existing product submission (18.8%).

Figure 1. Type of valid notifications within EU-CEG, Netherlands (n= 41,732)

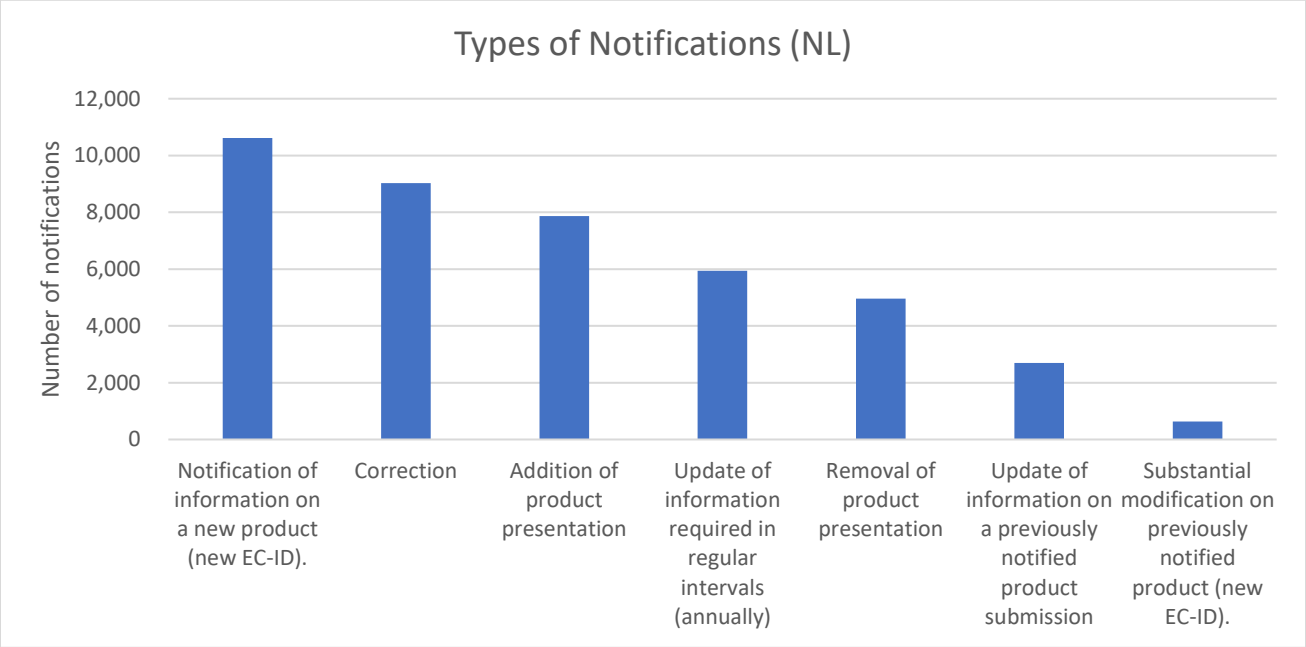


Table 1. Type of notifications within EU-CEG in Netherlands (N=41,732)

Type	n	% (valid)
Notification of information on a new product (new EC-ID).	10,616	25.4%
Correction of clerical/administrative errors in existing product submission.	9,031	21.6%
Addition of product presentation (e.g. national market) to an existing product submission.	7,865	18.8%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	5,939	14.2%
Removal of product presentation, including product withdrawal, from an existing product submission.	4,955	11.9%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	2,690	6.4%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	636	1.5%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 41,732 notifications (unique EC-IDs) submitted for Netherlands in the EU CEG, 4,945 (11.8%) products have been withdrawn, while 36,787 (88.2%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active.

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG for Netherlands is displayed in **Table 2** (below). Of the 36,787 notifications for products that are currently on the market, 74.1% (n=27,252) represented refill containers/cartridges containing an e-liquid, 7.6% (n=2,800) represented a refillable device (device only), and 5.6% (n=2,077) represented a kit, i.e. a pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge.

Figure 2. Product types active (not withdrawn) in EU-CEG, Netherlands (n=36,787)

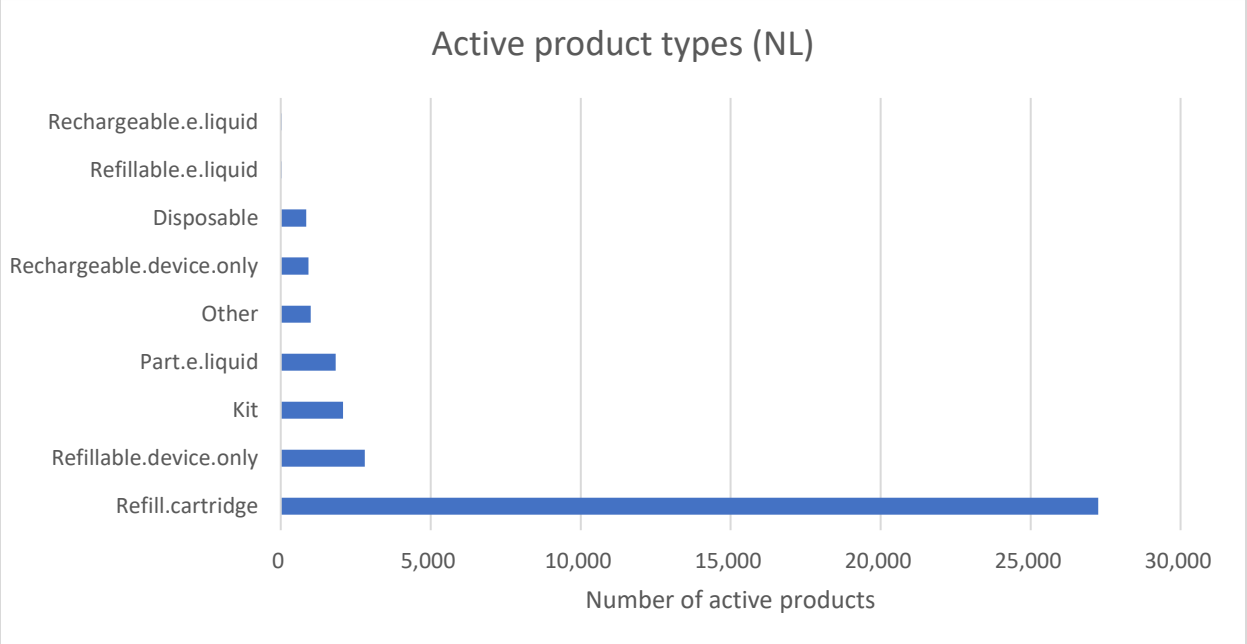


Table 2. Breakdown of product types active in EU-CEG types, Netherlands (n=36,787)

Product type	n	%
Refill container/cartridge containing e-liquid	27,252	74.1%
Refillable, device only	2,800	7.6%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	2,077	5.6%
Individual part of e-cigarette capable of containing e-liquid	1,830	5.0%
Other	995	2.7%
E-cigarette – Rechargeable, device only	926	2.5%
E-cigarette – Disposable	848	2.3%
E-cigarette – Refillable, placed on the market with one type of e-liquid	30	0.1%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	29	0.1%

2. Assessment of volume and nicotine content in nicotine containing liquids

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Volume of dedicated nicotine-containing refill containers/cartridges Among the 27,252 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 6 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 27,246 refill containers/cartridges reporting valid vial volumes (>0 ml), 24,655 were reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 24,655 nicotine-containing refill containers/cartridges that reported valid vial volumes in Netherlands, the average vial volume was 12.68 ml. The middle value of the vial volumes reported (median) was 10ml. The SD of vial volumes among all products was 58.2ml. This distribution is presented in **Table 3** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml.* Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.6% of products (n=24,553) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.75ml and the middle value of the vial volumes reported (median) was 10ml. This is depicted in **Table 3**.

There were 102 refill containers/cartridges identified as non-compliant (volume >10ml) in the Netherlands EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with large vial volumes (1,198ml). The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Netherlands

	Vial volume (ml)		
	All products n=24,655	**Compliant products (≦10ml)** n= 24,553	**Non-compliant products (>10ml)** n= 102
Min.	0.67	0.67	10.93
Median	10	10	1174.5
Mean	12.68	9.748	717.47
Max.	1198	10	1198
SD	58.21	1.43	568.11

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 6,428 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this includes all products except those listed as refill containers/cartridges, kits and "other"), 5,723 products reported a value for capacity and 705 products (10.9%) were missing reports. All of the 705

submissions that were missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 5,723 products which reported a value for capacity, 5,105 products (89.2%) reported valid capacity (>0 ml) and 618 products (10.8%) reported invalid values (i.e. 0 ml). More than a third of the 618 products reporting invalid values for capacity (n=240) were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.'

Among the 5,105 products that reported a valid capacity (>0 ml) in Netherlands, the average capacity was 2.72ml, and middle value of the capacity reported (median) was 2ml. The SD of volume capacities among all products was 2.34ml. This distribution is presented in **Table 4** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in cartridges or tanks which do not exceed a capacity of 2 ml*. Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 79.6% of products (n=4,067) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.81ml and the middle value of the volume capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant volume capacities greater than 2ml (n=1,038) had an average capacity of 6.26ml, and a SD of 3.28ml. The volume distribution of these non-compliant products is depicted in **Table 4**, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there were 316 non-compliant nicotine-containing disposable e-cigarettes (38.9%) and 3 non-compliant refillable e-cigarettes sold with an e-liquid product (10%). Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 68 products (6%) listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 56 (6%) of the rechargeable devices, and 595 (21.2%) of the refillable devices, were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Netherlands

	Capacity (ml) **All reported** (n= 5723)	**All valid (>0 ml)** (n=5105)	**Valid, Compliant (≦2ml)** (n= 40867)	**Valid, Non-compliant (>2ml)** (n=1038)
Min.	0	0.01	0.01	2.4
Median	2	2	2	5
Mean	2.424	2.717	1.814	6.255
Max.	60	60	2	60
SD	2.37	2.34	0.38	3.28
Invalid (=0 ml)	n= 618			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other,' and disposable e-cigarettes without nicotine.*

2.3 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 27,252 notifications on e-liquid products sold in refill cartridges/containers, 2,592 (9.5%) did not contain nicotine. The average nicotine concentration among the remaining 24,660 nicotine-containing e-liquid products was 9.57 mg/ml and the middle value of the reported nicotine concentrations (median) was 8 mg/ml. This distribution is depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* The overwhelming majority (99.8%) of the 24,660 nicotine-containing e-liquid products in the Netherlands EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 24,611 compliant products, the average nicotine concentration was 9.47 mg/ml and the middle value of the reported nicotine concentrations (median) was 8 mg/ml. This is displayed in **Table 5**.

Only 49 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. The distribution of nicotine concentration of these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Netherlands

	Nicotine concentration (mg/ml)		
	All products (n=24,660)	**Compliant products (≦20 mg/ml)** (n=24,611)	**Non-compliant products (>20 mg/ml)** (n= 49)
Min.	0.26	0.26	20.5
Median	8	8	60
Mean	9.569	9.472	58.71
Max.	180	20	180
SD	6.65	6.03	40.31

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Netherlands EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 338 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was a wide range of capacities reported among different product types, for example disposable e-cigarettes (mode: 350mA), refillable e-cigarette devices sold as ‘device only’ (mode: 3000mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 3000mA). With regards to whether the airflow is adjustable or if the wick is changeable, almost no disposable e-cigarettes were found to have the ability to alter airflow (0.0%) or change the wick (0.2%). However, among the 2,800 products listed as ‘refillable, device only’, 70.1% (n= 1963) noted the ability to adjust airflow and 37.9% (n=1,061) had the ability to change the wick, and among the 926 products listed as ‘rechargeable device only,’ 50.1% (n=464) had the ability to adjust airflow and 22.7% (n=210) had the ability to change the wick. This suggests the plethora of product designs available on the market. A similar pattern was identified for the presence of microprocessor, which was largely present in refillable devices sold as ‘device only’ (61.5%), rechargeable devices sold as ‘device only’ (77.4%) and kits (77.1%), whereas only 7.3% of the 848 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

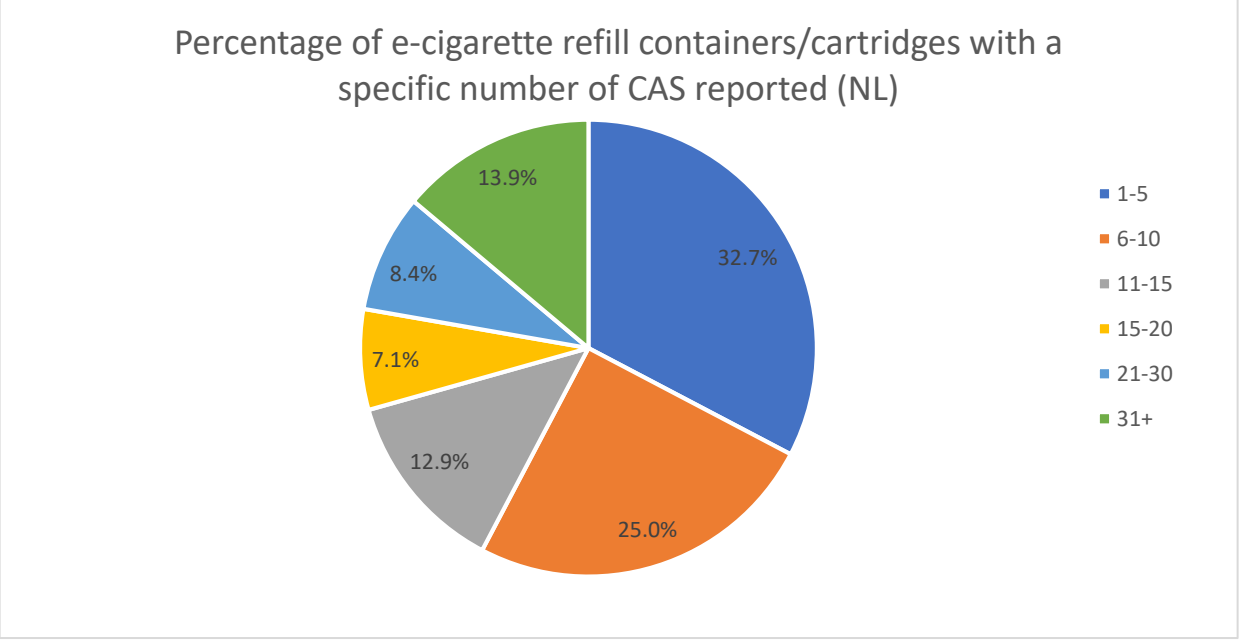
Among the 27,253 submissions for refill containers/cartridges within the Netherlands EU-CEG database with a "not withdrawn" status, 1,929 CAS numbers were submitted (Note that additional data cleaning is needed to further reduce this number).

Among the 27,253 submissions for refill containers/cartridges, 31.6% reported between 1 to 5 CAS, 24.1% reported between 6 to 10 CAS, and 13.4% reported more than 31 CAS. This breakdown is displayed in **Table 6**. A number of products (n=944) reported no CAS, thus their submissions were considered invalid and their EC-IDs are flagged in **Annex A**. **Figure 3** depicts the breakdown of the number of CAS reported within one product, excluding submissions with no CAS reported.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Netherlands (n=27,253)

Number of CAS per product	Number of products	% (total)	% (excluding invalid)
1-5	8602	31.6%	32.7%
6-10	6580	24.1%	25.0%
11-15	3402	12.5%	12.9%
16-20	1872	6.9%	7.1%
21-30	2203	8.1%	8.4%
31+	3650	13.4%	13.9%
Invalid (no CAS reported)	944	3.5%	

Figure 3. Breakdown of the number of CAS reported within one product (among those that reported a CAS), Netherlands (n=26,309)



Among valid submissions, the average number of ingredients per product was 14.7, ranging between 1 to 120 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID for all submissions and for all valid submissions is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall and among valid product submissions, Netherlands

	Number of CAS **All refill containers/cartridges** (n= 27,253)	**Valid CAS entry** (n= 26,309)
Min.	0	1
Median	8	9
Mean	14.15	14.66
Max.	120	120
SD	15.22	15.25
Invalid (i.e. no CAS reported)	n = 944	

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges that contain an e-liquid which reported any CAS (n=26,309), a total of 1,906 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Netherlands (n=26,309)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	25437	96.7%
2	56-81-5	Glycerol	24130	91.7%
3	54-11-5	Nicotine	23195	88.2%
4	121-33-5	Vanillin	9429	35.8%
5	7732-18-5	Water	8503	32.3%
6	105-54-4	Ethyl butyrate	8135	30.9%
7	4940-11-8	Ethyl maltol	8011	30.4%
8	105-54-4	Ethyl alcohol	6682	25.4%
9	141-78-6	Ethyl acetate	5937	22.6%
10	118-71-8	Maltol	5616	21.3%
11	3658-77-3	Furaneol	5243	19.9%
12	928-96-1	cis-3-Hexen-1-ol	4873	18.5%
13	123-92-2	Isoamyl acetate	4817	18.3%
14	121-32-4	Ethyl vanillin	4777	18.2%
15	706-14-9	γ-Decalactone	4476	17.0%
16	7452-79-1	Ethyl 2-methylbutyrate	4339	16.5%
17	64-19-7	Acetic acid	4318	16.4%
18	78-70-6	Linalool	3750	14.3%
19	100-51-6	Benzyl alcohol	3745	14.2%
20	107-92-6	Butyric acid	3647	13.9%

21	123-66-0	Ethyl hexanoate	3519	13.4%
22	102-76-1	Triacetin	3260	12.4%
23	142-92-7	Hexyl acetate	3125	11.9%
24	56038-13-2	Sucralose	2942	11.2%
25	100-52-7	Benzaldehyde	2808	10.7%
26	116-53-0	(±)-2-Methylbutyric acid	2771	10.5%
27	103-26-4	Methyl cinnamate	2720	10.3%
28	3681-71-8	cis-3-Hexenyl acetate	2718	10.3%
29	142-62-1	Hexanoic acid	2716	10.3%
30	105-37-3	Ethyl propionate	2715	10.3%
31	5471-51-2	Frambione	2673	10.2%
32	120-57-0	Piperonal	2639	10.0%
33	705-86-2	δ-Decalactone	2508	9.5%
34	140-11-4	Benzyl acetate	2503	9.5%
35	104-67-6	γ-Undecalactone	2460	9.4%
36	659-70-1	Isoamyl isovalerate	2431	9.2%
37	765-70-8	Methyl Cyclopentenolone	2429	9.2%
38	56-40-6	Glycine	2307	8.8%
39	123-11-5	p-Anisaldehyde	2229	8.5%
40	80-71-7	Methyl cyclopentenolone	2221	8.4%
41	108-64-5	Ethyl isovalerate	2208	8.4%
42	104-50-7	γ-Octalactone	2204	8.4%
43	2216-51-5	L-Menthol	2051	7.8%
44	713-95-1	δ-Dodecalactone	1967	7.5%
45	104-61-0	γ-Nonanoic lactone	1935	7.4%
46	5392-40-5	Citral	1891	7.2%
47	22047-25-2	2-Acetylpyrazine	1787	6.8%
48	106-27-4	Isoamyl butyrate	1758	6.7%
49	127-41-3	α-Ionone	1671	6.4%
50	89-78-1	Menthol	1627	6.2%
51	14667-55-1	2,3,5-Trimethylpyrazine	1572	6.0%
52	5989-27-5	(R)-(+)-Limonene	1562	5.9%
53	98-55-5	α-Terpineol	1509	5.7%
54	14901-07-6	β-Ionone	1505	5.7%
55	110-19-0	Isobutyl acetate	1504	5.7%
56	23696-85-7	Damascenone	1492	5.7%
57	513-86-0	Acetoin	1445	5.5%
58	97-53-0	Eugenol	1431	5.4%
59	111-27-3	1-Hexanol	1340	5.1%
60	60-12-8	2-Phenylethanol	1331	5.1%
61	119-84-6	Dihydrocoumarin	1312	5.0%
62	105-13-5	4-Methoxybenzyl alcohol	1305	5.0%
63	75-18-3	Dimethyl sulfide	1305	5.0%
64	123-51-3	Isoamyl alcohol	1301	4.9%
65	137-00-8	4-Methyl-5-thiazoleethanol	1293	4.9%
66	90-05-1	Guaiacol	1292	4.9%
67	106-24-1	Geraniol	1286	4.9%

68	123-68-2	Allyl hexanoate	1261	4.8%
69	6728-26-3	trans-2-Hexen-1-al	1238	4.7%
70	8008-56-8	Lemon oil	1127	4.3%
71	77-92-9	Citric acid	1090	4.1%
72	104-55-2	Cinnamaldehyde	1042	4.0%
73	695-06-7	γ-Hexalactone	1038	3.9%
74	79-09-4	Propionic acid	1019	3.9%
75	138-86-3	Dipentene	1014	3.9%
76	97-64-3	Ethyl lactate	996	3.8%
77	4180-23-8	trans-Anethole	981	3.7%
78	470-82-6	Eucalyptol	973	3.7%
79	134-20-3	Methyl anthranilate	969	3.7%
80	105-87-3	Geranyl acetate	949	3.6%
81	115-95-7	Linalyl acetate	947	3.6%
82	51115-67-4	2-Isopropyl-N,2,3-trimethylbutyramide	929	3.5%
83	77-93-0	Triethyl citrate	919	3.5%
84	123-86-4	Butyl acetate	918	3.5%
85	141-97-9	Ethyl acetoacetate	893	3.4%
86	66-25-1	Hexanal	884	3.4%
87	8008-57-9	Orange oil	873	3.3%
88	7492-70-8	Butyl butyryllactate	864	3.3%
89	5910-89-4	2,3-Dimethylpyrazine	776	2.9%
90	23726-91-2	β-Damascone	764	2.9%
91	16491-36-4	cis-3-Hexenyl butyrate	763	2.9%
92	127-91-3	β-Pinene	760	2.9%
93	620-02-0	5-Methylfurfural	759	2.9%
94	2305-05-7	4,5,6,7-Tetrahydroindazole	758	2.9%
95	39711-79-0	N-Ethyl-p-menthane-3-carboxamide	735	2.8%
96	124-07-2	Octanoic acid	720	2.7%
97	1124-11-4	Tetramethylpyrazine	715	2.7%
98	23726-92-3	(Z)- β-damascone	712	2.7%
99	120-51-4	Benzyl benzoate	698	2.7%
100	106-32-1	Ethyl octanoate	680	2.6%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=26,309)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity, concentration, and major function are presented below in **Table 9**. Nicotine was listed as the most common ingredient, primarily functioning as an addictive enhancer, followed by the carriers propylene glycol and glycerol. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers, except water which was most often reported as a water-wetting agent.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Netherlands

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4353.10	3830.50	447.90	393.70	Carrier	-
2	56-81-5	Glycerol	5000.00	13300.00	500.00	1337.00	Carrier	-
3	54-11-5	Nicotine	35.97	71.53	4.55	7.65	Addictive Enhancer	-
4	121-33-5	Vanillin	7.31	55.13	0.73	5.58	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
5	7732-18-5	Water	178.50	345.58	17.96	34.85	Water-Wetting Agents	-
6	105-54-4	Ethyl butyrate	4.65	19.22	0.48	1.91	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
7	4940-11-8	Ethyl maltol	11.05	29.96	1.17	3.05	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
8	105-54-4	Ethyl alcohol	35.92	123.58	3.89	12.45	Flavour and/or Taste Enhancer	-
9	141-78-6	Ethyl acetate	2.17	14.04	0.23	1.42	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
10	118-71-8	Maltol	2.20	10.36	0.24	1.07	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
11	3658-77-3	Furaneol	3.00	13.64	0.30	1.38	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
12	928-96-1	cis-3-Hexen-1-ol	2.60	8.17	0.28	0.82	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
13	123-92-2	Isoamyl acetate	3.06	21.05	0.32	2.15	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
14	121-32-4	Ethyl vanillin	8.47	29.43	0.87	2.97	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
15	706-14-9	γ-Decalactone	1.10	4.31	0.11	0.43	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
16	7452-79-1	Ethyl 2-methylbutyrate	3.39	16.54	0.34	1.66	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
17	64-19-7	Acetic acid	1.79	8.20	0.18	0.82	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
18	78-70-6	Linalool	0.94	4.93	0.10	0.50	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste
19	100-51-6	Benzyl alcohol	6.48	26.32	0.67	2.67	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste
20	107-92-6	Butyric acid	1.02	10.56	0.11	1.05	Flavour and/or Taste Enhancer	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Netherlands EU CEG.

**Flavour descriptions* are according to a desk literature review, where available.

Conclusions

Summary of Results

Within the current Netherlands EU-CEG dataset, there were 41,732 notifications (unique EC-IDs), of which 4,945 were indicated to be withdrawn from the market. The most common notification type was a notification for a new product leading to a new EC ID (n=10,616), followed by the correction of a clerical/administrative error in an existing product submission (n=9,031), and the most common active product type in the Netherlands EU CEG was refill containers/cartridges containing e-liquids (n=27,252).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.6% of products reporting a vial volume of 10ml or less. Non-compliant products (n=102) included outliers reporting a maximum vial volume of 1,198ml. A few invalid values (=0ml) were reported for vial volumes (n=6). Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the capacity, with 79.6% reporting a capacity of 2ml or less. Non-compliant products (n=1,038) included outliers reporting a maximum capacity of 60ml. Several invalid values (=0ml) were reported for capacity (n=618).

With regards to the nicotine concentration, the overwhelming majority (99.8%) of e-liquid refill cartridges/containers were compliant, with a nicotine concentration of 20 mg/ml or less. Non-compliant products (n=49) included outliers reporting a maximum nicotine concentration of 180mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,929 unique CAS numbers in the Netherlands EU CEG. The average number of ingredients per product, among products reporting CAS, was 14.7, ranging between 1 and 120 different CAS per product. A few products (3.5%) reported no CAS. The most common ingredients in frequency were the humectants propylene glycol and glycerol, followed by nicotine. The most frequently reported flavorings were vanilla, ethyl butyrate, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non-compliant products or to improve the quality of their EU CEG submissions in the case of missing data or outliers which are a result of reporting errors.
- ✓ Outliers remain a limitation of the current analysis of the Netherlands EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers (or, in the case that submissions truly reflect product properties, notifying manufacturers of non-compliance) would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Netherlands EU CEG (e.g. vial volumes, capacity, CAS) suggests a need to redefine or clarify product type categories and the relevant variables. For example, all products missing reports for capacity, and over a third of those reporting invalid values for capacity, were categorized as ‘individual parts of e-cigarettes capable of containing an e-liquid.’

- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (I.e. vial volumes , capacity and nicotine concentration), or to change the variable type from “text” variables to “numeric” variables to ensure correct and consistent reporting.
- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ A mechanism should be in place to ensure that all products with e-liquids enter CAS information, given that 3.5% of refill cartridge/containers in the Netherlands EU CEG reported no CAS.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report GREECE

Circulation: Internal

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Table of Contents

Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Below we provide an analysis for the EU MS Greece. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in October of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Greece EU-CEG dataset, there are 30,674 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type was a notification for a new product EC-ID (26.0%), followed by a correction of clerical/administrative errors in an existing product submission (19.9%), and the update of information required in regular intervals (annually) (19.4%).

Figure 1. Type of notifications within EU-CEG, Greece (N= 30,674)

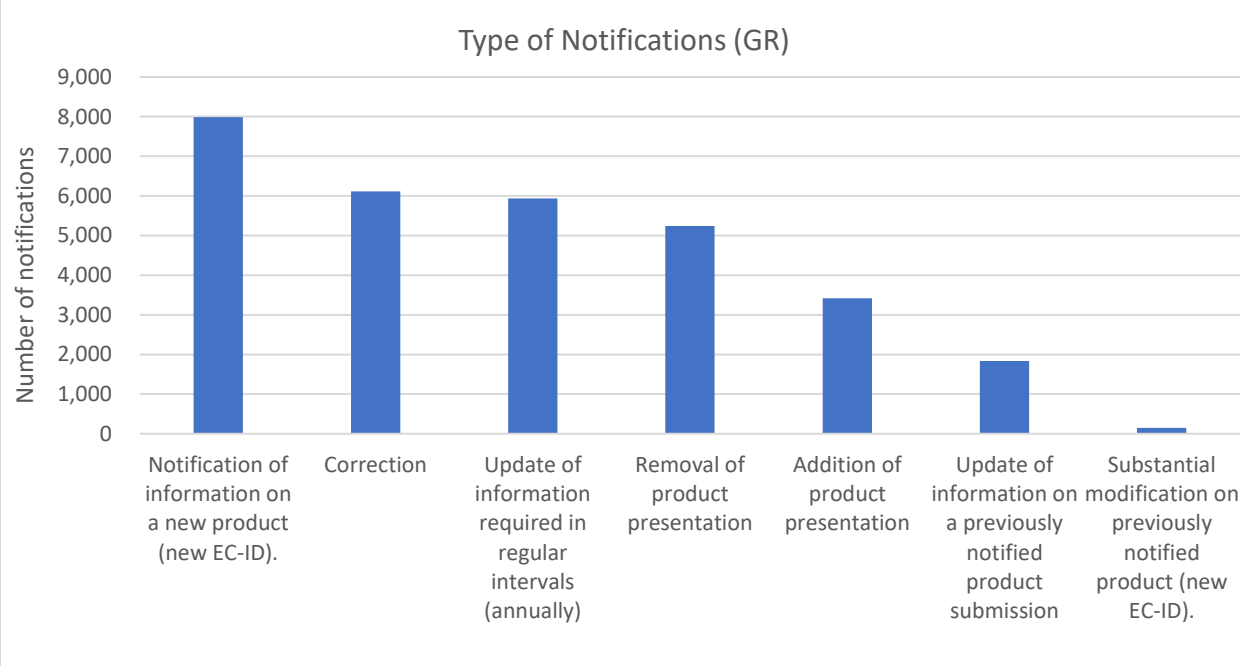


Table 1. Type of notifications within EU-CEG in Greece (N=30,674)

Notification Type	n	%
Notification of information on a new product (new EC-ID).	7,985	26.0%
Correction of clerical/administrative errors in existing product submission.	6,115	19.9%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	5,936	19.4%
Removal of product presentation, including product withdrawal, from an existing product submission.	5,242	17.1%
Addition of product presentation (e.g. national market) to an existing product submission.	3,418	11.1%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	1,832	6.0%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	146	0.5%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of October 2019, of the 30,674 notifications (unique EC-IDs) submitted for Greece for the EU CEG, 5,524 (18.0%) have been withdrawn while 25,150 (82.0%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active.

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG in Greece is displayed in **Table 2** (below). Of the 25,150 notifications for products that are currently on the market, 71.9% (n=18,086) represented refill containers/cartridges containing an e-liquid, 8.1% (n=2,043) represented a refillable device (device only), and 6.9% (n=1,724) represented an individual part of e-cigarette capable of containing e-liquid.

Figure 2. Product types active (not withdrawn) in EU-CEG, Greece (n=25,150)

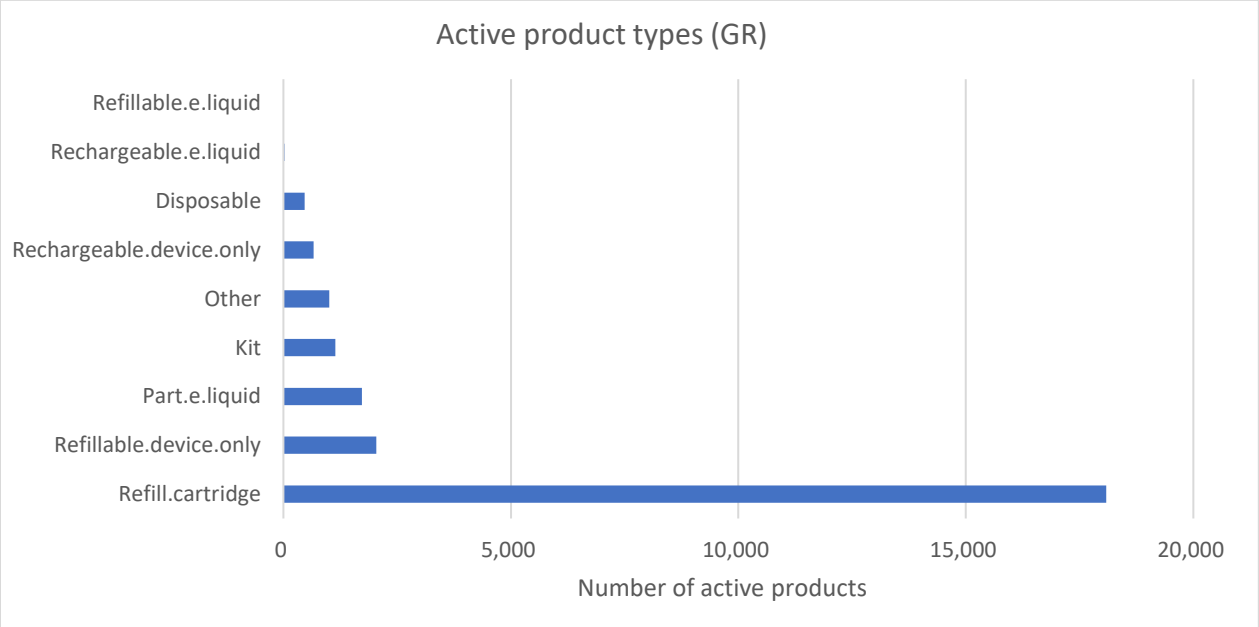


Table 2. Breakdown of product types active in EU-CEG, Greece (n=25,150)

Product type	n	%
Refill container/cartridge containing e-liquid	18,086	71.9%
Refillable, device only	2,043	8.1%
Individual part of e-cigarette capable of containing e-liquid	1,724	6.9%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	1,145	4.6%
Other	1,005	4.0%
E-cigarette – Rechargeable, device only	662	2.6%
E-cigarette – Disposable	469	1.9%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	21	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	5	0.0%

2. Assessment of volume and nicotine content in nicotine containing liquids

2.1 Volume/capacity of nicotine-containing e-cigarette liquid TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 18,086 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 3 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 18,083 refill containers/cartridges reporting valid vial volumes (> 0 ml), 17,027 are reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 17,027 nicotine-containing refill containers/cartridges that reported valid vial volumes in Greece, the average vial volume was 11.11 ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the wide range of vial volumes reported and outliers, the SD of vial volumes among all products was 122.65ml.

Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.7% of products (n=16,982) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.73ml and the middle value of the vial volumes reported (median) was 10ml. This is depicted in **Table 3**.

Only 45 non-compliant refill containers/cartridges (volume >10ml) were identified in the Greece EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with extremely large vial volumes. The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Greece

	Vial volume (ml)		
	All products n=17,027	**Compliant products (≦10ml)** n= 16,982	**Non-compliant products (>10ml)** n= 45
Min.	0.67	0.67	12
Median	10	10	30
Mean	11.11	9.733	532
Max.	11450	10	11450
SD	122.65	1.47	2354.162

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 4,924 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 4,233 products reported a value for capacity and 691 products (14.0%) were missing reports. All of the 691 submissions missing reports were listed as ‘individual parts of e-cigarettes capable of containing an e-liquid.’ Of the 4,233

products which reported a value for capacity, 3,746 products (88.5%) reported valid capacity (>0 ml) and 487 products (11.5%) reported invalid values (i.e. 0 ml). Over half of the 487 products reporting invalid values for capacity (n=281) were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.'

Among the 3,746 products that reported a valid capacity in Greece, the average capacity was 2.71ml (SD=2.05 ml). The middle value of the capacities reported (median) was 2ml. This distribution is presented in **Table 4** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in cartridges or tanks which do not exceed a capacity of 2 ml*. Given that cartridges or tanks placed on the market without a nicotine-containing e-liquid can still be used for the consumption of nicotine-containing vapour, compliance with Article 20.3 of the EU TPD of product types sold with, and/or capable of containing, an e-liquid was assessed in this analysis. Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 77.5% of products (n=2,902) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.83ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=844) had an average capacity of 5.72ml. The volume distribution of these non-compliant products is depicted in **Table 4** below, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, 171 non-compliant nicotine-containing disposable e-cigarettes (36.4%) were flagged, and one out of the five refillable e-cigarettes sold with an e-liquid product was non-compliant. Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 69 products (6.7%) listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 146 (31.3%) of the rechargeable devices, and 457 (22.4%) of the refillable devices, were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Greece

	Capacity (ml)			
	All reported (n= 4233)	**All valid (>0 ml)** (n= 3746)	**Valid, Compliant (≦2ml)** (n= 2902)	**Valid, Non-compliant (>2ml)** (n=844)
Min.	0	0.01	0.01	2.4
Median	2	2	2	5
Mean	2.394	2.705	1.827	5.724
Max.	10	10	2	10
SD	2.11	2.05	0.38	2.53
Invalid (=0 ml)	n= 487			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other,' and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 18,086 notifications on e-liquid products sold in refill cartridges/containers, 1,057 (5.8%) did not contain nicotine. The average nicotine concentration among the remaining 17,029 nicotine-containing e-liquid products was 9.62 mg/ml, and the middle value of the reported nicotine concentrations (median) was 8 mg/ml. These distributions are depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* The overwhelming majority (99.8%) of the 17,029 nicotine-containing e-liquid products in the Greece EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 16,990 compliant products, the average nicotine concentration was 9.53 mg/ml and the middle value of the reported nicotine concentrations (median) was 8 mg/ml. This is displayed in **Table 5**.

Only 39 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. The distribution of nicotine concentration for these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Greece

	Nicotine concentration (mg/ml)		
	All products (n=17,029)	**Compliant products (≦20 mg/ml)** (n=16,990)	**Non-compliant products (>20 mg/ml)** (n= 39)
Min.	0.05	0.05	30
Median	8	8	60
Mean	9.62	9.53	48.59
Max.	120	20	120
SD	6.36	6.01	20.49

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Greece EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 375 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was lower reported capacity for disposable e-cigarettes (mode: 280mA) compared to refillable e-cigarette devices sold as ‘device only’ (mode: 1500mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 3000mA). With regards to whether the airflow is adjustable or if the wick is changeable, no disposable e-cigarettes were found to have the ability to alter airflow or to change the wick. However, among the 2,209 products listed as ‘refillable, device only’, 68.2% (n=1507) noted the ability to adjust airflow and 35.9% (n=792) had the ability to change the wick, and

among the 705 products listed as ‘rechargeable device only’, 54.2% (n=382) had the ability to adjust airflow and 19.9% (n=140) had the ability to change the wick. This suggests plethora of product designs available on the market. A similar pattern was identified for the presence of a microprocessor, which was predominately present in refillable devices sold as ‘device only’ (62.4%), rechargeable devices sold as ‘device only’ (73.1%) and kits (63.0%), whereas only 7.2% of the 487 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

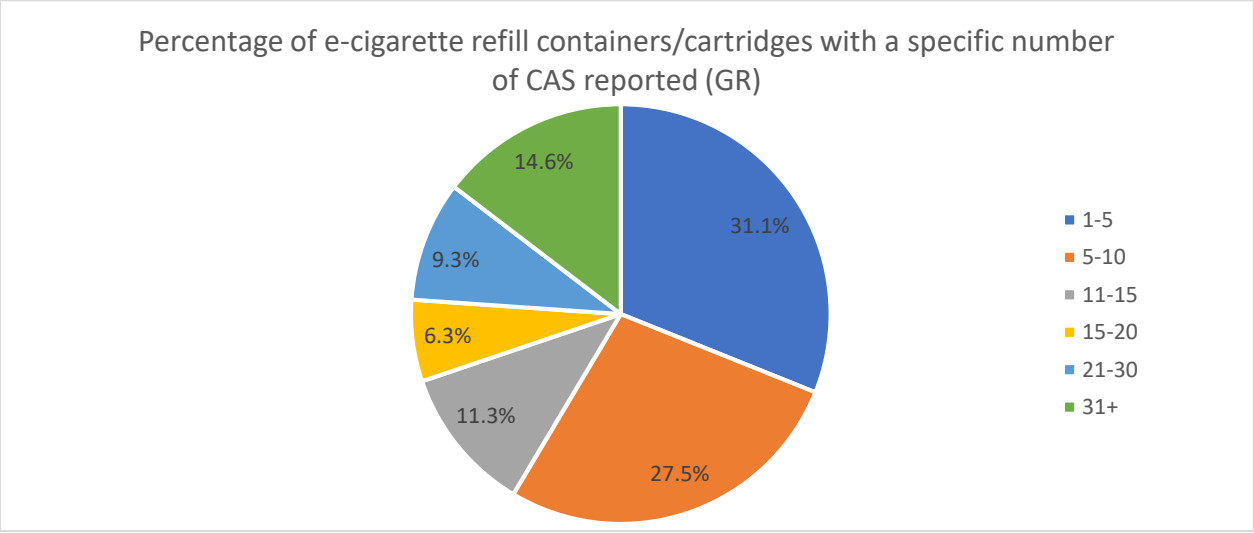
Among the 18,086 submissions for refill containers/cartridges within the Greece EU-CEG database with a "not withdrawn" status, 1,708 unique CAS numbers were submitted.

All products listed as refill containers/cartridges in the Greece EU CEG reported at least one CAS. Among the 18,086 submissions for refill containers/cartridges, 31.1% reported between 1 to 5 CAS, 27.5% reported between 6 to 10 CAS, and 14.6% reported more than 31 CAS. This breakdown is displayed in **Table 6** and depicted in **Figure 3**.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Greece (n=18,086)

Number of CAS per product	n	% (total)
1-5	5622	31.1%
6-10	4969	27.5%
11-15	2035	11.3%
16-20	1137	6.3%
21-30	1678	9.3%
31+	2645	14.6%
Invalid (no CAS reported)	0	0.0%

Figure 3. Breakdown of the number of CAS reported within one product (among all refill containers/cartridges), Greece (n=18,086)



The average number of ingredients per product was 14.85, ranging between 1 to 114 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall Greece, (n=18,086)

	Number of CAS All refill containers/cartridges (n= 18,086)
Min.	1
Median	9
Mean	14.85
Max.	114
SD	15.23
# Invalid (no CAS reported)	n=0

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges (n=18,086) a total of 1,708 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed below in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Greece (n=18,086)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	17,505	96.8%
2	56-81-5	Nicotine	16,800	92.9%
3	54-11-5	Glycerol	16,769	92.7%
4	121-33-5	Vanillin	7,189	39.7%
5	7732-18-5	Water	6,649	36.8%
6	4940-11-8	Ethyl maltol	6,009	33.2%
7	105-54-4	Ethyl butyrate	5,364	29.7%
8	64-17-5	Ethyl alcohol	4,866	26.9%
9	118-71-8	Maltol	4,196	23.2%
10	141-78-6	Ethyl acetate	3,895	21.5%
11	3658-77-3	Furaneol	3,794	21.0%
12	121-32-4	Ethyl vanillin	3,703	20.5%
13	123-92-2	Isoamyl acetate	3,088	17.1%
14	928-96-1	cis-3-Hexen-1-ol	3,077	17.0%
15	706-14-9	γ-Decalactone	2,970	16.4%
16	100-51-6	Benzyl alcohol	2,918	16.1%
17	7452-79-1	Ethyl 2-methylbutyrate	2,836	15.7%
18	64-19-7	Acetic acid	2,742	15.2%
19	107-92-6	Butyric acid	2,586	14.3%
20	78-70-6	Linalool	2,585	14.3%
21	102-76-1	Triacetin	2534	14.0%
22	123-66-0	Ethyl hexanoate	2276	12.6%
23	56038-13-2	Sucralose	2110	11.7%
24	100-52-7	Benzaldehyde	1979	10.9%
25	705-86-2	δ-Decalactone	1959	10.8%
26	142-62-1	Hexanoic acid	1956	10.8%
27	142-92-7	Hexyl acetate	1947	10.8%
28	120-57-0	Piperonal	1912	10.6%
29	142-62-1	Hexanoic acid	1907	10.5%

30	116-53-0	(±)-2-Methylbutyric acid	1887	10.4%
31	105-37-3	Ethyl propionate	1870	10.3%
32	3681-71-8	cis-3-Hexenyl acetate	1795	9.9%
33	5471-51-2	Frambione	1722	9.5%
34	103-26-4	Methyl cinnamate	1681	9.3%
35	80-71-7	Methyl cyclopentenolone	1663	9.2%
36	104-50-7	γ-Octalactone	1653	9.1%
37	104-67-6	γ-Undecalactone	1652	9.1%
38	659-70-1	Isoamyl isovalerate	1568	8.7%
39	123-11-5	p-Anisaldehyde	1548	8.6%
40	140-11-4	Benzyl acetate	1510	8.3%
41	108-64-5	Ethyl isovalerate	1482	8.2%
42	104-61-0	γ-Nonanoic lactone	1478	8.2%
43	713-95-1	δ-Dodecalactone	1369	7.6%
44	22047-25-2	2-Acetylpyrazine	1367	7.6%
45	2216-51-5	L-Menthol	1343	7.4%
46	56-40-6	Glycine	1278	7.1%
47	98-55-5	α-Terpineol	1169	6.5%
48	119-84-6	Dihydrocoumarin	1149	6.4%
49	5392-40-5	Citral	1138	6.3%
50	106-27-4	Isoamyl butyrate	1131	6.3%
51	89-78-1	Menthol	1112	6.1%
52	5989-27-5	(R)-(+)-Limonene	1096	6.1%
53	513-86-0	Acetoin	1064	5.9%
54	127-41-3	α-Ionone	1062	5.9%
55	110-19-0	Isobutyl acetate	1055	5.8%
56	14901-07-6	β-Ionone	1013	5.6%
57	137-00-8	4-Methyl-5-thiazoleethanol	1012	5.6%
58	97-53-0	Eugenol	962	5.3%
59	23696-85-7	Damascenone	955	5.3%
60	123-51-3	Isoamyl alcohol	953	5.3%
61	105-13-5	4-Methoxybenzyl alcohol	949	5.2%
62	60-12-8	2-Phenylethanol	937	5.2%
63	90-05-1	Guaiacol	920	5.1%
64	123-68-2	Allyl hexanoate	887	4.9%
65	14667-55-1	2,3,5-Trimethylpyrazine	887	4.9%
66	111-27-3	1-Hexanol	874	4.8%
67	106-24-1	Geraniol	868	4.8%
68	6728-26-3	trans-2-Hexen-1-al	857	4.7%
69	75-18-3	Dimethyl sulfide	819	4.5%
70	97-64-3	Ethyl lactate	813	4.5%
71	8008-56-8	Lemon oil	787	4.4%
72	695-06-7	γ-Hexalactone	778	4.3%
73	104-55-2	Cinnamaldehyde	778	4.3%
74	115-95-7	Linalyl acetate	777	4.3%
75	7492-70-8	Butyl butyryllactate	761	4.2%
76	77-92-9	Citric acid	732	4.0%

77	79-09-4	Propionic acid	726	4.0%
78	138-86-3	Dipentene	720	4.0%
79	134-20-3	Methyl anthranilate	713	3.9%
80	470-82-6	Eucalyptol	713	3.9%
81	77-93-0	Triethyl citrate	699	3.9%
82	8008-57-9	Orange oil	679	3.8%
83	105-87-3	Geranyl acetate	653	3.6%
84	66-25-1	Hexanal	639	3.5%
85	50-21-5	DL-Lactic acid	600	3.3%
86	123-86-4	Butyl acetate	589	3.3%
87	124-07-2	Octanoic acid	570	3.2%
88	2305-05-7	4,5,6,7-Tetrahydroindazole	555	3.1%
89	4180-23-8	trans-Anethole	553	3.1%
90	67-63-0	2-Propanol	533	2.9%
91	620-02-0	5-Methylfurfural	524	2.9%
92	120-51-4	Benzyl benzoate	520	2.9%
93	109-21-7	Butyl butyrate	481	2.7%
94	51115-67-4	2-Isopropyl-N,2,3-trimethylbutyramide	481	2.7%
95	127-91-3	β-Pinene	478	2.6%
96	16491-36-4	cis-3-Hexenyl butyrate	475	2.6%
97	141-97-9	Ethyl acetoacetate	474	2.6%
98	8008-26-2	Lime oil	470	2.6%
99	1124-11-4	2,3,5,6-Tetramethylpyrazine	466	2.6%
100	106-72-9	2,6-Dimethyl-5-heptenal	462	2.6%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=18,086)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity (mg per product), concentration, and major function are presented below in **Table 9**. Besides the carriers (propylene glycol and glycerol), nicotine was the most common ingredient, primarily functioning as an addictive enhancer. All other ingredients in the top 20 were mainly reported to be used as flavor/taste enhancers, except water which was most often reported as a water-wetting agent.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Greece

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4174.00	3593.00	429.60	375.00	Carrier	-
2	56-81-5	Nicotine	30.30	65.91	3.44	7.16	Addictive Enhancer	-
3	54-11-5	Glycerol	5000.00	14760.00	506.00	1492.00	Carrier	-
4	121-33-5	Vanillin	8.00	27.57	0.89	2.86	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
5	7732-18-5	Water	157.86	367.47	16.39	37.93	Water-Wetting Agents	-
6	4940-11-8	Ethyl maltol	9.99	27.23	1.00	2.71	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	105-54-4	Ethyl butyrate	3.16	13.36	0.34	1.33	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
8	64-17-5	Ethyl alcohol	26.00	101.70	2.80	10.35	Flavour and/or Taste Enhancer	-
9	118-71-8	Maltol	2.00	13.64	0.22	1.40	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
10	141-78-6	Ethyl acetate	1.50	9.86	0.17	0.98	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
11	3658-77-3	Furaneol	2.48	12.68	0.27	1.26	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
12	121-32-4	Ethyl vanillin	8.71	28.39	0.88	2.82	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
13	123-92-2	Isoamyl acetate	1.97	13.93	0.20	1.48	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
14	928-96-1	cis-3-Hexen-1-ol	1.64	7.47	0.17	0.74	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
15	706-14-9	γ-Decalactone	0.75	3.62	0.08	0.37	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
16	100-51-6	Benzyl alcohol	4.55	19.88	0.50	2.03	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste
17	7452-79-1	Ethyl 2-methylbutyrate	2.24	15.99	0.23	1.55	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
18	64-19-7	Acetic acid	1.22	6.85	0.13	0.65	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
19	107-92-6	Butyric acid	0.93	5.39	0.10	0.54	Flavour and/or Taste Enhancer	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor
20	78-70-6	Linalool	0.52	4.89	0.05	0.48	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Greece EU CEG.

**Flavour descriptions* are according to a desk literature review.

Conclusions

Summary of Results

Within the current Greece EU-CEG dataset, there are 30,674 notifications (unique EC-IDs), of which 5,524 were indicated to be withdrawn from the market. The most common type of product active in the Greece EU CEG was refill containers/cartridges containing e-liquids (n=18,086).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.7% of products reporting a vial volume of 10ml or less. Non-compliant products (n=45) included extreme outliers reporting a maximum vial volume of 11,450ml. Most containers/cartridges capable of carrying an e-liquid were compliant with regards to the capacity, with 77.5% reporting a capacity of 2ml or less. Non-compliant products (n=844) reported a maximum capacity of 10ml. A significant number of invalid values (=0ml) were reported for capacity (n=487), more than half of which were characterized as 'individual part of electronic cigarette capable of containing e-liquid.'

With regards to the nicotine concentration, the overwhelming majority (99.8%) of e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less. Non-compliant products (n=49) included extreme outliers reporting a maximum nicotine concentration of 11476mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,708 unique CAS numbers reported in the Greece EU CEG. The average number of ingredients per product was 14.85, ranging between 1 and 114 different CAS per product. The most common ingredients in frequency were the humectants propylene glycol and glycerol, and nicotine. The most frequently reported flavorings were vanilla, ethyl maltol and ethyl butyrate.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Outliers remain a limitation of the current analysis of the Greece EU-CEG dataset (in particular for vial volume and nicotine concentration)- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Greece EU CEG (e.g. vial volume, capacity) suggests a need to redefine or clarify product type categories and their relevant variables. For example, products missing reports for capacity, and over 50% of those reporting invalid values for capacity, were categorized as 'individual parts of e-cigarettes capable of containing an e-liquid.'
- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume/capacity and nicotine concentration), or to change the variable type from "text" variables to "numeric" variables to ensure correct and consistent reporting.

- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report FRANCE

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and results by research question

Below we provide an analysis for the EU MS France. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current France EU-CEG dataset, there are 45,240 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications, including 53 notifications which are missing information on their withdrawal status. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type, among products with valid notifications, was a notification for a new product EC-ID (30.6%), followed by the correction of clerical/administrative errors in an existing product submission (18.5%), and the removal of a product presentation, including product withdrawal, from an existing product submission (15.8%).

Figure 1. Type of valid notifications within EU-CEG, France (N= 45,240)

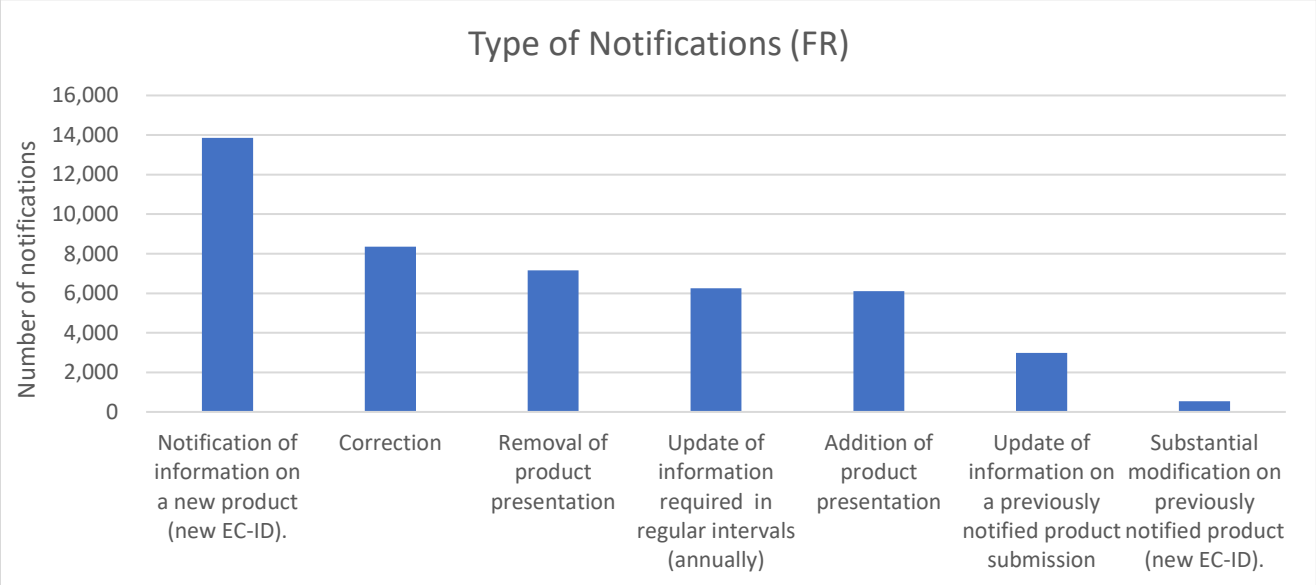


Table 1. Type of notifications within EU-CEG in France (N=45,240)

Type	n	% (valid)
Notification of information on a new product (new EC-ID).	13,861	30.6%
Correction of clerical/administrative errors in existing product submission.	8,348	18.5%
Removal of product presentation, including product withdrawal, from an existing product submission.	7,151	15.8%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	6,249	13.8%
Addition of product presentation (e.g. national market) to an existing product submission.	6,105	13.5%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	2,989	6.6%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	537	1.2%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 45,240 notifications (unique EC-IDs) submitted for France in the EU CEG, 9138 (20.2%) products have been withdrawn and 53 (0.1%) products indicated withdrawal but did not provide a specific date at the time of analysis, while 36,049 (79.7%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active (n=36,049).

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG for France is displayed in **Table 2** (below). Of the 36,049 notifications for products that are currently on the market, 76.6% (n=27,597) represented refill containers/cartridges containing an e-liquid, 7.7% (n=2,793) represented a refillable device (device only), and 5.1% (n=1,830) represented individual parts of e-cigarettes capable of containing e-liquids.

Figure 2. Product types active (not withdrawn) in EU-CEG, France (n=36,049)

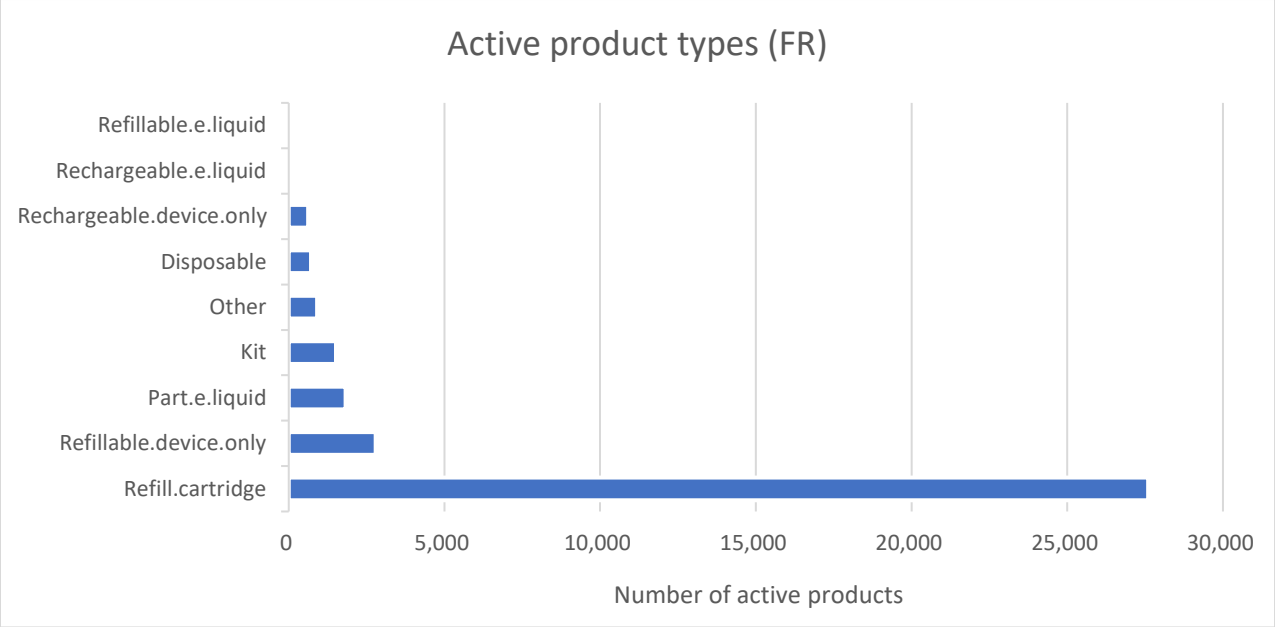


Table 2. Breakdown of product types active in EU-CEG types, France (n=36,049)

Product type	n	%
Refill container/cartridge containing e-liquid	27,597	76.6%
Refillable, device only	2,793	7.7%
Individual part of e-cigarette capable of containing e-liquid	1,830	5.1%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	1,513	4.2%
Other	916	2.5%
E-cigarette – Disposable	712	2.0%
E-cigarette – Rechargeable, device only	619	1.7%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	49	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	20	0.1%

2. Assessment of volume (capacity) and nicotine content

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 27,597 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 6 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 27,591 refill containers/cartridges reporting valid vial volumes (>0 ml), 27,009 were reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 27,009 nicotine-containing refill containers/cartridges that reported valid vial volumes in France, the average vial volume was 17.33 ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the large range of vial volumes reported and outliers, the SD of vial volumes among all products was 232.7ml.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml.* Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.5% of products (n=26,880) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.70ml and the middle value of the vial volume data set (median) was 10ml. This is depicted in **Table 3**.

There were 129 refill containers/cartridges identified as non-compliant (volume >10ml) in the France EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with extremely large vial volumes (e.g. 11,482ml). The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, France

	Vial volume (ml)		
	All products n=27,009	**Compliant products (≦10ml)** n= 26,880	**Non-compliant products (>10ml)** n= 129
Min.	0.67	0.670	11
Median	10.00	10	1174
Mean	17.33	9.697	1608
Max.	11482.00	10	11482
SD	232.7	1.55	2977.01

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 6,009 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to

the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 5,330 products reported a value for capacity and 679 products (11.3%) were missing reports. All of the 679 submissions that were missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 5,330 products which reported a value for capacity, 4,652 products (87.3%) reported valid capacity (>0 ml) and 678 products (12.7%) reported invalid values (i.e. 0 ml). Over half of the 678 products reporting invalid values for capacity (n=325) were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.'

Among the 4,652 products that reported a valid capacity (>0 ml) in France, the average capacity was 6.87ml, and the middle value of the capacities reported (median) was 2ml. It is important to note that, given the presence of extremely large outliers, the SD of capacity among all products was 273ml. This distribution is presented in **Table 4** below.

Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 73.8% of products (n=3,435) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.79ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=1,217) had an average capacity of 21.2ml, and an extremely large SD (534.4ml). The volume distribution of these non-compliant products is depicted in **Table 4**, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there were 289 non-compliant nicotine-containing disposable e-cigarettes (41.4%) and two non-compliant refillable e-cigarettes sold with an e-liquid product (10.5%). Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 88 products (7.7%) listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 54 (16.2%) of the rechargeable devices, and 784 (28.8%) of the refillable devices, were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* France

	Capacity (ml) **All reported** (n= 5330)	**All valid (>0 ml)** (n= 4652)	**Valid, Compliant (≦2ml)** (n= 3435)	**Valid, Non-compliant (>2ml)** (n=1217)
Min.	0	0.01	0.01	2.4
Median	2	2	2	5
Mean	5.998	6.872	1.789	21.22
Max.	18650	18650	2	18650
SD	255.43	273.41	0.4	534.44
Invalid (=0 ml)	n= 678			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other', and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 27,597 notifications on e-liquid products sold in refill cartridges/containers, 583 (2.1%) did not contain nicotine. The average nicotine concentration among the remaining 27,014 nicotine-containing e-liquid products was 9.48 mg/ml and the middle value of the reported nicotine concentrations (median) was 6 mg/ml. This distribution is depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* The overwhelming majority (99.8%) of the 27,014 nicotine-containing e-liquid products in the France EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 26,965 compliant products, the average nicotine concentration was 8.96 mg/ml and the middle value of the reported nicotine concentrations (median) was 6 mg/ml. This is displayed in **Table 5**.

Only 49 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. Among these, there were extreme outliers (with a maximum reported value of 11,475.8mg/ml), leading to a SD of 1630.9mg/ml. The distribution of nicotine concentration of these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, France

	Nicotine concentration (mg/ml)		
	All products (n=27,014)	**Compliant products (≦20 mg/ml)** (n=26,965)	**Non-compliant products (>20 mg/ml)** (n= 49)
Min.	0.03	0.03	30
Median	6	6	60
Mean	9.479	8.959	295.8
Max.	11475.75	20	11475.8
SD	70.05	5.61	1630.93

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the France EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 347 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was a wide range of capacities reported among different product types, for example disposable e-cigarettes (mode: 350mA), refillable e-cigarette devices sold as ‘device only’ (mode: 3000mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 18650mA). With regards to whether the airflow is adjustable or if the wick is changeable, almost no disposable e-cigarettes were found to have the ability to alter airflow (0.0%) or change the wick (0.1%). However, among the 2,939 products listed as ‘refillable, device only’, 69.6% (n= 2045) noted the ability to adjust airflow and 44.1% (n=1,295) had the ability to change the wick, and among the 696 products listed as ‘rechargeable device only’, 34.2% (n=238) had the ability to adjust airflow and 17.7% (n=123) had the ability to change the wick. This suggests the plethora of product designs available on the market. A similar pattern was identified for the presence of microprocessor, which was largely present in refillable devices sold as ‘device only’ (54.8%), rechargeable devices sold as ‘device only’ (64.4%) and kits (66.9%), whereas only 10.3% of the 749 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

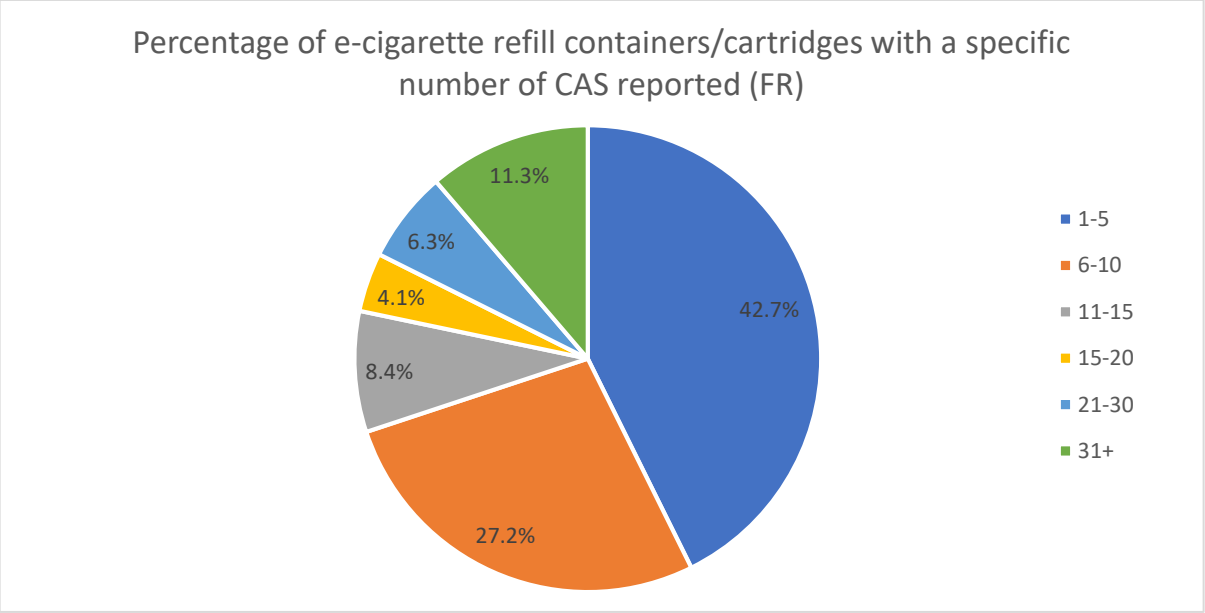
Among the 27,597 submissions for refill containers/cartridges within the France EU-CEG database with a "not withdrawn" status, 1,818 unique CAS numbers were submitted (Note that additional data cleaning is needed to further reduce this number).

