



Joint Action on Tobacco Control (JATC)

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

WP7 – First Report on e-cigarette product data analyses National Reports for GREECE and SPAIN

Circulation: Public

Authors: HCS

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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 Greece. The datasets used are those requested via the data request forms (provided in Annex B 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). The methodological approach for the cleaning, merging and analysis of the data is provided in **Annex A**.

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 B 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 Greek 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 in Greece (N= 30,674)

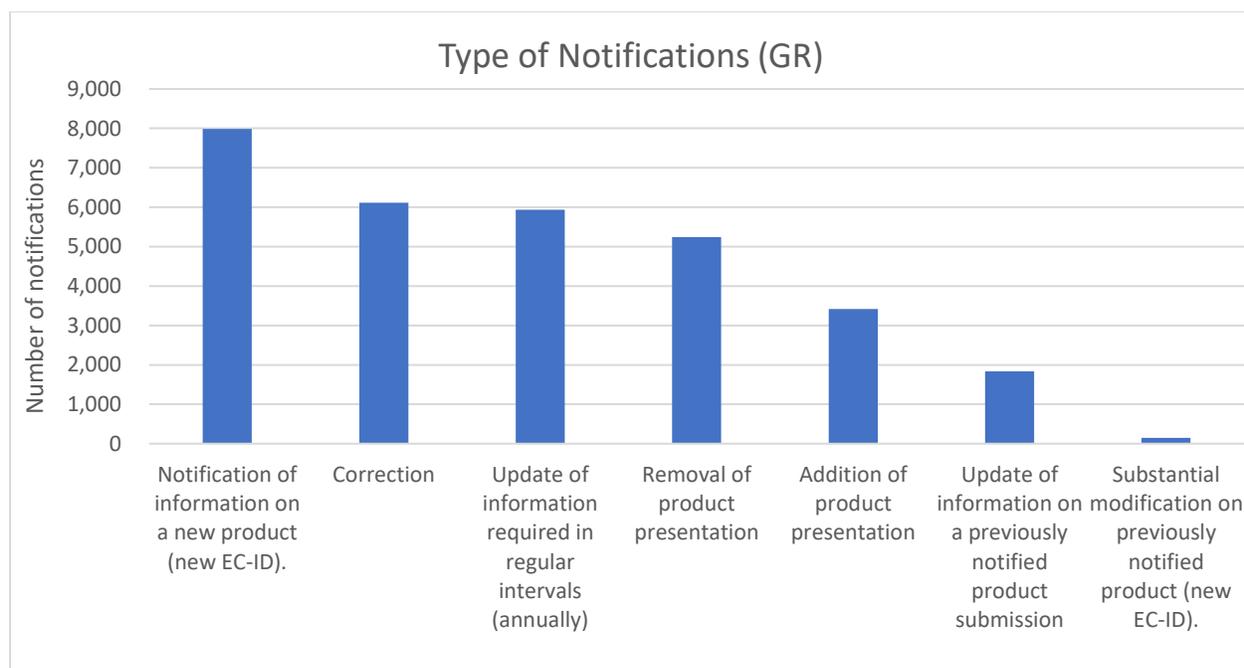


Table 1. Type of notifications within EU-CEG in Greece (N=30,674)

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 the 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.

Figure 2 displays the numbers of 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 that are currently on the market, 71.9% (18,086) represented refill containers/cartridges containing an e-liquid, 8.1% (2,043) represented a refillable device (device only), and 6.9% (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)

