Work Package 5 EU-CEG data and enhanced laboratory capacity for regulatory purposes

EU-CEG E-cigarette Emission Data

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Introduction

This deliverable initially aimed to gather and describe analytical results obtained by various independent laboratories in the field of tobacco control. Unfortunately, it was not possible to get such data. We requested through e-mails but we did not receive any responses, or when they did arrive, they were negative responses related to data confidentiality.

Indeed, laboratories often work under strict confidentiality agreements with private clients where intellectual property, trade secrets, or sensitive competitive information is involved. Sharing data, even in an aggregated form, could breach these agreements and expose the laboratory to legal liabilities or loss of trust with clients. In many private contracts, the data and results generated by the laboratory belong to the client, not the laboratory itself. As a result, the laboratory has limited or no authority to disclose or repurpose the data for other uses, including research, unless explicitly authorized by the client. Such factors contribute, inter alia, to a laboratory's caution when handling requests to share privately obtained data, ensuring that both legal obligations and client relationships are maintained while adhering to the principles of ISO 17025.

For this reason, this deliverable was repurposed on the analysis of some still unexplored EUCEG data: e-cigarette emission data. Actually, pursuant Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers[1], submitters have the possibility to declare some emission values as generated by analytical procedures involving vaping machines.

This report describe the emission data reported on EU-CEG for the French market as of July 2024.

1 Chemicals in e-cigarette emissions

The data dictionnary regarding common format for the notification of electronic cigarettes and refill containers[2] provides some chemicals to be quantified in the emissions.

Table. Closed list of chemicals for e-cigarette emissions to be reported in EU-CEG.

Item#	Emission Name
1	Nicotine
2	Ethylene glycol
3	Diethylene glycol
4	Formaldehyde
5	Acetaldehyde
6	Acrolein
7	Crotonaldehyde
8	TSNA: NNN
9	TSNA: NNK
10	Cadmium
11	Chromium
12	Copper
13	Lead
14	Nickel
15	Arsenic
16	Toluene
17	Benzene
18	1,3-Butadiene

1 https://eur-lex.europa.eu/eli/dec_impl/2015/2183/oj
2 https://health.ec.europa.eu/eu-common-entry-gate-eu-ceg/download-section_en

Item#	Emission Name
19	Isoprene
20	Diacetyl
21	Acetyl Propionyl
22	Other

In this report, it has been decided to focus on 20 chemicals (items 2 to 21, Ethylene glycol to Acetyl Propionyl). Indeed, "nicotine" values may vary a lot depending on e-liquid composition and they are more reported for the purpose of checking that e-cigarettes deliver nicotine doses at consistent levels under normal conditions of use. Regarding "other" chemicals, many of them are actually reported as emissions while they are e-liquids components.

2 Data curation

As previously reported (see JATC-1 reports), many EU-CEG data are given as free text, thus many errors and discrepancies remain in the data provided. This the case of the correct identification of the chemical as an emission, the analytical method and the unit used to provide the result. As a consequence, data have to be curated prior any descriptive analysis. Should any uncertainty remains on the correct interpretation of any information, this should be discarded.

Fo each emission reported data corresponding to an item (2 to 21), we checked that the CAS registry number, the IUPAC Chemical Name and Other Name provided by submitters matched the corresponding emission. When the conditions were not met, the record was not considered.

Regarding measurement units, a mapping table was built between units (as reported) and a unique unit (mg.m^3), taking into account the quanttiy measured, the actual puff volume (standardized to 55mL) and the number of puffs. When no conversion was possible, the emission measurement had to be discarded.

Table. Example of mapping table between reported emission units and mg.m^3. One has to multiply the reported value by the coefficent in the last column to convert the values in mg.m^3. A blank value means no mapping.

Unit	To_mg	N_puff	V_puff_mL	To_mg_m3
ng /200 puffs	1.00E-06	200	55	9.09E-05
ng/ten inhalations	1.00E-06	10	55	1.82E-03
ug/1000puffs	1.00E-03	1000	55	1.82E-02
µg /200 puffs	1.00E-03	200	55	9.09E-02
µg /100 puffs	1.00E-03	100	55	1.82E-01
µg/20 puffs	1.00E-03	20	55	9.09E-01
mg/100 Puffs	1.00E+00	100	55	1.82E+02
mg/10 puffs of 70 ml each	1.00E+00	10	70	1.43E+03
mg/10 puffs of 40 ml each	1.00E+00	10	40	2.50E+03
microgram				
ng/cig				

When information regarding detection or quantitation limits was given (value below 'x' or no more than 'y'), this was also taken into account to give the result as an interval instead of a single value. For instance, the numerous 'zero' values in the various datasets have been considered left-censored by the minimum single value (as the lower bound).