Among the 27,597 submissions for refill containers/cartridges, 40.0% reported between 1 to 5 CAS, 25.5% reported between 6 to 10 CAS, and 10.6% reported more than 31 CAS. This breakdown is displayed in **Table 6**. A number of products (n=1,741) reported no CAS, thus their submissions were considered invalid and their EC-IDs are flagged in **Annex A**. **Figure 3** depicts the breakdown of the number of CAS reported within one product, excluding submissions with no CAS reported.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, France (n=27,597)

Number of CAS per product	Number of products	% (total)	% (excluding invalid)
1-5	11035	40.0%	42.7%
6-10	7042	25.5%	27.2%
11-15	2165	7.8%	8.4%
16-20	1058	3.8%	4.1%
21-30	1641	5.9%	6.3%
31+	2915	10.6%	11.3%
Invalid (no CAS reported)	1741	6.3%	

Figure 3. Breakdown of the number of CAS reported within one product (among those that reported a CAS), France (n=24,513)



Among valid submissions, the average number of ingredients per product was 12.3, ranging between 1 to 132 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID for all submissions and for all valid submissions is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall and among valid product submissions, France

	Number of CAS **All refill containers/cartridges** (n= 27,597)	**Valid CAS entry** (n= 25,856)
Min.	0	1
Median	6	6
Mean	11.53	12.31
Max.	132	132
SD	14.19	14.33
Invalid (i.e. no CAS reported)	n = 1741	

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges that contain an e-liquid which reported any CAS (n=25,856), a total of 1,818 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, France (n=25,856)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	54-11-5	Nicotine	25038	96.8%
2	57-55-6	Propylene glycol	24898	96.3%
3	56-81-5	Glycerol	23839	92.2%
4	7732-18-5	Water	8783	34.0%
5	121-33-5	Vanillin	7779	30.1%
6	4940-11-8	Ethyl maltol	7060	27.3%
7	64-17-5	Ethyl alcohol	6851	26.5%
8	105-54-4	Ethyl butyrate	6123	23.7%
9	118-71-8	Maltol	4787	18.5%
10	141-78-6	Ethyl acetate	4541	17.6%
11	3658-77-3	Furaneol	4441	17.2%
12	121-32-4	Ethyl vanillin	4349	16.8%
13	123-92-2	Isoamyl acetate	3767	14.6%
14	928-96-1	cis-3-Hexen-1-ol	3634	14.1%
15	7452-79-1	Ethyl 2-methylbutyrate	3437	13.3%
16	706-14-9	γ-Decalactone	3326	12.9%
17	56038-13-2	Sucralose	3181	12.3%
18	107-92-6	Butyric acid	3140	12.1%
19	64-19-7	Acetic acid	3064	11.9%
20	78-70-6	Linalool	2773	10.7%
21	123-66-0	Ethyl hexanoate	2680	10.4%

22	100-51-6	Benzyl alcohol	2637	10.2%
23	102-76-1	Triacetin	2634	10.2%
24	142-62-1	Hexanoic acid	2297	8.9%
25	120-57-0	Piperonal	2243	8.7%
26	116-53-0	(±)-2-Methylbutyric acid	2233	8.6%
27	765-70-8	Methyl Cyclopentenolone	2231	8.6%
28	142-92-7	Hexyl acetate	2228	8.6%
29	705-86-2	δ-Decalactone	2164	8.4%
30	105-37-3	Ethyl propionate	2103	8.1%
31	56-40-6	Glycine	2066	8.0%
32	5471-51-2	Frambione	2040	7.9%
33	3681-71-8	cis-3-Hexenyl acetate	2020	7.8%
34	100-52-7	Benzaldehyde	1960	7.6%
35	2216-51-5	L-Menthol	1942	7.5%
36	104-67-6	γ-Undecalactone	1924	7.4%
37	103-26-4	Methyl cinnamate	1783	6.9%
38	659-70-1	Isoamyl isovalerate	1733	6.7%
39	104-50-7	γ-Octalactone	1700	6.6%
40	89-78-1	Menthol	1625	6.3%
41	108-64-5	Ethyl isovalerate	1620	6.3%
42	80-71-7	Methyl cyclopentenolone	1616	6.3%
43	104-61-0	γ-Nonanoic lactone	1612	6.2%
44	713-95-1	δ-Dodecalactone	1611	6.2%
45	123-11-5	p-Anisaldehyde	1537	5.9%
46	5392-40-5	Citral	1407	5.4%
47	140-11-4	Benzyl acetate	1393	5.4%
48	22047-25-2	2-Acetylpyrazine	1360	5.3%
49	110-19-0	Isobutyl acetate	1252	4.8%
50	513-86-0	Acetoin	1220	4.7%
51	137-00-8	4-Methyl-5-thiazoleethanol	1204	4.7%
52	5989-27-5	(R)-(+)-Limonene	1171	4.5%
53	23696-85-7	Damascenone	1164	4.5%
54	105-13-5	4-Methoxybenzyl alcohol	1147	4.4%
55	98-55-5	α-Terpineol	1123	4.3%
56	119-84-6	Dihydrocoumarin	1101	4.3%
57	106-27-4	Isoamyl butyrate	1093	4.2%
58	127-41-3	α-Ionone	1068	4.1%
59	77-92-9	Citric acid	1061	4.1%
60	75-18-3	Dimethyl sulfide	1057	4.1%
61	14901-07-6	β-Ionone	1056	4.1%
62	106-24-1	Geraniol	1052	4.1%
63	8008-56-8	Lemon oil	1047	4.0%
64	79-09-4	Propionic acid	1023	4.0%
65	123-68-2	Allyl hexanoate	1014	3.9%
66	90-05-1	Guaiacol	1003	3.9%
67	123-51-3	Isoamyl alcohol	990	3.8%
68	14667-55-1	2,3,5-Trimethylpyrazine	955	3.7%

69	695-06-7	γ-Hexalactone	924	3.6%
70	6728-26-3	trans-2-Hexen-1-al	918	3.6%
71	97-53-0	Eugenol	894	3.5%
72	97-64-3	Ethyl lactate	878	3.4%
73	4180-23-8	trans-Anethole	876	3.4%
74	470-82-6	Eucalyptol	872	3.4%
75	51115-67-4	2-Isopropyl-N,2,3-trimethylbutyramide	863	3.3%
76	111-27-3	1-Hexanol	809	3.1%
77	39711-79-0	N-Ethyl-p-menthane-3-carboxamide	807	3.1%
78	7492-70-8	Butyl butyryllactate	806	3.1%
79	138-86-3	Dipentene	805	3.1%
80	104-55-2	Cinnamaldehyde	758	2.9%
81	77-93-0	Triethyl citrate	747	2.9%
82	105-87-3	Geranyl acetate	744	2.9%
83	124-07-2	Octanoic acid	735	2.8%
84	134-20-3	Methyl anthranilate	723	2.8%
85	8008-57-9	Orange oil	713	2.8%
86	50-21-5	DL-Lactic acid	700	2.7%
87	115-95-7	Linalyl acetate	680	2.6%
88	120-51-4	Benzyl benzoate	679	2.6%
89	60-12-8	2-Phenylethanol	678	2.6%
90	109-21-7	Butyl butyrate	659	2.5%
91	66-25-1	Hexanal	650	2.5%
92	532-32-1	Sodium Benzoate	639	2.5%
93	110-44-1	Sorbic Acid	630	2.4%
94	16491-36-4	cis-3-Hexenyl butyrate	594	2.3%
95	2305-05-7	4,5,6,7-Tetrahydroindazole	584	2.3%
96	68-04-2	Sodium Citrate	576	2.2%
97	8008-26-2	Lime oil	560	2.2%
98	123-86-4	Butyl acetate	554	2.1%
99	8006-90-4	Peppermint oil	532	2.1%
100	127-91-3	β-Pinene	524	2.0%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=25,856)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity, concentration, and major function are presented below in **Table 9**. Nicotine was listed as the most common ingredient, primarily functioning as an addictive enhancer, followed by the carriers propylene glycol and glycerol. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, France

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	54-11-5	Nicotine	50.00	70.34	5.60	7.55	Addictive Enhancer	-
2	57-55-6	Propylene glycol	4496.00	3881.80	459.60	405.16	Carrier	-
3	56-81-5	Glycerol	4810.00	14840.00	494.00	1503.00	Carrier	-
4	7732-18-5	Water	104.00	1122.00	10.60	136.90	Flavour and/or Taste Enhancer	-
5	121-33-5	Vanillin	12.47	46.84	1.40	4.92	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
6	4940-11-8	Ethyl maltol	12.50	32.01	1.32	3.28	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	64-17-5	Ethyl alcohol	39.65	114.93	4.13	11.64	Flavour and/or Taste Enhancer	-
8	105-54-4	Ethyl butyrate	5.12	17.39	0.55	1.83	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
9	118-71-8	Maltol	3.09	11.81	0.35	1.25	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
10	141-78-6	Ethyl acetate	1.88	13.75	0.20	1.41	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
11	3658-77-3	Furaneol	3.54	13.56	0.38	1.40	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
12	121-32-4	Ethyl vanillin	14.10	33.60	1.46	3.42	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
13	123-92-2	Isoamyl acetate	3.23	23.31	0.36	2.42	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
14	928-96-1	cis-3-Hexen-1-ol	2.35	9.12	0.24	0.95	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
15	7452-79-1	Ethyl 2-methylbutyrate	3.51	14.57	0.36	1.52	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
16	706-14-9	γ-Decalactone	0.77	4.45	0.09	0.48	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
17	56038-13-2	Sucralose	13.45	32.00	1.35	3.24	Flavour and/or Taste Enhancer	-
18	107-92-6	Butyric acid	0.98	7.07	0.11	0.71	Flavour and/or Taste Enhancer	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor
19	64-19-7	Acetic acid	1.88	8.24	0.19	0.84	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
20	78-70-6	Linalool	0.76	4.04	0.08	0.42	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the France EU CEG.

**Flavour descriptions* are according to a desk literature review, where available.

Conclusions

Summary of Results

Within the current France EU-CEG dataset, there are 45,240 notifications (unique EC-IDs), of which 9,138 were indicated to be withdrawn from the market. The most common type of product active in the France EU CEG was refill containers/cartridges containing e-liquids (n=27,597). Among the categories assessed in the analysis (volume and nicotine concentration), there were extremely large outliers in the France EU CEG dataset.

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.5% of products reporting a vial volume of 10ml or less. Non-compliant products (n=129) included outliers reporting a maximum vial volume of 11,482ml. Six invalid values (=0ml) were reported for vial volumes. Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the capacity, with 73.8% reporting a volume capacity of 2ml or less. Non-compliant products (n=1217) included extreme outliers which reported a maximum capacity of 18,650ml. A significant number of invalid values (=0ml) were reported for capacity (n=678), more than half of which were characterized as 'individual part of electronic cigarette capable of containing e-liquid.'

With regards to the nicotine concentration, the overwhelming majority (99.8%) of e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less. Non-compliant products (n=49) included extreme outliers reporting a maximum nicotine concentration of 11476mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,818 unique CAS numbers reported in the France EU CEG. The average number of ingredients per product, among products reporting CAS, was 12.3, ranging between 1 and 132 different CAS per product. A few products (6.3%) reported no CAS. The most common ingredient in frequency was nicotine, followed by the humectants propylene glycol and glycerol. The most frequently reported flavorings were vanilla, ethyl maltol, and ethyl butyrate.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Extremely large outliers across all reporting categories remain a limitation of the current analysis of the France EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting and limiting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ Missing and invalid data in the France EU CEG (e.g. vial volumes, capacity, CAS) suggests a need to redefine or clarify product type categories and their relevant variables. For example, all products missing reports for volume capacity, and over 50% of those reporting invalid values for volume capacity, were categorized as 'individual parts of e-cigarettes capable of containing an e-liquid.'

- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume/capacity and nicotine concentration), or to change the variable type from “text” variables to “numeric” variables to ensure correct and consistent reporting.
- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ A mechanism should be in place to ensure that all products with e-liquids enter CAS information, given that 6.3% of refill cartridge/containers in the France EU CEG reported no CAS.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report DENMARK

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Below we provide an analysis for the EU MS Denmark. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in October of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Denmark EU-CEG dataset, there are 9,576 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type was a notification for a new product EC-ID (37.5%), followed by the removal of a product presentation (25.2%), and the update of information required in regular intervals (annually) (14.0%).

Figure 1. Type of notifications within EU-CEG, Denmark (N= 9,576)

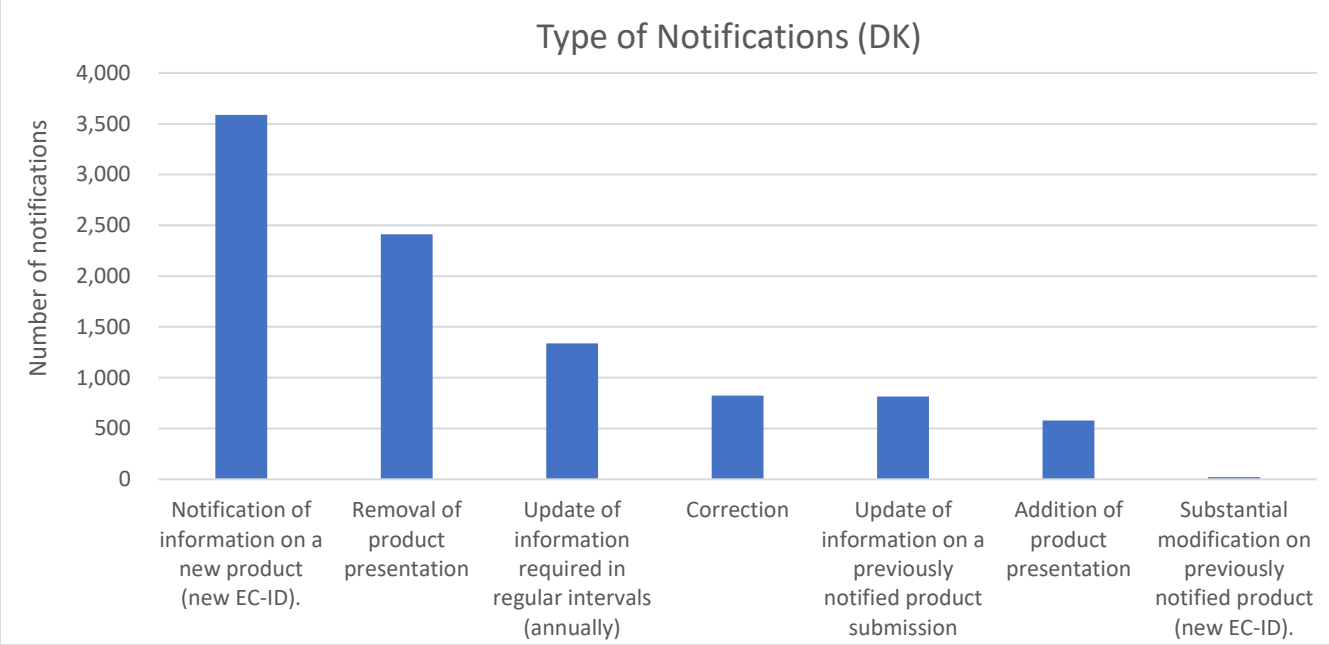


Table 1. Type of notifications within EU-CEG in Denmark (N=9,576)

Notification Type	N	%
Notification of information on a new product (new EC-ID).	3,588	37.5%
Removal of product presentation, including product withdrawal, from an existing product submission.	2,413	25.2%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	1,338	14.0%
Correction of clerical/administrative errors in existing product submission.	824	8.6%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	814	8.5%
Addition of product presentation (e.g. national market) to an existing product submission.	577	6.0%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	22	0.2%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 9,576 notifications (unique EC-IDs) submitted for Denmark for the EU CEG, 2,704 (28.2%) have been withdrawn while 6,872 (71.8%) unique EC-IDs remain active on the market. This analysis is restricted to products that are currently active.

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG in Denmark is displayed in **Table 2** (below). Of the 6,872 notifications for products that are currently on the market, 47% (n=3,233) represented refill containers/cartridges containing an e-liquid, 18.2% (n=1,251) represented a submission for 'other' product type, and 11.5% (n=792) represented a submission for an individual part of e-cigarette capable of containing e-liquid.

Figure 2. Product types active (not withdrawn) in EU-CEG, Denmark (n=6,872)

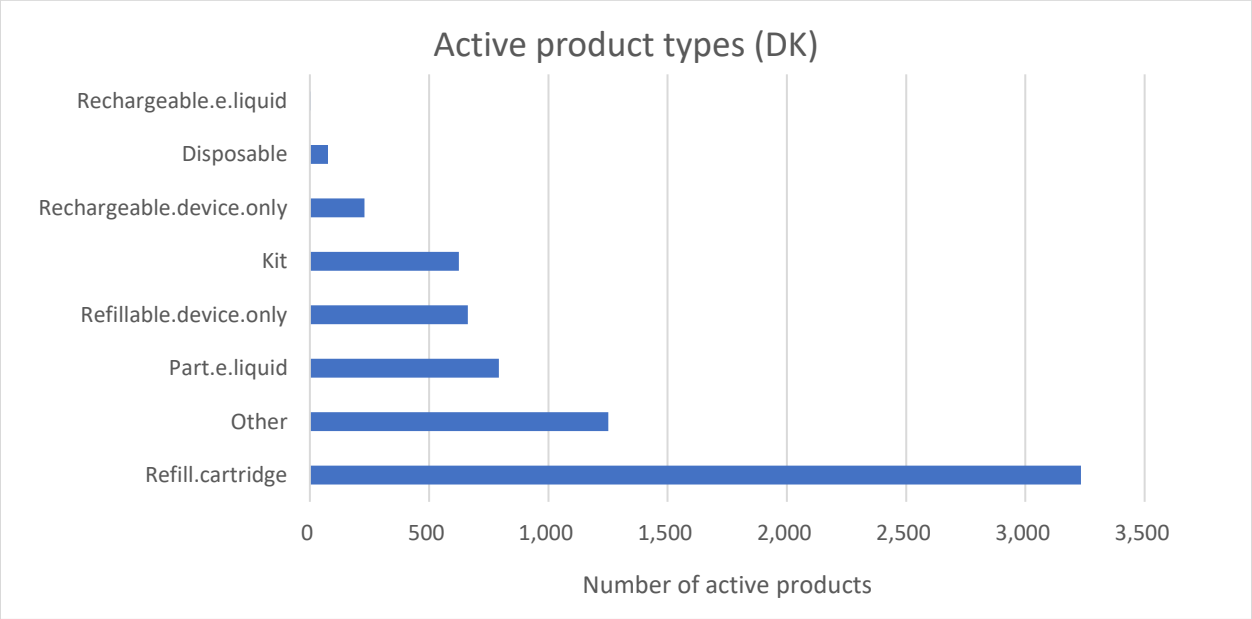


Table 2. Breakdown of product types active in EU-CEG, Denmark (n=6,872)

Product type	n	%
Refill container/cartridge containing e-liquid	3,233	47.0%
Other	1251	18.2%
Individual part of e-cigarette capable of containing e-liquid	792	11.5%
Refillable, device only	662	9.6%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	625	9.1%
E-cigarette – Rechargeable, device only	229	3.3%
E-cigarette – Disposable	76	1.1%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	4	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	0	0.0%

2. Assessment of volume and nicotine content in nicotine containing liquids

2.1 Volume/capacity of nicotine-containing e-cigarette liquid TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

All of the 3,233 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID) reported valid vial volumes (>0ml). Of these refill containers/cartridges, 3,006 are reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 3,006 nicotine-containing refill containers/cartridges that that reported valid vial volumes in Denmark, the average vial volume was 13.53 ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the wide range of vial volumes reported and outliers, the SD of vial volumes among all products was 208.93ml.

Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.2% of products (n=2,981) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.57ml and the middle value of the vial volumes reported (median) was 10ml. This is depicted in **Table 3**.

Only 25 non-compliant refill containers/cartridges (volume >10ml) were identified in the Denmark EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with extremely large vial volumes. The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Denmark

	Vial volume (ml)		
	All products n=3006	**Compliant products (≦10ml)** n= 2981	**Non-compliant products (>10ml)** n= 25
Min.	0.67	0.67	12
Median	10	10	30
Mean	13.53	9.574	485.4
Max.	11464	10	11464
SD	208.93	1.85	2287.21

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 1,763 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 1,403 products reported a value for capacity and 360 products (20.4%) were missing reports. All of the 360 submissions missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 1,403 products which reported a value for capacity, 1,166 products (83.1%) reported valid capacity (>0 ml) and

237 products (16.9%) reported invalid values (i.e. 0 ml). Over half of the 237 products reporting invalid values for capacity (n=164) were listed as 'rechargeable, device only.'

Among the 1,166 products that reported a valid capacity in Denmark, the average capacity was 2.22ml (SD=1.37 ml). The middle value of the capacities reported (median) was 2ml. This distribution is presented in **Table 4** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in cartridges or tanks which do not exceed a capacity of 2 ml*. Given that cartridges or tanks placed on the market without a nicotine-containing e-liquid can still be used for the consumption of nicotine-containing vapour, compliance with Article 20.3 of the EU TPD of product types sold with, and/or capable of containing, an e-liquid was assessed in this analysis. Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 88.9% of products (n=1,037) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.83ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=129) had an average capacity of 5.36ml. The volume distribution of these non-compliant products is depicted in **Table 4** below, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, 12 non-compliant nicotine-containing disposable e-cigarettes (15.8%) were flagged. Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 9 (2.1%) of submissions listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 8 (3.5%) of the rechargeable devices, and 100 (15.3%) of the refillable devices, were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Denmark

	Capacity (ml)			
	All reported (n= 1403)	**All valid (>0 ml)** (n= 1166)	**Valid, Compliant (≦2ml)** (n= 1037)	**Valid, Non-compliant (>2ml)** (n=129)
Min.	0	0.01	0.01	2.4
Median	2	2	2	5
Mean	1.845	2.22	1.83	5.358
Max.	12	12	2	12
SD	1.5	1.37	0.38	2.18
Invalid (=0 ml)	n= 237			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other,' and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 3,233 notifications on e-liquid products sold in refill cartridges/containers, 227 (7%) did not contain nicotine. The average nicotine concentration among the remaining 3,006 nicotine-containing e-liquid products was 8.60 mg/ml, and the middle value of the reported nicotine concentrations (median) was 6 mg/ml. These distributions are depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* All of the 3,233 nicotine-containing e-liquid products in the Denmark EU CEG reported to be compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Denmark

	Nicotine concentration (mg/ml)
	All products (n=3006)
Min.	0.3
Median	6
Mean	8.6
Max.	20
SD	6.11

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Denmark EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 180 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was lower reported capacity for disposable e-cigarettes (mode: 285mA) compared to refillable e-cigarette devices sold as ‘device only’ (mode: 3000mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 1500/18650mA). With regards to whether the airflow is adjustable or if the wick is changeable, none of the 76 disposable e-cigarettes were found to have the ability to alter airflow or to change the wick. However, among the 662 products listed as ‘refillable, device only’, 74.6% (n=494) noted the ability to adjust airflow and 46.4% (n=305) had the ability to change the wick, and among the 229 products listed as ‘rechargeable device only’, 21.4% (n=49) had the ability to adjust airflow and 9.2% (n=21) had the ability to change the wick. This represents the plethora of product designs available on the market. A similar pattern was identified for the presence of a microprocessor, which was predominately present in rechargeable devices sold as ‘device only’ (61.6%) and in kits (70.7%), whereas only 10.5% of the 76 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

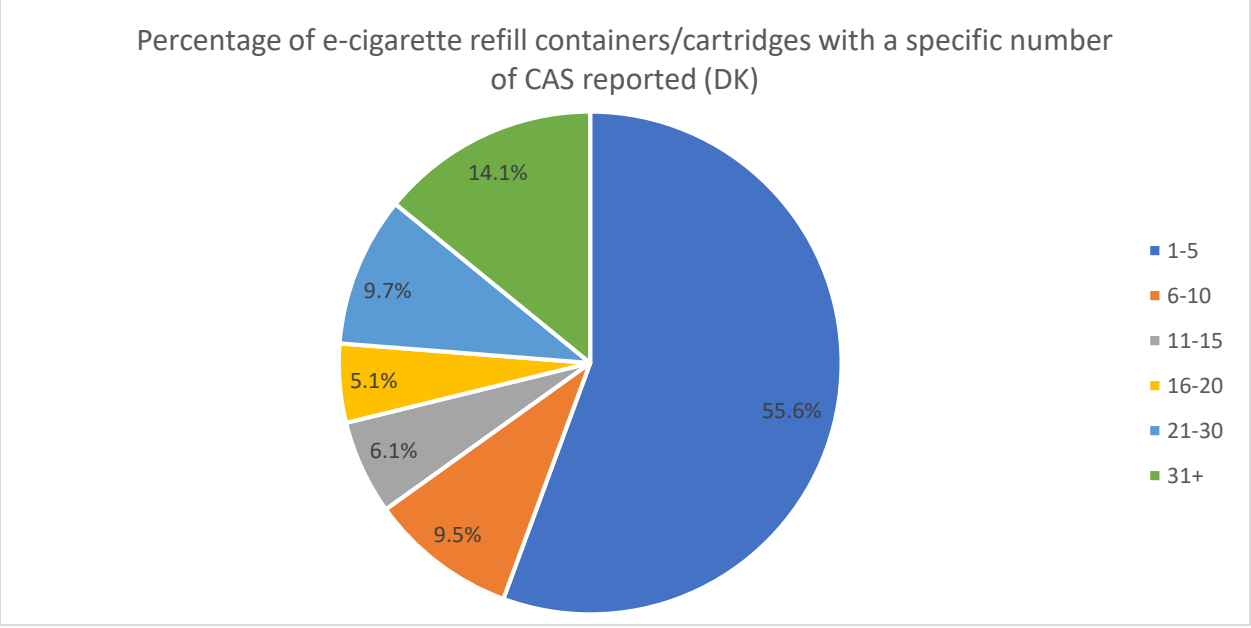
Among the 3,233 submissions for refill containers/cartridges within the Denmark EU-CEG database with a "not withdrawn" status, 702 unique CAS numbers were submitted.

All products listed as refill containers/cartridges in the Denmark EU CEG reported at least one CAS. Among the 3,233 submissions for refill containers/cartridges, 55.6% reported between 1 to 5 CAS and 14.1% reported more than 31 CAS. The complete breakdown is displayed in **Table 6** and depicted in **Figure 3**.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Denmark (n=3,233)

Number of CAS per product	n	% (total)
1-5	1798	55.6%
6-10	307	9.5%
11-15	196	6.1%
16-20	164	5.1%
21-30	312	9.7%
31+	456	14.1%
Invalid (no CAS reported)	0	0.0%

Figure 3. Breakdown of the number of CAS reported within one product (among all refill containers/cartridges), Denmark (n=3,233)



The average number of ingredients per product was 13.04, ranging between 1 to 136 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall Denmark, (n=3,233)

	Number of CAS **All refill containers/cartridges** (n= 3233)
Min.	1
Median	4
Mean	13.04
Max.	136
SD	15.96
# Invalid (no CAS reported)	n=0

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges (n=3,233) a total of 702 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed below in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Denmark (n=3,233)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	3,108	96.1%
2	54-11-5	Nicotine	3,093	95.7%
3	56-81-5	Glycerol	3,033	93.8%
4	105-54-4	Ethyl butyrate	932	28.8%
5	121-33-5	Vanillin	867	26.8%
6	4940-11-8	Ethyl maltol	760	23.5%
7	3658-77-3	Furaneol	694	21.5%
8	118-71-8	Maltol	657	20.3%
9	141-78-6	Ethyl acetate	646	20.0%
10	7732-18-5	Water	586	18.1%
11	706-14-9	γ-Decalactone	574	17.8%
12	7452-79-1	Ethyl 2-methylbutyrate	548	17.0%
13	928-96-1	cis-3-Hexen-1-ol	526	16.3%
14	64-17-5	Ethyl alcohol	526	16.3%
15	123-92-2	Isoamyl acetate	514	15.9%
16	107-92-6	Butyric acid	507	15.7%
17	78-70-6	Linalool	458	14.2%
18	64-19-7	Acetic acid	458	14.2%
19	121-.32-4	Ethyl vanillin	454	14.0%
20	123-66-0	Ethyl hexanoate	406	12.6%
21	765-70-8	Methyl Cyclopentenolone	383	11.8%
22	705-86-2	δ-Decalactone	377	11.7%
23	116-53-0	(±)-2-Methylbutyric acid	371	11.5%
24	104-67-6	γ-Undecalactone	368	11.4%
25	56038-13-2	Sucralose	368	11.4%

26	142-62-1	Hexanoic acid	364	11.3%
27	3681-71-8	cis-3-Hexenyl acetate	357	11.0%
28	104-50-7	γ-Octalactone	337	10.4%
29	102-76-1	Triacetin	323	10.0%
30	100-52-7	Benzaldehyde	313	9.7%
31	142-92-7	Hexyl acetate	309	9.6%
32	108-64-5	Ethyl isovalerate	305	9.4%
33	5471-51-2	Frambione	298	9.2%
34	100-51-6	Benzyl alcohol	297	9.2%
35	120-57-0	Piperonal	289	8.9%
36	659-70-1	Isoamyl isovalerate	287	8.9%
37	123-11-5	p-Anisaldehyde	277	8.6%
38	105-37-3	Ethyl propionate	257	7.9%
39	140-11-4	Benzyl acetate	245	7.6%
40	105-13-5	4-Methoxybenzyl alcohol	240	7.4%
41	98-55-5	α-Terpineol	237	7.3%
42	104-61-0	γ-Nonanoic lactone	230	7.1%
43	103-26-4	Methyl cinnamate	223	6.9%
44	713-95-1	δ-Dodecalactone	217	6.7%
45	5392-40-5	Citral	205	6.3%
46	22047-25-2	2-Acetylpyrazine	200	6.2%
47	2216-51-5	L-Menthol	187	5.8%
48	110-19-0	Isobutyl acetate	185	5.7%
49	115-95-7	Linalyl acetate	183	5.7%
50	80-71-7	Methyl cyclopentenolone	181	5.6%
51	137-00-8	4-Methyl-5-thiazoleethanol	181	5.6%
52	513-86-0	Acetoin	180	5.6%
53	77-93-0	Triethyl citrate	176	5.4%
54	695-06-7	γ-Hexalactone	169	5.2%
55	56-40-6	Glycine	167	5.2%
56	124-07-2	Octanoic acid	165	5.1%
57	134-20-3	Methyl anthranilate	163	5.0%
58	7492-70-8	Butyl butyryllactate	162	5.0%
59	106-24-1	Geraniol	158	4.9%
60	79-09-4	Propionic acid	158	4.9%
61	106-27-4	Isoamyl butyrate	156	4.8%
62	23696-85-7	Damascenone	148	4.6%
63	123-51-3	Isoamyl alcohol	147	4.5%
64	127-41-3	α-Ionone	145	4.5%
65	14667-55-1	2,3,5-Trimethylpyrazine	144	4.5%
66	123-68-2	Allyl hexanoate	135	4.2%
67	111-27-3	1-Hexanol	134	4.1%
68	79-77-6	(E)-β-ionone	133	4.1%
69	8008-56-8	Lemon oil	132	4.1%
70	90-05-1	Guaiacol	127	3.9%
71	6728-26-3	trans-2-Hexen-1-al	125	3.9%
72	38462-22-5	8-Mercaptomenthone	124	3.8%

73	14901-07-6	β-Ionone	123	3.8%
74	106-22-9	β-Citronellol	120	3.7%
75	97-53-0	Eugenol	113	3.5%
76	75-18-3	Dimethyl sulfide	110	3.4%
77	66-25-1	Hexanal	109	3.4%
78	8008-57-9	Orange oil	107	3.3%
79	119-84-6	Dihydrocoumarin	107	3.3%
80	106-72-9	Melonal	106	3.3%
81	89-78-1	Menthol	106	3.3%
82	120-51-4	Benzyl benzoate	104	3.2%
83	105-87-3	Geranyl acetate	100	3.1%
84	60-12-8	2-Phenylethanol	100	3.1%
85	97-64-3	Ethyl lactate	99	3.1%
86	109-21-7	Butyl butyrate	99	3.1%
87	16491-36-4	cis-3-Hexenyl butyrate	98	3.0%
88	2305-05-7	4,5,6,7-Tetrahydroindazole	97	3.0%
89	138-86-3	Dipentene	88	2.7%
90	67-63-0	2-Propanol	88	2.7%
91	104-55-2	Cinnamaldehyde	88	2.7%
92	2432-51-1	Methyl thiobutyrate	86	2.7%
93	334-48-5	Decanoic acid	84	2.6%
94	23726-91-2	β-Damascone	83	2.6%
95	112-31-2	Decanol	80	2.5%
96	51115-67-4	2-Isopropyl-N,2,3-trimethylbutyramide	78	2.4%
97	1754-62-7	Methyl trans-cinnamate	74	2.3%
98	106-32-1	Ethyl octanoate	72	2.2%
99	8006-90-4	Peppermint oil	68	2.1%
100	127-91-3	β-Pinene	67	2.1%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=3,233)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity (mg per product), concentration, and major function are presented below in **Table 9**. Besides the carriers (propylene glycol and glycerol), nicotine was the most common ingredient, primarily functioning as an addictive enhancer. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Denmark

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4662.00	3126.40	470.00	321.64	4662.00	-
2	54-11-5	Nicotine	30.00	61.18	6.00	6.84	30.00	-
3	56-81-5	Glycerol	6268.08	4671.21	630.50	469.78	6268.08	-
4	105-54-4	Ethyl butyrate	2.27	14.11	0.28	1.48	2.27	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
5	121-33-5	Vanillin	4.24	32.06	0.55	3.10	4.24	Powerful, creamy, vanilla-like odor & sweet taste
6	4940-11-8	Ethyl maltol	9.74	46.60	0.97	4.06	9.74	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	3658-77-3	Furaneol	1.78	9.25	0.20	0.92	1.78	Fruity, caramelized pineapple-strawberry odor & taste; roasted
8	118-71-8	Maltol	1.44	8.68	0.20	0.89	1.44	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
9	141-78-6	Ethyl acetate	0.81	4.59	0.11	0.52	0.81	Ethereal, sharp, wine-brandy like odor
10	7732-18-5	Water	40.14	124.84	5.04	17.27	40.14	-
11	706-14-9	γ-Decalactone	1.02	3.57	0.12	0.36	1.02	Coconut-peach like odor; in dilution, peach taste
12	7452-79-1	Ethyl 2-methylbutyrate	2.50	16.39	0.28	1.76	2.50	Strong, green, fruity, apple odor and taste; also some strawberry notes
13	928-96-1	cis-3-Hexen-1-ol	1.00	5.25	0.12	0.54	1.00	Strong, fresh, green, grassy odor
14	64-17-5	Ethyl alcohol	11.63	93.99	1.56	8.20	11.63	-
15	123-92-2	Isoamyl acetate	1.20	7.35	0.15	0.81	1.20	Sweet, fruity, banana, pear odor & taste
16	107-92-6	Butyric acid	0.84	6.19	0.09	0.58	0.84	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor
17	78-70-6	Linalool	0.40	2.79	0.05	0.29	0.40	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste
18	64-19-7	Acetic acid	0.84	3.47	0.10	0.36	0.84	Pungent, sour, vinegar odor with sour, acid taste
19	121-.32-4	Ethyl vanillin	6.76	27.87	0.68	2.85	6.76	Intense, sweet, vanilla like odor; creamy vanilla taste
20	123-66-0	Ethyl hexanoate	0.36	3.68	0.05	0.39	0.36	Strong, fruity, pineapple, banana with strawberry, pear & tropical notes

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Denmark EU CEG.