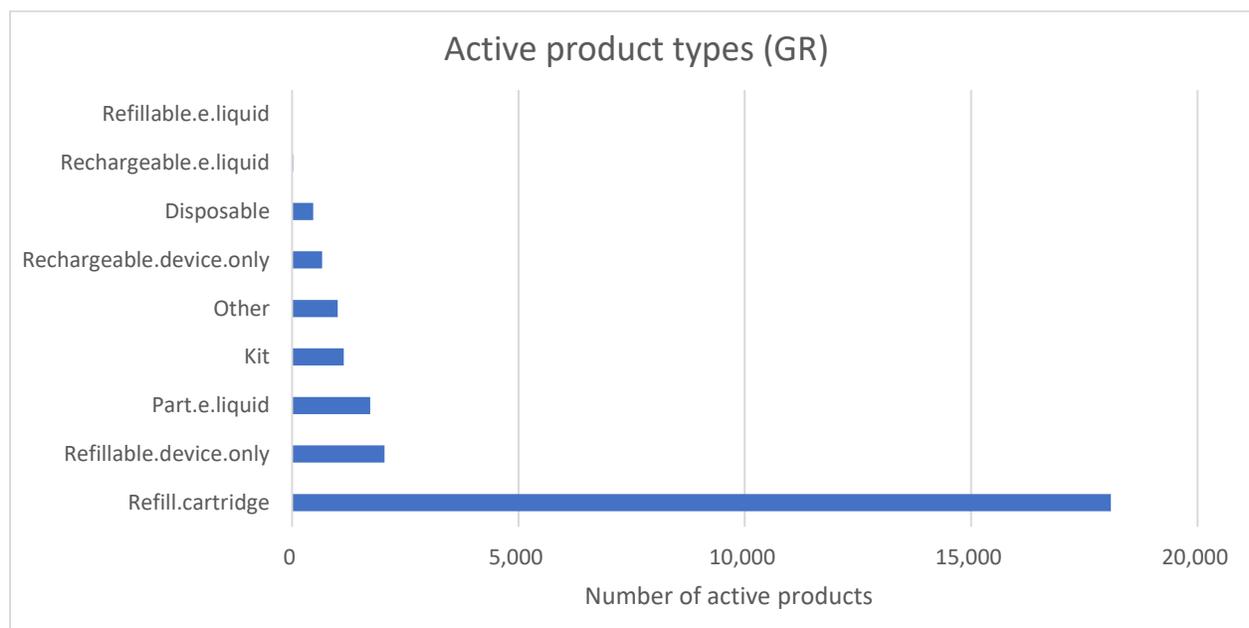


Table 2. Breakdown of product types active in EU-CEG, Greece (n=25,150)

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 Vial volume of nicotine-containing refill containers [TPD Art 20(3)a]

Among the 18,086 notifications on refill containers/cartridges (not taking into account potential corrections that change the product EC-ID), three products reported invalid vial (container/cartridge) volumes (i.e. 0 ml) and were thus excluded from the distribution analysis. The products are flagged in **Annex B**. Of the 18,083 refill containers/cartridges reporting valid vial volumes (> 0 ml), 17,027 are reported to contain nicotine. Products that have a nicotine concentration of 0mg/ml do not need to comply with 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 most commonly reported vial volume (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 9.733ml, and the most commonly reported vial volume (median) was 10ml. This is depicted in **Table 3**.

Only 45 non-compliant products (volume >10ml) were identified in the Greek 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 B**.

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 (≤ 10 ml) n= 16,982	Non-compliant products (>10ml) n= 45
Min.	0.67	0.67	12
1st Qu.	0	10	20
Median	10	10	30
Mean	11.11	9.733	532
3rd Qu.	10	10	30
Max.	11450	10	11450
SD	122.65	1.47	2354.162

2.2 Volume capacity of cartridges or tanks with nicotine-containing liquids [TPD Art 20(3)a]

Focusing on the 4,929 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this includes all product except those listed as kits, refill containers/cartridges and "other"), 4,233 products reported a value for volume 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 volume capacity, 3,746 products (88.5%) reported valid volume 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 volume 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 volume capacity in Greece, the average volume capacity was 2.71ml (SD=2.05 ml). The most commonly reported volume capacity (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 volume capacity, with 77.5% of products (n=2,902) reporting a volume capacity of 2ml or less. Among compliant products, the average volume capacity was 1.83ml, and the most commonly reported volume capacity (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant volume capacities (n=844) had an average volume 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 B**.