Eventually, after this curation process, each measurement with a valid chemical name from the closed list and a reported unit mappable to a mg.m^3 concentration was considered.

3 https://jaotc.eu/

3 E-cigarette emissions curated datasets

The curation process as previously described allowed to keep an average of 73% of the emission data.

Table. Number of e-cigarette emission measurements before and after the curation proces (French EU-CEG dataset, July 2024).

Item#	Emission Name	Total Measurements	Curated Measurements	%
1	Nicotine	135 692	-	-
2	Ethylene glycol	54 142	38 123	70%
3	Diethylene glycol	51 528	37 303	72%
4	Formaldehyde	112 086	89 042	79%
5	Acetaldehyde	114 257	86 537	76%
6	Acrolein	106 763	80 401	75%
7	Crotonaldehyde	65 704	45 673	70%
8	TSNA: NNN	41 653	30 801	74%
9	TSNA: NNK	41 890	30 977	74%
10	Cadmium	61 300	47 490	77%
11	Chromium	69 220	52 044	75%
12	Copper	32 569	18 599	57%
13	Lead	65 567	48 856	75%
14	Nickel	69 121	52 090	75%
15	Arsenic	62 881	46 968	75%
16	Toluene	48 307	32 554	67%
17	Benzene	48 415	31 831	66%
18	1,3-Butadiene	45 788	31 485	69%
19	Isoprene	45 596	31 215	68%
20	Diacetyl	79 233	58 481	74%
21	Acetyl Propionyl	31 967	25 802	81%
22	Other	231 420	-	-

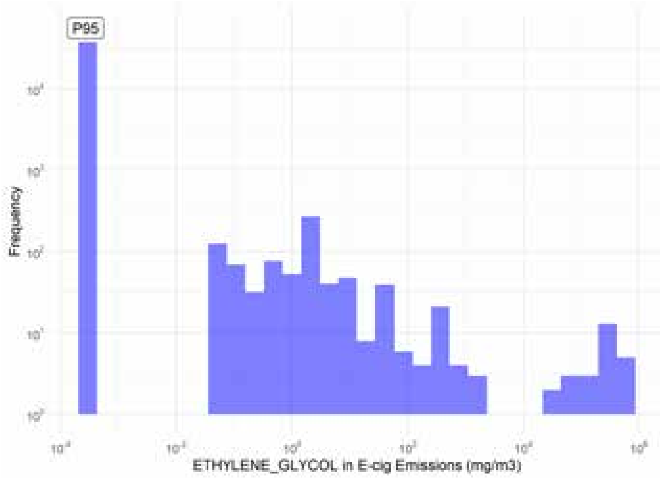
Since raw data are not disclosed in this report, descriptive statistics are provided for each emission. In case of interval or censored data, values were transformed using the center between lower bound (LB) and upper bound (UB) : emission_value = (LB + UB) / 2.

4 E-cigarette emissions descriptive statistics

For each emission, the number of values (N), their mean, minimum and maximun along with some percentile values are given. An histogram in log-log-scale shows each distribution.

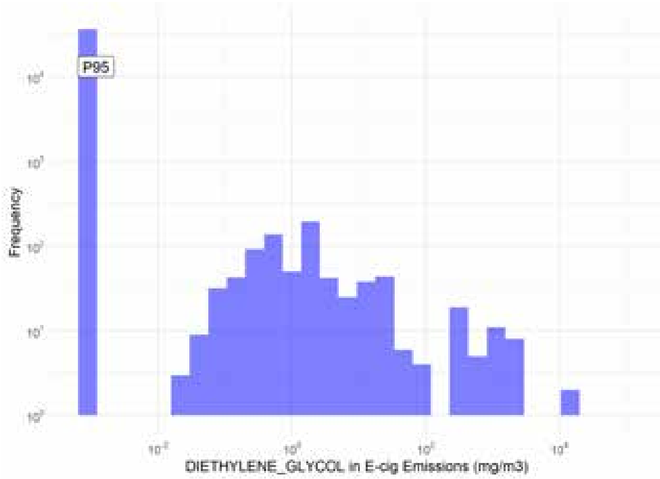
4.1 Ethylene glycol

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
ETHYLENE_GLYCOL	38123	1.54E+02	2.73E-04	5.55E+05	2.73E-04	2.73E-04	2.73E-04	2.73E-04	2.73E-04	2.73E-04	2.73E-04	1.82E+00



