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Investigation of the compliance of single use e-cigarettes in Switzerland

Number of samples: 32

Number of non-compliant samples: 32 (100%)

Reasons for non-compliance: Food law: Exceedance of maximum e-liquid volume (28), substances without declaration (24), false declaration of nicotine content (8), no declaration of nicotine content (6), no warnings in official language (12), no lot number (15), no warning on addictiveness of nicotine (2), Exceeded use by date (2), discrepancy of information on packaging and product leaflet (1).

Chemical law: false warning (1), no payment of recycling fee (19), no or false declaration of compliance (26), no registration of chemical product (19), exceedance of limit for heavy metals in solder (4), no contact address of manufacturer of importer (20).



Background

E-cigarettes, also known as electronic cigarettes, are used widely in Switzerland. In recent years, there was a trend towards disposable e-cigarettes. Almost one tonne of these products are sold in Switzerland every day. The original idea of e-cigarettes was to offer smokers a less harmful alternative to traditional cigarette smoking¹. However, many non-smokers and, due to a lack of harmonised laws in Switzerland, underage users have begun consuming these products.

Disposable e-cigarettes are designed for maximum convenience and can be used without any further action after purchase. Since they cannot be refilled, disposable e-cigarettes must be discarded along with their batteries and electronic components once the liquid is depleted. Consumers of disposable e-cigarettes are required to dispose of batteries correctly at a collection point, for instance the points of sale, which are required to take the products back. SENS eRecycling is currently setting up a system with collection points for the used devices, so that both the electronic components and the batteries are recycled appropriately. However, it is likely that a significant number of these products end up in normal household waste or are disposed of in the environment while on the move, which largely increases the burden on the environment.

¹ Patent US3200819A: *Smokeless non-tobacco cigarette*. Registered on April 17, 1963, published on August 17, 1965, inventor: Herbert A. Gilbert.

The main components of e-liquids are the aerosol producing propylene glycol and glycerin. They also contain fragrances and flavourings, nicotine and other additives that facilitate inhalation. Health risks to vapers can arise from the nicotine, the aerosol producers and additives as well as potential contaminants. Very little is currently known about the long-term health consequences of e-cigarettes. A recent publication even suggests that the difference of vaping compared to smoking is smaller than had previously been assumed².

The fragrances and flavourings in vapes were, in most cases, originally intended as food additives and their safety has been well studied with respect to oral toxicity. Almost nothing is known about the toxicity of most substances upon inhalation.

While oral intake of propylene glycol and glycerin is largely harmless, inhalation of glycerin and propylene glycol can sometimes lead to health problems. Lipophilic pneumonia has been reported, which may develop after inhaling glycerin-based aroma oils in nicotine-containing aerosols. Propylene glycol is also used in fog machines. A study of employees in the entertainment industry showed irritation of the respiratory tract and an increased risk of asthma after single and repeated exposure³.

Nicotine is a highly addictive substance and often leads to dependence. The acute reference dose (ARfD) for nicotine is 0.8 µg/kg body weight per day: for an adult (70 kg) this corresponds to 56 µg and for a child (12 kg) 9.6 µg nicotine per day. The lethal dose for an adult after ingestion is 40-60 mg, for a child roughly 5 mg. Many single use e-cigarettes contain over 40 mg of nicotine, which is why the products must be kept away from children at all times⁴.

By February 2020, over 2,800 people in the USA suffered lung damage, some of them severe, after consuming e-cigarettes. According to the American health authority CDC, 68 people died [3]. Vitamin E acetate has been linked to these cases. However, it has not been proven with certainty that this substance is actually responsible for the damage. There is little and sometimes contradictory data on inhaling this substance. However, due to its properties, it seems plausible that inhaling high concentrations of vitamin E acetate can cause damage to the lungs. The substance accumulates in the alveoli, which can hinder the absorption of oxygen. Inflammation and tissue damage can also be a consequence of this inhalation.

In Europe, there are stricter regulations on e-cigarettes than in the USA. For example, vitamins may not be added to e-liquids in the EU. Accordingly, no cases of the aforementioned American lung injury have yet been reported in Europe in connection with vaping commercially available e-liquids. However, according to media reports, an 18-year-old man died in Belgium in November 2019 as a result of severe pneumonia after smoking an e-liquid containing cannabinoids⁵.

The discrepancy between the declaration of ingredients and the actual content of the e-liquids can be very large. Both existing literature and our own research indicate that, for instance, the nicotine content in vapes from the US often does not match the declared levels.

Aims of the campaign

The nicotine content, the volume of liquid in the disposable e-cigarettes and the presence of toxic or prohibited ingredients were checked for compliance. The heavy metal content of the solder was also checked. In addition, the declaration on the packaging and the information leaflets, as well as the obligation to register the products in the product register, were checked. We investigated whether the up front disposal fee for batteries had been paid by the importer and whether they could provide the EU declaration of conformity, which is mandatory for electrical devices.