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

Volume 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
1stQu.	1.8	2	1.913	4
Median	2	2	2	5
Mean	2.394	2.705	1.827	5.724
3rdQu.	2	2	2	7.5
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 and ‘other’

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

Among the 18,086 notifications on e-liquid products (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 most commonly reported nicotine concentration (median) was 8 mg/ml. These distributions are depicted below in **Table 5**.

The overwhelming majority (99.8%) of the 17,029 nicotine-containing e-liquid products in the Greek 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 most commonly reported nicotine concentration (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 volume distribution of these non-compliant products is depicted in **Table 5**, and their EC-IDs are flagged in **Annex B**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing products, 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
1st Qu.	3	3	30
Median	8	8	60
Mean	9.62	9.53	48.59
3rd Qu.	16	16	60
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 the complication of the reporting.

With regards to battery capacity, there was a 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 a 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, 1,709 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 Greek EU CEG reported at least one CAS. The average number of ingredients per product was 14.85, ranging from 1 to 114 unique CAS per product. An overview of the distribution of numbers of unique CAS per EC-ID is depicted in **Table 6**.

Table 6. Distribution of number of CAS contained in one refill container/cartridge product, overall

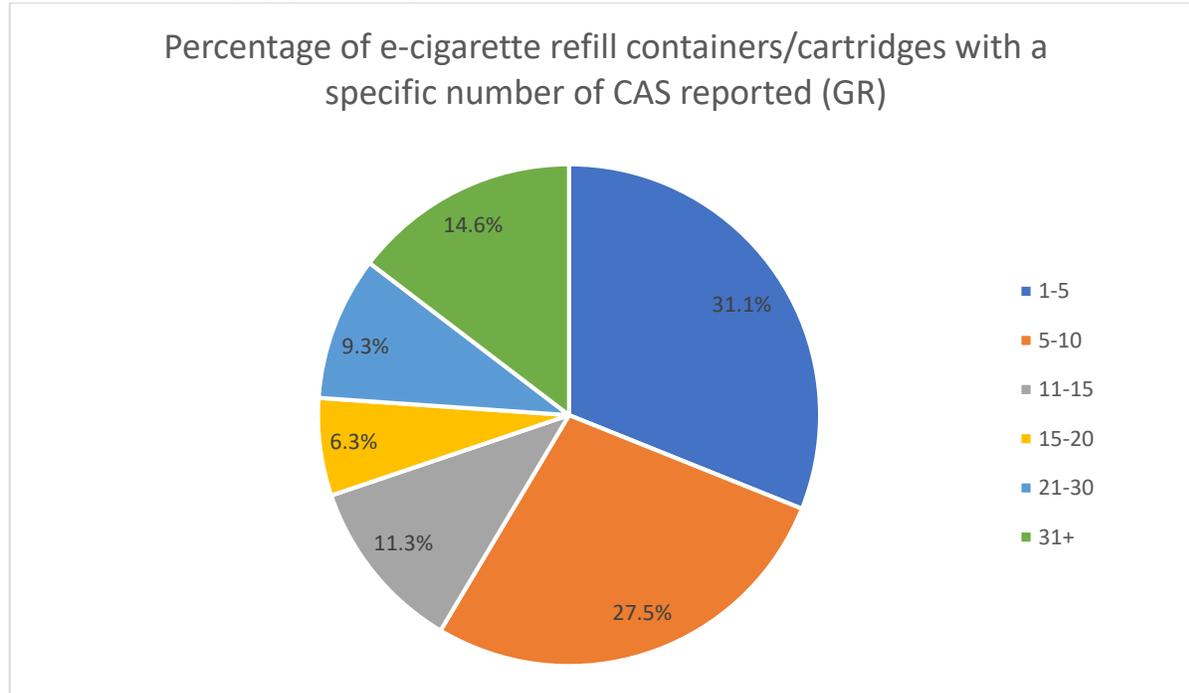
Number of CAS	
All refill containers/cartridges (n= 18,086)	
Min.	1
1stQu.	5
Median	9
Mean	14.85
3rdQu.	19
Max.	114
SD	15.23
# Invalid (no CAS reported)	n=0

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 7** and depicted in **Figure 3**.