**Flavour descriptions* are according to a desk literature review.

Conclusions

Summary of Results

Within the current Denmark EU-CEG dataset, there are 9,576 notifications (unique EC-IDs), of which 2,704 were indicated to be withdrawn from the market. The most common type of product active in the Denmark EU CEG was refill containers/cartridges containing e-liquids (n=3,233).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.2% of products reporting a vial volume of 10ml or less. Non-compliant products (n=25) included extreme outliers reporting a maximum vial volume of 11,464ml. Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the capacity, with 88.9% reporting a capacity of 2ml or less. Non-compliant products (n=129) reported a maximum capacity of 10ml. A significant number of invalid values (=0ml) were reported for capacity (n=237), more than half of which were characterized as rechargeable e-cigarette devices (device only).

With regards to the nicotine concentration, all of the e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 702 unique CAS numbers reported in the Denmark EU CEG. The average number of ingredients per product was 13, ranging between 1 and 136 different CAS per product. The most common ingredients in frequency were the humectants propylene glycol and glycerol, and nicotine. The most frequently reported flavorings were ethyl butyrate, vanilla, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Outliers are a limitation of the current analysis of the Denmark EU-CEG dataset (in particular for vial volume) a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Denmark EU CEG (specifically for capacity) suggests a need to redefine or clarify product type categories and their relevant variables. For example, products missing reports for capacity, and over 50% of those reporting invalid values for capacity, were categorized as ‘individual parts of e-cigarettes capable of containing an e-liquid.’
- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume/capacity and nicotine concentration), or to change the variable type from “text” variables to “numeric” variables to ensure correct and consistent reporting.

- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report SLOVENIA

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Below we provide an analysis for the EU MS Slovenia. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in October of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Slovenia EU-CEG dataset, there are 25,040 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type was a notification for a new product EC-ID (28.1%), followed by the removal of a product presentation (20.5%), and the addition of a product presentation (18.1%).

Figure 1. Type of notifications within EU-CEG, Slovenia (N= 25,040)

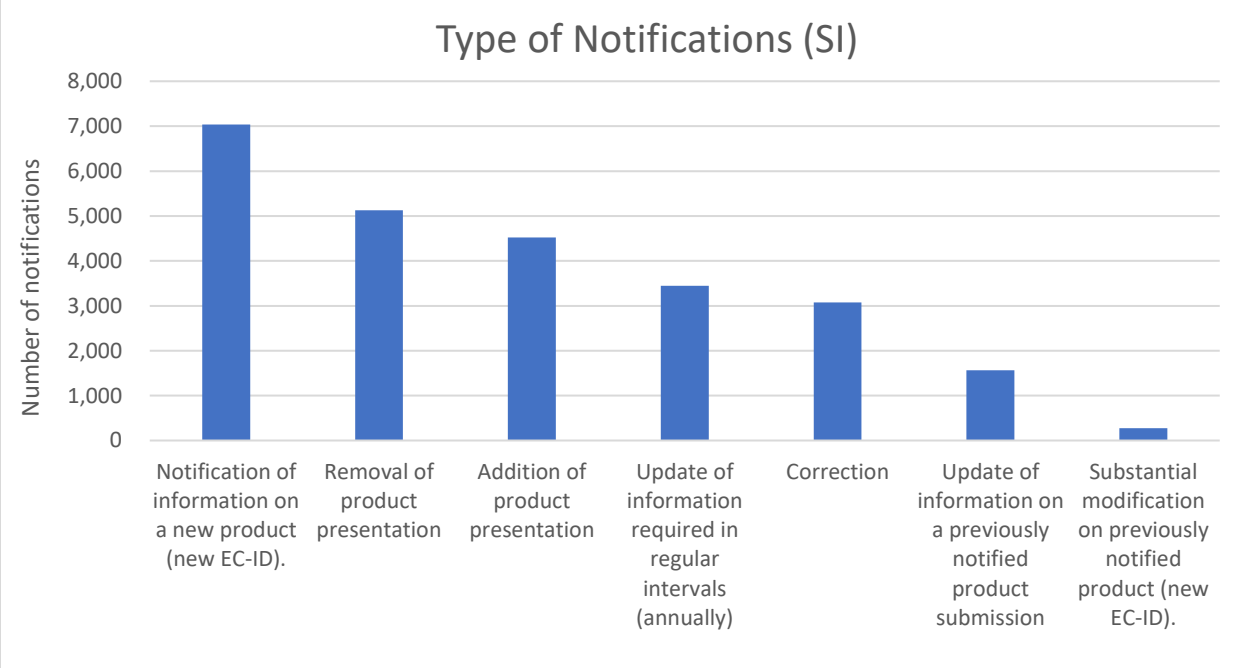


Table 1. Type of notifications within EU-CEG in Slovenia (N=25,040)

Notification Type	N	%
Notification of information on a new product (new EC-ID).	7,035	28.1%
Removal of product presentation, including product withdrawal, from an existing product submission.	5,124	20.5%
Addition of product presentation (e.g. national market) to an existing product submission.	4,523	18.1%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	3,443	13.8%
Correction of clerical/administrative errors in existing product submission.	3,077	12.3%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	1,561	6.2%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	277	1.1%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 25,040 notifications (unique EC-IDs) submitted for Slovenia in the EU CEG, 4,902 (19.6%) have been withdrawn while 20,138 (80.4%) unique EC-IDs remain active on the market. This analysis is restricted to products that are currently active.

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG in Slovenia is displayed in **Table 2** (below). Of the 20,138 notifications for products that are currently on the market, 62.5% (n=12,585) represented refill containers/cartridges containing an e-liquid, 10.8% (n=2,174) represented a submission for 'other' product type, and 9.0% (n=1,817) represented a submission for an individual part of e-cigarette capable of containing e-liquid.

Figure 2. Product types active (not withdrawn) in EU-CEG, Slovenia (n=20,138)

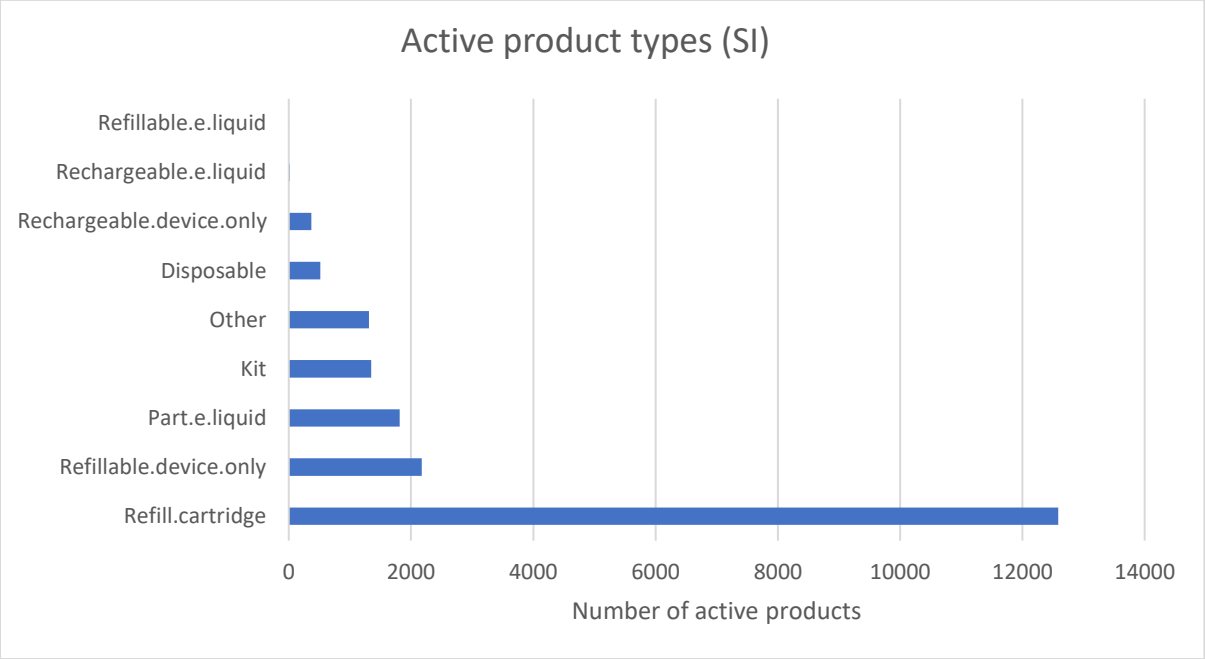


Table 2. Breakdown of product types active in EU-CEG, Slovenia (n=20,138)

Product type	n	%
Refill container/cartridge containing e-liquid	12585	62.5%
Refillable, device only	2174	10.8%
Individual part of e-cigarette capable of containing e-liquid	1817	9.0%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	1351	6.7%
Other	1310	6.5%
E-cigarette– Disposable	514	2.6%
E-cigarette – Rechargeable, device only	368	1.8%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	17	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	2	0.0%

2. Assessment of volume and nicotine content in nicotine containing liquids

2.1 Volume/capacity of nicotine-containing e-cigarette liquid TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 12,585 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 4 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 12,581 refill containers/cartridges reporting valid vial volumes (> 0 ml), 12,001 are reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 12,001 nicotine-containing refill containers/cartridges that that reported valid vial volumes in Slovenia, the average vial volume was 9.86 ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the wide range of vial volumes reported and outliers, the SD of vial volumes among all products was 1.81ml.

Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.6% of products (n=11,956) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.79ml and the middle value of the vial volumes reported (median) was 10ml. This is depicted in **Table 3**.

Only 45 non-compliant refill containers/cartridges (volume >10ml) were identified in the Slovenia EU-CEG, reporting a maximum vial volume of 50ml. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with extremely large vial volumes. The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Slovenia

	Vial volume (ml)		
	All products n=12001	**Compliant products (≦10ml)** n=11956	**Non-compliant products (>10ml)** n= 45
Min.	0.67	0.67	12
Median	10	10	30
Mean	9.857	9.789	27.82
Max.	50	10	50
SD	1.81	1.33	8.87

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 4,883 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 4,046 products reported a value for capacity and 837 products (17.1%) were missing reports. All of the 837 submissions missing

reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 4,046 products which reported a value for capacity, 3,823 products (94.5%) reported valid capacity (>0 ml) and 223 products (5.5%) reported invalid values (i.e. 0 ml). Over half of the 223 products reporting invalid values for capacity (n=127) were listed as 'rechargeable, device only, and the majority of the remaining invalid values for capacity (n=84) were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.'

Among the 3,823 products that reported a valid capacity in Slovenia, the average capacity was 2.88ml (SD= 2.5ml). The middle value of the capacities reported (median) was 2ml. This distribution is presented in **Table 4** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in cartridges or tanks which do not exceed a capacity of 2 ml*. Given that cartridges or tanks placed on the market without a nicotine-containing e-liquid can still be used for the consumption of nicotine-containing vapour, compliance with Article 20.3 of the EU TPD of product types sold with, and/or capable of containing, an e-liquid was assessed in this analysis. Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 75.5% of products (n=2,885) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.83ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=938) had an average capacity of 6.11ml and reported a maximum capacity of 60ml. The volume distribution of these non-compliant products is depicted in **Table 4** below, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, 938 non-compliant nicotine-containing disposable e-cigarettes (49.9%) were flagged. Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 85 submissions listed as 'individual parts of e-cigarettes capable of containing an e-liquid' (9.49%), 34 rechargeable devices (14.1%), and 567 refillable devices (26.2%), were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Slovenia

	Capacity (ml)			
	All reported (n= 4046)	**All valid (>0 ml)** (n= 3823)	**Valid, Compliant (≦2ml)** (n=2885)	**Valid, Non-compliant (>2ml)** (n=938)
Min.	0	0.01	0.01	2.2
Median	2	2	2	5
Mean	2.721	2.88	1.829	6.112
Max.	60	60	2	60
SD	2.52	2.5	0.38	3.36
Invalid (=0 ml)	n=223			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other,' and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 12,585 notifications on e-liquid products sold in refill cartridges/containers, 581 (4.6%) did not contain nicotine. The average nicotine concentration among the remaining 12,004 nicotine-containing e-liquid products was 9.75 mg/ml, and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. These distributions are depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* Almost all (99.9%) of the 12,004 nicotine-containing e-liquid products in the Slovenia EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 11,995 compliant products, the average nicotine concentration was 9.74 mg/ml and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. This is displayed in **Table 5**.

Only 9 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. The maximum nicotine concentration reported among non-compliant products was 60mg/ml. The distribution of nicotine concentration for these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Slovenia

	Nicotine concentration (mg/ml)		
	All products (n=12,004)	**Compliant products (≦20 mg/ml)** (n=11,995)	**Non-compliant products (>20 mg/ml)** (n= 9)
Min.	0.3	0.3	20.02
Median	9	9	20.5
Mean	9.751	9.737	29.17
Max.	60	20	60
SD	6.12	6.08	17.48

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Slovenia EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 255 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was lower reported capacity for disposable e-cigarettes (mode: 350mA) compared to refillable e-cigarette devices sold as ‘device only’ (mode: 350mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 3000mA). With regards to whether the airflow is adjustable or if the wick is changeable, almost none of the 350 disposable e-cigarettes were found to have the ability to alter airflow (n=0) or to change the wick (n=1). However, among the 2,147 products listed as

'refillable, device only', 70.4% (n=1,530) noted the ability to adjust airflow and 31.7% (n=688) had the ability to change the wick, and among the 368 products listed as 'rechargeable device only', 44.8% (n=165) had the ability to adjust airflow and 16.0% (n=59) had the ability to change the wick. This represents the plethora of product designs available on the market. A similar pattern was identified for the presence of a microprocessor, which was predominately present in refillable devices sold as 'device only' (69.5%) and in rechargeable devices sold as 'device only' (78.8%), whereas only 10.9% of the 514 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

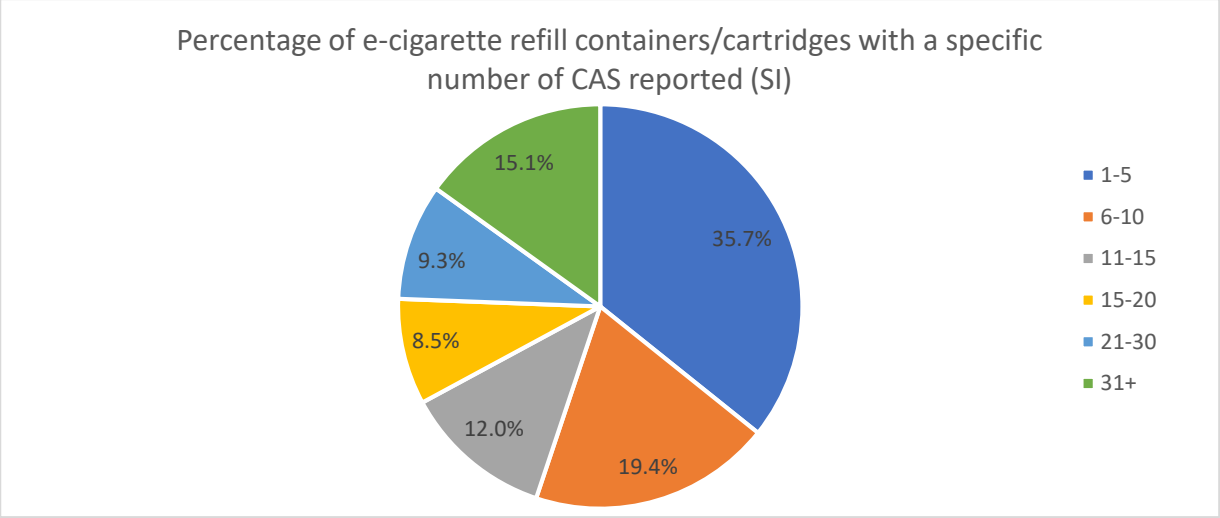
Among the 12,585 submissions for refill containers/cartridges within the Slovenia EU-CEG database with a "not withdrawn" status, 1,286 unique CAS numbers were submitted.

All products listed as refill containers/cartridges in the Slovenia EU CEG reported at least one CAS. Among the 12,585 submissions for refill containers/cartridges, 35.7% reported between 1 to 5 CAS, 19.4% reported between 6 to 10 CAS, and 14.1% reported more than 31 CAS. The complete breakdown is displayed in **Table 6** and depicted in **Figure 3**.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Slovenia (n=12,585)

Number of CAS per product	n	% (total)
1-5	4499	35.7%
6-10	2440	19.4%
11-15	1508	12.0%
16-20	1068	8.5%
21-30	1171	9.3%
31+	1899	15.1%
Invalid (no CAS reported)	0	0.0%

Figure 3. Breakdown of the number of CAS reported within one product (among all refill containers/cartridges), Slovenia (n=12,585)



The average number of ingredients per product was 15.09, ranging between 1 to 112 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall Slovenia, (n=12,585)

	Number of CAS **All refill containers/cartridges** (n= **12,585**)
Min.	1
Median	9
Mean	15.09
Max.	112
SD	15.68
# Invalid (no CAS reported)	n=0

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges (n=12,585) a total of 1,286 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed below in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Slovenia (n=12,585)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	12294	97.7%
2	54-11-5	Nicotine	11987	95.2%
3	56-81-5	Glycerol	10455	83.1%
4	105-54-4	Ethyl butyrate	4451	35.4%
5	121-33-5	Vanillin	4294	34.1%
6	4940-11-8	Ethyl maltol	3604	28.6%
7	7732-18-5	Water	3491	27.7%
8	141-78-6	Ethyl acetate	3107	24.7%
9	118-71-8	Maltol	3043	24.2%
10	64-17-5	Ethyl alcohol	2884	22.9%
11	3658-77-3	Furaneol	2641	21.0%
12	121-.32-4	Ethyl vanillin	2562	20.4%
13	56-40-6	Glycine	2453	19.5%
14	123-92-2	Isoamyl acetate	2413	19.2%
15	928-96-1	cis-3-Hexen-1-ol	2347	18.6%
16	706-14-9	γ-Decalactone	2321	18.4%
17	64-19-7	Acetic acid	2162	17.2%
18	7452-79-1	Ethyl 2-methylbutyrate	2102	16.7%
19	100-51-6	Benzyl alcohol	1980	15.7%
20	78-70-6	Linalool	1959	15.6%
21	107-92-6	Butyric acid	1957	15.6%
22	123-66-0	Ethyl hexanoate	1784	14.2%
23	765-70-8	3-Methyl-1,2-cyclopentanedione	1645	13.1%

24	120-57-0	Piperonal	1575	12.5%
25	105-37-3	Ethyl propionate	1481	11.8%
26	100-52-7	Benzaldehyde	1452	11.5%
27	102-76-1	Triacetin	1450	11.5%
28	705-86-2	δ-Decalactone	1443	11.5%
29	142-92-7	Hexyl acetate	1391	11.1%
30	3681-71-8	cis-3-Hexenyl acetate	1353	10.8%
31	5471-51-2	Frambione	1338	10.6%
32	104-50-7	γ-Octalactone	1301	10.3%
33	108-64-5	Ethyl isovalerate	1280	10.2%
34	142-62-1	Hexanoic acid	1272	10.1%
35	104-67-6	γ-Undecalactone	1243	9.9%
36	140-11-4	Benzyl acetate	1232	9.8%
37	659-70-1	Isoamyl isovalerate	1204	9.6%
38	56038-13-2	Sucralose	1196	9.5%
39	116-53-0	(±)-2-Methylbutyric acid	1189	9.4%
40	123-11-5	p-Anisaldehyde	1180	9.4%
41	104-61-0	γ-Nonanoic lactone	1097	8.7%
42	103-26-4	Methyl cinnamate	1078	8.6%
43	713-95-1	δ-Dodecalactone	1029	8.2%
44	2216-51-5	L-Menthol	991	7.9%
45	80-71-7	Methyl cyclopentenolone	968	7.7%
46	5392-40-5	Citral	892	7.1%
47	127-41-3	α-Ionone	866	6.9%
48	22047-25-2	2-Acetylpyrazine	859	6.8%
49	137-00-8	4-Methyl-5-thiazoleethanol	838	6.7%
50	106-27-4	Isoamyl butyrate	828	6.6%
51	98-55-5	α-Terpineol	778	6.2%
52	14901-07-6	β-Ionone	776	6.2%
53	75-18-3	Dimethyl sulfide	762	6.1%
54	90-05-1	Guaiacol	762	6.1%
55	105-13-5	4-Methoxybenzyl alcohol	739	5.9%
56	513-86-0	Acetoin	739	5.9%
57	110-19-0	Isobutyl acetate	733	5.8%
58	97-53-0	Eugenol	730	5.8%
59	23696-85-7	Damascenone	720	5.7%
60	123-68-2	Allyl hexanoate	719	5.7%
61	119-84-6	Dihydrocoumarin	710	5.6%
62	106-24-1	Geraniol	678	5.4%
63	695-06-7	γ-Hexalactone	676	5.4%
64	60-12-8	2-Phenylethanol	676	5.4%
65	14667-55-1	2,3,5-Trimethylpyrazine	670	5.3%
66	111-27-3	1-Hexanol	668	5.3%
67	97-64-3	Ethyl lactate	661	5.3%
68	8008-56-8	Lemon oil	659	5.2%
69	123-51-3	Isoamyl alcohol	646	5.1%
70	7492-70-8	Butyl butyryllactate	578	4.6%

71	6728-26-3	trans-2-Hexen-1-al	573	4.6%
72	5989-27-5	(R)-(+)-Limonene	569	4.5%
73	134-20-3	Methyl anthranilate	539	4.3%
74	120-51-4	Benzyl benzoate	537	4.3%
75	115-95-7	Linalyl acetate	529	4.2%
76	105-87-3	Geranyl acetate	514	4.1%
77	104-55-2	Cinnamaldehyde	502	4.0%
78	77-92-9	Citric acid	501	4.0%
79	470-82-6	Eucalyptol	500	4.0%
80	138-86-3	Dipentene	488	3.9%
81	66-25-1	Hexanal	472	3.8%
82	2305-05-7	4,5,6,7-Tetrahydroindazole	469	3.7%
83	79-09-4	Propionic acid	466	3.7%
84	77-93-0	Triethyl citrate	458	3.6%
85	8008-57-9	Orange oil	452	3.6%
86	124-07-2	Octanoic acid	434	3.4%
87	620-02-0	5-Methylfurfural	421	3.3%
88	106-32-1	Ethyl octanoate	411	3.3%
89	89-78-1	Menthol	393	3.1%
90	38462-22-5	8-Mercaptomenthone	390	3.1%
91	79-77-6	β-Ionone	381	3.0%
92	93-92-5	1-Phenylethyl acetate	363	2.9%
93	928-95-0	trans-2-Hexen-1-ol	361	2.9%
94	8008-26-2	Lime oil	356	2.8%
95	150-78-7	1,4-Dimethoxybenzene	349	2.8%
96	1124-11-4	2,3,5,6-Tetramethylpyrazine	346	2.7%
97	4180-23-8	trans-Anethole	336	2.7%
98	110-38-3	Ethyl decanoate	332	2.6%
99	8006-90-4	Peppermint oil	324	2.6%
100	127-91-3	β-Pinene	319	2.5%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=12,585)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity (mg per product), concentration, and major function are presented below in **Table 9**. Besides the carriers (propylene glycol and glycerol), nicotine was the most common ingredient, primarily functioning as an addictive enhancer. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers, except for water, which was listed as a water-wetting agent, and glycine, which was most often reported as a carrier.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Slovenia

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4633.00	3877.40	467.58	392.18	Carrier	-
2	54-11-5	Nicotine	30.00	60.25	3.00	6.41	Addictive Enhancer	-
3	56-81-5	Glycerol	5000.00	4405.99	500.00	452.28	Carrier	-
4	105-54-4	Ethyl butyrate	3.99	17.36	0.40	1.76	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
5	121-33-5	Vanillin	5.56	27.24	0.58	2.85	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
6	4940-11-8	Ethyl maltol	9.02	26.82	0.91	2.74	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	7732-18-5	Water	180.33	426.27	18.03	43.00	Water-Wetting Agents	-
8	141-78-6	Ethyl acetate	2.24	14.96	0.24	1.51	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
9	118-71-8	Maltol	2.00	8.64	0.20	0.93	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
10	64-17-5	Ethyl alcohol	26.42	96.95	2.95	10.07	Flavour and/or Taste Enhancer	-
11	3658-77-3	Furaneol	2.88	9.76	0.29	1.02	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
12	121-.32-4	Ethyl vanillin	7.20	34.85	0.72	3.49	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
13	56-40-6	Glycine	7046.40	7188.18	704.64	718.82	Carrier	-
14	123-92-2	Isoamyl acetate	2.58	15.55	0.26	1.62	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
15	928-96-1	cis-3-Hexen-1-ol	2.03	7.82	0.21	0.80	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
16	706-14-9	γ-Decalactone	1.44	5.70	0.15	0.58	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
17	64-19-7	Acetic acid	2.55	8.74	0.26	0.88	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
18	7452-79-1	Ethyl 2-methylbutyrate	2.78	16.84	0.28	1.69	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
19	100-51-6	Benzyl alcohol	5.87	30.10	0.60	3.04	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste
20	78-70-6	Linalool	0.80	5.82	0.09	0.59	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Slovenia EU CEG.

**Flavour descriptions* are according to a desk literature review.

Conclusions

Summary of Results

Within the current Slovenia EU-CEG dataset, there are 25,040 notifications (unique EC-IDs), of which 4,902 were indicated to be withdrawn from the market. The most common type of product active in the Slovenia EU CEG was refill containers/cartridges containing e-liquids (n=12,585).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.6% of products reporting a vial volume of 10ml or less. Non-compliant products (n=45) included reported a maximum vial volume of 50ml. Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the capacity, with 75.5% reporting a capacity of 2ml or less. Non-compliant products (n=938) reported a maximum capacity of 60ml. A significant number of invalid values (=0ml) were reported for capacity (n=223).

With regards to the nicotine concentration, almost all (99.9%) of e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less. Only 9 products reported non-compliant nicotine concentrations, with a maximum reported nicotine concentration of 60mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,286 unique CAS numbers reported in the Slovenia EU CEG. The average number of ingredients per product was 15.09, ranging between 1 and 112 different CAS per product. The most common ingredients in frequency were the humectants propylene glycol and glycerol, and nicotine. The most frequently reported flavorings were ethyl butyrate, vanilla, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Missing and invalid data in the Slovenia EU CEG (specifically for capacity) suggests a need to redefine or clarify product type categories and their relevant variables. For example, products missing reports for capacity, and almost 50% of those reporting invalid values for capacity, were categorized as 'individual parts of e-cigarettes capable of containing an e-liquid.'
- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume/capacity and nicotine concentration), or to change the variable type from "text" variables to "numeric" variables to ensure correct and consistent reporting.
- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report LUXEMBOURG

Circulation: Internal

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and results by research question

Below we provide an analysis for the EU MS Luxembourg. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Luxembourg EU-CEG dataset, there are 13,275 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type, among products with valid notifications, was a notification for a new product EC-ID (25.6%), followed by the removal of a product presentation, including product withdrawal, from an existing product submission (20.4%), and the update of information required at regular intervals (20.2%).

Figure 1. Type of valid notifications within EU-CEG, Luxembourg (N= 13,275)

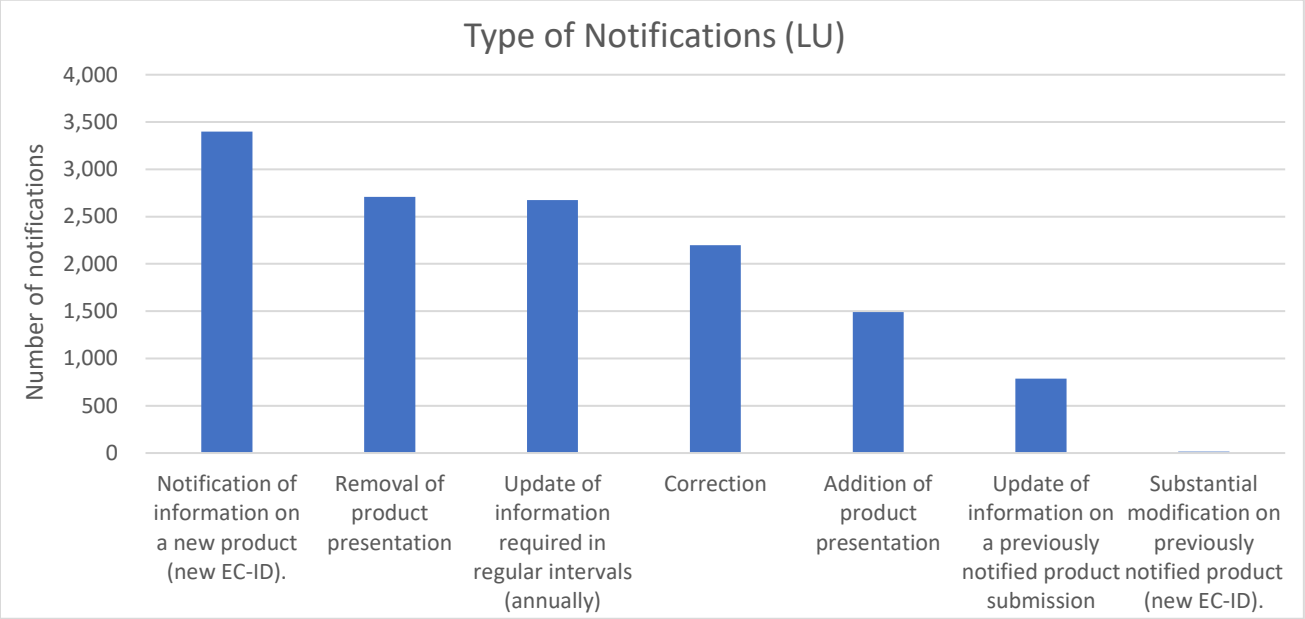


Table 1. Type of notifications within EU-CEG in Luxembourg (N=13,275)

Type	n	% (valid)
Notification of information on a new product (new EC-ID).	3,398	25.6%
Removal of product presentation, including product withdrawal, from an existing product submission.	2,708	20.4%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	2,676	20.2%
Correction of clerical/administrative errors in existing product submission.	2198	16.6%
Addition of product presentation (e.g. national market) to an existing product submission.	1,491	11.2%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	788	5.9%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	422	0.9%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 13,275 notifications (unique EC-IDs) submitted for Luxembourg in the EU CEG, 3,320 (25.0%) products have been withdrawn, while 9,955 (75.0%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active (n=9,955).

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG for Luxembourg is displayed in **Table 2** (below). Of the 9,995 notifications for products that are currently on the market, 78.3% (n=7,789) represented refill containers/cartridges containing an e-liquid, 6.3% (n=632) represented a refillable device (device only), and 4.7% (n=471) represented individual parts of e-cigarettes capable of containing e-liquids.