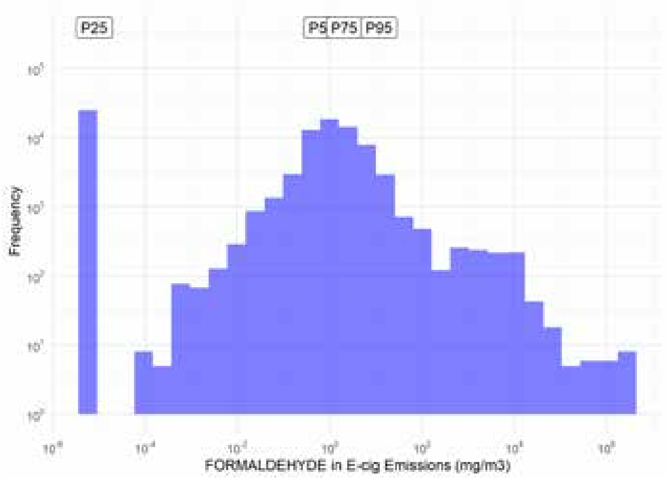
4.2 Diethylene glycol

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
DIETHYLENE_GLYCOL	37303	5.58E+00	1.18E-03	1.32E+05	1.18E-03	1.18E-03	1.18E-03	1.18E-03	1.18E-03	1.18E-03	1.18E-03	1.82E+00



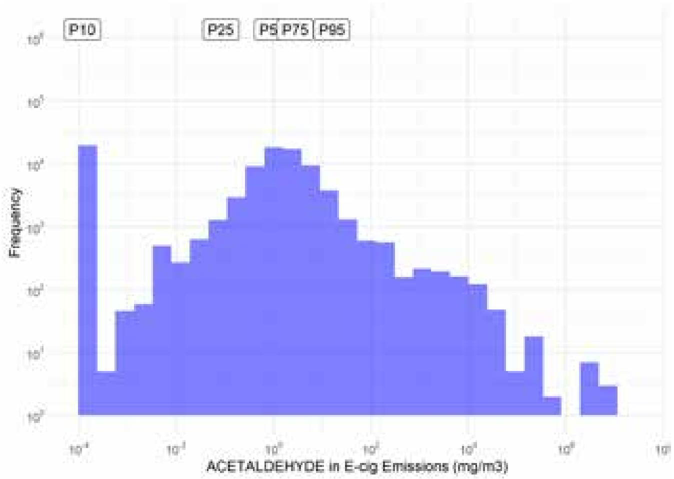
4.3 Formaldehyde

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
FORMALDEHYDE	89042	5.03E+02	7.95E-06	3.87E+06	7.95E-06	7.95E-06	6.82E-01	2.10E+00	6.00E+00	1.19E+01	2.89E+01	7.50E+02



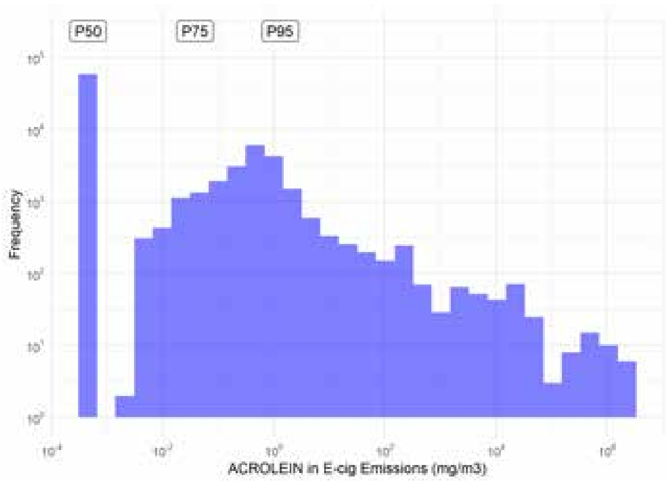
4.4 Acetaldehyde

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
ACETALDEHYDE	86537	8.02E+02	1.19E-04	1.36E+07	1.19E-04	8.33E-02	9.55E-01	2.78E+00	7.51E+00	1.57E+01	4.93E+01	4.30E+02