Table 7. Breakdown of the number of CAS reported within one product, among all refill containers/cartridges (n=18,086)

Number of CAS per product	n	% (total)
1-5	5622	31.1%
5-10	4969	27.5%
11-15	2035	11.3%
15-20	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), (n=18,086)



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

Among the refill containers/cartridges (n=18,086) a total of 1,709 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, 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	3-Methyl-1,2-cyclopentanedione	1907	10.5%
30	116-53-0	(\pm)-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 the 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 additive enhancer. All other ingredients in the top 20 were mainly reported to be used as flavour/taste enhancers, except water which was most commonly reported as a water-wetting agent.

Table 9. Recipe quantity, concentration, and the major function of the top 20 most common ingredients of e-liquid, Greece

Rank	CAS	Name	Recipe quantity (mg/product)		Concentration (mg/ml)		Major function	Flavor description *
			Median	Mean	Median	Mean		
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 Greek EU CEG.

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

Conclusions for GR

Summary of Results

Within the current Greek 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 that was active in the Greek EU CEG data 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. Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the volume capacity, with 77.5% reporting a volume capacity of 2ml or less. With regards to the nicotine concentration, the overwhelming majority (99.8%) of products that contain an e-liquid 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.

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

- ✓ Missing and invalid data in the Greek EU CEG (specifically for volume capacity) suggests a need to redefine or clarify product type categories and their relevant variables. 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.’
- ✓ Outliers remain a limitation of the current analysis of the Greek EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ 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 were 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 flavour resulting from specific ingredient combinations is needed.
- ✓ Regulators should use the flagged EC-IDs in **Annex B** to communicate with manufacturers with regards to product compliance and improve the quality of EU CEG submissions.



Joint Action on Tobacco Control (JATC)

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

WP7 – National Report for SPAIN

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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 the 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 B 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). The methodological approach for the cleaning, merging and analysis of the data is provided in **Annex A**.

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 B 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 Spanish 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 in Spain (N= 44,029)