Legal background

The manufacturing and sales of e-liquids is not yet specifically regulated in Swiss legislation. E-cigarettes currently fall under the scope of the Swiss Food Act (SR 817.0) and are treated as consumer goods. E-cigarettes without nicotine can be sold freely in Switzerland. The ban on trading in e-liquids containing nicotine was overturned following a ruling by the Federal Court ruling on April 24, 2018. Now, e-cigarettes containing nicotine can be sold legally in Switzerland, if they meet the technical requirements of EU Directive 2014/40/EU from 3 April 2014. The products are generally considered safe if they comply with this directive⁶.

2 Cigarette smoking and e-cigarette use induce shared DNA methylation changes linked to carcinogenesis. C. Herzog et al. Available at: <http://aacrjournals.org/cancerres/article-pdf/doi/10.1158/0008-5472.CAN-23-2957/3430413/can-23-2957.pdf>

3 https://www.bag.admin.ch/dam/bag/de/dokumente/chem/themen-a-z/factsheet-e-liquid.pdf.download.pdf/Factsheet_e-Liquid_DE.pdf

4 CDC 2020. Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products. Centers for Disease Control and Prevention. Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products | Electronic Cigarettes | Smoking & Tobacco Use | CDC

5 https://www.bfr.bund.de/de/presseinformation/2019/43/dampfen_bfr_raet_vom_selbstmischen_von_e_liquids_ab-243082.html

6 <https://www.blv.admin.ch/blv/de/home/gebrauchsgegenstaende/e-zigaretten.html>

In addition, appendices 2.15 (batteries and their advance disposal fee) and 2.18 (compliance with the RoHS Directive with regard to substances prohibited in electrical devices such as heavy metals in solder) of the Chemicals Risk Reduction Ordinance (ChemRRV; SR 814.81) apply to electrical devices containing batteries. The chemicals contained in the liquid are subject to the Chemicals Ordinance (ChemV, SR 813.11). Under the planned Tobacco Products Act, set to take effect in autumn 2024, e-liquids and e-cigarettes will be subject to specific regulations. Once this law comes into effect, e-cigarettes will be classified as tobacco replacement products rather than consumer goods under Swiss food law.

Sample description

A total of 32 samples were collected from 12 retailers. These included 29 disposable e-cigarettes with nicotine, 2 disposable e-cigarettes without nicotine and an additional sample of an e-liquid for refilling. The declared nicotine content of the nicotine-containing samples was 10 mg/mL (1), 16 mg/mL (1), 17 mg/mL (1) and 20 mg/mL (26). However, the nicotine content is often labelled ambiguously, because no distinction is made between nicotine salt and free nicotine.

Methods

Several analytical techniques were used to test the e-liquids. The nicotine content was quantified using a liquid chromatographic method with spectrophotometric detection (HPLC-PDA). The tests for other critical ingredients were carried out using HPLC-PDA and gas chromatography with mass spectrometric detection (GC-MS). With these analytical methods, many other substances can be determined qualitatively and quantitatively in addition to nicotine. These substances include coumarin, safrole, many CMR substances (carcinogenic, mutagenic and substances toxic to reproduction), vitamin E and vitamin E acetate. The volume was determined gravimetrically. The soldering points were examined for the presence of lead, mercury and cadmium using X-ray fluorescence analysis (XRF) in the Cantonal Laboratory of Zurich.

Results

No nicotine was found in either product with a declared nicotine content of 0 mg/mL. The maximum permitted nicotine content of 20 mg/mL was exceeded twice (35.9 mg/mL and 24.9 mg/mL). For the remaining 28 products, a deviation of up to 48% in the declared nicotine content was found. In eight samples, the declared content deviated by more than 15% from the measured content. In six products, the nicotine content was stated as nicotine salt content. However, no nicotine content can be derived from this, as several different salts are used.

One sample contained salicylic acid in a high concentration, two other products contained methylsalicylic acid in a low concentration. Both salicylic acid and methylsalicylic acid are classified as toxic to reproduction.

Other prohibited ingredients such as coumarin, safrole, quassin, vitamin E, vitamin E acetate or diacetyl could not be detected in any of the samples.

The nicotine salt used was not declared in 19 samples. 29 samples contain the ingredient 2-isopropyl-N,2,3-trimethylbutyramide (also known as WS-23) as an additive with a cooling effect, but in 24 samples this additive is not indicated on the label. The available data on the toxicity of WS-23 is not very extensive. The request for a safety assessment from the importers, on whose products the substance was listed, showed that the documents are far from a conclusive assessment. There are no studies on the effects of WS-23 in the literature that allow the conclusion that the substance is safe when inhaled. The vaping industry appears to be insufficiently aware of its duty of care to the consumers in this regard. Currently, the consumers themselves will eventually provide the data on toxicity. The findings on the long-term effects will only be available in several years.