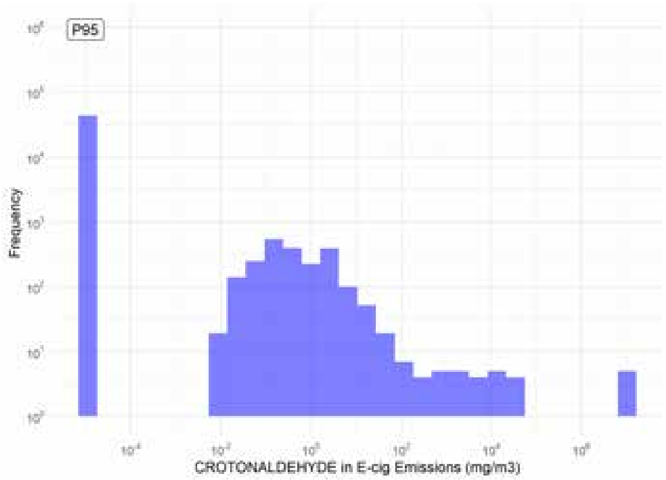
4.5 Acrolein

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
ACROLEIN	80401	4.49E+02	4.55E-04	2.31E+06	4.55E-04	4.55E-04	4.55E-04	3.82E-02	6.55E-01	1.31E+00	3.64E+00	6.85E+01



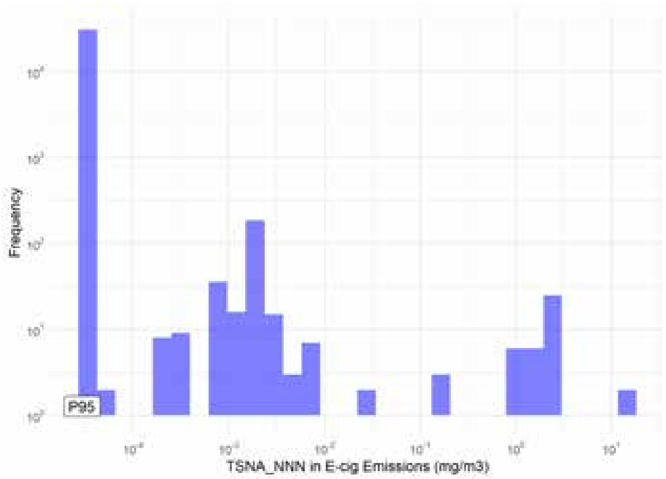
4.6 Crotonaldehyde

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
CROTONALDEHYDE	45673	1.01E+03	9.88E-06	9.18E+06	9.88E-06	9.88E-06	9.88E-06	9.88E-06	9.88E-06	9.88E-06	3.64E-01	1.82E+00



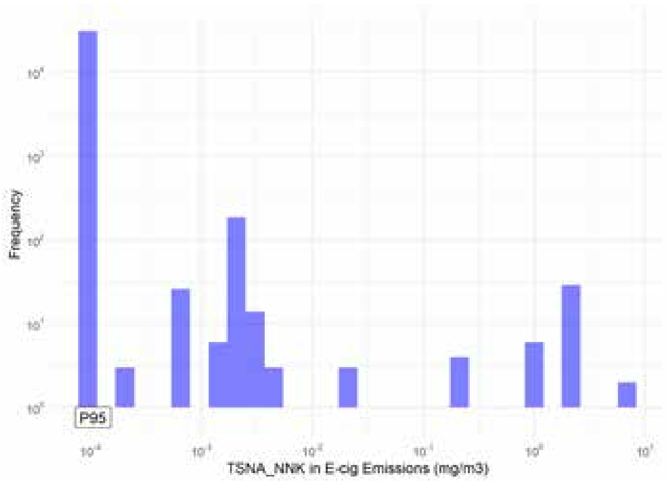
4.7 TSNA: NNN

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
TSNA_NNN	30801	3.47E-03	2.91E-05	1.27E+01	2.91E-05	2.91E-05	2.91E-05	2.91E-05	2.91E-05	2.91E-05	2.91E-05	6.44E-04



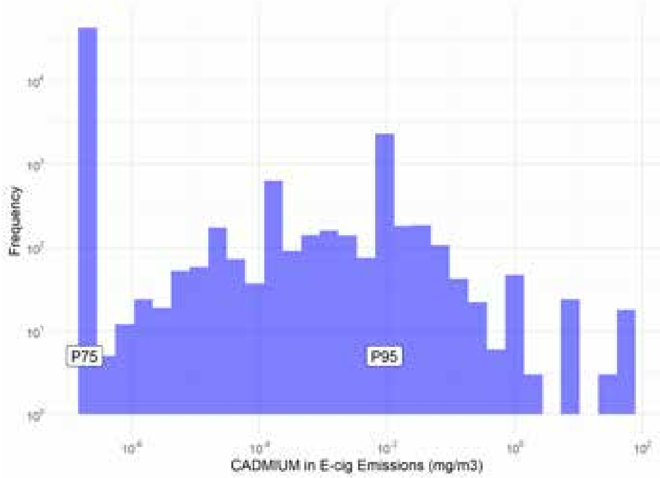
4.8 TSNA: NNK

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
TSNA_NNK	30977	3.04E-03	1.05E-04	7.64E+00	1.05E-04	1.05E-04	1.05E-04	1.05E-04	1.05E-04	1.05E-04	1.05E-04	1.05E-04