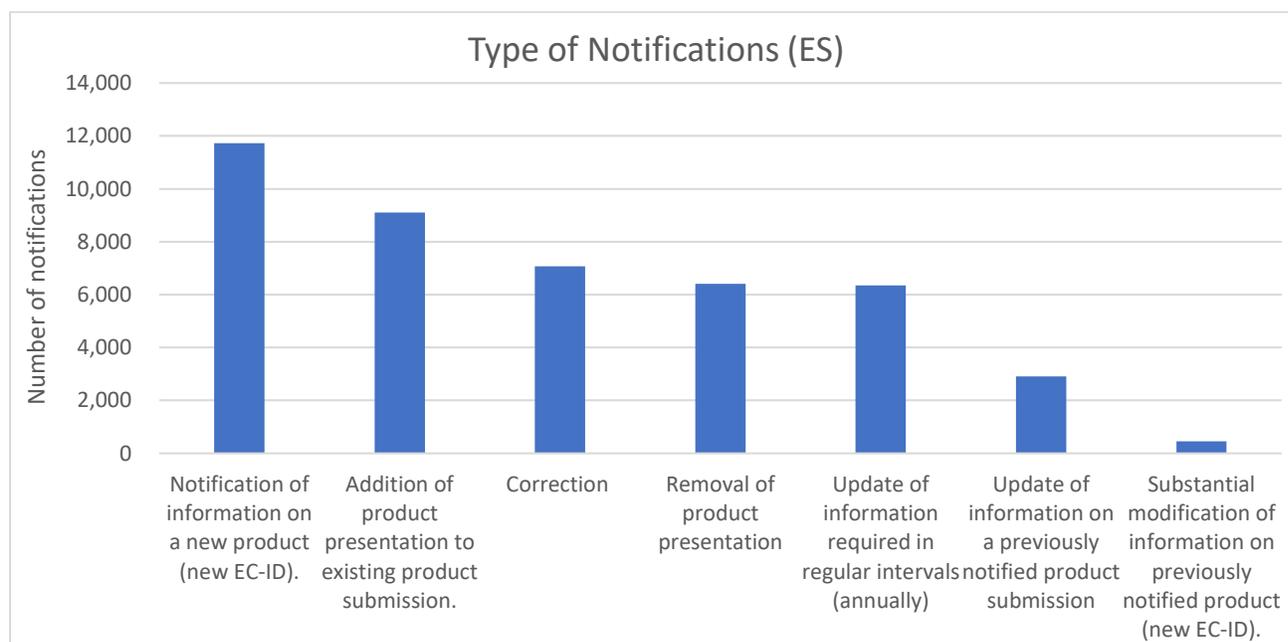


Table 1. Type of notifications within EU-CEG in Spain (N=44,029)

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 the 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, two 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.

Figure 2 displays the numbers of 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 that are currently on the market, 71.9% (30,121) represented refill containers/cartridges containing an e-liquid, 8.1% (2,358) represented individual parts of e-cigarettes capable of containing e-liquids, and 6.9% (2,146) represented a refillable device (device only).

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

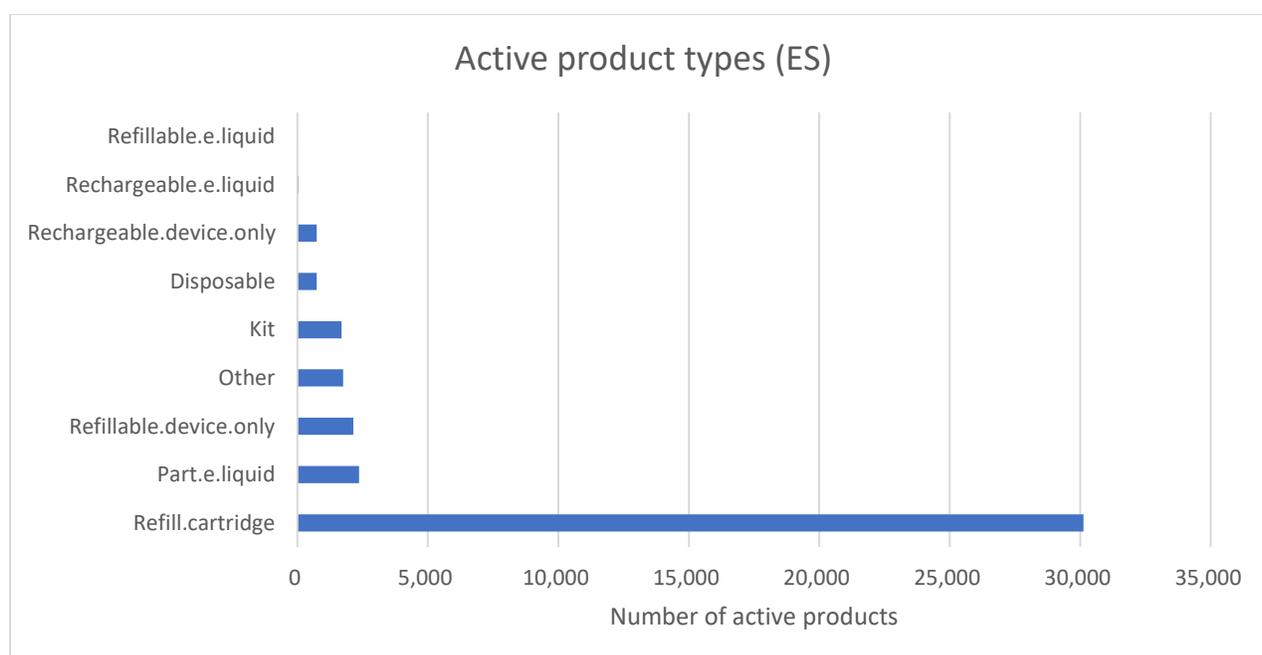


Table 2. Breakdown of product types active in EU-CEG, Spain (N=39,601)

Product type	n	%
Refill container/cartridge containing e-liquid	30121	71.9%
The 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 Vial volume of nicotine-containing refill containers [TPD Art 20(3)a]

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

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 most commonly reported vial volume (median) was 10ml. This is depicted in **Table 3**.