The deviation of the declared volume from the actual volume of e-liquid was greater than 10% for 22 products (71%), greater than 20% for 18 products (58%) and greater than 30% for 15 products (48%). In the 10 samples taken from the market, which declared volume of 2 mL, the specific volume of liquid was between 2.2 mL and 4.0 mL and thus reached up to twice the maximum permissible volume. Of the 29 disposable e-cigarettes containing nicotine, only one was legally compliant with regard to the volume of the liquid.

35 different flavour substances were detected. The most common were benzyl alcohol (24) and linalool (24), followed by vanillin (22) and cinnamon compounds (16). Several of the flavorings detected can cause an allergic reaction in sensitive people. The effect of these substances on the lungs when vaping is also largely unknown.

A nicotine-free product was labelled with a skull and crossbones hazard pictogram. This label is intended for products with a nicotine content of more than 1.8% or if they contain other chemicals classified as dangerous.

In two samples, the lead content in the solder was above the legal limit of 0.1%. In one of these samples, the limit of 0.01% cadmium was also exceeded. Mercury could not be detected in any of the samples. Importers of electrical devices containing batteries must report the imported amount of batteries to INOBAT and pay an up front disposal fee. Of the 31 products checked, the fee had not been paid for 19 products (61%). Of the 23 importers covered, 16 (70%) did not pay the fee. Since the importers did not comply with this reporting obligation, an investigation of all imports into Switzerland in the last year was carried out in collaboration with border control. Of a total of 143 importers of disposable e-cigarettes, 125 companies (87.4%) did not pay the up front disposal fee. The situation in terms of tonnage looks better across Switzerland: of a total of 354 tonnes of imported disposable e-cigarettes, the fee was not paid for 75 tonnes (21%).

The EU declarations of conformity required for the import of electrical devices was not available for 16 products (52%). For a further 10 products (32%), the EU declaration of conformity was incomplete.

For 19 products (61%), the importers did not comply with the reporting obligation for dangerous chemicals in the Swiss product register, and for a further 4 products (13%) the report was incorrect.

For 18 products (58%) the name and address of the importer were not provided, for another 2 products (6.5%) the importer was named but the address was missing.

Reasons for non-compliance	Occurrences	%
Exceedance of maximum permissible nicotine concentration	2 / 30	6.7
Maximum permissible volume exceeded	28 / 29	96.6
Reprotoxic ingredient	3 / 32	9.4
No declaration of nicotine content	6 / 32	18.8
False declaration of nicotine content	8 / 32	25
Additive WS-23 not listed as ingredient	24 / 32	75
Additive benzoic acid not listed as ingredient	19 / 32	59.4
No lot number on product	15 / 30	50
Warnings not in official language	12 / 30	40
No warning on addictiveness of nicotine	2 / 30	6.7
Passed best before date	2 / 32	6.3
Discrepancy of information on packaging and product leaflet	1 / 32	3.1
Label «For sale only in United States»	1 / 32	3.1
Maximum permissible amount of lead in solder exceeded	2 / 31	6.5
Not registered with INOBAT and recycling fee not paid by importer	19 / 31	61.3
EU-Certificate of Compliance not available or incorrect	26 / 31	83.9
Not in Product register or incorrect in product register	23 / 31	74.2
Missing or wrong contact details of importer on product	20 / 31	64.5

red: Sales were banned
blue: Future Import was banned

Measures taken

The sales of e-cigarettes with a nicotine content above the maximum permitted concentration of 20 mg/mL and of e-cigarettes with a reproductively toxic ingredient were banned with immediate effect.

Due to a change in the interpretation of the legal texts by the federal authorities, the sale of nicotine-containing e-cigarettes with a volume above the maximum permitted volume of 2 mL was temporarily tolerated, but the import of further such products is prohibited.

Electrical devices with too high a lead content in the solder banned for sale with immediate effect.

A correction to the declaration and products was ordered for other non-compliances.

Payment of the up front disposal fee for electrical devices containing batteries was ordered retroactively, so that the importers must pay the fee for all devices imported in the last 5 years.

Companies were asked to obtain the EU declarations of conformity from the foreign manufacturers or, if necessary, to bring them into compliance with the law. They were also ordered to register the disposable e-cigarettes in the product register and to mark the label with a Swiss address. The importer of the nicotine-free e-cigarette with the skull and crossbones hazard pictogram on the packaging was ordered to remove it.

Conclusions

Importers must take care to ensure that their products comply with legislation, especially for critical points such as nicotine content or tank volume. Many non-compliances should have been obvious to importers just by reading the label.

Producers should not to use CMR substances as flavorings or salt formers.

Too many importers do not pay the up front disposal fee for batteries and do not ensure the products they import complies with European law.

The situation will require further monitoring and market controls.