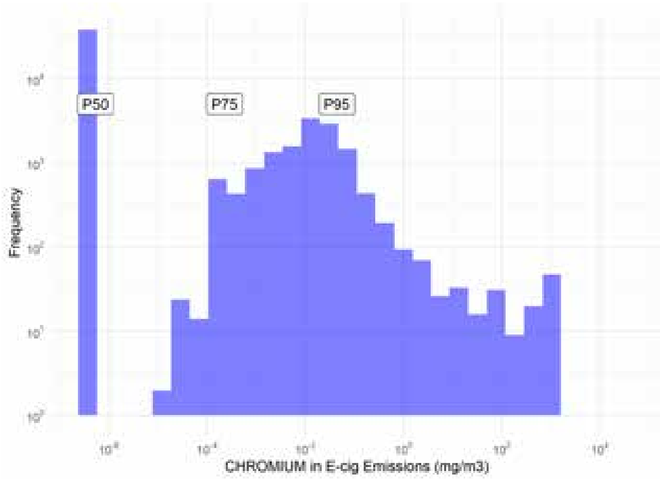
4.9 Cadmium

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
CADMIUM	47490	2.84E-02	1.82E-07	5.00E+01	1.82E-07	1.82E-07	1.82E-07	1.82E-07	1.82E-07	9.09E-03	9.09E-03	2.18E-02



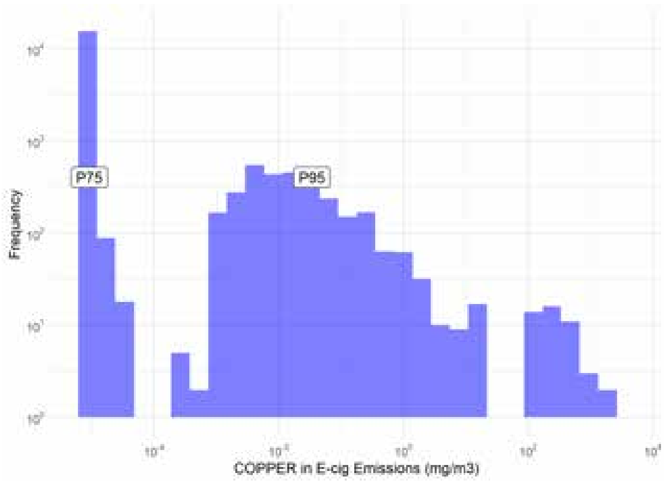
4.10 Chromium

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
CHROMIUM	52044	2.24E+00	5.45E-07	5.00E+04	5.45E-07	5.45E-07	5.45E-07	2.30E-04	2.09E-02	4.44E-02	8.09E-02	3.64E-01



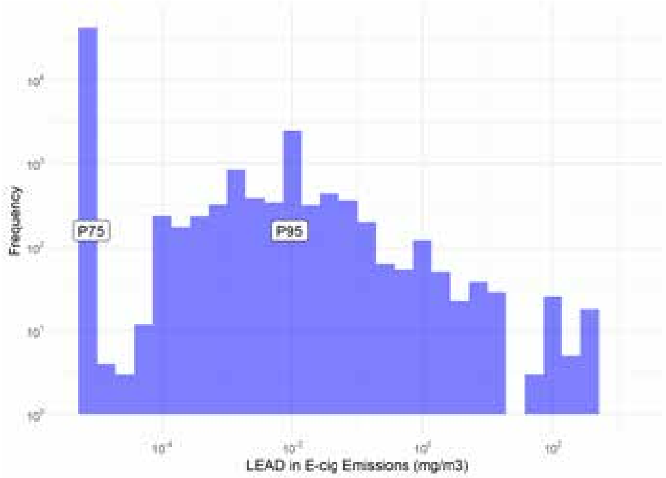
4.11 Copper

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
COPPER	18599	1.20E+00	9.09E-06	4.00E+03	9.09E-06	9.09E-06	9.09E-06	9.09E-06	7.38E-03	3.40E-02	1.27E-01	6.00E-01



