



SLOVENSKI STANDARD
SIST-TP CEN/TR 17236:2018
01-december-2018

Elektronske cigarete in e-tekočine - Sestavine, ki jih je treba meriti v aerosolu inhalacijskih proizvodov

Electronic cigarettes and e-liquids - Constituents to be measured in the aerosol of vaping products

iTeh STANDARD PREVIEW

Cigarettes électroniques et e-liquides - Composants dont la teneur est à mesurer dans l'aérosol des produits de vapotage

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ICS:

65.160	Tobak, tobačni izdelki in oprema	Tobacco, tobacco products and related equipment
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TECHNICAL REPORT

CEN/TR 17236

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

September 2018

ICS 65.160

English Version

Electronic cigarettes and e-liquids - Constituents to be measured in the aerosol of vaping products

Cigarettes électroniques et e-liquides - Composants dont la teneur est à mesurer dans l'aérosol des produits de vapotage

Elektronische Zigaretten und Liquids für elektronische Zigaretten - Inhaltsstoffe, die im Aerosol von Verdampfungsprodukten gemessen werden

This Technical Report was approved by CEN on 4 June 2018. It has been drawn up by the Technical Committee CEN/TC 437.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (CEN/TR 17236:2018) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”, the secretariat of which is held by AFNOR.

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CEN/TR 17236:2018 (E)**1 Scope**

This document gives a list of constituents of interest proposed for measurement in the aerosol for the purpose of regulatory submission under the Directive 2014/40/EU (TPD) [2], for

- prefilled products such as disposable e-cigarettes and refill cartridges,
- e-liquids sold in refill containers,
- the following categories of hardware: coils or other heater elements of the vaping product, atomisers, rebuildable atomisers and all open tank or dripper products with inbuilt atomisers, including clearomisers.

This list is not intended to be comprehensive but rather, it represents the default minimum requirement. Depending on the device/liquid combination and the toxicological assessment other substances might have to be measured as well.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>
<https://standards.iteh.ai/catalog/standards/sist/0d446b1c-3878-4d8e-a729-87380e686da1/sist-tp-cen-tr-17236-2018>

4 Mandate

TPD requires:

- “Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States“ [...] ”The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:” [...];
- “(b) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof”.

5 What is the purpose of the emissions reporting?**5.1 General**

There can be many reasons to measure constituents in vaping aerosol. Different purposes will focus on different constituents to be measured and different aerosol generation protocols under which to measure them. TPD requires submission of data across the range of vaping products in order to allow comparisons between products, analogous to the required tar/nicotine/carbon monoxide measurements required for cigarettes under the TPD. This requires:

- a) constituents to be measured that can reasonably be expected to be present in all vaping products;
- b) measurement under a standardised machine vaping regime to allow comparisons. This regime should be consumer relevant.

5.2 TPD guidance

One of the purposes of the TPD is to help safeguard consumer safety. This would suggest emissions of interest should be selected based on risk, i.e. a combination of inherent hazards and absolute abundance in aerosol.

TPD definition: “emissions’ means substances that are released when a tobacco or related product is consumed as intended...”. (Emphasis added.) The proposal should thus address emissions of potential toxicological concern, that can be expected when the products are used as intended, i.e. where the products allow choice (e.g. of e-liquid, coil type, wattage and air flow settings, etc.), the interest is in emissions that are produced when the compatible choices are made.

5.3 Hardware versus e-liquids

By mass, the bulk of the aerosol from vaping products are components that were present in the e-liquid and have been aerosolised unchanged. Besides the e-liquid ingredients, this could include a small contribution from e-liquid contaminants, potential reaction products between ingredients and potential degradation products over time. Given the added aspects introduced by aerosolising the e-liquid (e.g. choice of vaping device, machine vaping regime, analytical collection challenges), such compounds are more appropriately measured in the e-liquid than in the aerosol.

Additionally some constituents in the aerosol derive from the hardware, i.e. from the materials the different device parts are made of. These are thus hardware specific and measurement of them is relevant to that hardware, not to e-liquids. The TPD already recognises that information submitted can differ between e-liquids and hardware: “The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information: ...”

