AUGUST 1, 2018

TESTING OF E CIGARETTE DEVICES

OLIVER JEWELL
KENT COUNTY COUNCIL
For the Chartered Trading Standards Institute

Contents

1. Introduction 2
1.1 Requirements 2
2. Method 3
2.1 Limitations 4
3. Results 4
4. Conclusions and Recommendations 56

1. Introduction

Following Phase 3a of the National Rapid Review of the Tobacco and Related Product Regulations 2016, e-cigarette samples purchased as part of that review were submitted for laboratory testing to determine the presence of heavy metals that may leach into the liquid in a simulation of normal use.

A total of five samples were submitted for analysis to provide an indication as to whether further, more formal research is required in this area.

The basis of concerns stemmed from anecdotal information provided during the National Rapid Review. The information provided suggested a consumer had bought replacement coils which were later thought to be counterfeit, and as a result of using these had suffered zinc poisoning.

1.1 Requirements

The Tobacco and Related Product Regulations 2016[1] (TRPR) do not refer to specific requirements for the composition of the device. Regulation 36 only refers to tank size, dosage delivered, tamper proof, child protection and leak protection measures. This contrasts with the requirement of liquids which include under Regulation 36(5) that the liquid:

(c)must not contain substances other than the ingredients notified under regulation 31, unless present in trace levels, where such trace levels are technically unavoidable during manufacture; and

(d)must not include ingredients (except for nicotine) which pose a risk to human health in heated or unheated form

The basic principle of the product to be safe therefore falls back to the General Product Safety Regulations 2005[2].

In addition, The Restriction of Hazardous Substances Directive (RoHS) 2011/55/EU[3] now covers electronic cigarette devices. Compliance with RoHS is a matter enforced by the Office of Product Safety and Standards (OPSS). The CE mark where applied does however indicate compliance with all relevant directives of which RoHS included. On that basis any enquiries by Trading Standards into technical files should be checking for the presence of evidence of compliance.

RoHS restricts the following metals (taken from EU directive 2015/863[4]) based on environmental concerns at the end of life for the products:

Lead (Pb)
Mercury (Hg)
Cadmium (Cd)
Hexavalent chromium (Cr6+)

---

[1] http://www.legislation.gov.uk/uksi/2016/507/part/6/made Tobacco and Related Product Regulations 2016 Part 6 – viewed online 13 August 2018

[2] http://www.legislation.gov.uk/uksi/2005/1803/pdfs/uksi_20051803_en.pdf General Product Safety Regulations 2005 – viewed online 13 August 2018

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0065&from=en Restriction of Hazardous Substances Directive – viewed online 13 August 2018

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0863&from=EN EU directive 2015/863 – viewed online 13 August 2018

Polybrominated biphenyls (PBB)
Polybrominated diphenyl ether (PBDE)
Bis(2-ethylhexyl) phthalate (DEHP)
Butyl benzyl phthalate (BBP)
Dibutyl phthalate (DBP)
Diisobutyl phthalate (DIBP)

An online article from Science Alert[5] referred to research conducted into the presence of heavy metals in e-liquids. The article cited a study in 2016, **The association of e-cigarette use with exposure to nickel and chromium: A Preliminary study of non-invasive biomarkers**[6] which detected the presence of elevated nickel and cadmium levels in the saliva of e-cigarette users. The study noted that e-cigarette coils were commonly made of either Nickel or Chromium.

The Science Alert article went on to reference a more recent study published in Environmental Health Perspectives in February 2018. The study titled **Metal Concentrations in e-Cigarette Liquid and Aerosol Samples: The Contribution of Metallic Coils**[7] sampled 56 e-cigarette devices looking at samples from the refilling dispenser, aerosol and e-liquid held in the tank. That study found that e-cigarettes were a potential source of exposure to Chromium, Nickel, Lead, Manganese and Zinc.

2. Method

The original intention was to test devices for their physical composition specifically in terms of the coil and any metallic element directly in contact with the e-liquid. Limited testing funds however required that an alternative method be developed.

An alternative method was agreed whereby a simulant would be left in the tank chamber for 30 minutes to replicate an e-liquid being left in a device prior to being inhaled. Using this method, the five metals indicated (Chromium, Nickel, Lead, Manganese and Zinc) would be tested for in the simulant. This methodology would be similar to that used for testing materials in contact with foods. The testing proposed would not be an evidential basis of a product being unsafe but would produce an indication as to whether further research is required in this area.

The devices to be tested were those test purchased as part of the National Rapid Review Phase 3a online testing. The devices were bought from UK based, online retailers, but were found to be non-compliant with the TRPR either due to incorrect labelling, tank sizes, non-notification to MHRA or a combination of all three. The fact that these were all widely available, non-compliant devices, may therefore provide an indication as to whether products produced specifically for the EU market were likely to contain harmful (cheaper) elements in their design and composition.

---

[5] https://www.sciencealert.com/toxic-levels-heavy-metals-heating-coil-ecigarette-vaping - Science Alert The association of e-cigarette use with exposure to nickel and chromium: A Preliminary study of non-invasive biomarkers – published 23rd February 2018

[6] https://www.sciencedirect.com/science/article/pii/S0013935117308642?via%3Dihub - Abstract from Environmental Research Volume 159 – dated November 2017

[7] https://ehp.niehs.nih.gov/ehp2175/ Environmental Health Perspectives - Metal Concentrations in e-Cigarette Liquid and Aerosol Samples: The Contribution of Metallic Coils – dated February 2018

2.1 Limitations

The method above would only determine if any of the metals being tested for would leach into the simulant when heated to 70c. It would not fully replicate the vaporisation process which could be hypothesised to accelerate or catalyse the leaching from the coil to the liquid.