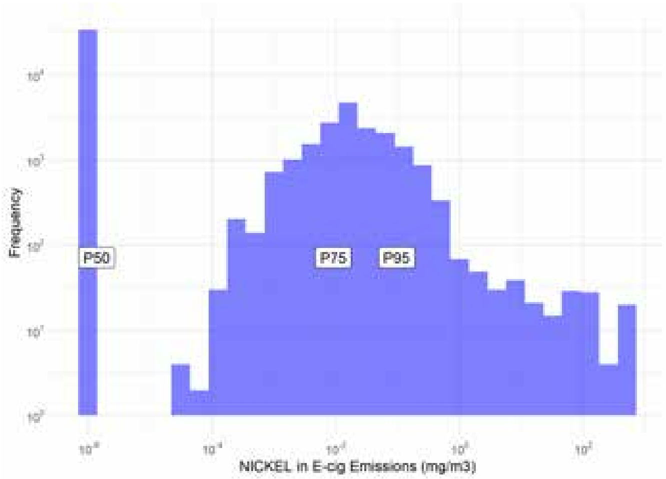
4.12 Lead

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
LEAD	48856	3.25E-01	8.18E-06	1.57E+03	8.18E-06	8.18E-06	8.18E-06	8.18E-06	2.14E-03	9.09E-03	2.91E-02	1.82E-01



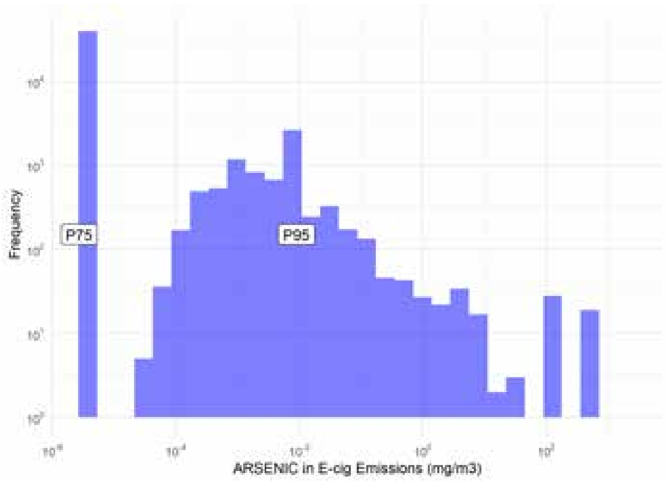
4.13 Nickel

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
NICKEL	52090	3.48E-01	1.36E-06	7.11E+02	1.36E-06	1.36E-06	1.36E-06	9.09E-03	4.15E-02	9.59E-02	1.95E-01	4.18E-01



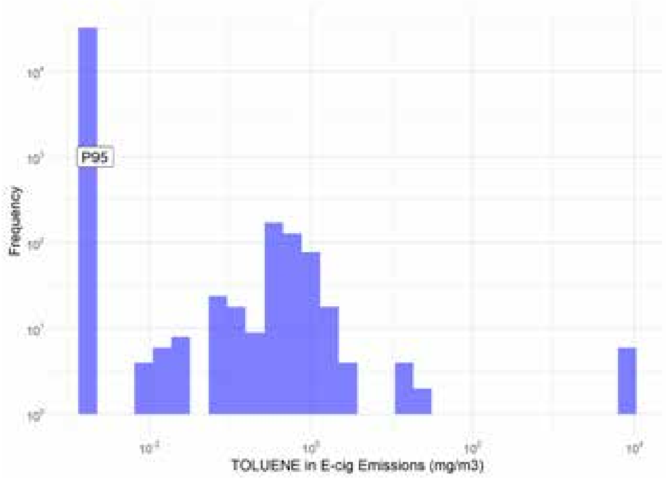
4.14 Arsenic

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
ARSENIC	46968	3.14E-01	2.73E-06	1.50E+03	2.73E-06	2.73E-06	2.73E-06	2.73E-06	2.18E-03	9.09E-03	9.36E-03	4.55E-02