Only 42 non-compliant products (volume >10ml) were identified in the Spanish 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 B**.

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 (≤ 10 ml) n= 28,437	Non-compliant products (>10ml) n= 42
Min.	0.67	0.67	12
1st Qu.	10	10	22.5
Median	10	10	30
Mean	10.59	9.763	573.2
3rd Qu.	10	10	30
Max.	11482	10	11482
SD	93.38	1.39	2465.24

2.2 Volume capacity of cartridges or tanks with nicotine-containing liquids [TPD Art 20(3)a]

Focusing on the 6,034 notifications on cartridges or tanks capable of carrying nicotine-containing e-liquids (this includes all product except those listed as kits, refill containers/cartridges and "other"), 5,090 products reported value for volume 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 5,090 products which reported a value for volume capacity, 4,554 products (89.5%) reported valid volume capacity (>0 ml) and 536 products (10.5%) reported invalid values (i.e. 0 ml). Over half of the 536 products reporting invalid values for volume capacity (n=302) were listed as ‘individual parts of e-cigarettes capable of containing an e-liquid.’

Among the 4,554 products that reported a valid volume capacity (>0 ml) in Spain, the average volume capacity was 2.51ml (SD=2.01 ml). The most commonly reported volume capacity (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 volume capacity, with 83.9% of products (n=3,823) reporting a volume capacity of 2ml or less. Among compliant products, the average volume capacity was 1.80ml, and the most commonly reported volume capacity (median) was 2ml. This is depicted in **Table 4**.

Products reporting non-compliant volume capacities (n=731) had an average volume 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 B**.

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

Volume capacity (ml)				
	All reported (n= 5090)	All valid (>0 ml) (n= 4554)	Valid, Compliant (\leq 2ml) (n= 3823)	Valid, Non-compliant (>2ml) (n=731)
Min.	0	0.01	0.01	2.2
1stQu.	1.6	2	1.8	4
Median	2	2	2	5
Mean	2.248	2.513	1.804	6.221
3rdQu.	2	2	2	10
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 and ‘other’*

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

Among the 30,121 notifications on e-liquid products (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 most commonly reported nicotine concentration (median) was 9 mg/ml. This distribution is depicted below in **Table 5**.

The overwhelming majority (99.8%) of the 28,481 nicotine-containing e-liquid products in the Spanish 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 most commonly reported nicotine concentration (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 volume distribution of these non-compliant products is depicted in Table 5, and their EC-IDs are flagged in **Annex B**.

Table 5. Distribution of nicotine concentration (mg/ml) among all nicotine-containing products, 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
1st Qu.	4	4	30
Median	9	9	60
Mean	9.678	9.594	55.91
3rd Qu.	16	16	60
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 the complication of the reporting.

With regards to battery capacity, there was a 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 19.43% (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.

4. 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 CAS numbers were submitted (Note that additional data cleaning is needed to further reduce this number).

A significant number of products (5,608) reported no CAS; thus the submissions were considered invalid. 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 6**.

Table 6. Distribution of the number of CAS contained in one refill container/cartridge product, overall and among valid product submissions