Another source of aerosol constituents is the thermal degradation products of the e-liquid that are created from the aerosolisation process. These are dependent on the combination of e-liquid and hardware used and should thus be measured for both vaping hardware and e-liquids, but with the product combination clearly defined.

6 Existing regulatory guidance on compounds to be measured

6.1 TPD

The TPD itself contains no specifics on which emissions should be measured for vaping products. However, assuming that emission measurement for cigarettes and vaping products will serve similar TPD purposes, it is relevant to note that “emission levels” for cigarettes, as per paragraph 11 of the preamble, refers to the tar, nicotine and carbon monoxide yields. This suggests an interest in a measure of the overall aerosol yield, in nicotine in aerosol and in the main, high abundance, acute toxicant present in the aerosol of all cigarettes.

6.2 European Commission guidance

No specific guidance from the European Commission exists. However, the TPD data dictionary electronic cigarettes [3] makes provision for the potential notification of a number of named emissions (reference data 10.4 in the data dictionary), listed in Table 1. The compounds have been sorted based on their most likely source of origin if they were to be found in the vaping aerosol. Some could arise from more than one source of origin and therefore appear in more than one row.

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6.3 Member State guidance

One of the Member States, the UK, has published guidance on the emissions to be measured and notified under the TPD. This guidance was discussed with the other Member States [4]. The guidance with regards to the emissions to be measured for notification is based on the toxicologically most important emissions expected to be present across the range of vaping products and indicates additional metals could be included, depending on the construction and the material composition of the hardware. This guidance is included in Table 1.

6.4 Existing voluntary standards/specification

Regulatory guidance exists in the form of the BSI PAS 54115 [6], a voluntary British Public Available Specification that covers the emissions to be measured in vaping products. The BSI PAS 54115 recommendations are essentially the same as those taken over by the MHRA and these guidances have therefore been combined in Table 1. An additional voluntary French Experimental Standard, AFNOR XP D90-300-3 [5], has therefore also been included in Table 1.

6.5 FDA

The final published FDA deeming regulations indicates the FDA still needs to decide on what constituents in aerosol should be reported on and exempts vaping products from emissions reporting obligations for 3 years.

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Table 1 — Existing regulatory guidance on potential constituent to be measured in the aerosol, sorted by likely source of origin

Potential source	Data dictionary options	MHRA guidance & BSI PAS 54115	AFNOR XP D90-300-3
Nicotine	Nicotine		Nicotine
Potential thermal degradation products from PG/VG under normal use	Formaldehyde Acetaldehyde Acrolein 1,3-Butadiene	Formaldehyde Acetaldehyde Acrolein	Formaldehyde Acetaldehyde Acrolein
Potential hardware compounds into aerosol from aerosolisation process (i.e. coil or wicking materials)	Chromium Nickel Iron	Chromium Iron Nickel Aluminium	Nickel Chromium
Potential degradation products from other e-liquid ingredients	Crotonaldehyde Benzene		
Potential e-liquid ingredients or contaminants:	Formaldehyde Ethylene glycol Diethylene glycol TSNA: NNN TSNA: NNK Cadmium Chromium Copper Lead Nickel Arsenic Toluene Diacetyl Acetyl propionyl (i.e. 2,3-pentanedione]	Depending on the particular device / e-liquid combination and the toxicological assessment Diethylene glycol, Ethylene glycol, Diacetyl Pentane 2,3 dione	Formaldehyde Diacetyl Lead
Potential hardware leachables into e-liquid	Chromium Copper Lead Nickel Isoprene	Depending on the material composition of the hardware: Aluminium Chromium Iron Nickel Tin Lead and mercury if present in the hardware	Lead Antimony Arsenic Nickel Chromium Cadmium
Other	Other		

7 Recommended compounds to be measured in vaping aerosol

7.1 Aerosol versus e-liquid

It is recommended to only measure constituents in aerosol that are created or affected by the aerosolisation process. Everything that is already present in the e-liquid, i.e. e-liquid ingredients and any contaminants of those ingredients as well as leachables from device materials, will be easier and more accurate to measure in the e-liquid. Table 1 is divided by likely origin of the constituent.