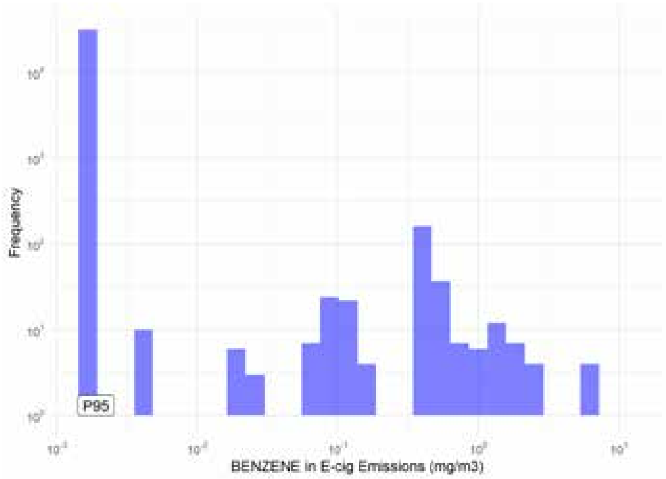
4.15 Toluene

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
TOLUENE	32554	1.89E+00	2.13E-03	1.00E+04	2.13E-03	2.13E-03	2.13E-03	2.13E-03	2.13E-03	2.13E-03	2.13E-03	3.64E-01



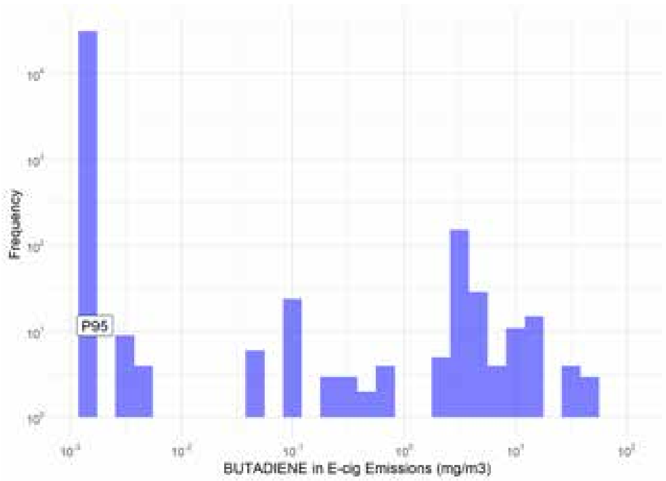
4.16 Benzene

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
BENZENE	31831	7.75E-03	1.91E-03	1.31E+01	1.91E-03	1.91E-03	1.91E-03	1.91E-03	1.91E-03	1.91E-03	1.91E-03	1.91E-03



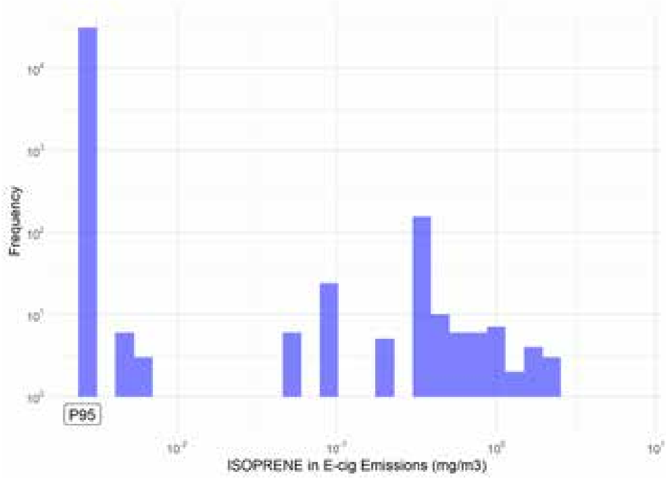
4.17 1,3-Butadiene

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
BUTADIENE	31485	4.96E-02	1.66E-03	1.17E+02	1.66E-03	1.66E-03	1.66E-03	1.66E-03	1.66E-03	1.66E-03	1.66E-03	1.66E-03



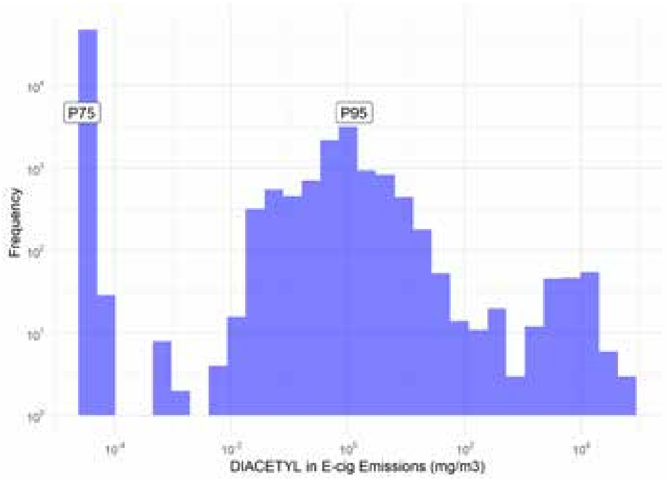
4.18 Isoprene

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
ISOPRENE	31215	5.95E-03	2.56E-03	6.04E+00	2.56E-03	2.56E-03	2.56E-03	2.56E-03	2.56E-03	2.56E-03	2.56E-03	2.56E-03



