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E-liquids

Nicotine content, prohibited substances, labelling, compliance with food and chemical safety laws

Joint campaign of 4 cantons (Aargau, Basel-Landschaft, Bern, Solothurn and Basel-Stadt)

Number of samples:	59
Non-compliant:	39 (66%)
Reasons for non-compliance:	Non-compliant with food law 16 (27%) Non-compliant with chemical safety law 35 (59%) Non-compliant with both 12 (20%)



Background

E-cigarettes consist of a mouthpiece, a battery, an electric vaporiser and a cartridge containing the liquid to be vaporized (e-liquid). When vaping, the liquid is heated and vaporised by a battery-powered heating element. The main components of e-liquids are propylene glycol and glycerol. They also contain fragrances and flavours and, if desired, nicotine. The composition of e-liquids varies greatly depending on the product. Risks to health for vapers can arise from the nicotine itself, from the nebulizing agents, active substances and other additives and their impurities. Currently, very little is known about the long-term health effects from e-cigarette vaping.

In e-cigarettes, propylene glycol and glycerol are responsible for the formation of vapor. The fragrances and flavours used are normally food additives, and have been proven to be harmless for oral use, however, very little is known about the inhalative toxicity. Furthermore, nicotine in e-liquids is a highly addictive substance. (Accidental) ingestion of e-liquids containing nicotine can lead to dangerous levels of exposure.

Up until February 2020, more than 2,800 people in the United States suffered lung damage, some severe, after vaping e-cigarettes. The symptoms have been termed EVALI (e-cigarette vaping associated lung injury). According to the American health authority (Centers for Disease Control and Prevention, CDC), 68 people died. These cases have been linked to vitamin E acetate, which is banned in European e-liquids. The discrepancy between the declaration of the ingredients and the actual content of e-liquids can be large. It is known from literature and from our own work that, for example, the declared nicotine content in e-liquids does not always correspond to the actual nicotine content.

Legal basis

The production and distribution of e-liquids is not yet specifically regulated in Switzerland. Currently e-cigarettes fall within the scope of the Federal Act on Foodstuffs and Utility Articles. A ban on trading e-liquids containing nicotine was lifted following a ruling by the Swiss Federal Supreme Court from April 24, 2018. E-cigarettes containing nicotine and their e-liquids can now also be sold in Switzerland if they meet the technical requirements of an EU or EEA member state. Therefore, the requirements of EU Directive 2014/40/EU apply to nicotine-containing e-cigarettes and their liquids in Switzerland. Liquids that comply with these requirements are considered safe. In the EU, this directive harmonises the national regulations on the placing on the market and labeling of e-cigarettes containing nicotine.

As preparations, e-liquids are also subject to the Swiss Chemicals Act (ChemA). Dangerous chemicals may only be sold, if the products are correctly classified according to art. 7 of the Chemicals Ordinance (ChemO), correctly labelled according to art. 10, properly packaged according to art. 8 and a safety data sheet according to art. 20 is available. In addition, the products must be entered in the product register in accordance with art. 48. Furthermore, according to art. 10 (3.a), a Swiss "manufacturer's" address must be on the product and according to art. 10 (3.b) the labelling must be in the official language of the location of sales.

In the drafted Swiss Tobacco Products Act, most regulations for e-liquids and e-cigarettes are planned to be regulated. After this law enters into force, e-cigarettes will be subject to further regulation including advertising restrictions and a ban on sale to minors.

Study aims

The nicotine content and the presence of toxic or prohibited ingredients and allergenic fragrances were determined in e-liquids. In addition, the labelling of the e-liquids and compliance with the food and chemical safety acts were assessed.

Sample description

A total of 59 samples were taken from 17 retailers in the cantons Aargau, Bern, Basel-Landschaft, Basel-Stadt and Solothurn. There were 34 samples without nicotine and 25 samples with a declared nicotine content between 3 mg/mL and 20 mg/mL.

Testing methods

Several methods were used to analyse the e-liquids. The nicotine content was quantified using an HPLC method with spectrophotometric detection (HPLC-PDA). Analysis for other critical ingredients were carried out using HPLC-PDA and gas chromatography with mass spectrometric detection (GC-MS). With these analytical methods, many substances can be determined qualitatively and quantitatively in addition to nicotine. These substances include the hazardous substances coumarin, safrole, quassin, diacetyl, many CMR substances (carcinogenic, mutagenic and reprotoxic substances), vitamin E and allergenic fragrances.

Results and measures

Nicotine content

Concentrations of 0.19 mg/mL and 0.02 mg/mL were determined in two e-liquids that were declared to contain no nicotine. This discrepancy was evaluated not to be relevant. No nicotine was detected in the other samples declared as nicotine-free. The permitted maximum nicotine content of 20 mg/mL was never exceeded. Otherwise, the declarations regarding the nicotine content corresponded to the measured values for all remaining samples. The highest deviation of -19.4% was found in an e-liquid with a declared nicotine content of 3 mg/mL.