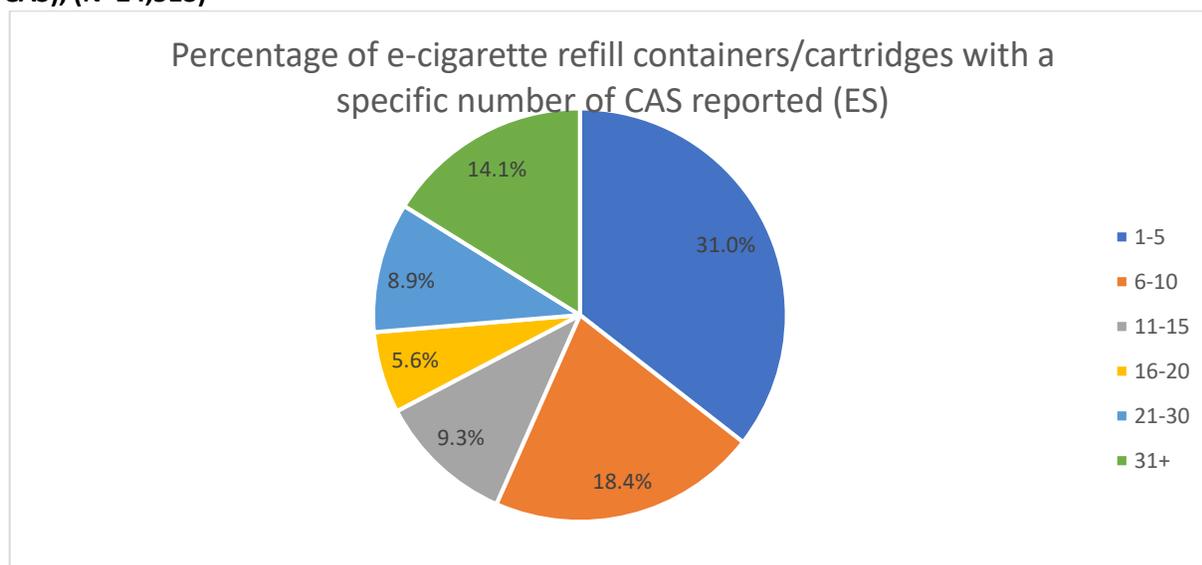
	Number of CAS	
	All refill containers/cartridges (n= 30,121)	Valid CAS entry (n= 24,513)
Min.	0	1
1stQu.	3	5
Median	7	9
Mean	13.06	16.18
3rdQu.	18	23
Max.	113	113
SD	15.86	16.14
Invalid (i.e. no CAS reported)	n = 5608	

Among the 30,121 submissions for refill containers/cartridges, 31.0% 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 7**. **Figure 3** depicts the breakdown of the number of CAS reported within one product, excluding submissions with no CAS reported.

Table 7. 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)



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, 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 additive enhancer. All other ingredients in the top 20 were mainly reported to be used as flavor/taste enhancers.

Table 9. Recipe quantity, concentration, and the major function of the top 20 most common ingredients of e-liquid, Spain

Rank	CAS	Name	Recipe quantity (mg/product)		Concentration (mg/ml)		Major function	Flavor description *
			Median	Mean	Median	Mean		
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 odour; 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 odour 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. The major function was obtained as the most commonly reported function for the respective ingredients in the Spanish EU CEG.

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

Conclusions for ES

Summary of Results

Within the current Spanish EU-CEG dataset, there are 44,027 notifications (unique EC-IDs), of which 4426 were indicated to be withdrawn from the market. The most common type of product active in the Spanish 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. Most cartridges/containers capable of carrying an e-liquid were compliant with regards to the volume capacity, with 83.9% reporting a volume capacity of 2ml or less. With regards to the nicotine concentration, the overwhelming majority (99.8%) of products that contain an e-liquid 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.

The average number of ingredients per product, among products reporting CAS, was 16.18, ranging between 1 and 113 different CAS per product. The most common ingredients in frequency were the humectants propylene glycol and glycerol, and nicotine. The most frequently reported flavourings were vanilla, ethyl butyrate, and ethyl maltol.

Recommendations

- ✓ Missing and invalid data in the Spanish EU CEG (specifically for volume capacity) suggests a need to redefine or clarify product type categories and their relevant variables. 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.’
- ✓ Outliers remain a limitation of the current analysis of the Spanish EU-CEG dataset- a thorough cleaning of the JATC dataset by correcting submissions from the manufacturers would improve the quality of the submitted information.
- ✓ 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 were 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 with e-liquids enter CAS information, given that 18.6% of refill cartridge/containers in the Spanish EU CEG reported no CAS.
- ✓ Further research on the function and reported toxicity of each reported additive is needed.
- ✓ Further research on the composite flavour resulting from specific ingredient combinations is needed.
- ✓ Regulators should use the flagged EC-IDs in **Annex B** to communicate with manufacturers with regards to product compliance and improve the quality of EU CEG submissions.