Figure 2. Product types active (not withdrawn) in EU-CEG, Luxembourg (n=9,955)

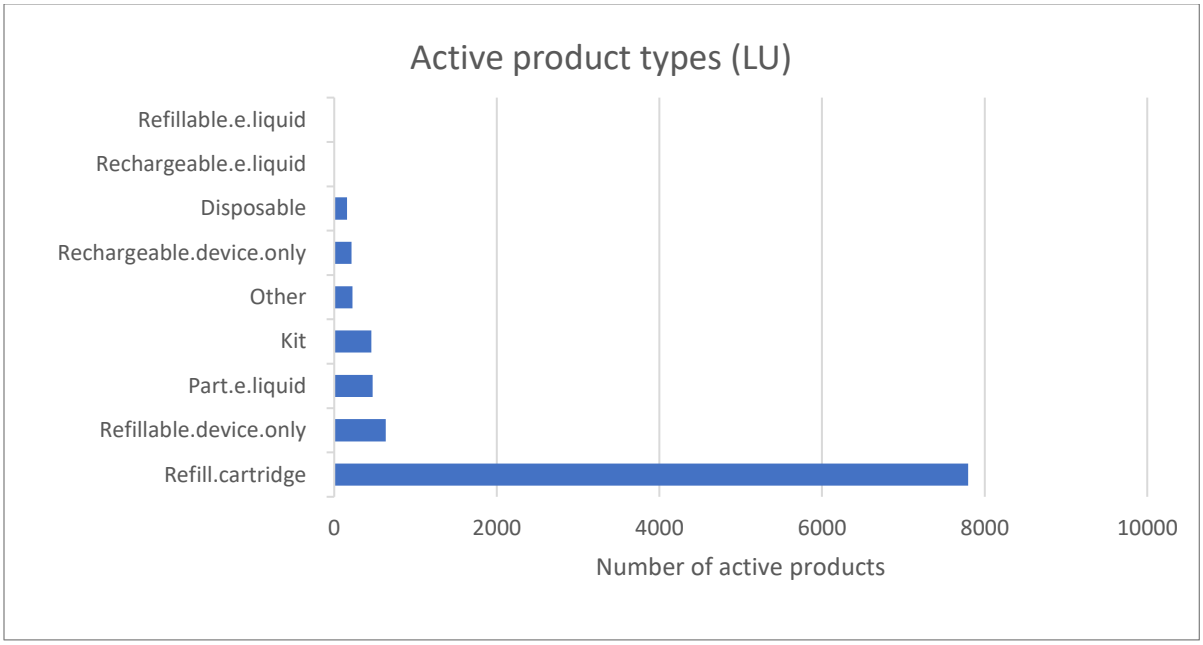


Table 2. Breakdown of product types active in EU-CEG types, Luxembourg (n=9,955)

Product type	n	%
Refill container/cartridge containing e-liquid	7797	78.3%
Refillable, device only	632	6.3%
Individual part of e-cigarette capable of containing e-liquid	471	4.7%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	458	4.6%
Other	226	2.3%
E-cigarette – Rechargeable, device only	211	2.1%
E-cigarette – Disposable	156	1.6%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	4	0.0%
E-cigarette – Refillable, placed on the market with one type of e-liquid	0	0.0%

2. Assessment of volume (capacity) and nicotine content

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 7,797 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), one product (flagged in **Annex A**) reported an invalid vial (container/cartridge) volume (i.e. 0 ml) and was thus excluded from the distribution analysis. Of the 7,796 refill containers/cartridges reporting valid vial volumes (>0 ml), 6,907 were reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 6,907 nicotine-containing refill containers/cartridges that reported valid vial volumes in Luxembourg, the average vial volume was 9.81ml. The middle value of the vial volumes reported (median) was 10ml, and the SD of values was 2.19. This distribution is presented in **Table 3** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml.* Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.5% of products (n=6,875) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.71ml and the middle value of the vial volume data set (median) was 10ml. This is depicted in **Table 3**.

There were 32 refill containers/cartridges identified as non-compliant (volume >10ml) in the Luxembourg EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below. The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Luxembourg

	Vial volume (ml)		
	All products n=6,907	**Compliant products (≦10ml)** n= 6,875	**Non-compliant products (>10ml)** n= 32
Min.	0.67	0.67	12
Median	10	10	30
Mean	9.813	9.714	31
Max.	50	10	50
SD	2.19	1.54	8.69

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 1,432 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 1,274 products reported a value for capacity and 158 products (11.0%) were missing reports. All of the 158 submissions that were missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the

1,274 products which reported a value for capacity, 1,058 products (83.0%) reported a valid capacity (>0 ml) and 216 products (17.0%) reported invalid values for capacity (i.e. 0 ml). Over half of the 216 products reporting invalid values for capacity (n=58) were listed as rechargeable e-cigarettes devices (device only).

Among the 1,058 products that reported a valid capacity (>0 ml) in Luxembourg, the average capacity was 2.34ml, and the middle value of the capacities reported (median) was 2ml. The SD of capacity among all products was 1.42ml. This distribution is presented in **Table 4** below.

Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 81.3% of products (n=860) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.78ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=198) had an average capacity of 4.81ml, and middle value (median) of 4.5ml. The maximum recorded capacity for products reporting non-compliant capacities was 10 ml and the SD was 1.6ml. The volume distribution of these non-compliant products is depicted in **Table 4**, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there were only 2 non-compliant nicotine-containing disposable e-cigarettes. Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 21 products listed as 'individual parts of e-cigarettes capable of containing an e-liquid'(8.9%), 16 rechargeable devices(18.8%), and 159 refillable devices (25.7%), were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Luxembourg

	Capacity (ml) **All reported** (n= 1274)	**All valid (>0 ml)** (n= 1058)	**Valid, Compliant (≦2ml)** (n= 860)	**Valid, Non-compliant (>2ml)** (n=198)
Min.	0	0.01	0.01	2.4
Median	2	2	2	4.5
Mean	1.946	2.343	1.775	4.811
Max.	10	10	2	10
SD	1.57	1.42	0.42	1.6
Invalid (=0 ml)	n= 216			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other', and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 7,797 notifications on e-liquid products sold in refill cartridges/containers, 890 (11.4%) did not contain nicotine. The average nicotine concentration among the remaining 6,907 nicotine-containing e-liquid products was 10.14 mg/ml and the middle value of the reported nicotine concentrations (median) was 10 mg/ml. This distribution is depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* Apart from 6 non-compliant products, almost all of the 6,907 nicotine-containing e-liquid products in the Luxembourg EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 6,907 compliant products, the average nicotine concentration was 10.06 mg/ml and the middle value of the reported nicotine concentrations (median) was 10 mg/ml. This is displayed in **Table 5**.

Among the 6 non-compliant products reporting a nicotine concentration greater than 20 mg/ml, the maximum recorded nicotine concentrations was 160 mg/ml, with an SD of 40.82mg/ml. The distribution of nicotine concentration of these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Luxembourg

	Nicotine concentration (mg/ml)		
	All products (n=6,907)	**Compliant products (≦20 mg/ml)** (n=6,901)	**Non-compliant products (>20 mg/ml)** (n= 6)
Min.	0.26	0.26	60
Median	10	10	85
Mean	10.14	10.06	93.33
Max.	160	20	160
SD	6.71	6.15	40.82

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Luxembourg EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 151 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was a wide range of capacities reported among different product types, for example disposable e-cigarettes (mode: 280mA), refillable e-cigarette devices sold as ‘device only’ (mode: 1500mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 1500mA). With regards to whether the airflow is adjustable or if the wick is changeable, none of the 156 disposable e-cigarettes were found to have the ability to alter airflow or change the wick. However, among the 632 products listed as ‘refillable, device only’, 71.0% (n= 449) noted the ability to adjust airflow and 2.7% (n=333) had the ability to change the wick, and among the 211 products listed as ‘rechargeable device only’, 31.3% (n=66) had the ability to adjust airflow and 19.9% (n=42) had the ability to change the wick. This suggests the plethora of product designs available on the market. A similar pattern was identified for the presence of microprocessor, which was largely present in rechargeable devices sold as ‘device only’ (84.8%), kits (77.3%), and refillable devices sold as ‘device only’ (52.1%), whereas only 8.9% of the 156 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

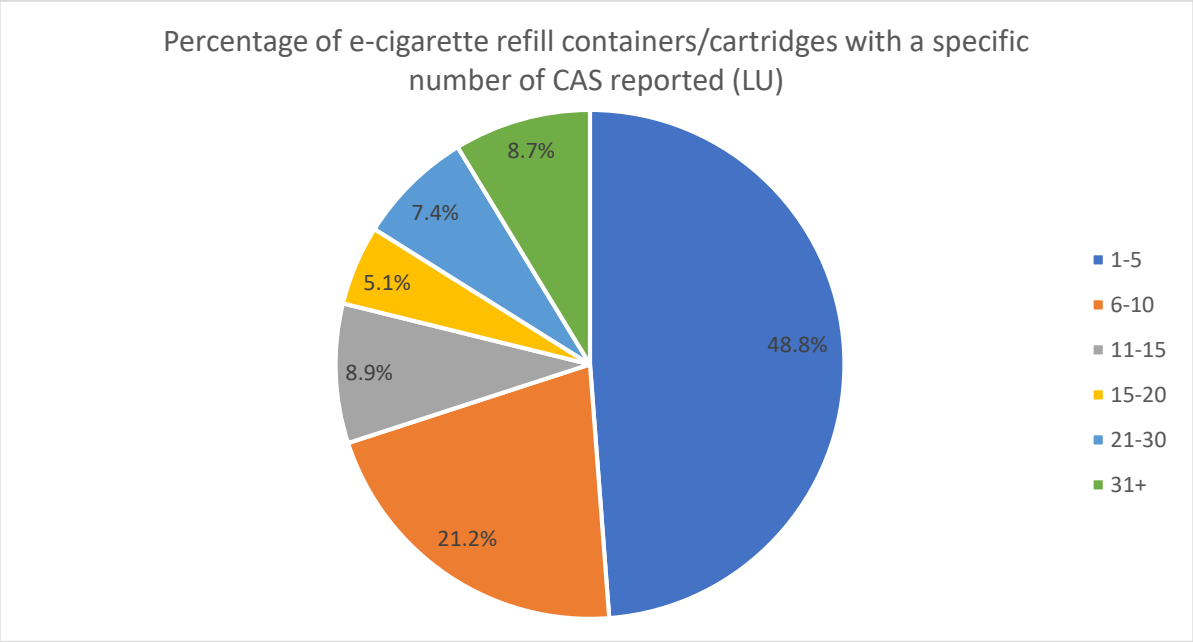
Among the 7,797 submissions for refill containers/cartridges within the Luxembourg EU-CEG database with a "not withdrawn" status, 1,107 unique CAS numbers were submitted.

Among the 7,797 submissions for refill containers/cartridges, 45.4% reported between 1 to 5 CAS and 19.7% reported between 6 to 10 CAS. The breakdown of number of CAS reported per product is displayed in **Table 6**. A proportion of products (6.9%) reported no CAS, thus their submissions were considered invalid and their EC-IDs are flagged in **Annex A**. **Figure 3** depicts the breakdown of the number of CAS reported within one product, excluding submissions with no CAS reported.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Luxembourg (n=7,797)

Number of CAS per product	Number of products	% (total)	% (excluding invalid)
1-5	3542	45.4%	48.8%
6-10	1539	19.7%	21.2%
11-15	643	8.2%	8.9%
16-20	368	4.7%	5.1%
21-30	535	6.9%	7.4%
31+	632	8.1%	8.7%
Invalid (no CAS reported)	538	6.9%	

Figure 3. Breakdown of the number of CAS reported within one product (among those that reported a CAS), Luxembourg (n=7,259)



Among valid submissions, the average number of ingredients per product was 11, ranging between 1 to 98 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID for all submissions and for all valid submissions is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall and among valid product submissions, Luxembourg

	Number of CAS All refill containers/cartridges (n= 7,797)	Valid CAS entry (n= 7,259)
Min.	0	1
Median	5	6
Mean	10.24	11
Max.	98	98
SD	12.62	12.76
Invalid (i.e. no CAS reported)	n = 538	

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges that contain an e-liquid which reported any CAS (n=7,259), a total of 1,107 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Luxembourg (n=7,259)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	56-81-5	Glycerol	6980	96.2%
2	57-55-6	Propylene glycol	6846	94.3%
3	54-11-5	Nicotine	6020	82.9%
4	121-33-5	Vanillin	2286	31.5%
5	105-54-4	Ethyl butyrate	1666	23.0%
6	4940-11-8	Ethyl maltol	1654	22.8%
7	7732-18-5	Water	1459	20.1%
8	118-71-8	Maltol	1162	16.0%
9	141-78-6	Ethyl acetate	1056	14.5%
10	64-17-5	Ethyl alcohol	1052	14.5%
11	121-32-4	Ethyl vanillin	1001	13.8%
12	123-92-2	Isoamyl acetate	988	13.6%
13	706-14-9	γ-Decalactone	935	12.9%
14	928-96-1	cis-3-Hexen-1-ol	865	11.9%
15	3658-77-3	Furaneol	833	11.5%
16	64-19-7	Acetic acid	744	10.2%
17	100-51-6	Benzyl alcohol	723	10.0%
18	7452-79-1	Ethyl 2-methylbutyrate	705	9.7%
19	107-92-6	Butyric acid	664	9.1%
20	78-70-6	Linalool	637	8.8%

21	765-70-8	3-Methyl-1,2-cyclopentanedione	626	8.6%
22	123-66-0	Ethyl hexanoate	606	8.3%
23	5471-51-2	Frambione	584	8.0%
24	102-76-1	Triacetin	581	8.0%
25	100-52-7	Benzaldehyde	579	8.0%
26	104-67-6	γ-Undecalactone	567	7.8%
27	120-57-0	Piperonal	567	7.8%
28	705-86-2	δ-Decalactone	543	7.5%
29	2216-51-5	L-Menthol	532	7.3%
30	3681-71-8	cis-3-Hexenyl acetate	512	7.1%
31	142-92-7	Hexyl acetate	509	7.0%
32	56038-13-2	Sucralose	501	6.9%
33	123-11-5	p-Anisaldehyde	496	6.8%
34	142-62-1	Hexanoic acid	487	6.7%
35	659-70-1	Isoamyl isovalerate	474	6.5%
36	116-53-0	(±)-2-Methylbutyric acid	461	6.4%
37	104-50-7	γ-Octalactone	458	6.3%
38	108-64-5	Ethyl isovalerate	449	6.2%
39	80-71-7	Methyl cyclopentenolone	424	5.8%
40	104-61-0	γ-Nonanoic lactone	417	5.7%
41	140-11-4	Benzyl acetate	398	5.5%
42	105-37-3	Ethyl propionate	386	5.3%
43	713-95-1	δ-Dodecalactone	385	5.3%
44	103-26-4	Methyl cinnamate	376	5.2%
45	106-27-4	Isoamyl butyrate	354	4.9%
46	22047-25-2	2-Acetylpyrazine	350	4.8%
47	105-13-5	4-Methoxybenzyl alcohol	346	4.8%
48	513-86-0	Acetoin	346	4.8%
49	14667-55-1	2,3,5-Trimethylpyrazine	330	4.5%
50	5989-27-5	(R)-(+)-Limonene	327	4.5%
51	123-51-3	Isoamyl alcohol	317	4.4%
52	5392-40-5	Citral	305	4.2%
53	137-00-8	4-Methyl-5-thiazoleethanol	294	4.1%
54	127-41-3	α-Ionone	291	4.0%
55	14901-07-6	β-Ionone	282	3.9%
56	110-19-0	Isobutyl acetate	280	3.9%
57	98-55-5	α-Terpineol	277	3.8%
58	119-84-6	Dihydrocoumarin	276	3.8%
59	4180-23-8	trans-Anethole	272	3.7%
60	6728-26-3	trans-2-Hexen-1-al	266	3.7%
61	89-78-1	Menthol	265	3.7%
62	104-55-2	Cinnamaldehyde	260	3.6%
63	66-25-1	Hexanal	258	3.6%
64	97-53-0	Eugenol	257	3.5%
65	60-12-8	2-Phenylethanol	255	3.5%
66	695-06-7	γ-Hexalactone	240	3.3%
67	111-27-3	1-Hexanol	238	3.3%

68	23696-85-7	Damascenone	235	3.2%
69	106-24-1	Geraniol	233	3.2%
70	123-68-2	Allyl hexanoate	230	3.2%
71	77-93-0	Triethyl citrate	227	3.1%
72	90-05-1	Guaiacol	223	3.1%
73	470-82-6	Eucalyptol	221	3.0%
74	123-86-4	Butyl acetate	220	3.0%
75	124-07-2	Octanoic acid	209	2.9%
76	97-64-3	Ethyl lactate	204	2.8%
77	105-87-3	Geranyl acetate	202	2.8%
78	115-95-7	Linalyl acetate	199	2.7%
79	79-09-4	Propionic acid	195	2.7%
80	23726-92-3	(Z)-β-Damascone	186	2.6%
81	2305-05-7	4,5,6,7-Tetrahydroindazole	185	2.5%
82	134-20-3	Methyl anthranilate	183	2.5%
83	7492-70-8	Butyl butyryllactate	182	2.5%
84	75-18-3	Dimethyl sulfide	178	2.5%
85	1122-62-9	2-Acetylpyridine	178	2.5%
86	50-21-5	DL-Lactic acid	175	2.4%
87	57817-89-7	Stevioside hydrate	175	2.4%
88	39711-79-0	N-Ethyl-p-menthane-3-carboxamide	174	2.4%
89	620-02-0	5-Methylfurfural	165	2.3%
90	1124-11-4	2,3,5,6-Tetramethylpyrazine	159	2.2%
91	120-51-4	Benzyl benzoate	151	2.1%
92	38462-22-5	8-Mercaptomenthone	138	1.9%
93	16491-36-4	cis-3-Hexenyl butyrate	138	1.9%
94	65-85-0	Benzoic acid	138	1.9%
95	101-41-7	Methyl phenylacetate	137	1.9%
96	141-97-9	Ethyl acetoacetate	132	1.8%
97	138-86-3	Dipentene	130	1.8%
98	106-32-1	Ethyl octanoate	129	1.8%
99	334-48-5	Decanoic acid	128	1.8%
100	94-86-0	Propenylguaethol	128	1.8%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=7,259)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity, concentration, and major function are presented below in **Table 9**. The carriers propylene glycol and glycerol were listed as the most common ingredients, followed by nicotine, primarily functioning as an addictive enhancer. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers, except water which was listed as a water-wetting agent.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Luxembourg

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	56-81-5	Glycerol	5000.00	11250.00	500.00	1125.00	Carrier	-
2	57-55-6	Propylene glycol	4900.00	4144.00	490.00	420.72	Carrier	-
3	54-11-5	Nicotine	30.00	61.57	3.00	6.39	Addictive Enhancer	-
4	121-33-5	Vanillin	10.00	29.39	1.00	2.97	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
5	105-54-4	Ethyl butyrate	4.00	11.45	0.40	1.16	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
6	4940-11-8	Ethyl maltol	10.00	24.42	1.16	2.53	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	7732-18-5	Water	112.03	475.79	11.50	47.73	Water-Wetting Agents	-
8	118-71-8	Maltol	2.16	7.90	0.22	0.77	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
9	141-78-6	Ethyl acetate	2.20	17.33	0.24	2.02	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
10	64-17-5	Ethyl alcohol	10.88	66.68	1.19	7.05	Flavour and/or Taste Enhancer	-
11	121-32-4	Ethyl vanillin	17.48	33.32	1.79	3.36	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
12	123-92-2	Isoamyl acetate	4.50	25.94	0.50	2.83	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
13	706-14-9	γ-Decalactone	1.16	4.63	0.12	0.46	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
14	928-96-1	cis-3-Hexen-1-ol	1.00	6.32	0.12	0.64	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
15	3658-77-3	Furaneol	1.98	11.85	0.20	1.16	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
16	64-19-7	Acetic acid	2.00	6.13	0.20	0.61	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
17	100-51-6	Benzyl alcohol	12.38	33.90	1.37	3.44	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste
18	7452-79-1	Ethyl 2-methylbutyrate	2.50	18.75	0.28	1.86	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
19	107-92-6	Butyric acid	0.85	4.34	0.09	0.40	Flavour and/or Taste Enhancer	-
20	78-70-6	Linalool	0.76	6.01	0.08	0.61	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Luxembourg EU CEG.
**Flavour descriptions* are according to a desk literature review, where available.

Conclusions

Summary of Results

Within the current Luxembourg EU-CEG dataset, there are 13,275 notifications (unique EC-IDs), of which 3,320 were indicated to be withdrawn from the market. The most common type of product active in the Luxembourg EU CEG was refill containers/cartridges containing e-liquids (n=7,797).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.5% of products reporting a vial volume of 10ml or less. Among products reporting non-compliant vial volumes (n=32), the maximum value was 50ml. Most containers/cartridges capable of carrying an e-liquid were compliant with regards to the capacity, with 81.3% reporting a volume capacity of 2ml or less. Non-compliant products (n=198) reported a maximum capacity of 10ml. A significant proportion of submissions reported invalid values (=0ml) for capacity (n=216), more than half of which were characterized as rechargeable e-cigarette devices (device only).

With regards to the nicotine concentration, almost all e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less. Only 6 products reported non-compliant nicotine concentrations products, among which the maximum nicotine concentration was 160 mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,107 unique CAS numbers reported in the Luxembourg EU CEG. The average number of ingredients per product, among products reporting CAS, was 11, ranging between 1 and 98 different CAS per product. A significant proportion of products (18.2%) reported no CAS. The most common ingredient in frequency were the humectants propylene glycol and glycerol, followed by nicotine. The most frequently reported flavorings were vanilla, ethyl butyrate, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Missing and invalid data in the Luxembourg EU CEG (e.g. vial volumes, capacity, CAS) suggests a need to redefine or clarify product type categories and their relevant variables. For example, all products missing reports for volume capacity were categorized as ‘individual parts of e-cigarettes capable of containing an e-liquid,’ suggesting a need to clarify the categorical definition.
- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables, or to change the variable type from “text” variables to “numeric” variables to ensure correct and consistent reporting (e.g. in battery type reporting).
- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ A mechanism should be in place to ensure that all products with e-liquids enter CAS information, given that 6.9% of refill cartridge/containers in the Luxembourg EU CEG reported no CAS.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report BELGIUM

Circulation: Internal

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Below we provide an analysis for the EU MS Belgium. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Belgium EU-CEG dataset, there are 27,754 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type was a correction of clerical/administrative errors in an existing product submission (25.1%), followed by a notification for a new product EC-ID (21.0%), and the removal of a product presentation, including product withdrawal (17.9%).

Figure 1. Type of notifications within EU-CEG, Belgium (N= 27,754)

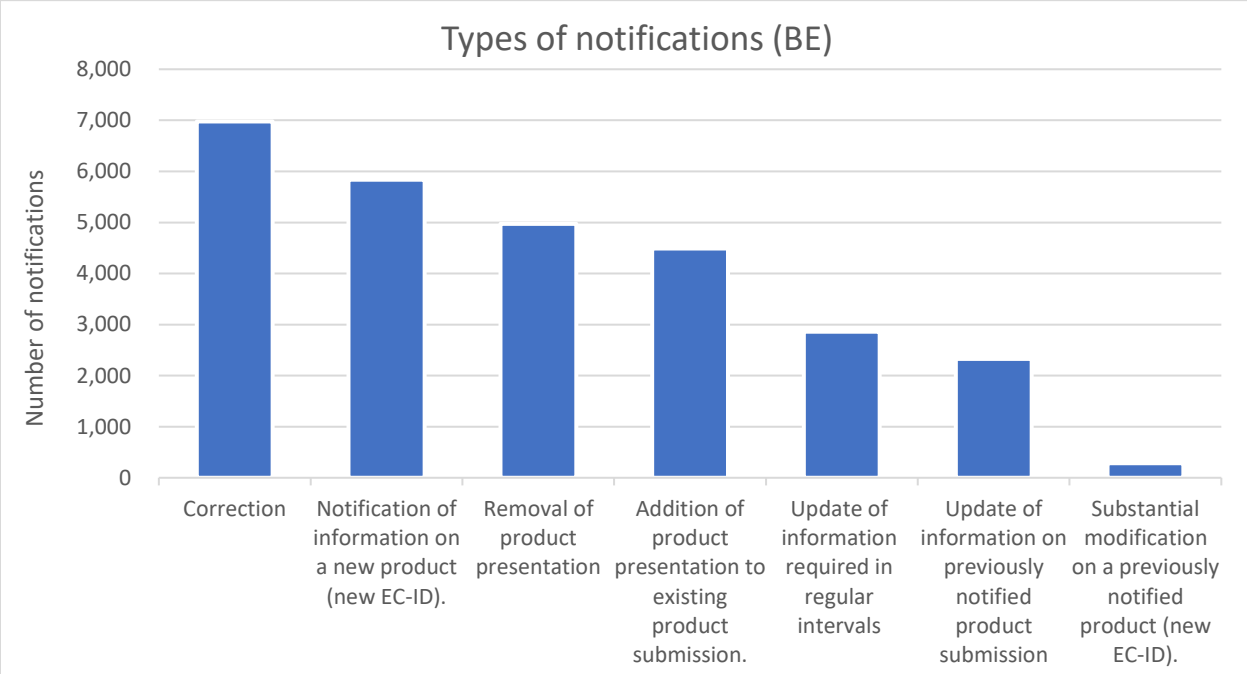


Table 1. Type of notifications within EU-CEG in Belgium (N=27,754)

Notification Type	n	%
Correction of clerical/administrative errors in existing product submission.	6,979	25.1%
Notification of information on a new product (new EC-ID).	5,834	21.0%
Removal of product presentation, including product withdrawal, from an existing product submission.	4,974	17.9%
Addition of product presentation (e.g. national market) to an existing product submission.	4,491	16.2%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	2,859	10.3%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	2,330	8.4%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	287	1.0%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 27,754 notifications (unique EC-IDs) submitted for Belgium for the EU CEG, 114 products indicated withdrawal but did not provide a specific date and were thus excluded from the analysis. Among valid notifications, 7,846 (28.4%) have been withdrawn and 19,794 (71.6%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active.

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG in Belgium is displayed in **Table 2** (below). Of the 19,794 notifications for products that are currently on the market, 74.0% (n=14,646) represented refill containers/cartridges containing an e-liquid, 7.9% (n=1,568) represented a refillable device (device only), and 7.3% (n=1,450) represented individual parts of e-cigarettes capable of containing e-liquids.

Figure 2. Product types active (not withdrawn) in EU-CEG, Belgium (n=19,794)

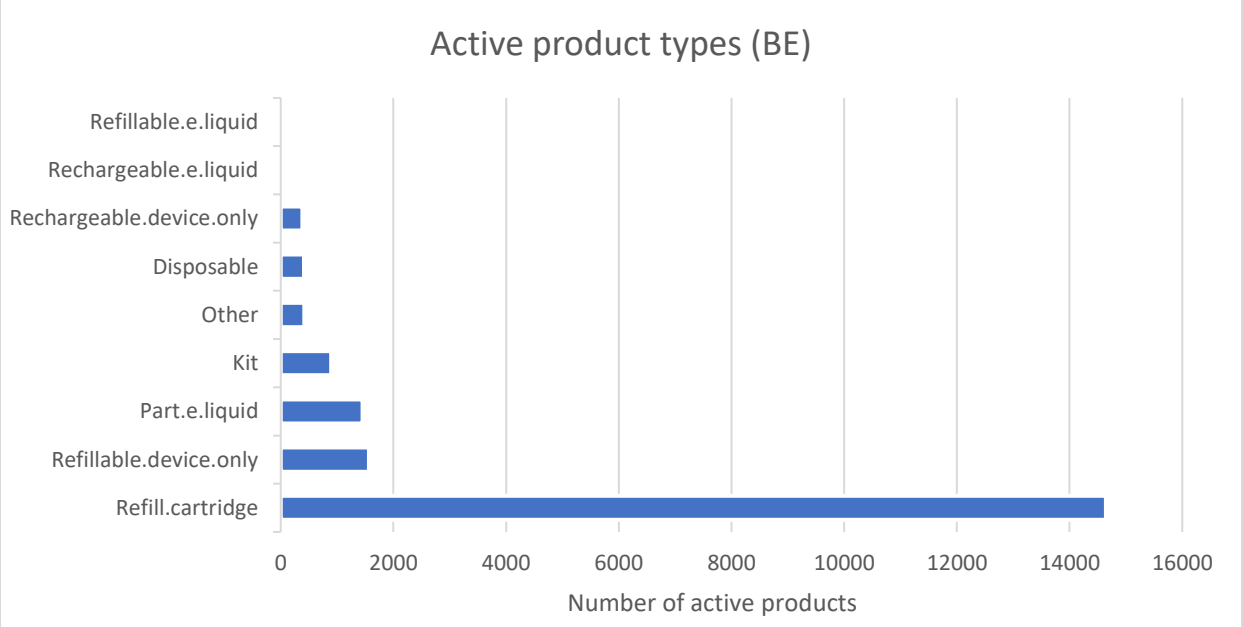


Table 2. Breakdown of product types active in EU-CEG, Belgium (n=19,794)

Product type	n	%
Refill container/cartridge containing e-liquid	14646	74.0%
Refillable, device only	1568	7.9%
Individual part of e-cigarette capable of containing e-liquid	1450	7.3%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	893	4.5%
Other	416	2.1%
E-cigarette – Disposable	412	2.1%
E-cigarette – Rechargeable, device only	383	1.9%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	19	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	7	0.0%

2. Assessment of volume and nicotine content in nicotine containing liquids

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 14,646 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 5 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A**. Of the 14,641 refill containers/cartridges reporting valid vial volumes (>0 ml), 14,391 were reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 14,391 nicotine-containing refill containers/cartridges that reported valid vial volumes in Belgium, the average vial volume was 14.6ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the wide range of vial volumes reported and outliers, the SD of vial volumes among all products was 76.12ml.

Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.4% of products (n=14,302) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.60ml and the middle value of the vial volumes reported (median) was 10ml. This is depicted in **Table 3**.

Only 89 non-compliant refill containers/cartridges (volume >10ml) were identified in the Belgium EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with large vial volumes (e.g. 1,198ml). The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Belgium

	Vial volume (ml)		
	All products n=14,391	**Compliant products (≦10ml)** n= 14,302	**Non-compliant products (>10ml)** n= 89
Min.	0.67	0.67	11
Median	10	10	1179
Mean	14.6	9.601	817.5
Max.	1198	10	1198
SD	76.12	1.77	539.41

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 3,838 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 3,243 products reported a value for capacity and 595 products (15.5%) were missing reports. All of the 595 submissions missing

reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 3,243 products which reported a value for capacity, 3,040 products (93.7%) reported valid capacity (>0 ml) and 204 products (6.3%) reported invalid values (i.e. 0 ml).

Among the 3,039 products that reported a valid capacity (>0 ml) in Belgium, the average capacity was 2.50ml (SD=1.95 ml). The middle value of the capacities reported (median) was 2ml. This distribution is presented in **Table 4** below.

Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 84.6% of products (n=2,570) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.82ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities (n=469) had an average capacity of 6.19ml. The volume distribution of these non-compliant products is depicted in **Table 4**, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there were 133 non-compliant nicotine-containing disposable e-cigarettes (32.4%). Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 80 products (9.4%) listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 21 (5.5%) of the rechargeable devices, and 235 (15.0%) of the refillable devices, were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Belgium

	Capacity (ml) **All reported** (n= 3243)	**All valid (>0 ml)** (n= 3039)	**Valid, Compliant (≦2ml)** (n= 2570)	**Valid, Non-compliant (>2ml)** (n=469)
Min.	0	0.01	0.01	2.4
Median	2	2	2	5
Mean	2.341	2.498	1.824	6.191
Max.	20	20	2	20
SD	1.98	1.95	0.38	2.78
Invalid (=0 ml)	n= 595			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other', and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 14,646 notifications on e-liquid products sold in refill cartridges/containers, 250 (1.7%) did not contain nicotine. The average nicotine concentration among the remaining 14,396 nicotine-containing e-liquid products was 9.53 mg/ml and the middle value of the reported nicotine concentrations (median) was 6 mg/ml. This distribution is depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* The overwhelming majority (99.7%) of the 14,646

nicotine-containing e-liquid products in the Belgium EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 14,352 compliant products, the average nicotine concentration was 9.38 mg/ml and the middle value of the reported nicotine concentrations (median) was 6 mg/ml. This is displayed in **Table 5**.