Banned Ingredients

Prohibited ingredients according to EU Directive 2014/40/EU such as coumarin, safrole, quassin, vitamin E, vitamin E acetate or diacetyl could not be detected in any sample.

13.8 – 19.9 mg/mL salicylic acid was measured in three samples. This substance is known to be toxic to reproduction. The corresponding e-liquids are declared to contain nicotine in the form of a salt (nicotine salt, nicotine benzoate or nicotine salicylate). However, since the salt nicotine salicylate is not listed as a CMR and the analysis method cannot distinguish between nicotine salicylate and salicylic acid, the salicylate finding was deemed to be compliant. However, in one case a nicotine salt was incorrectly labelled (nicotine benzoate instead of nicotine salicylate) and, therefore, not compliant.

Problematic ingredients such as furfural (3 samples), dihydrocoumarin (4 samples) or 7-methoxycoumarin (1 sample) were only found in very low concentrations, not leading to any more non-compliances.

Other ingredients and findings

A total of 44 flavourings and 4 colourings were identified in the 59 e-liquids. In one sample 17 different flavour substances were detected. The most commonly identified flavour compounds were linalool (40) followed by methyl cinnamate (27), vanillin (27), limonene (23) and citral (21). High concentrations of flavour substances were measured for menthol (11 mg/mL), benzyl alcohol (7.5 mg/mL), trans-anethole (2.5 mg/mL) and 2-phenylethanol (1.1 mg/mL). The colorants identified were food colorants yellow orange S (CI 15985, E110), amaranth (CI 16185, E123), brilliant blue FCF (CI 42090, E133) and azorubine (CI 14720, E122). For four e-liquids, the best-before date printed by the manufacturer had already expired at the time the sample had been taken from the market, which is non-compliant.

Directive 2014/40/EU stipulates that e-liquids containing nicotine may only be placed on the market in specially designed refill containers with a maximum volume of 10 mL or in disposable electronic cigarettes or in disposable cartridges, whereby the cartridges or tanks may have a maximum volume of 2 mL. Two products exceeded the maximum permitted volumes, leading to their sales being banned.

Summary of results

Non-compliant samples	Number of samples (total 59)
Non-compliant samples with food law	16 (27%)
Non-compliant samples with chemical safety law	35 (59%)
Total number of non-compliant samples	39 (66%)

Samples for which sales were banned	Number of samples (total 59)
Due to non-compliance with food safety law	13 (22%)
Due to non-compliance with chemicals law	22 (37%)
Total number of samples whose sale was banned	26 (44%)

Summary of compliance assessment with food law

Reasons for ban of sales according to food safety law	Number of samples (total 59)
Incorrectly labelled ingredient (nicotine-benzoate instead of salicylate)	1 (2%)
Nicotine warning not in official language	11 (19%)
Single use Tank volume > 2 ml	1 (2%)
Liquid refill packaging volume > 10 ml	1 (2%)

Other reasons for non-compliance without a ban on sales	Number of samples (total 59)
Best before date exceeded	4 (7%)
Insufficient legibility of warnings	1 (2%)
Incorrect warning in German	1 (2%)
Lot number missing	1 (2%)

Summary of compliance assessment to chemicals law

Of the 59 Samples 36 (61%) were classed as dangerous preparations and were assessed according to the provisions in chemicals safety law. Of these 35 samples 22 (61%) were banned from sales. Of the 25 products containing nicotine 12 (48%) were banned from sales, while 10 (91%) of the other non nicotine samples were banned.

Reasons for sales ban based on chemicals safety law	Number of samples (total 22)
No safety data sheet	12 (55%)
Wrong classification	15 (68%)

Of the 36 samples classed as dangerous preparations only one sample (3%) was fully compliant according to the tested parameters.

Other non-compliances according to chemicals safety law without a ban on sales	Number of relevant samples (36)
Labelling language	14 (39%)
No Swiss address	21 (58%)
No registration product registry	27 (75%)
Insufficient safety data sheet	16 (67%) (von 24)*
Labelling too small or otherwise not legible enough	2 (6%)
Danger pictogram too small	4 (11%)

* No safety data sheet at all was available for 12 products.

Conclusions

In this campaign the analytically determined nicotine content corresponded with the declared content. The detection of reprotoxic salicylic acid in three e-liquids can be traced back to the use of the nicotine salt nicotine salicylate. Nicotine salicylate itself is not classified as toxic to reproduction. However, nicotine salicylate is most probably converted to nicotine and salicylic acid when the vapour from the e-liquid reaches the mucous membranes in the lungs. Other problematic substances were not found at toxicologically relevant concentrations in any sample.

A total of 66% of all samples were not compliant, while 44% of all samples were subject to sales bans. This high rate shows that the manufacturers and importers of e-liquids are not aware that these products are regulated by both food and chemical safety laws and that the corresponding requirements must be met in order for the products to be sold.

The fate of the food colorants in e-liquids when vaping remains unclear. Some products contained colorants, which could not be identified. In the future more analytical methods for analysing e-liquids will need to be developed and market surveillance will be continued.