This was also a very small sample size of five devices and therefore could only be used to provide an early indication from the products test purchased. The original complaint referred to replacement coils being potentially counterfeit, however given the agreed test method and limitation on the number of tests to be performed, individual components could not be tested at this time.

3. Results

The results from the laboratory are detailed below. Financial limitations precluded the testing for zinc at this time.

Device 1 – rebuildable tank atomiser (3ml of solution)

Chromium <0.001mg/L, equivalent to <0.003 μg of chromium in simulant
Lead <0.1mg/L, equivalent to <0.3 μg of lead in the simulant
Nickel <0.1mg/L, equivalent to <0.3 μg of nickel in the simulant
Manganese <0.1mg/L, equivalent to <0.3 μg of manganese in the simulant

Device 2 – rebuildable tank atomiser (3ml of solution)

Chromium 0.008mg/L, equivalent to 0.024 μg of chromium in simulant
Lead <0.1mg/L, equivalent to <0.3 μg of lead in the simulant
Nickel <0.1mg/L, equivalent to <0.3 μg of nickel in the simulant
Manganese <0.1mg/L, equivalent to <0.3 μg of manganese in the simulant

Device 3 – rebuildable tank atomiser (4ml of solution)

Chromium 0.003mg/L, equivalent to 0.012 μg of chromium in simulant
Lead <0.1mg/L, equivalent to <0.4 μg of lead in the simulant
Nickel <0.1mg/L, equivalent to <0.4 μg of nickel in the simulant
Manganese <0.1mg/L, equivalent to <0.4 μg of manganese in the simulant

Device 4 – e-cigarette complete device (2ml of solution)

Chromium 0.001mg/L, equivalent to 0.002 μg of chromium in simulant
Lead <0.1mg/L, equivalent to <0.2 μg of lead in the simulant
Nickel <0.1mg/L, equivalent to <0.2 μg of nickel in the simulant
Manganese <0.1mg/L, equivalent to <0.2 μg of manganese in the simulant

Device 5 – rebuildable tank atomiser (3.5ml of solution)

Chromium 0.009mg/L, equivalent to 0.03 μg of chromium in simulant

Lead <0.1mg/L, equivalent to <0.35 μg of lead in the simulant
Nickel 0.23mg/L, equivalent to 0.81 μg of nickel in the simulant
Manganese <0.1mg/L, equivalent to <0.35 μg of manganese in the simulant

The levels detected in most cases do not give immediate cause for concern although device 5 did have elevated levels compared to the other four. The European Food Safety Authority reported in February 2018 in **Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water**[8] a tolerable level of nickel in drinking water of 2.8 μg/kg of body weight per day. The current finding would suggest a user going through 10ml of liquid a day may inhale approximately 2.31 μg in a day which would therefore be well within the tolerable level suggested, furthermore an American report from the Centre for Disease Control (undated)[9] estimated with an intake of 2litres of water a day, a person could expect an intake of 4-8.6 μg of Nickel per day.

Both manganese and lead were below detectable levels in all samples and therefore are presumed to not be present.

Chromium was detected in four of the samples between 0.001-0.009 mg/L of the simulant (0.002-0.03μg actual). The World Health Organisation sets a tolerable level in drinking water as 0.05mg/L. These figures can be compared to the levels found in cigarette smoke in popular American brands as between 1.4-3.2μg/g of tobacco, as reported in Toxic Metal Concentrations in Cigarettes Obtained from U.S. Smokers in 2009[10]

4. Conclusions and Recommendations

The findings of the tests, while within suggested levels, do leave questions. While theoretically safe, one of the devices did indicate the presence of heavy metals. This raises the questions specifically in relation to these results:

- Would the vaporisation process increase the transference of heavy metal to the liquid?
- Do any ingredients of e-liquids accelerate this transference?
- Do the devices have an initial ‘leach period’ after which no further metal is transferred to the liquid?

Additional questions for further work include:

- Where analysis indicates the presence of metals subject to RoHS, are these properly declared on technical documentation even if within prescribed limits?

[8] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4002 - Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water – published 28th February 2018
[9] https://www.atsdr.cdc.gov/ToxProfiles/tp15-c2.pdf - Centre for Disease Control report published online (undated) – viewed 13th August 2018
10 www.mdpi.com/1660-4601/11/1/202/pdf - Toxic Metal Concentrations in Cigarettes Obtained from U.S. Smokers in 2009 – published 20th December 2013

- Where replacement parts such as coils are identified, what is the composition of these parts and do they pose a greater risk to the user?

To answer these questions, it is recommended that Trading Standards authorities with importers or manufacturers within their areas should consider liaison with those businesses to inspect technical documentation to determine the product composition and compliance in terms of those technical files.

Furthermore, it is recommended that more thorough testing of devices be carried out to replicate the conditions of e-cigarette use, both with a wider range of products, but also to include replacement parts and to test the any long-term cumulative impact on 'real-use' scenarios.

Finally while it is difficult to predict when test purchasing whether a replacement part is likely to be counterfeit, low cost parts on internet marketplace sites could be targeted as part of a test purchase campaign for further testing.