Only 44 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. The distribution of nicotine concentration for these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Belgium

	Nicotine concentration (mg/ml)		
	All products (n=14396)	**Compliant products (≦20 mg/ml)** (n=14352)	**Non-compliant products (>20 mg/ml)** (n= 44)
Min.	0.26	0.26	30
Median	6	6	52
Mean	9.53	9.383	57.21
Max.	180	20	180
SD	6.76	5.85	39.34

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Belgium EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 265 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was lower reported capacity for disposable e-cigarettes (mode: 350mA) compared to refillable e-cigarette devices sold as ‘device only’ (mode: 1500mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 1850mA). With regards to whether the airflow is adjustable or if the wick is changeable, almost no disposable e-cigarettes were found to have the ability to alter airflow (0.0%) or change the wick (0.2%). However, among the 1,568 products listed as ‘refillable, device only’, 67.5% (n= 1059) noted the ability to adjust airflow and 40.5% (n=635) had the ability to change the wick, and among the 383 products listed as ‘rechargeable device only,’ 50.9% (n=195) had the ability to adjust airflow and 24.3% (n=93) had the ability to change the wick. This suggests the plethora of product designs available on the market. A similar pattern was identified for the presence of microprocessor, which was predominately present in refillable devices sold as ‘device only’ (62.5%), rechargeable devices sold as ‘device only’ (80.4%) and kits (81.0%), whereas only 10.4% of the 412 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

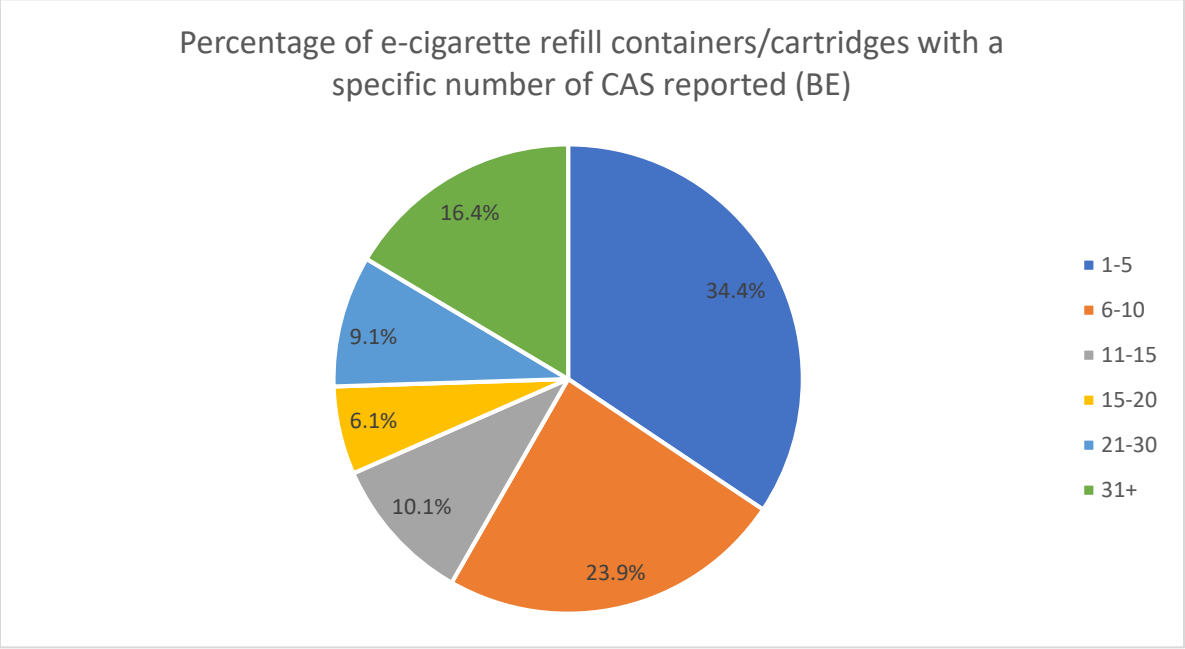
Among the 14,646 submissions for refill containers/cartridges within the Belgium EU-CEG database with a "not withdrawn" status, 1,473 CAS numbers were submitted (Note that additional data cleaning is needed to further reduce this number).

Among the 14,646 submissions for refill containers/cartridges, 34.4% reported between 1 to 5 CAS, 23.9% reported between 6 to 10 CAS, and 16.4% reported more than 31 CAS. This breakdown is displayed in **Table 6**. A few products (n=6) in the Belgium EU CEG reported no CAS, thus the submissions were considered invalid and their EC-IDs are flagged in **Annex A**. **Figure 3** depicts the breakdown of the number of CAS reported within one product, excluding submissions with no CAS reported.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges (n=14,646)

Number of CAS per product	Number of products	% (total)	% (excluding invalid)
1-5	5035	34.4%	34.4%
6-10	3496	23.9%	23.9%
11-15	1485	10.1%	10.1%
16-20	890	6.1%	6.1%
21-30	1326	9.1%	9.1%
31+	2408	16.4%	16.4%
Invalid (no CAS reported)	6	0.0%	

Figure 3. Breakdown of the number of CAS reported within one product (among those that reported a CAS), (n=14,640)



Among valid submissions, the average number of ingredients per product was 15.5, ranging between 1 to 120 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID for all submissions and for all valid submissions is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall and among valid product submissions, Belgium

	Number of CAS **All refill containers/cartridges** (n= 14,646)	**Valid CAS entry** (n= 14,640)
Min.	0	1
Median	8	8
Mean	15.49	15.5
Max.	120	120
SD	0	1
Invalid (i.e. no CAS reported)	n = 6	

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges that contain an e-liquid which reported any CAS (n=14,640), a total of 1,473 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Belgium (n=14,640)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	14203	97.0%
2	54-11-5	Nicotine	13942	95.2%
3	56-81-5	Glycerol	13484	92.1%
4	121-33-5	Vanillin	5407	36.9%
5	7732-18-5	Water	4664	31.9%
6	105-54-4	Ethyl butyrate	4535	31.0%
7	4940-11-8	Ethyl maltol	4513	30.8%
8	64-17-5	Ethyl alcohol	4076	27.8%
9	141-78-6	Ethyl acetate	3589	24.5%
10	118-71-8	Maltol	3253	22.2%
11	3658-77-3	Furaneol	3188	21.8%
12	123-92-2	Isoamyl acetate	2952	20.2%
13	928-96-1	cis-3-Hexen-1-ol	2788	19.0%
14	121-32-4	Ethyl vanillin	2722	18.6%
15	706-14-9	γ-Decalactone	2606	17.8%
16	7452-79-1	Ethyl 2-methylbutyrate	2529	17.3%
17	107-92-6	Butyric acid	2409	16.5%
18	64-19-7	Acetic acid	2343	16.0%
19	78-70-6	Linalool	2113	14.4%
20	100-51-6	Benzyl alcohol	2109	14.4%

21	123-66-0	Ethyl hexanoate	1984	13.6%
22	56038-13-2	Sucralose	1908	13.0%
23	102-76-1	Triacetin	1882	12.9%
24	142-92-7	Hexyl acetate	1849	12.6%
25	142-62-1	Hexanoic acid	1836	12.5%
26	116-53-0	(±)-2-Methylbutyric acid	1748	11.9%
27	120-57-0	Piperonal	1717	11.7%
28	765-70-8	3-Methyl-1,2-cyclopentanedione	1710	11.7%
29	105-37-3	Ethyl propionate	1681	11.5%
30	100-52-7	Benzaldehyde	1652	11.3%
31	705-86-2	δ-Decalactone	1647	11.3%
32	659-70-1	Isoamyl isovalerate	1632	11.1%
33	3681-71-8	cis-3-Hexenyl acetate	1622	11.1%
34	5471-51-2	Frambione	1619	11.1%
35	103-26-4	Methyl cinnamate	1561	10.7%
36	104-67-6	γ-Undecalactone	1520	10.4%
37	140-11-4	Benzyl acetate	1433	9.8%
38	2216-51-5	L-Menthol	1374	9.4%
39	104-50-7	γ-Octalactone	1374	9.4%
40	108-64-5	Ethyl isovalerate	1352	9.2%
41	123-11-5	p-Anisaldehyde	1343	9.2%
42	56-40-6	Glycine	1331	9.1%
43	713-95-1	δ-Dodecalactone	1281	8.8%
44	104-61-0	γ-Nonanoic lactone	1256	8.6%
45	5392-40-5	Citral	1143	7.8%
46	513-86-0	Acetoin	1093	7.5%
47	80-71-7	Methyl cyclopentenolone	1026	7.0%
48	106-27-4	Isoamyl butyrate	952	6.5%
49	105-13-5	4-Methoxybenzyl alcohol	941	6.4%
50	22047-25-2	2-Acetylpyrazine	938	6.4%
51	23696-85-7	Damascenone	924	6.3%
52	14901-07-6	β-Ionone	920	6.3%
53	110-19-0	Isobutyl acetate	910	6.2%
54	98-55-5	α-Terpineol	905	6.2%
55	127-41-3	α-Ionone	887	6.1%
56	119-84-6	Dihydrocoumarin	884	6.0%
57	90-05-1	Guaiacol	861	5.9%
58	137-00-8	4-Methyl-5-thiazoleethanol	860	5.9%
59	106-24-1	Geraniol	844	5.8%
60	6728-26-3	trans-2-Hexen-1-al	822	5.6%
61	123-51-3	Isoamyl alcohol	822	5.6%
62	75-18-3	Dimethyl sulfide	820	5.6%
63	5989-27-5	(R)-(+)-Limonene	812	5.5%
64	89-78-1	Menthol	807	5.5%
65	111-27-3	1-Hexanol	801	5.5%
66	97-53-0	Eugenol	785	5.4%
67	695-06-7	γ-Hexalactone	761	5.2%

68	14667-55-1	2,3,5-Trimethylpyrazine	759	5.2%
69	123-51-3	Isoamyl alcohol	747	5.1%
70	79-09-4	Propionic acid	736	5.0%
71	4180-23-8	trans-Anethole	732	5.0%
72	8008-56-8	Lemon oil	724	4.9%
73	97-64-3	Ethyl lactate	678	4.6%
74	105-87-3	Geranyl acetate	668	4.6%
75	77-92-9	Citric acid	666	4.5%
76	123-86-4	Butyl acetate	647	4.4%
77	60-12-8	2-Phenylethanol	634	4.3%
78	138-86-3	Dipentene	630	4.3%
79	115-95-7	Linalyl acetate	619	4.2%
80	77-93-0	Triethyl citrate	584	4.0%
81	51115-67-4	2-Isopropyl-N,2,3-trimethylbutyramide	583	4.0%
82	104-55-2	Cinnamaldehyde	564	3.9%
83	7492-70-8	Butyl butyryllactate	561	3.8%
84	66-25-1	Hexanal	560	3.8%
85	120-51-4	Benzyl benzoate	552	3.8%
86	470-82-6	Eucalyptol	540	3.7%
87	134-20-3	Methyl anthranilate	529	3.6%
88	23726-91-2	β -Damascone	513	3.5%
89	16491-36-4	cis-3-Hexenyl butyrate	504	3.4%
90	39711-79-0	N-Ethyl-p-menthane-3-carboxamide	490	3.3%
91	8008-57-9	Orange oil	480	3.3%
92	141-97-9	Ethyl acetoacetate	472	3.2%
93	124-07-2	Octanoic acid	472	3.2%
94	50-21-5	Lactic acid	466	3.2%
95	23726-92-3	cis-β-Damascone	446	3.0%
96	928-95-0	trans-2-Hexen-1-ol	441	3.0%
97	8028-48-6	Orange oil	427	2.9%
98	106-32-1	Ethyl octanoate	420	2.9%
99	2305-05-7	γ-dodecalactone	417	2.8%
100	532-32-1	Sodium benzoate	417	2.8%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=14,640)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity, concentration, and major function are presented below in **Table 9**. Propylene glycol (a carrier), nicotine (an addictive enhancer), and glycerol (primarily listed as a solvent processing aid), were listed as the three most common ingredients. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Belgium

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4430.00	3789.90	452.72	398.72	Carrier	-
2	54-11-5	Nicotine	30.00	64.02	3.03	6.92	Addictive Enhancer	-
3	56-81-5	Glycerol	5000.00	4334.53	500.00	450.65	Solvent - Processing Aid	-
4	121-33-5	Vanillin	9.00	69.82	0.90	7.13	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
5	7732-18-5	Water	135.20	319.20	13.33	32.94	Flavour and/or Taste Enhancer	-
6	105-54-4	Ethyl butyrate	4.06	14.31	0.44	1.48	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
7	4940-11-8	Ethyl maltol	10.00	30.24	1.00	3.12	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
8	64-17-5	Ethyl alcohol	27.90	99.54	3.00	10.28	Flavour and/or Taste Enhancer	
9	141-78-6	Ethyl acetate	2.39	15.94	0.26	1.70	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
10	118-71-8	Maltol	2.25	7.71	0.24	0.83	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
11	3658-77-3	Furaneol	3.00	10.67	0.31	1.12	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
12	123-92-2	Isoamyl acetate	2.77	25.46	0.29	2.62	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
13	928-96-1	cis-3-Hexen-1-ol	2.23	6.53	0.24	0.67	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
14	121-32-4	Ethyl vanillin	11.44	28.94	1.18	2.94	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
15	706-14-9	γ-Decalactone	1.00	4.05	0.10	0.42	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
16	7452-79-1	Ethyl 2-methylbutyrate	2.60	11.95	0.28	1.21	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
17	107-92-6	Butyric acid	0.98	6.11	0.11	0.61	Flavour and/or Taste Enhancer	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor
18	64-19-7	Acetic acid	1.44	6.59	0.15	0.67	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
19	78-70-6	Linalool	0.78	4.83	0.08	0.49	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste
20	100-51-6	Benzyl alcohol	5.87	33.78	0.61	3.45	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Belgium EU CEG.

**Flavour descriptions* are according to a desk literature review.

Conclusions

Summary of Results

Within the current Belgium EU-CEG dataset, 28.4% (n=7,846) of the 27,754 notifications (unique EC-IDs) were indicated to be withdrawn from the market. The most common type of notification was a correction of a clerical/administrative error in an existing product submission (n=6,979). The majority of active products in the Belgium EU CEG were refill containers/cartridges containing e-liquids (n=19,794).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.4% of products reporting a vial volume of 10ml or less. Non-compliant products (n=89) included outliers reporting a maximum vial volume of 1,198ml. Five invalid values (=0ml) were reported for vial volumes. Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the capacity, with 84.6% reporting a capacity of 2ml or less. There were 469 non-compliant products, and 204 products reported invalid values (=0ml) for capacity, more than half of which were characterized as 'individual part of electronic cigarette capable of containing e-liquid.'

With regards to the nicotine concentration, the overwhelming majority (99.7%) of e-liquid refill cartridges/containers were compliant, with a nicotine concentration of 20 mg/ml or less. Non-compliant products (n=44) included outliers reporting a maximum nicotine concentration of 180mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,473 unique CAS numbers reported in the Belgium EU CEG. The average number of ingredients per product, among products reporting CAS, was 15.49, ranging between 1 and 120 different CAS per product. A few products (n=6) reported no CAS. The most common ingredients in frequency were the propylene glycol, nicotine, and glycerol. The most frequently reported flavorings were vanilla, ethyl butyrate, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Outliers remain a limitation of the current analysis of the Belgium EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Belgium EU CEG (e.g. vial volumes, capacity and CAS) suggests a need to redefine or clarify product type categories and their relevant variables. For example, all products missing reports for capacity were categorized as 'individual parts of e-cigarettes capable of containing an e-liquid.'
- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume/capacity and nicotine concentration), or to change the variable type from "text" variables to "numeric" variables to ensure correct and consistent reporting.

- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report ESTONIA

Circulation: Internal

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and Results by research question

Below we provide an analysis for the EU MS Estonia. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in October of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Estonia EU-CEG dataset, there are 36,172 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type was a notification for a new product EC-ID (23.5%), followed by the addition of a product presentation (19.5%), and the removal of a product presentation (18.6%).

Figure 1. Type of notifications within EU-CEG, Estonia (N= 36,172)

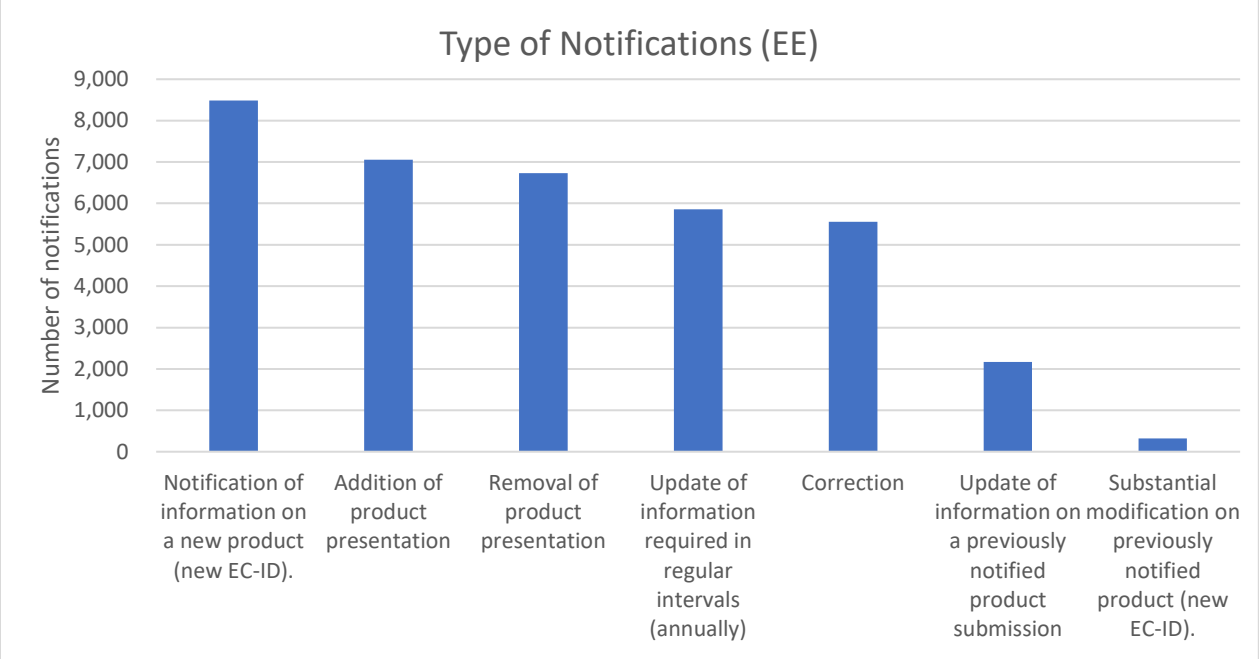


Table 1. Type of notifications within EU-CEG in Estonia (N=36,172)

Notification Type	n	%
Notification of information on a new product (new EC-ID).	8,487	23.5%
Addition of product presentation (e.g. national market) to an existing product submission.	7,057	19.5%
Removal of product presentation, including product withdrawal, from an existing product submission.	6,734	18.6%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	5,855	16.2%
Correction of clerical/administrative errors in existing product submission.	5,554	15.4%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	2,167	6.0%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	318	0.9%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of October 2019, of the 36,172 notifications (unique EC-IDs) submitted for Estonia for the EU CEG, 5,232 (14.5%) have been withdrawn while 30,940 (85.5%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active.

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG in Estonia is displayed in **Table 2** (below). Of the 30,940 notifications for products that are currently on the market, 66.4% (n=20,559) represented refill containers/cartridges containing an e-liquid, 8.8% (n=2,713) represented a refillable device (device only), and 7.4% (n=2,276) represented an individual part of e-cigarette capable of containing e-liquid.

Figure 2. Product types active (not withdrawn) in EU-CEG, Estonia (n= 30,940)

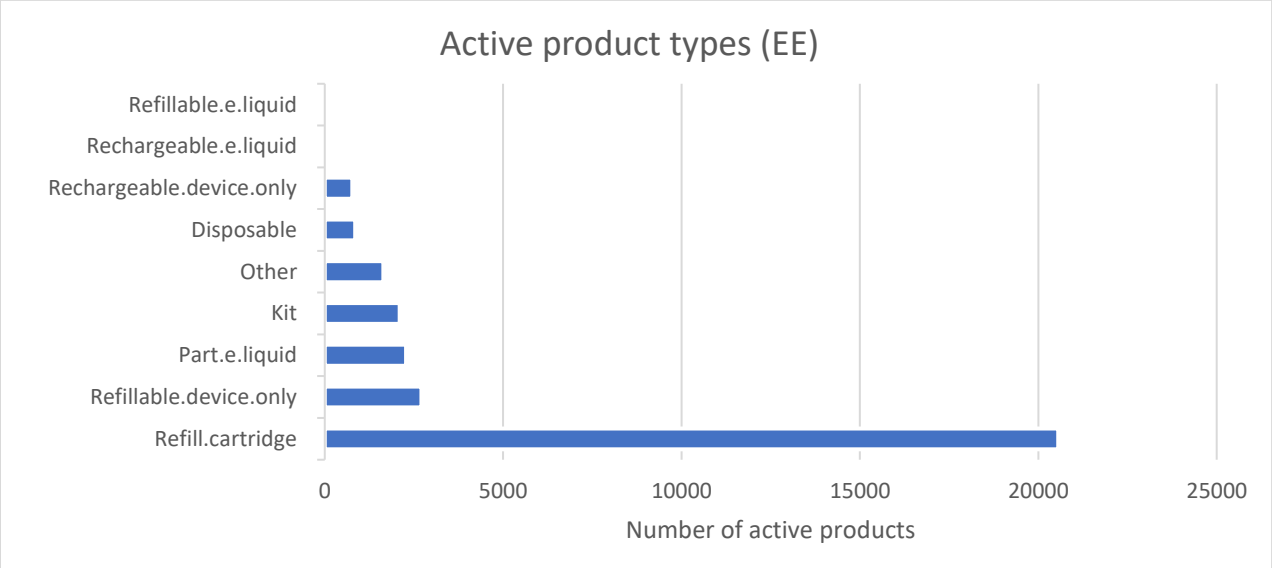


Table 2. Breakdown of product types active in EU-CEG, Estonia (n=30,940)

Product type	n	%
Refill container/cartridge containing e-liquid	20559	66.4%
Refillable, device only	2713	8.8%
Individual part of e-cigarette capable of containing e-liquid	2276	7.4%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	2101	6.8%
Other	1642	5.3%
E-cigarette – Disposable	852	2.8%
E-cigarette – Rechargeable, device only	768	2.5%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	25	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	4	0.0%

2. Assessment of volume and nicotine content in nicotine containing liquids

2.1 Volume/capacity of nicotine-containing e-cigarette liquid TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 20,559 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 4 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 20,555 refill containers/cartridges reporting valid vial volumes (> 0 ml), 19,327 contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 19,237 nicotine-containing refill containers/cartridges that reported valid vial volumes in Estonia, the average vial volume was 11.01 ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the wide range of vial volumes reported and outliers, the SD of vial volumes among all products was 116.55ml.

Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.8% of products (n=19,288) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.79ml and the middle value of the vial volumes reported (median) was 10ml. This is depicted in **Table 3**.

Only 39 non-compliant refill containers/cartridges (volume >10ml) were identified in the Estonia EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with extremely large vial volumes. The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Estonia

	Vial volume (ml)		
	All products n=19,327	**Compliant products (≦10ml)** n= 19,288	**Non-compliant products (>10ml)** n= 39
Min.	0.6	0.6	12
Median	10	10	30
Mean	11.01	9.789	616
Max.	11482	10	11482
SD	116.55	1.32	2555.57

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 6,616 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 5,611 products reported a value for capacity and 1,005 products (15.2%) were missing reports. All of the 1,005 submissions missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 5,611

product notifications which reported a value for capacity, 5,128 products (91.4%) reported valid values for capacity (>0 ml) and 483 products (8.6%) reported invalid values (i.e. 0 ml). Over half of the 483 products reporting invalid values for capacity (n=247) were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.'

Among the 5,128 products that reported a valid capacity in Estonia, the average capacity was 6.55ml. Due to the presence of large outliers, the SD was 248.95 ml. The middle value of the capacities reported (median) was 2ml. This distribution is presented in **Table 4** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in cartridges or tanks which do not exceed a capacity of 2 ml*. Given that cartridges or tanks placed on the market without a nicotine-containing e-liquid can still be used for the consumption of nicotine-containing vapour, compliance with Article 20.3 of the EU TPD of product types sold with, and/or capable of containing, an e-liquid was assessed in this analysis. Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 73.9% of products (n=3,791) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.81ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=1,337) had an average capacity of 20ml, and an extremely large SD of 509.9ml. The volume distribution of these non-compliant products is depicted in **Table 4** below, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, 372 non-compliant nicotine-containing disposable e-cigarettes (44.8%) were flagged. Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 85 products listed as 'individual parts of e-cigarettes capable of containing an e-liquid'(8.3%), 161 of the rechargeable devices (9.1%), and 719 of the refillable devices (26.7%) were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Estonia

	Capacity (ml)			
	All reported (n= 5611)	**All valid (>0 ml)** (n= 5128)	**Valid, Compliant (≦2ml)** (n= 3791)	**Valid, Non-compliant (>2ml)** (n=1337)
Min.	0	0.01	0.01	2.2
Median	2	2	2	5
Mean	5.99	6.554	1.813	20
Max.	18650	18650	2	18650
SD	248.95	260.41	0.37	509.89
Invalid (=0 ml)	n= 483			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other,' and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 20,559 notifications on e-liquid products sold in refill cartridges/containers, 1,229 (6.0%) did not contain nicotine. The average nicotine concentration among the remaining 19,330 nicotine-containing e-liquid products was 9.78 mg/ml, and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. These distributions are depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* Almost all (99.9%) of the 19,330 nicotine-containing e-liquid products in the Estonia EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 19,318 compliant products, the average nicotine concentration was 9.75 mg/ml and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. This is displayed in **Table 5**.

Only 12 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. The maximum nicotine concentration reported among non-compliant products was 180mg/ml. The distribution of nicotine concentration for these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Estonia

	Nicotine concentration (mg/ml)		
	All products (n=19330)	**Compliant products (≦20 mg/ml)** (n=19318)	**Non-compliant products (>20 mg/ml)** (n= 12)
Min.	0.25	0.25	20.02
Median	9	9	35.48
Mean	9.783	9.746	69.36
Max.	180	20	180
SD	6.37	5.98	68.54

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Estonia EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 425 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was lower reported capacity for disposable e-cigarettes (mode: 280mA) compared to refillable e-cigarette devices sold as ‘device only’ (mode: 1500mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 3000mA). With regards to whether the airflow is adjustable or if the wick is changeable, a negligible number of the 852 disposable e-cigarettes were found to have the ability to alter airflow (n=) or to change the wick (n=1). However, among the 2,713 products listed as ‘refillable, device only’, 71.8% (n=1,949) noted the ability to adjust airflow and 42.4% (n=1,151) had the ability to change the wick, and among the 768 products listed as ‘rechargeable device only’, 50.4% (n=387) had the ability to adjust airflow and 19.0% (n=146) had the ability to change the wick. This suggests plethora of product designs available on the market. A similar pattern was identified for the presence of a microprocessor, which was predominately present in rechargeable devices sold as ‘device only’ (68.5%), kits (66.0%) refillable devices sold as ‘device only’ (56.8%), whereas only 7.4% of the 852 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

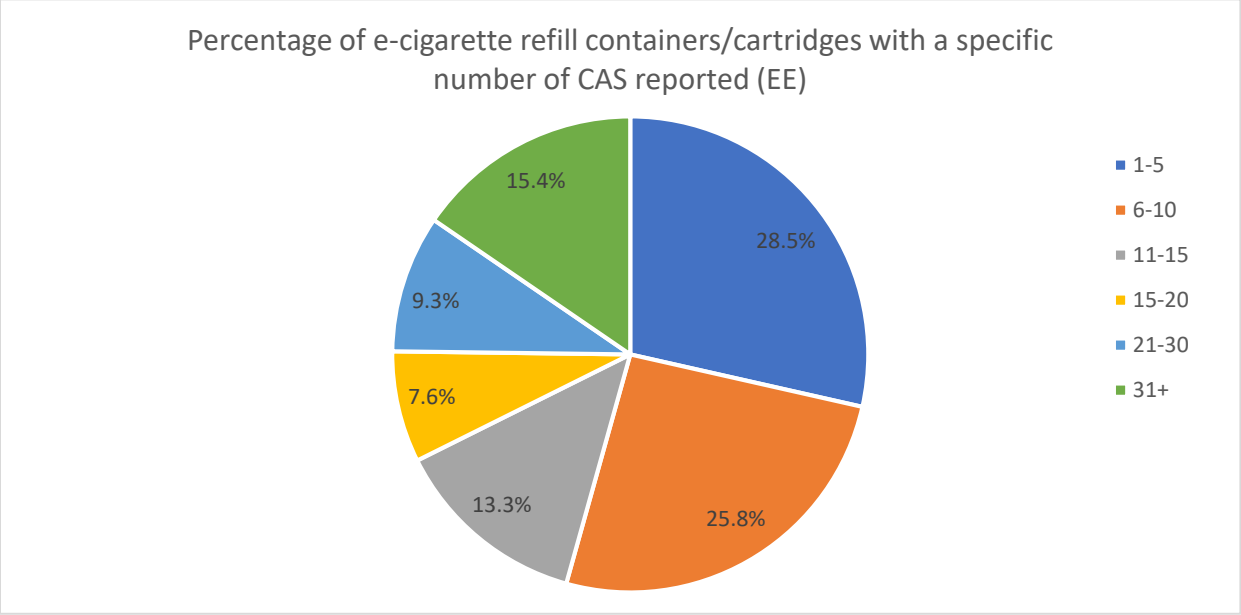
Among the 20,559 submissions for refill containers/cartridges within the Estonia EU-CEG database with a "not withdrawn" status, 1,580 unique CAS numbers were submitted (note that additional data cleaning is needed to further reduce this number).

All products listed as refill containers/cartridges in the Estonia EU CEG reported at least one CAS. Among the 20,559 submissions for refill containers/cartridges, 28.5% reported between 1 to 5 CAS, 25.8% reported between 6 to 10 CAS, and 15.4% reported more than 31 CAS. This breakdown is displayed in **Table 6** and depicted in **Figure 3**.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Estonia (n=20,559)

Number of CAS per product	n	% (total)
1-5	5867	28.5%
6-10	5304	25.8%
11-15	2736	13.3%
16-20	1555	7.6%
21-30	1922	9.3%
31+	3175	15.4%
Invalid (no CAS reported)	0	0.0%

Figure 3. Breakdown of the number of CAS reported within one product (among all refill containers/cartridges), Estonia (n=20,559)



The average number of ingredients per product was 15.64, ranging between 1 to 112 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall Estonia, (n=20,559)

	Number of CAS All refill containers/cartridges (n= **20,559**)
Min.	1
Median	9
Mean	15.64
Max.	112
SD	15.67

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges (n=20,559) a total of 1,580 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed below in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Estonia (n=20,559)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	19929	96.7%
2	54-11-5	Nicotine	18567	90.1%
3	56-81-5	Glycerol	17173	83.4%
4	121-33-5	Vanillin	7646	37.1%
5	105-54-4	Ethyl butyrate	7559	36.7%
6	7732-18-5	Water	7180	34.9%
7	4940-11-8	Ethyl maltol	7107	34.5%
8	64-17-5	Ethyl alcohol	5977	29.0%
9	141-78-6	Ethyl acetate	5382	26.1%
10	118-71-8	Maltol	5104	24.8%
11	121-32-4	Ethyl vanillin	4724	22.9%
12	3658-77-3	Furaneol	4443	21.6%
13	928-96-1	cis-3-Hexen-1-ol	4133	20.1%
14	123-92-2	Isoamyl acetate	4128	20.0%
15	56-40-6	Glycine	3999	19.4%
16	64-19-7	Acetic acid	3815	18.5%
17	7452-79-1	Ethyl 2-methylbutyrate	3805	18.5%
18	706-14-9	γ-Decalactone	3739	18.2%
19	78-70-6	Linalool	3406	16.5%
20	107-92-6	Butyric acid	3169	15.4%
21	100-51-6	Benzyl alcohol	3145	15.3%
22	123-66-0	Ethyl hexanoate	2896	14.1%
23	102-76-1	Triacetin	2841	13.8%
24	765-70-8	3-Methyl-1,2-cyclopentanedione	2677	13.0%
25	56038-13-2	Sucralose	2601	12.6%
26	5471-51-2	Frambione	2487	12.1%

27	100-52-7	Benzaldehyde	2483	12.1%
28	105-37-3	Ethyl propionate	2475	12.0%
29	120-57-0	Piperonal	2431	11.8%
30	142-92-7	Hexyl acetate	2423	11.8%
31	3681-71-8	cis-3-Hexenyl acetate	2301	11.2%
32	705-86-2	δ-Decalactone	2275	11.0%
33	116-53-0	(±)-2-Methylbutyric acid	2233	10.8%
34	142-62-1	Hexanoic acid	2192	10.6%
35	659-70-1	Isoamyl isovalerate	2057	10.0%
36	140-11-4	Benzyl acetate	2047	9.9%
37	80-71-7	Methyl cyclopentenolone	2044	9.9%
38	123-11-5	p-Anisaldehyde	2035	9.9%
39	104-67-6	γ-Undecalactone	2009	9.8%
40	104-50-7	γ-Octalactone	2005	9.7%
41	103-26-4	Methyl cinnamate	1916	9.3%
42	104-61-0	γ-Nonanoic lactone	1825	8.9%
43	713-95-1	δ-Dodecalactone	1805	8.8%
44	108-64-5	Ethyl isovalerate	1800	8.7%
45	2216-51-5	L-Menthol	1764	8.6%
46	5392-40-5	Citral	1579	7.7%
47	22047-25-2	2-Acetylpyrazine	1533	7.4%
48	127-41-3	α-Ionone	1460	7.1%
49	14901-07-6	β-Ionone	1400	6.8%
50	75-18-3	Dimethyl sulfide	1367	6.6%
51	106-27-4	Isoamyl butyrate	1364	6.6%
52	137-00-8	4-Methyl-5-thiazoleethanol	1342	6.5%
53	98-55-5	α-Terpineol	1305	6.3%
54	97-53-0	Eugenol	1283	6.2%
55	90-05-1	Guaiacol	1263	6.1%
56	110-19-0	Isobutyl acetate	1260	6.1%
57	105-13-5	4-Methoxybenzyl alcohol	1243	6.0%
58	513-86-0	Acetoin	1241	6.0%
59	23696-85-7	Damascenone	1236	6.0%
60	89-78-1	Menthol	1211	5.9%
61	106-24-1	Geraniol	1154	5.6%
62	8008-56-8	Lemon oil	1153	5.6%
63	14667-55-1	2,3,5-Trimethylpyrazine	1149	5.6%
64	123-68-2	Allyl hexanoate	1144	5.6%
65	695-06-7	γ-Hexalactone	1134	5.5%
66	111-27-3	1-Hexanol	1110	5.4%
67	123-51-3	Isoamyl alcohol	1103	5.4%
68	97-64-3	Ethyl lactate	1097	5.3%
69	119-84-6	Dihydrocoumarin	1093	5.3%
70	6728-26-3	trans-2-Hexen-1-al	1053	5.1%
71	60-12-8	2-Phenylethanol	1036	5.0%
72	5989-27-5	(R)-(+)-Limonene	1026	5.0%
73	77-92-9	Citric acid	972	4.7%

74	134-20-3	Methyl anthranilate	959	4.7%
75	105-87-3	Geranyl acetate	934	4.5%
76	8008-57-9	Orange oil	923	4.5%
77	104-55-2	Cinnamaldehyde	901	4.4%
78	7492-70-8	Butyl butyryllactate	896	4.3%
79	77-93-0	Triethyl citrate	871	4.2%
80	120-51-4	Benzyl benzoate	830	4.0%
81	66-25-1	Hexanal	824	4.0%
82	470-82-6	Eucalyptol	823	4.0%
83	115-95-7	Linalyl acetate	818	4.0%
84	79-09-4	Propionic acid	814	4.0%
85	138-86-3	Dipentene	781	3.8%
86	2305-05-7	4,5,6,7-Tetrahydroindazole	726	3.5%
87	620-02-0	5-Methylfurfural	692	3.4%
88	8008-26-2	Lime oil	677	3.3%
89	124-07-2	Octanoic acid	668	3.2%
90	4180-23-8	trans-Anethole	631	3.1%
91	93-92-5	1-Phenylethyl acetate	612	3.0%
92	6915-15-7	DL Malic acid	607	2.9%
93	150-78-7	1,4-Dimethoxybenzene	604	2.9%
94	1124-11-4	2,3,5,6-Tetramethylpyrazine	578	2.8%
95	106-32-1	Ethyl octanoate	575	2.8%
96	50-21-5	DL-Lactic acid	573	2.8%
97	928-95-0	trans-2-Hexen-1-ol	559	2.7%
98	127-91-3	β-Pinene	555	2.7%
99	79-77-6	β-Ionone	546	2.7%
100	141-97-9	Ethyl acetoacetate	543	2.6%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=20,559)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity (mg per product), concentration, and major function are presented below in **Table 9**. Besides the carriers (propylene glycol and glycerol), nicotine was the most common ingredient, primarily functioning as an addictive enhancer. All other ingredients in the top 20 were mainly reported to be used as flavor/taste enhancers, except glycine which was most often reported as a carrier.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Estonia

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4250.00	9539.00	438.08	382.12	Carrier	-
2	54-11-5	Nicotine	30.00	61.88	3.00	6.69	Addictive Enhancer	-
3	56-81-5	Glycerol	5002.00	29589.00	504.00	1451.00	Carrier	-
4	121-33-5	Vanillin	8.64	29.10	0.89	2.98	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
5	105-54-4	Ethyl butyrate	5.00	22.12	0.50	2.18	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
6	7732-18-5	Water	127.00	2333.00	13.20	29.91	Flavour and/or Taste Enhancer	-
7	4940-11-8	Ethyl maltol	11.71	27.19	1.21	2.74	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
8	64-17-5	Ethyl alcohol	43.50	123.88	4.56	12.45	Flavour and/or Taste Enhancer	-
9	141-78-6	Ethyl acetate	2.28	13.49	0.24	1.37	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
10	118-71-8	Maltol	2.39	12.48	0.28	1.31	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
11	121-32-4	Ethyl vanillin	13.82	35.99	1.41	3.63	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
12	3658-77-3	Furaneol	3.09	11.48	0.34	1.17	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
13	928-96-1	cis-3-Hexen-1-ol	2.47	8.91	0.27	0.89	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
14	123-92-2	Isoamyl acetate	2.95	18.25	0.33	1.97	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
15	56-40-6	Glycine	7046.00	7086.00	704.64	711.65	Carrier	-
16	64-19-7	Acetic acid	2.68	9.14	0.28	0.91	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
17	7452-79-1	Ethyl 2-methylbutyrate	3.88	19.79	0.41	2.01	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
18	706-14-9	γ-Decalactone	1.22	5.17	0.12	0.52	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
19	78-70-6	Linalool	0.95	5.79	0.10	0.58	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste
20	107-92-6	Butyric acid	1.77	9.23	0.18	0.93	Flavour and/or Taste Enhancer	-

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Estonia EU CEG.