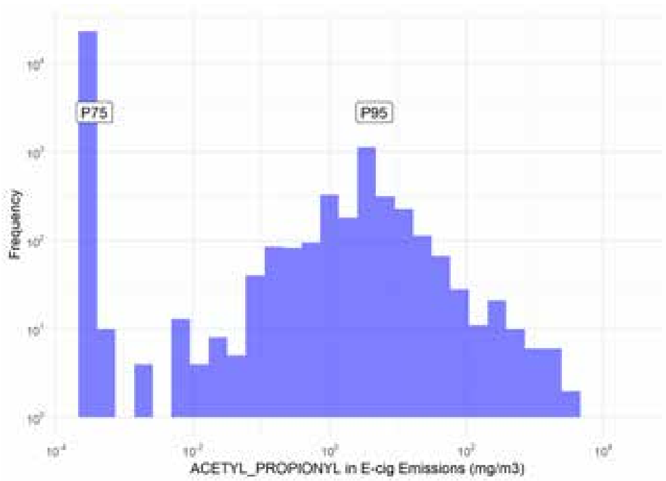
4.19 Diacetyl

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
DIACETYL	58481	2.75E+01	2.73E-05	4.76E+04	2.73E-05	2.73E-05	2.73E-05	2.73E-05	8.00E-01	1.28E+00	4.11E+00	1.01E+01



4.20 Acetyl Propionyl

Emission	N	Mean	Min	Max	P10	P25	P50	P75	P90	P95	P97.5	P99
ACETYL_PROPIONYL	25802	3.13E+00	3.64E-04	2.78E+04	3.64E-04	3.64E-04	3.64E-04	3.64E-04	2.36E-01	4.52E+00	6.01E+00	1.73E+01



5 Conclusion

The results that immediately stand out from a first observation are the large variability of the reported data. In general, it is noted that emissions range from (excluding zero values) 10-4 to 104 mg/m^3, with peaks reaching 10^6, such as for acetaldehyde.

The datasets are highly skewed, leading to an arithmetic mean much higher than the 95th percentile. This happens because the mean is highly sensitive to extreme values (outliers), while percentiles are not affected by the magnitude of outliers, only their position.

It is clear that these emission values cannot be considered realistic or, in any case, comparable. Consequently, they cannot be used for any type of assertion. It is very likely that not only are the measurement methods very different, but there is also a strong suspicion of errors in the use of measurement units, or perhaps errors in the transcription of Greek letters or other conversion errors.

It is worth noting that the majority of the data shows a monotonic trend, which supports a hypothesis of random errors, if they exist. Only diacetyl or a few other substances display a trend in the reported emissions with a tail towards the higher end.

For the majority of these emissions, the values of the high percentiles are either zero or close to zero, which means that most of the products in which they were investigated either were below the LOD of the method or did not produce emissions under the measurement conditions, which are assumed to be similar to normal usage conditions. Again, in the absence of the use of a standardized method for emissions, it is not possible to use the data coming from laboratories, but also to assume that the sampling conditions (topography and emissions collection) were those shared by the scientific community and therefore representative of the population's exposure.

However, formaldehyde and acetaldehyde from the vaporization of e-liquids, as well as metals transferred by electronic cigarette devices, show a greater number of relatively high values.

A more detailed analysis of these data in connection with the provided analysis reports would be necessary to rule out outliers from an analytical perspective. Nevertheless, it should be noted that the volume of emission data is considerable, making it a valuable source of information when validated or, at least, treated statistically.

Several toxic and carcinogenic compounds are declared in emission, being this a relevant problem, with serious public health concerns. These data need to be validated, first, and compared to the reference toxicological values for inhalation of the substances, either available or to be developed, and to different exposure scenarios, which fall under risk assessment studies not covered in this initial report.

As mentioned before, given the variability in the methods used and the data recording modalities, which are not free from variability or errors, measurements on a representative sample of products conducted under standardized and identical conditions would provide more reliable information on the issue of emitted substances.