**Flavour descriptions* are according to a desk literature review.

Conclusions

Summary of Results

Within the current Estonia EU-CEG dataset, there are 36,172 notifications (unique EC-IDs), of which 5,232 were indicated to be withdrawn from the market. The most common type of product active in the Estonia EU CEG was refill containers/cartridges containing e-liquids (n=20,559).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.8% of products reporting a vial volume of 10ml or less. Non-compliant products (n=39) included extreme outliers reporting a maximum vial volume of 11,482ml. Most containers/cartridges capable of carrying an e-liquid were compliant with regards to the capacity, with 73.9% reporting a capacity of 2ml or less. Non-compliant products (n=1,337) reported a maximum capacity of 18,650ml. A significant number of invalid values (=0ml) were reported for capacity (n=483), more than half of which were characterized as 'individual part of electronic cigarette capable of containing e-liquid.'

With regards to the nicotine concentration, almost all (99.9%) of e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less. Only 12 products reported non-compliant nicotine concentrations, with a maximum reported nicotine concentration of 180mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,580 unique CAS numbers reported in the Estonia EU CEG. The average number of ingredients per product was 15.64, ranging between 1 and 112 different CAS per product. The most common ingredients in frequency were the humectants propylene glycol and glycerol, and nicotine. The most frequently reported flavorings were vanilla, ethyl butyrate, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Outliers remain a limitation of the current analysis of the Estonia EU-CEG dataset (in particular for vial volume and capacity). A thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Estonia EU CEG (e.g. for capacity) suggests a need to redefine or clarify product type categories and their relevant variables. For example, products missing reports for capacity, and over 50% of those reporting invalid values for capacity, were categorized as 'individual parts of e-cigarettes capable of containing an e-liquid,' suggesting a need to clarify the categorical definition.
- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume/capacity and nicotine concentration), or to change the variable

type from “text” variables to “numeric” variables to ensure correct and consistent reporting (e.g. in battery type reporting).

- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report LATVIA

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and results by research question

Below we provide an analysis for the EU MS Latvia. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Latvia EU-CEG dataset, there are 11,522 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type, among products with valid notifications, was the removal of a product presentation, including product withdrawal (33.3%), followed by notifications on new products (24.9%), and the addition of a product presentation to an existing product submission (13.2%).

Figure 1. Type of valid notifications within EU-CEG, Latvia (N= 11,522)

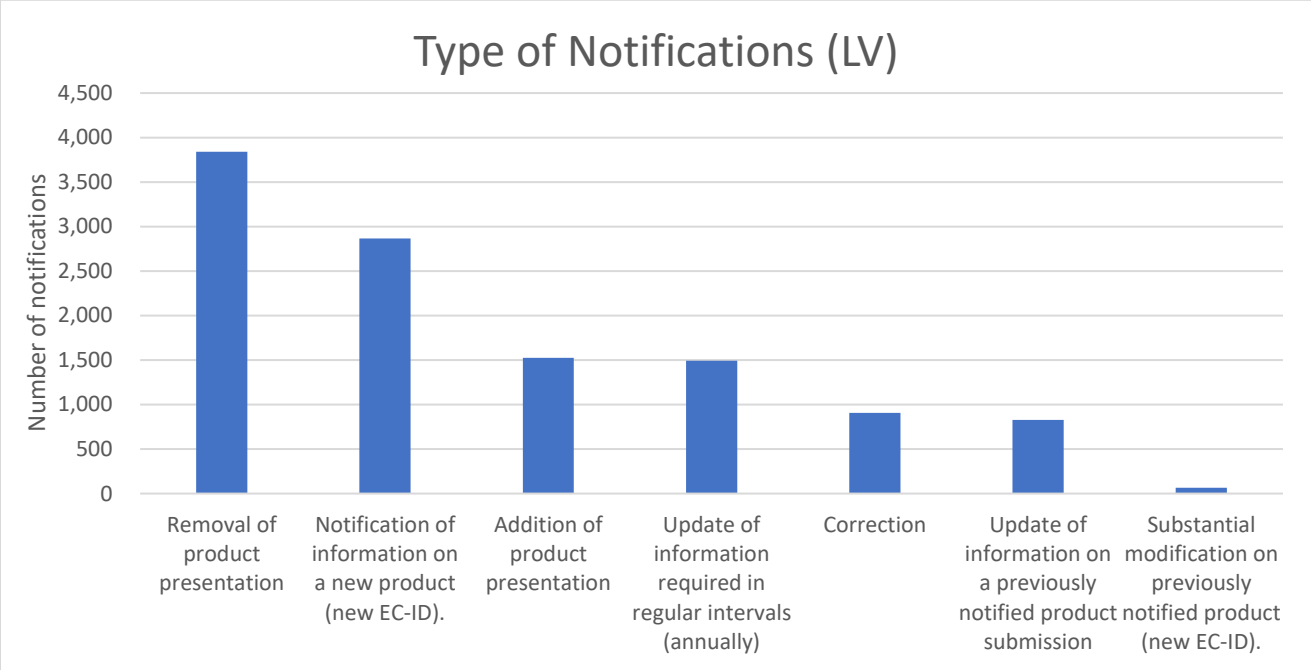


Table 1. Type of notifications within EU-CEG in Latvia (N=11,522)

Type	n	% (valid)
Removal of product presentation, including product withdrawal, from an existing product submission.	3,841	33.3%
Notification of information on a new product (new EC-ID).	2,865	24.9%
Addition of product presentation (e.g. national market) to an existing product submission.	1,524	13.2%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	1,492	12.9%
Correction of clerical/administrative errors in existing product submission.	905	7.9%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	829	7.2%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	66	0.6%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 11,522 notifications (unique EC-IDs) submitted for Latvia in the EU CEG, 4,904 (42.6%) products have been withdrawn and 75 (0.7%) products indicated withdrawal but did not provide a specific date at the time of analysis, while 6,543 (56.8%) unique EC-IDs remain active on the market. This analysis is restricted to products that are currently active (n=6,543).

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG for Latvia is displayed in **Table 2** (below). Of the 6,543 notifications for products that are currently on the market, 59.2% (n=3,875) represented refill containers/cartridges containing an e-liquid, 15.2% (n=995) represented a refillable device (device only), and 10.3% (n=675) represented individual parts of e-cigarettes capable of containing e-liquids.

Figure 2. Product types active (not withdrawn) in EU-CEG, Latvia (n=6,543)

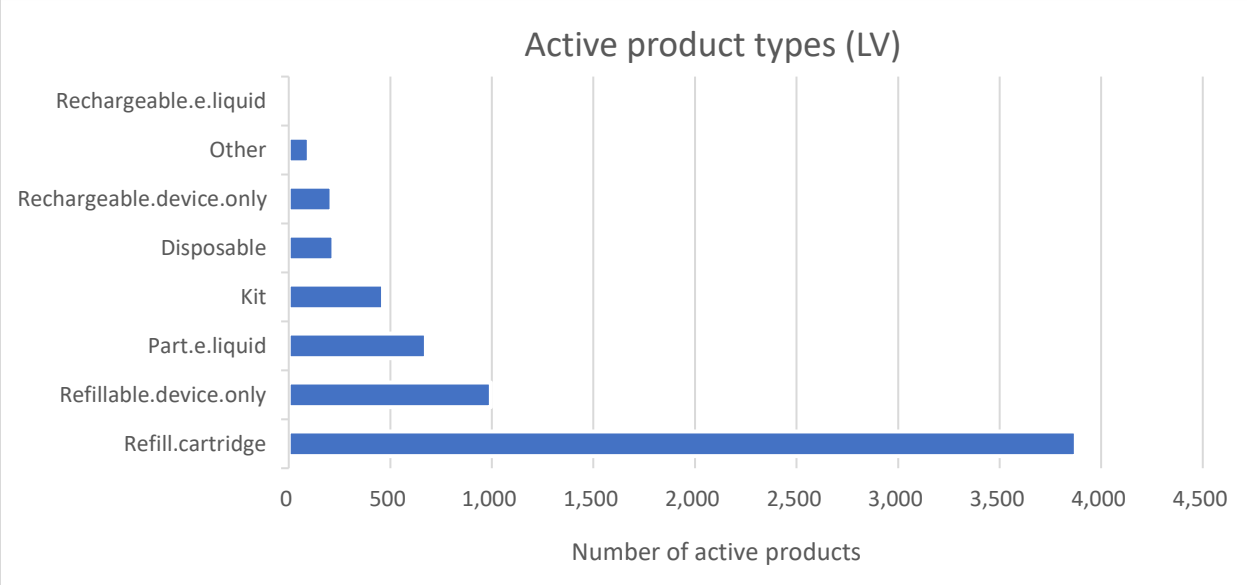


Table 2. Breakdown of product types active in EU-CEG types, Latvia (n=6,543)

Product type	n	%
Refill container/cartridge containing e-liquid	3,875	59.2%
Refillable, device only	995	15.2%
Individual part of e-cigarette capable of containing e-liquid	675	10.3%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	465	7.1%
E-cigarette – Disposable	220	3.4%
E-cigarette – Rechargeable, device only	211	3.2%
Other	99	1.5%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	3	0.0%
E-cigarette – Refillable, placed on the market with one type of e-liquid	0	0.0%

2. Assessment of volume (capacity) and nicotine content

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 3,875 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), only one product reported an invalid vial (container/cartridge) volume (i.e. 0 ml) and was thus excluded from the distribution analysis. This product is flagged in **Annex A.** Of the 3,875 refill containers/cartridges reporting valid vial volumes (>0 ml), 3,774 were reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 3,774 nicotine-containing refill containers/cartridges that reported valid vial volumes in Latvia, the average vial volume was 9.78ml. The middle value of all vial volumes reported (median) was 10ml and the SD was 2.25ml. This distribution is presented in **Table 3** below.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml.* Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.4% of products (n=3,750) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.66ml and the middle value of the vial volume data set (median) was 10ml. This is depicted in **Table 3**.

There were 24 refill containers/cartridges identified as non-compliant (volume >10ml) in the Latvia EU-CEG, reporting a maximum volume of 30ml. The volume distribution of these non-compliant products is depicted in **Table 3** below, andthe non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Latvia

	Vial volume (ml)		
	All products n=3,774	**Compliant products (≦10ml)** n= 3,750	**Non-compliant products (>10ml)** n= 24
Min.	0.67	0.67	12
Median	10	10	30
Mean	9.779	9.662	28
Max.	30	10	30
SD	2.25	1.66	5.43

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 2,104 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 1,773 products reported a

value for capacity and 331 products (15.7%) were missing reports. All of the 331 submissions that were missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 1,773 products which reported a value for capacity, 1,617 products (91.2%) reported a valid capacity (>0 ml) and 156 products (8.8%) reported invalid values for capacity (i.e. 0 ml). Over half of the 156 products reporting invalid values for capacity (n=97) were rechargeable e-cigarettes (device only).'

Among the 1,617 products that reported a valid capacity (>0 ml) in Latvia, the average capacity was 2.21ml, and the middle value of the capacities reported (median) was 2ml. The SD of capacity among all products was 1.24ml. This distribution is presented in **Table 4** below.

Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 87.4% of products (n=1,414) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.84ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=203) had an average capacity of 4.82ml, a middle value (median) of 4.2ml, and a maximum value of 10ml. The SD for products reporting non-compliant capacities was 1.85ml. The volume distribution of these non-compliant products is depicted in **Table 4**, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there were 10 non-compliant nicotine-containing disposable e-cigarettes (4.5%). Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 29 products (9.8%) listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 17 rechargeable e-cigarette devices (14.9%), and 147 of the refillable devices (14.9%), were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Latvia

	Capacity (ml) **All reported** (n= 1773)	**All valid (>0 ml)** (n= 1617)	**Valid, Compliant (≦2ml)** (n=1414)	**Valid, Non-compliant (>2ml)** (n=203)
Min.	0	0.01	0.01	2.4
Median	2	2	2	4.2
Mean	2.015	2.209	1.835	4.821
Max.	10	10	2	10
SD	1.34	1.24	0.37	1.85
Invalid (=0 ml)	n= 156			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other', and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 3,875 notifications on e-liquid products sold in refill cartridges/containers, 101 (2.6%) did not contain nicotine. The average nicotine concentration among the remaining 3,774 nicotine-containing e-

liquid products was 8.85 mg/ml and the middle value of the reported nicotine concentrations (median) was 6 mg/ml. This distribution is depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* All of the 3,875 nicotine-containing e-liquid products in the Latvia EU CEG reported compliant nicotine concentration values, with a nicotine concentration of 20 mg/ml or less.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Latvia

Nicotine concentration (mg/ml) **All products** (n=3,774)	
Min.	0.3
Median	6
Mean	8.85
Max.	20
SD	6.11

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Latvia EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 167 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was a wide range of capacities reported among different product types, for example disposable e-cigarettes (mode: 350mA), refillable e-cigarette devices sold as ‘device only’ (mode: 3000mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 18650mA). With regards to whether the airflow is adjustable or if the wick is changeable, none of the 220 disposable e-cigarettes were found to have the ability to alter airflow or to change the wick. However, among the 995 products listed as ‘refillable, device only’, 63.6% (n= 633) noted the ability to adjust airflow and 31.9% (n=317) had the ability to change the wick, and among the 211 products listed as ‘rechargeable device only’, 37.4% (n=79) had the ability to adjust airflow and 18.5% (n=39) had the ability to change the wick. This suggests the plethora of product designs available on the market. Microprocessors were present in the majority of rechargeable devices sold as ‘device only’ (84.3%), kits (75.1%), and refillable devices sold as ‘device only’ (64.9%), whereas only 7.3% of the 220 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

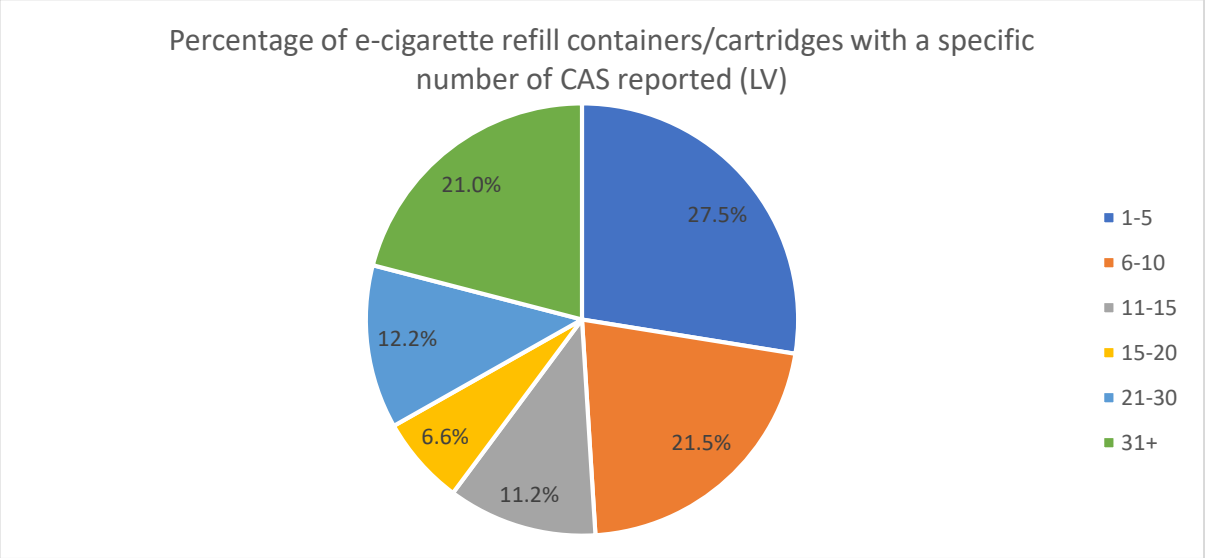
Among the 3,875 submissions for refill containers/cartridges within the Latvia EU-CEG database with a "not withdrawn" status, 964 unique CAS numbers were submitted.

Among the 3,875 submissions for refill containers/cartridges, 27.5% reported between 1 to 5 CAS, 21.5% reported between 6-10 CAS, and 21.0% reported more than 30 CAS. This breakdown is displayed in **Table 6** and in **Figure 3**.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Latvia (n=3,875)

Number of CAS per product	Number of products	% (total)
1-5	1067	27.5%
6-10	832	21.5%
11-15	433	11.2%
16-20	257	6.6%
21-30	474	12.2%
31+	812	21.0%
Invalid (no CAS reported)	-	

Figure 3. Breakdown of the number of CAS reported within one product Latvia (n=3,875)



The average number of ingredients per product was 17.88, ranging between 1 to 105 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall, Latvia (n=3,875)

Number of CAS All refill containers/cartridges	
Min.	0
Median	5
Mean	17.88
Max.	105
SD	16.89

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges that contain an e-liquid), a total of 964 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Latvia (n=3,875)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	3717	95.9%
2	54-11-5	Nicotine	3555	91.7%
3	56-81-5	Glycerol	3425	88.4%
4	105-54-4	Ethyl butyrate	1681	43.4%
5	121-33-5	Vanillin	1587	41.0%
6	4940-11-8	Ethyl maltol	1491	38.5%
7	118-71-8	Maltol	1178	30.4%
8	141-78-6	Ethyl acetate	1174	30.3%
9	3658-77-3	Furaneol	1151	29.7%
10	7732-18-5	Water	1125	29.0%
11	64-17-5	Ethyl alcohol	1056	27.3%
12	121-32-4	Ethyl vanillin	1037	26.8%
13	928-96-1	cis-3-Hexen-1-ol	927	23.9%
14	7452-79-1	Ethyl 2-methylbutyrate	919	23.7%
15	123-92-2	Isoamyl acetate	901	23.3%
16	706-14-9	γ-Decalactone	874	22.6%
17	64-19-7	Acetic acid	848	21.9%
18	107-92-6	Butyric acid	821	21.2%
19	56038-13-2	Sucralose	779	20.1%
20	78-70-6	Linalool	722	18.6%
21	123-66-0	Ethyl hexanoate	702	18.1%
22	100-51-6	Benzyl alcohol	661	17.1%
23	104-67-6	γ-Undecalactone	610	15.7%
24	705-86-2	δ-Decalactone	600	15.5%
25	116-53-0	(±)-2-Methylbutyric acid	582	15.0%
26	765-70-8	3-Methylcyclopentane-1,2-dione	567	14.6%
27	142-62-1	3-Methyl-1,2-cyclopentanedione	562	14.5%
28	100-52-7	Benzaldehyde	561	14.5%

29	104-50-7	γ-Octalactone	556	14.3%
30	142-92-7	Hexyl acetate	549	14.2%
31	105-37-3	Ethyl propionate	548	14.1%
32	102-76-1	Triacetin	505	13.0%
33	659-70-1	Isoamyl isovalerate	502	13.0%
34	3681-71-8	cis-3-Hexenyl acetate	496	12.8%
35	120-57-0	Piperonal	490	12.6%
36	108-64-5	Ethyl isovalerate	482	12.4%
37	80-71-7	Methyl cyclopentenolone	456	11.8%
38	5471-51-2	Frambione	454	11.7%
39	56-40-6	Glycine	449	11.6%
40	22047-25-2	2-Acetylpyrazine	434	11.2%
41	713-95-1	δ-Dodecalactone	428	11.0%
42	104-61-0	γ-Nonanoic lactone	399	10.3%
43	103-26-4	Methyl cinnamate	384	9.9%
44	2216-51-5	L-Menthol	384	9.9%
45	140-11-4	Benzyl acetate	374	9.7%
46	123-11-5	p-Anisaldehyde	372	9.6%
47	98-55-5	α-Terpineol	351	9.1%
48	110-19-0	Isobutyl acetate	338	8.7%
49	5392-40-5	Citral	331	8.5%
50	513-86-0	Acetoin	323	8.3%
51	105-13-5	4-Methoxybenzyl alcohol	318	8.2%
52	7492-70-8	Butyl butyryllactate	306	7.9%
53	106-27-4	Isoamyl butyrate	299	7.7%
54	134-20-3	Methyl anthranilate	297	7.7%
55	137-00-8	4-Methyl-5-thiazoleethanol	289	7.5%
56	75-18-3	Dimethyl sulfide	279	7.2%
57	123-51-3	Isoamyl alcohol	277	7.1%
58	77-93-0	Triethyl citrate	271	7.0%
59	127-41-3	α-Ionone	270	7.0%
60	115-95-7	Linalyl acetate	258	6.7%
61	123-68-2	Allyl hexanoate	256	6.6%
62	106-24-1	Geraniol	248	6.4%
63	23696-85-7	Damascenone	244	6.3%
64	60-12-8	2-Phenylethanol	243	6.3%
65	8008-56-8	Lemon oil	240	6.2%
66	124-07-2	Octanoic acid	239	6.2%
67	119-84-6	Dihydrocoumarin	231	6.0%
68	97-53-0	Eugenol	230	5.9%
69	79-09-4	Propionic acid	227	5.9%
70	97-64-3	Ethyl lactate	224	5.8%
71	111-27-3	1-Hexanol	221	5.7%
72	51115-67-4	2-Isopropyl-N,2,3-trimethylbutyramide	221	5.7%
73	14667-55-1	2,3,5-Trimethylpyrazine	217	5.6%
74	90-05-1	Guaiacol	213	5.5%
75	89-78-1	Menthol	210	5.4%

76	6728-26-3	trans-2-Hexen-1-al	208	5.4%
77	38462-22-5	8-Mercaptomenthone	208	5.4%
78	14901-07-6	β-Ionone	205	5.3%
79	77-92-9	Citric acid	201	5.2%
80	105-87-3	Geranyl acetate	195	5.0%
81	695-06-7	γ-Hexalactone	193	5.0%
82	8008-57-9	Orange oil	187	4.8%
83	138-86-3	Dipentene	182	4.7%
84	104-55-2	Cinnamaldehyde	180	4.6%
85	106-22-9	β-Citronellol	173	4.5%
86	334-48-5	Decanoic acid	168	4.3%
87	2305-05-7	4,5,6,7-Tetrahydroindazole	168	4.3%
88	8008-26-2	Lime oil	166	4.3%
89	50-21-5	DL-Lactic acid	164	4.2%
90	79-77-6	β-Ionone	156	4.0%
91	141-97-9	Ethyl acetoacetate	152	3.9%
92	66-25-1	Hexanal	149	3.8%
93	106-72-9	2,6-Dimethyl-5-heptenal	148	3.8%
94	94-86-0	Propenylguaethol	145	3.7%
95	39711-79-0	Ethyl menthane carboxamide	141	3.6%
96	120-51-4	Benzyl benzoate	138	3.6%
97	109-21-7	Butyl butyrate	137	3.5%
98	65-85-0	Benzoic acid	137	3.5%
99	69-72-7	Salicylic acid	135	3.5%
100	16491-36-4	cis-3-Hexenyl butyrate	133	3.4%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=3,875)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity, concentration, and major function are presented below in **Table 9**. The carriers propylene glycol and glycerol, in addition to nicotine (primarily functioning as an addictive enhancer) were listed as the most common ingredients. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers, except water which was listed as a carrier.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Latvia

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	1958.08	2411.16	228.48	245.86	Carrier	-
2	54-11-5	Nicotine	12.00	51.76	1.60	5.45	Addictive Enhancer	-
3	56-81-5	Glycerol	1134.00	3564.78	318.58	359.34	Carrier	-
4	105-54-4	Ethyl butyrate	3.28	14.11	0.33	1.43	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
5	121-33-5	Vanillin	4.00	24.54	0.42	2.52	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
6	4940-11-8	Ethyl maltol	8.83	22.36	0.90	2.31	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
7	118-71-8	Maltol	1.39	7.81	0.15	0.77	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
8	141-78-6	Ethyl acetate	1.07	9.94	0.12	1.01	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
9	3658-77-3	Furaneol	1.59	13.76	0.17	1.36	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
10	7732-18-5	Water	34.70	124.55	3.58	12.70	Carrier	-
11	64-17-5	Ethyl alcohol	12.16	66.72	1.63	7.05	Flavour and/or Taste Enhancer	-
12	121-32-4	Ethyl vanillin	7.70	28.71	0.77	2.88	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
13	928-96-1	cis-3-Hexen-1-ol	1.10	5.74	0.12	0.58	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
14	7452-79-1	Ethyl 2-methylbutyrate	2.50	19.50	0.28	1.95	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
15	123-92-2	Isoamyl acetate	1.31	11.30	0.13	1.20	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
16	706-14-9	γ-Decalactone	0.75	3.64	0.09	0.36	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
17	64-19-7	Acetic acid	1.03	4.74	0.10	0.48	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
18	107-92-6	Butyric acid	0.85	5.84	0.09	0.56	Flavour and/or Taste Enhancer	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor
19	56038-13-2	Sucralose	10.00	24.03	1.00	2.39	Flavour and/or Taste Enhancer	-
20	78-70-6	Linalool	0.28	3.43	0.03	0.36	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Latvia EU CEG.

**Flavour descriptions* are according to a desk literature review, where available.

Conclusions

Summary of Results

Within the current Latvia EU-CEG dataset, there are 11,522 notifications (unique EC-IDs), of which 4,905 were indicated to be withdrawn from the market and 75 indicated withdrawal but did not provide a specific date. The most common type of product active in the Latvia EU CEG was refill containers/cartridges containing e-liquids (n=3,875).

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.4% of products reporting a vial volume of 10ml or less. Non-compliant products (n=24) reported a maximum vial volume of 30ml. Most containers/cartridges capable of carrying an e-liquid were compliant with regards to the capacity, with 87.4% reporting a volume capacity of 2ml or less. Non-compliant products (n=203) reported a maximum capacity of 10ml. A significant number of invalid values (=0ml) were reported for capacity (n=156), more than half of which were characterized as rechargeable e-cigarettes (device only). With regards to the nicotine concentration, all e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 964 unique CAS numbers reported in the Latvia EU CEG. The average number of ingredients per product, among products reporting CAS, was 17.9, ranging between 1 and 105 different CAS per product. The most common ingredient in frequency were the humectants propylene glycol and glycerol, and nicotine. The most frequently reported flavorings were ethyl butyrate, vanilla, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Missing and invalid data in the Latvia EU CEG (specifically for vial volumes and capacity) suggests a need to redefine or clarify product type categories and their relevant variables. For example, all products missing reports for volume capacity were categorized as ‘individual parts of e-cigarettes capable of containing an e-liquid,’ suggesting a need to clarify the categorical definition.
- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume capacity and nicotine concentration), or to change the variable type from “text” variables to “numeric” variables to ensure correct and consistent reporting (e.g. in battery type reporting).
- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

Joint Action on Tobacco Control (JATC)

Agreement n°: 761297— JATC — HP-JA-03-2016

WP7 – E-cigarette product National Report ITALY

Circulation: Internal

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Background

Under the European Union (EU) Tobacco Products Directive (TPD) (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information, to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. This reporting is performed through the EU Common Entry Gate (EU-CEG), an Information Technology (IT) tool developed to provide a standard format for manufacturers and importers to report this information. EU-CEG was designed to facilitate a harmonised reporting system that lessens the administrative burden for submitters, as well as enhances the EC and MS's ability to compare data and ultimately regulate products on the EU market. As such, the European Commission has worked closely with both MS and industry stakeholders to develop EU-CEG, which became operational in May 2016, and is periodically updated through an iterative process informed by stakeholders to maximize the system's utility and output.

Through EU-CEG, manufacturers and importers are required to submit information on any new product before it is placed on the market, and to update the data should new information become available. Once data is uploaded and successfully passes a technical validation process, the data are directed to the relevant national data repository that is accessible to the EC and the relevant competent EU MS authority.

This reporting format has substantially enhanced and harmonized the collection of product-related information across the 28 EU MS through this common platform, however, to maximize the potential of the platform and data handling system it is essential that the system and its data are evaluated, both collectively and at the EU MS level.

With the above in mind the purpose of this report of the JATC is to perform an assessment of the data submitted through the reporting platform and highlight regulatory issues for the consideration of the competent EU MS authorities.

Approach and results by research question

Below we provide an analysis for the EU MS Italy. The datasets used are those requested via the data request forms (provided in Annex A of JATC D5.3) and were extracted from EU-CEG in December of 2019. Accordingly, the analysis reflects the data reported at that time, i.e., the results are static and not dynamic.

Data were handled according to JATC deliverable 5.3, and analysed using two statistical programmes, R (which is open source) and Stata (which is a proprietary software).

As one of the primary objectives of this activity was to flag product IDs that were flagged with regards to compliance with the notification standards or with the TPD standards based on the submitted EU-CEG data. **Annex A** provides a list of the EC-IDs of products that were flagged through this process and the justification of their status.

1. Notification compliance

1.1 Status of all notifications for electronic cigarettes and refill containers in the EU MS [TPD Art20(2)]

Within the current Italy EU-CEG dataset, there are 46,079 notifications (unique EC-IDs). **Figure 1** reflects the numbers of different types of notifications. The percentage breakdown of the types of notifications can be seen in **Table 1** (below). The most common notification type, among products with valid notifications, was a notification for a new product EC-ID (28.7%), followed by the addition of a product presentation (17.5%), and the correction of clerical/administrative errors in an existing product submission (16.9%).

Figure 1. Type of valid notifications within EU-CEG, Italy (N= 46,079)

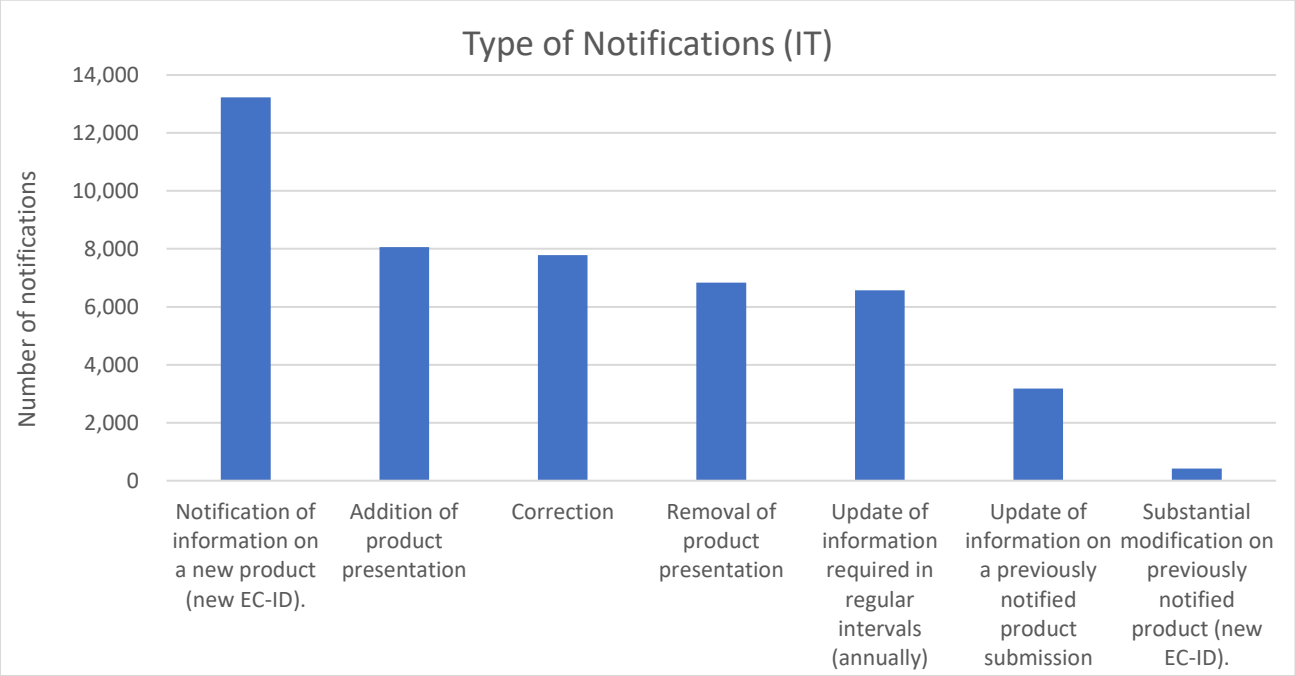


Table 1. Type of notifications within EU-CEG in Italy (N=46,079)

Type	n	% (valid)
Notification of information on a new product (new EC-ID).	13,232	28.7%
Addition of product presentation (e.g. national market) to an existing product submission.	8,057	17.5%
Correction of clerical/administrative errors in existing product submission.	7,783	16.9%
Removal of product presentation, including product withdrawal, from an existing product submission.	6,837	14.8%
Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients	6,569	14.3%
Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.	3,179	6.9%
Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).	422	0.9%

1.2. Product types currently active in EU-CEG [TPD Art20(2)]

As of December 2019, of the 46,079 notifications (unique EC-IDs) submitted for Italy in the EU CEG, 4,669 (10.1%) products have been withdrawn and 103 (0.2%) products indicated withdrawal but did not provide a specific date at the time of analysis, while 41,307 (89.6%) unique EC-IDs remain active on the market. The analysis is restricted to products that are currently active (n=41,307).

Figure 2 displays the numbers of the active product types. The percentage breakdown of the types of products reported active in EU-CEG for Italy is displayed in **Table 2** (below). Of the 41,307 notifications for products that are currently on the market, 72.2% (n=29,809) represented refill containers/cartridges containing an e-liquid, 7.8% (n=3,215) represented a refillable device (device only), and 6.8% (n=2,799) represented individual parts of e-cigarettes capable of containing e-liquids.

Figure 2. Product types active (not withdrawn) in EU-CEG, Italy (n=41,307)

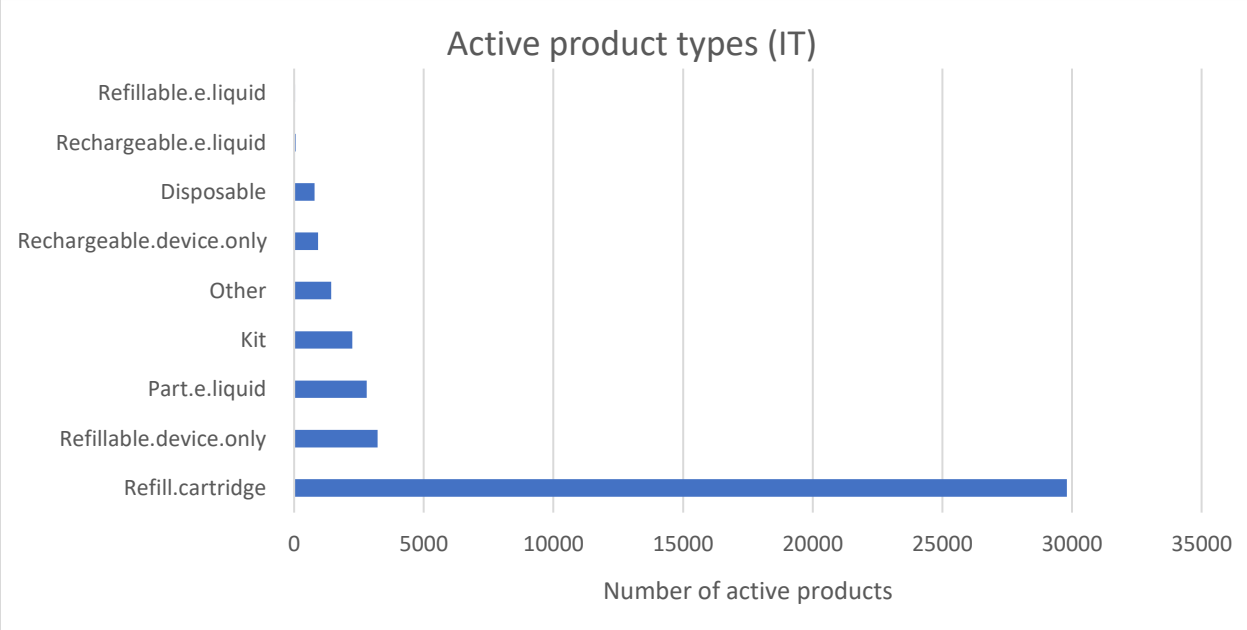


Table 2. Breakdown of product types active in EU-CEG types, Italy (n=41,307)

Product type	n	%
Refill container/cartridge containing e-liquid	29809	72.2%
Refillable, device only	3215	7.8%
Individual part of e-cigarette capable of containing e-liquid	2799	6.8%
Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge	2245	5.4%
Other	1433	3.5%
E-cigarette – Rechargeable, device only	925	2.2%
E-cigarette – Disposable	791	1.9%
E-cigarette – Rechargeable, placed on the market with one type of e-liquid	54	0.1%
E-cigarette – Refillable, placed on the market with one type of e-liquid	36	0.1%

2. Assessment of volume (capacity) and nicotine content

2.1 Volume/capacity of nicotine-containing e-cigarette liquid [TPD Art 20(3)a]

Volume of dedicated nicotine-containing refill containers/cartridges

Among the 29,809 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), 3 products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. These products are flagged in **Annex A.** Of the 29,806 refill containers/cartridges reporting valid vial volumes (>0 ml), 27,816 were reported to contain nicotine. Products that do not contain nicotine (i.e. have a nicotine concentration of 0mg/ml) do not need to comply to the TPD restrictions on vial volume.

Among the 27,816 nicotine-containing refill containers/cartridges that reported valid vial volumes in Italy, the average vial volume was 10.61ml. The middle value of the vial volumes reported (median) was 10ml. This distribution is presented in **Table 3** below. It is important to note that, given the range of vial volumes reported and outliers, the SD of vial volumes among all products was 97.34ml.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml.* Nicotine-containing refill vials were predominantly compliant with regards to the vial volume, with 99.8% of products (n=27,761) reporting a vial volume of 10ml or less. Among compliant products, the average vial volume was 9.71ml and the middle value of the vial volume data set (median) was 10ml. This is depicted in **Table 3**.

There were 55 refill containers/cartridges identified as non-compliant (volume >10ml) in the Italy EU-CEG. The volume distribution of these non-compliant products is depicted in **Table 3** below, depicting some outliers with extremely large vial volumes (e.g. 11,482ml). The non-compliant EC-IDs are flagged in **Annex A**.

Table 3. Distribution of vial volumes (ml) among nicotine-containing refill containers/cartridges, with valid reported vial volumes, Italy

	Vial volume (ml)		
	All products n=27,816	**Compliant products (≦10ml)** n= 27,761	**Non-compliant products (>10ml)** n= 55
Min.	0.67	0.67	12
Median	10	10	30
Mean	10.61	9.713	461.9
Max.	11482	10	11482
SD	97.34	1.52	2161.34

Volume (capacity) of cartridges or tanks sold with nicotine-containing liquids

Focusing on the 7,793 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this excludes products listed as refill containers/cartridges, as these are addressed in the previous sections and are subject to different regulations, and kits, refill containers/cartridges and "other" due to

the ambiguity of those reporting categories, and disposable e-cigarettes that do not contain nicotine, as these single-use products are not subject to the same volume regulations), 6,740 products reported a value for capacity and 1,053 products (13.5%) were missing reports. All of the 1,053 submissions that were missing reports were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.' Of the 6,740 products which reported a value for capacity, 5,833 products (86.5%) reported a valid capacity (>0 ml) and 907 products (13.5%) reported invalid values for capacity (i.e. 0 ml). Over half of the 907 products reporting invalid values for capacity (n=495) were listed as 'individual parts of e-cigarettes capable of containing an e-liquid.'

Among the 5,833 products that reported a valid capacity (>0 ml) in Italy, the average capacity was 2.74ml, and the middle value of the capacities reported (median) was 2ml. The SD of capacity among all products was 2.23ml. This distribution is presented in **Table 4** below.

Cartridges or tanks capable of carrying nicotine-containing e-liquids were mostly compliant with regards to the capacity, with 75.4% of products (n=4,399) reporting a capacity of 2ml or less. Among compliant products, the average capacity was 1.79ml and the middle value of the capacities reported (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant capacities greater than 2ml (n=1,434) had an average capacity of 5.64ml, and middle value (median) of 4.5ml. The SD for products reporting non-compliant capacities was 2.94ml. The volume distribution of these non-compliant products is depicted in **Table 4**, and their EC-IDs are flagged in **Annex A**. The number of non-compliant products varies per product type category, although there are different numbers of each product type included in the analysis. Thus, compliance 'rates' per product type should be interpreted with caution. Among products sold with an e-liquid, there were 255 non-compliant nicotine-containing disposable e-cigarettes (33.4%) and 4 non-compliant refillable e-cigarettes sold with an e-liquid product (11.4%). Among products sold without an e-liquid, which can still be used for the consumption of nicotine-containing e-liquids, 137 products (10.9%) listed as 'individual parts of e-cigarettes capable of containing an e-liquid', 170 (29.8%) of the rechargeable devices, and 868 (27.5%) of the refillable devices, were flagged for non-compliant capacities.

Table 4. Reported distribution of capacity (ml) among cartridges or tanks capable of carrying nicotine-containing e-liquids,* Italy

	Capacity (ml) **All reported** (n= 6740)	**All valid (>0 ml)** (n= 5833)	**Valid, Compliant (≦2ml)** (n= 4399)	**Valid, Non-compliant (>2ml)** (n=1434)
Min.	0	0.01	0.01	2.2
Median	2	2	2	4.5
Mean	2.372	2.741	1.798	5.635
Max.	60	60	2	60
SD	2.28	2.23	0.39	2.94
Invalid (=0 ml)	n= 907			

**Note: This includes all product types except those listed as refill containers/cartridges, kits, 'other', and disposable e-cigarettes without nicotine.*

2.2 Nicotine concentration in nicotine-containing e-liquids [TPD Art 20(3)b]

Among the 29,809 notifications on e-liquid products sold in refill cartridges/containers, 1,991 (6.7%) did not contain nicotine. The average nicotine concentration among the remaining 27,818 nicotine-containing e-liquid products was 10.25 mg/ml and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. This distribution is depicted below in **Table 5**.

Under Article 20.3 of the EU TPD (2014/40/EU), MS are obliged to ensure that *nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.* The overwhelming majority (99.8%) of the 27,818 nicotine-containing e-liquid products in the Italy EU CEG were compliant with regards to the nicotine concentration, reporting a nicotine concentration of 20 mg/ml or less. Among these 27,764 compliant products, the average nicotine concentration was 9.75 mg/ml and the middle value of the reported nicotine concentrations (median) was 9 mg/ml. This is displayed in **Table 5**.

Only 54 products were identified to be non-compliant, with a nicotine concentration greater than 20 mg/ml. Among these, there were extreme outliers (with a maximum reported value of 11,475.75mg/ml), leading to a SD of 1554.61mg/ml. The distribution of nicotine concentration of these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex A**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing refill cartridges/containers, Italy

	Nicotine concentration (mg/ml)		
	All products (n=27,818)	**Compliant products (≦20 mg/ml)** (n=27,764)	**Non-compliant products (>20 mg/ml)** (n= 54)
Min.	0.25	0.25	20.02
Median	9	9	60
Mean	10.25	9.748	267.28
Max.	11475.75	20	11475.75
SD	69.05	5.89	1554.61

3. Assessment of design components

3.1 Design components of e-cigarette products [TPD Art 20(2)e]

There were substantial differences in the reporting of the type of battery in the Italy EU-CEG data, due primarily to the fact that this was a “text” field with no restrictions. Hence, 468 unique responses were recorded and included both text responses such as “LI-ION,” and numeric responses such as “1400mAh”. A preliminary assessment identified that the most used type of battery was a Li-ION battery (for rechargeable, refillable devices, and kits). There was significant reporting of responses such as “no battery” for certain reporting categories (such as refill vials), that should be cleaned at the submission phase and reported as 0 or “missing” to avoid complication of the reporting.

With regards to battery capacity, there was a wide range of capacities reported among different product types, for example disposable e-cigarettes (mode: 280mA), refillable e-cigarette devices sold as ‘device only’ (mode: 1500mA) and rechargeable e-cigarette devices sold as ‘device only’ (mode: 1500mA). With regards to whether the airflow is adjustable or if the wick is changeable, none of the 791 disposable e-cigarettes were found to have the ability to alter airflow and only one reported the ability to change the wick (0.1%). However, among the 3,215 products listed as ‘refillable, device only’, 70.9% (n= 2,282) noted the ability to adjust airflow and 41.0% (n=1,319) had the ability to change the wick, and among the 925 products listed as ‘rechargeable device only’, 44.3% (n=410) had the ability to adjust airflow and 16.4% (n=152) had the ability to change the wick. This suggests the plethora of product designs available on the market. A similar pattern was identified for the presence of microprocessor, which was largely present in rechargeable devices sold as ‘device only’ (67.1%), kits (63.3%), and refillable devices sold as ‘device only’ (57.8%), whereas only 9.6% of the 791 disposable e-cigarettes had a microprocessor.

4. Ingredient Analysis

4.1 Number of ingredients contained per product [TPD Art 20(2)b]

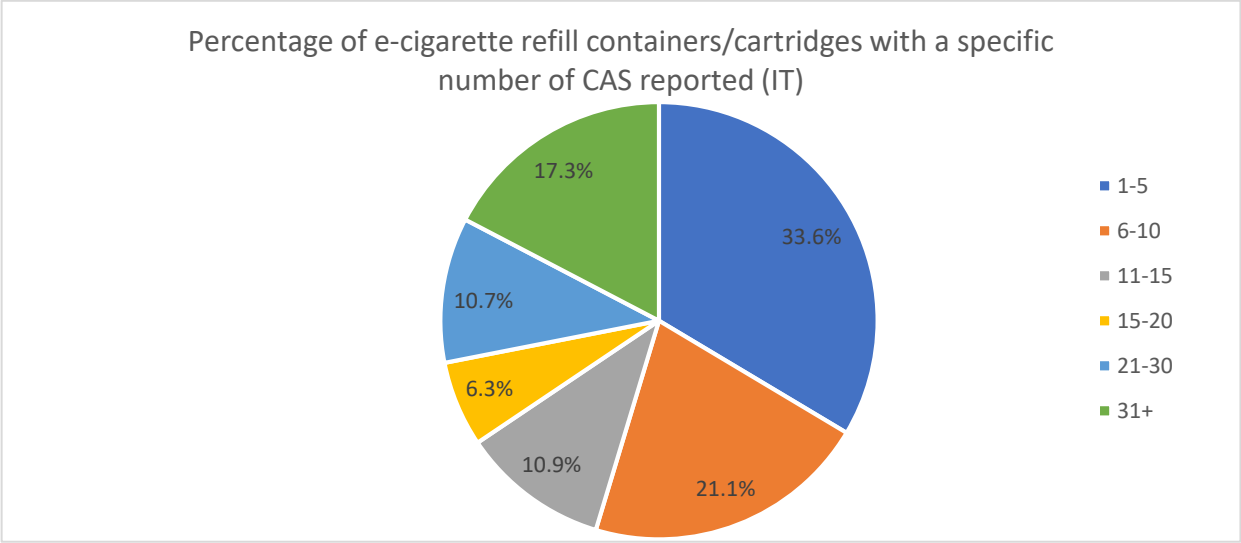
Among the 29,809 submissions for refill containers/cartridges within the Italy EU-CEG database with a "not withdrawn" status, 1,923 unique CAS numbers were submitted.

Among the 29,809 submissions for refill containers/cartridges, 27.5% reported between 1 to 5 CAS. A significant proportion (18.2%) of products reported no CAS (n=5,422), thus their submissions were considered invalid and their EC-IDs are flagged in **Annex A**. The breakdown of number of CAS reported per product is displayed in **Table 6**. **Figure 3** depicts the breakdown of the number of CAS reported within one product, excluding submissions with no CAS reported.

Table 6. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges, Italy (n=29,809)

Number of CAS per product	Number of products	% (total)	% (excluding invalid)
1-5	8187	27.5%	33.6%
6-10	5145	17.3%	21.1%
11-15	2661	8.9%	10.9%
16-20	1544	5.2%	6.3%
21-30	2621	8.8%	10.7%
31+	4229	14.2%	17.3%
Invalid (no CAS reported)	5422	18.2%	

Figure 3. Breakdown of the number of CAS reported within one product (among those that reported a CAS), Italy (n=24,387)



Among valid submissions, the average number of ingredients per product was 16.05, ranging between 1 to 120 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID for all submissions and for all valid submissions is depicted in **Table 7**.

Table 7. Distribution of number of CAS contained in one refill container/cartridge product, overall and among valid product submissions, Italy

	Number of CAS All refill containers/cartridges (n= 29,809)	Valid CAS entry (n= 24,387)
Min.	0	1
Median	7	9
Mean	13.13	16.05
Max.	120	120
SD	16.05	16.37
Invalid (i.e. no CAS reported)	n = 1923	

4.2 Most frequently used ingredients [TPD Art 20(2)b]

Among the refill containers/cartridges that contain an e-liquid which reported any CAS (n=24,387), a total of 1,923 unique ingredients (CAS numbers) were reported. The top 100 most common ingredients are listed in **Table 8**.

Table 8. Top 100 most common ingredients of e-liquids in refill containers/cartridges, Italy (n=24,387)

Rank	CAS	Ingredient name	Product count (n)	Percentage of products (%)
1	57-55-6	Propylene glycol	23760	97.4%
2	56-81-5	Glycerol	22583	92.6%
3	54-11-5	Nicotine	22000	90.2%
4	121-33-5	Vanillin	9943	40.8%
5	7732-18-5	Water	8747	35.9%
6	105-54-4	Ethyl butyrate	8088	33.2%
7	4940-11-8	Ethyl maltol	7928	32.5%
8	141-78-6	Ethyl acetate	6178	25.3%
9	118-71-8	Maltol	6161	25.3%
10	64-17-5	Ethyl alcohol	5846	24.0%
11	3658-77-3	Furaneol	5418	22.2%
12	121-32-4	Ethyl vanillin	5063	20.8%
13	928-96-1	cis-3-Hexen-1-ol	4816	19.7%
14	706-14-9	γ-Decalactone	4723	19.4%
15	123-92-2	Isoamyl acetate	4674	19.2%
16	7452-79-1	Ethyl 2-methylbutyrate	4558	18.7%
17	100-51-6	Benzyl alcohol	4522	18.5%
18	64-19-7	Acetic acid	4262	17.5%
19	78-70-6	Linalool	4047	16.6%
20	107-92-6	Butyric acid	3855	15.8%
21	123-66-0	Ethyl hexanoate	3713	15.2%
22	100-52-7	Benzaldehyde	3310	13.6%
23	102-76-1	Triacetin	3301	13.5%
24	142-92-7	Hexyl acetate	3192	13.1%
25	56038-13-2	Sucralose	3064	12.6%

26	705-86-2	δ-Decalactone	3031	12.4%
27	3681-71-8	cis-3-Hexenyl acetate	3015	12.4%
28	116-53-0	(±)-2-Methylbutyric acid	2892	11.9%
29	105-37-3	Ethyl propionate	2868	11.8%
30	120-57-0	Piperonal	2855	11.7%
31	5471-51-2	Frambione	2824	11.6%
32	142-62-1	Hexanoic acid	2822	11.6%
33	104-67-6	γ-Undecalactone	2740	11.2%
34	765-70-8	3-Methyl-1,2-cyclopentanedione	2634	10.8%
35	80-71-7	Methyl cyclopentenolone	2626	10.8%
36	103-26-4	Methyl cinnamate	2526	10.4%
37	104-50-7	γ-Octalactone	2499	10.2%
38	659-70-1	Isoamyl isovalerate	2499	10.2%
39	108-64-5	Ethyl isovalerate	2423	9.9%
40	140-11-4	Benzyl acetate	2369	9.7%
41	123-11-5	p-Anisaldehyde	2290	9.4%
42	713-95-1	δ-Dodecalactone	2269	9.3%
43	104-61-0	γ-Nonanoic lactone	2205	9.0%
44	2216-51-5	L-Menthol	2021	8.3%
45	513-86-0	Acetoin	1868	7.7%
46	56-40-6	Glycine	1849	7.6%
47	127-41-3	α-Ionone	1846	7.6%
48	5392-40-5	Citral	1778	7.3%
49	22047-25-2	2-Acetylpyrazine	1746	7.2%
50	106-27-4	Isoamyl butyrate	1741	7.1%
51	119-84-6	Dihydrocoumarin	1738	7.1%
52	137-00-8	4-Methyl-5-thiazoleethanol	1712	7.0%
53	14901-07-6	β-Ionone	1663	6.8%
54	90-05-1	Guaiacol	1643	6.7%
55	98-55-5	α-Terpineol	1633	6.7%
56	5989-27-5	(R)-(+)-Limonene	1593	6.5%
57	110-19-0	Isobutyl acetate	1546	6.3%
58	111-27-3	1-Hexanol	1430	5.9%
59	60-12-8	2-Phenylethanol	1425	5.8%
60	123-51-3	Isoamyl alcohol	1422	5.8%
61	23696-85-7	Damascenone	1410	5.8%
62	75-18-3	Dimethyl sulfide	1405	5.8%
63	97-53-0	Eugenol	1390	5.7%
64	105-13-5	4-Methoxybenzyl alcohol	1384	5.7%
65	14667-55-1	2,3,5-Trimethylpyrazine	1364	5.6%
66	6728-26-3	trans-2-Hexen-1-al	1362	5.6%
67	123-68-2	Allyl hexanoate	1357	5.6%
68	97-64-3	Ethyl lactate	1330	5.5%
69	106-24-1	Geraniol	1308	5.4%
70	695-06-7	γ-Hexalactone	1256	5.2%
71	8008-56-8	Lemon oil	1170	4.8%
72	79-09-4	Propionic acid	1167	4.8%

73	134-20-3	Methyl anthranilate	1142	4.7%
74	77-92-9	Citric acid	1122	4.6%
75	104-55-2	Cinnamaldehyde	1113	4.6%
76	89-78-1	Menthol	1087	4.5%
77	105-87-3	Geranyl acetate	1055	4.3%
78	7492-70-8	Butyl butyryllactate	1045	4.3%
79	115-95-7	Linalyl acetate	996	4.1%
80	66-25-1	Hexanal	975	4.0%
81	123-86-4	Butyl acetate	969	4.0%
82	4180-23-8	trans-Anethole	961	3.9%
83	8008-26-2	Lime oil	951	3.9%
84	2305-05-7	4,5,6,7-Tetrahydroindazole	889	3.6%
85	77-93-0	Triethyl citrate	870	3.6%
86	124-07-2	Octanoic acid	835	3.4%
87	109-21-7	Butyl butyrate	825	3.4%
88	106-32-1	Ethyl octanoate	824	3.4%
89	470-82-6	Eucalyptol	819	3.4%
90	138-86-3	Dipentene	792	3.2%
91	620-02-0	5-Methylfurfural	770	3.2%
92	93-92-5	1-Phenylethyl acetate	755	3.1%
93	23726-92-3	(Z)-β-Damascone	743	3.0%
94	16491-36-4	cis-3-Hexenyl butyrate	740	3.0%
95	141-97-9	Ethyl acetoacetate	722	3.0%
96	120-51-4	Benzyl benzoate	720	3.0%
97	928-95-0	trans-2-Hexen-1-ol	699	2.9%
98	532-32-1	Sodium benzoate	686	2.8%
99	51115-67-4	2-Isopropyl-N,2,3-trimethylbutyramide	679	2.8%
100	110-44-1	Sorbic acid	670	2.7%

Note: Product percentage was calculated by dividing the product count by the total number of refill container/cartridge products that reported any CAS (n=24,387)

4.3 Concentration, recipe quantity and major function of the top 20 ingredients used [TPD Art 20(2)b]

Focusing on the top 20 most common ingredients, the recipe quantity, concentration, and major function are presented below in **Table 9**. The carriers propylene glycol and glycerol were listed as the most common ingredients, followed by Nicotine, primarily functioning as an addictive enhancer. All other ingredients in the top 20 were reported to be used as flavor/taste enhancers, except water which was listed as a water-wetting agent.

Table 9. Recipe quantity, concentration, and major function of the top 20 most common ingredients of e-liquids in refill containers/cartridges, Italy

			Recipe quantity (mg/product)		Concentration (mg/ml)			
Rank	**CAS**	**Name**	**Median**	**Mean**	**Median**	**Mean**	**Major function**	**Flavor description ***
1	57-55-6	Propylene glycol	4530.00	6894.00	462.00	413.00	Carrier	-
2	56-81-5	Glycerol	5280.00	21516.00	538.00	1268.00	Carrier	-
3	54-11-5	Nicotine	59.49	74.87	6.00	8.27	Addictive Enhancer	-
4	121-33-5	Vanillin	7.72	27.26	0.85	3.22	Flavour and/or Taste Enhancer	Powerful, creamy, vanilla-like odor & sweet taste
5	7732-18-5	Water	195.00	2046.00	21.18	41.69	Water-Wetting Agents	-
6	105-54-4	Ethyl butyrate	3.51	13.99	0.36	1.56	Flavour and/or Taste Enhancer	Ethereal, fruity odor; buttery-pineapple-banana, ripe fruit & juicy notes
7	4940-11-8	Ethyl maltol	9.42	23.59	1.00	2.41	Flavour and/or Taste Enhancer	Sweet, fruity-caramellic cotton candy odor; fruity preserve taste
8	141-78-6	Ethyl acetate	1.92	9.64	0.20	1.05	Flavour and/or Taste Enhancer	Ethereal, sharp, wine-brandy like odor
9	118-71-8	Maltol	2.35	9.40	0.27	0.99	Flavour and/or Taste Enhancer	Sweet, fruity, berry, caramellic odor; strawberry, fruity preserve-like
10	64-17-5	Ethyl alcohol	29.40	96.28	3.05	9.94	Flavour and/or Taste Enhancer	-
11	3658-77-3	Furaneol	2.65	10.48	0.28	1.09	Flavour and/or Taste Enhancer	Fruity, caramelized pineapple-strawberry odor & taste; roasted
12	121-32-4	Ethyl vanillin	8.91	28.03	0.96	2.88	Flavour and/or Taste Enhancer	Intense, sweet, vanilla like odor; creamy vanilla taste
13	928-96-1	cis-3-Hexen-1-ol	2.00	6.28	0.21	0.66	Flavour and/or Taste Enhancer	Strong, fresh, green, grassy odor
14	706-14-9	γ-Decalactone	0.80	3.59	0.09	0.39	Flavour and/or Taste Enhancer	Coconut-peach like odor; in dilution, peach taste
15	123-92-2	Isoamyl acetate	2.14	15.68	0.24	1.72	Flavour and/or Taste Enhancer	Sweet, fruity, banana, pear odor & taste
16	7452-79-1	Ethyl 2-methylbutyrate	2.50	14.77	0.26	1.54	Flavour and/or Taste Enhancer	Strong, green, fruity, apple odor and taste; also some strawberry notes
17	100-51-6	Benzyl alcohol	4.04	21.75	0.48	2.25	Flavour and/or Taste Enhancer	Faint, sweet, almond fruity aroma; sweet, but somewhat chemical taste
18	64-19-7	Acetic acid	1.69	6.65	0.18	0.68	Flavour and/or Taste Enhancer	Pungent, sour, vinegar odor with sour, acid taste
19	78-70-6	Linalool	0.54	3.61	0.06	0.37	Flavour and/or Taste Enhancer	Floral-woody, faint citrus note odor; sweet floral & slight citrus taste
20	107-92-6	Butyric acid	0.95	5.20	0.10	0.54	Flavour and/or Taste Enhancer	Fruity floral, plum-apricot aroma; plum, apricot-pear-like tropical flavor

Note: Concentration was calculated by dividing the recipe quantity by vial volume of the respective products. Major function was obtained as the most commonly reported function for the respective ingredients in the Italy EU CEG.

**Flavour descriptions* are according to a desk literature review, where available.

Conclusions

Summary of Results

Within the current Italy EU-CEG dataset, there are 46,079 notifications (unique EC-IDs), of which 4,669 were indicated to be withdrawn from the market and 103 indicated withdrawal but did not provide a specific date. The most common type of product active in the Italy EU CEG was refill containers/cartridges containing e-liquids (n=27,597). Among the categories assessed in the analysis (volume and nicotine concentration), there were large outliers in the Italy EU CEG dataset.

Nicotine-containing refill containers/cartridges were predominantly compliant with regards to the vial volume, with 99.8% of products reporting a vial volume of 10ml or less. Non-compliant products (n=55) included outliers reporting a maximum vial volume of 11,482ml. Two invalid values (=0ml) were reported for vial volumes. Most containers/cartridges capable of carrying an e-liquid were compliant with regards to the capacity, with 75.4% reporting a volume capacity of 2ml or less. Non-compliant products (n=1,434) included outliers which reported a maximum capacity of 60ml. A significant number of invalid values (=0ml) were reported for capacity (n=907), more than half of which were characterized as 'individual part of electronic cigarette capable of containing e-liquid.'

With regards to the nicotine concentration, the overwhelming majority (99.8%) of e-liquid refill containers/cartridges were compliant, with a nicotine concentration of 20 mg/ml or less. Non-compliant products (n=54) included extreme outliers reporting a maximum nicotine concentration of 11,476mg/ml.

Refillable and rechargeable e-cigarettes had specific design parameters (higher battery capacity, changeable wick and airflow) when compared to disposable products.

There were 1,923 unique CAS numbers reported in the Italy EU CEG. The average number of ingredients per product, among products reporting CAS, was 16.1, ranging between 1 and 120 different CAS per product. A significant proportion of products (18.2%) reported no CAS. The most common ingredient in frequency were the humectants propylene glycol and glycerol, followed by nicotine. The most frequently reported flavorings were vanilla, ethyl butyrate, and ethyl maltol.

Recommendations

- ✓ Regulators should use the flagged EC-IDs in **Annex A** to communicate with manufacturers with regards to non- compliant products or to improve the quality of EU CEG submissions, in the case of missing data or outliers which are a result of reporting errors.
- ✓ Extremely large outliers across reporting categories (specifically for vial volume and nicotine concentration) remain a limitation of the current analysis of the Italy EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting and limiting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ Missing and invalid data in the Italy EU CEG (e.g. vial volumes, capacity, CAS) suggests a need to redefine or clarify product type categories and their relevant variables. For example, all products missing reports for volume capacity, and over 50% of those reporting invalid values for volume

capacity, were categorized as ‘individual parts of e-cigarettes capable of containing an e-liquid,’ suggesting a need to clarify the categorical definition.

- ✓ Specific variables should be modified in the EU-CEG submission system to include limits set for variables (e.g. in reporting volume capacity and nicotine concentration), or to change the variable type from “text” variables to “numeric” variables to ensure correct and consistent reporting (e.g. in battery type reporting).
- ✓ Specific data entry points should be blocked for products where irrelevant (e.g. prohibiting data entry for battery information for refill vials) to avoid complications in reporting and analysis.
- ✓ A mechanism should be in place to ensure that all products with e-liquids enter CAS information, given that 18.2% of refill cartridge/containers in the Italy EU CEG reported no CAS.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavor resulting from specific ingredient combinations is needed.

JOINT ACTION ON TOBACCO CONTROL

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