

Recommendations on the Regulation of Electronic Inhalation Products

Background

Electronic inhalation products (e-inhalation products) are products similar to tobacco products. They either vaporise a chemical mixture with or without nicotine, the so-called liquid, or heat tobacco without burning it. The user inhales the aerosol formed in this process similarly to smoking conventional cigarettes. During use, emissions from the exhaled aerosol are released into the air. Examples of e-inhalation products are e-cigarettes, e-shishas, e-cigars and e-pipes. Both disposable and rechargeable products are available.

In Germany as well as in many other countries there are no legal regulations for e-inhalation products: standards for product safety and protection against potential damage to health are absent. Adolescents and young adults are not protected against products which might lead to nicotine addiction and could facilitate smoking initiation. In addition, there is no regulation on the use of e-inhalation products in locations where smoking is banned (public facilities, pubs, places of work, schools, etc.). Therefore, regulation of these products is urgently required.

Provisions for product safety and for the protection of children and adolescents from nicotine-containing e-cigarettes were included in the revision of Directive 2001/37/EC, now Directive 2014/40/EU²⁰. According to this Directive, e-cigarettes that contain nicotine will be regulated either like tobacco products, or if the product is claimed to be provided for tobacco cessation, it will be regulated as human medicines or medical devices. Nicotine-free e-inhalation products are

not regulated by Directive 40/2014/EU. The member states are obliged to put into force legal and administrative laws by 20 May 2016, in order to transpose Directive 2014/40/EU into national law.

Recommendations on regulation

The new EU Directive only applies to nicotine-containing products; furthermore, it focusses mainly on consumer protection. It neglects most aspects of youth protection, the protection of non-smokers, and waste disposal. Therefore further legal amendments should be made beyond the transposition of the Directive into national law. These are elaborated and substantiated hereafter (Fig. 1).

Consumer and health protection

To date, there are no legally regulated standards neither for the technical requirements of the components of the products, nor for the maximum permitted concentrations, nor for the purity of the substances used in the liquids, nor for the warning and safety indications on the packaging. Even though the products underwent continuous development, technical faults remain: in some models, liquid may leak during puffing³⁴ as well as during changing or refilling the cartridges⁴⁶.

In some products, the concentration of nicotine in the liquids is declared incorrectly and in some products that were labeled as nicotine-free nicotine has been detected^{10,23,45}. The amount of nicotine released in the aerosol varies substantially

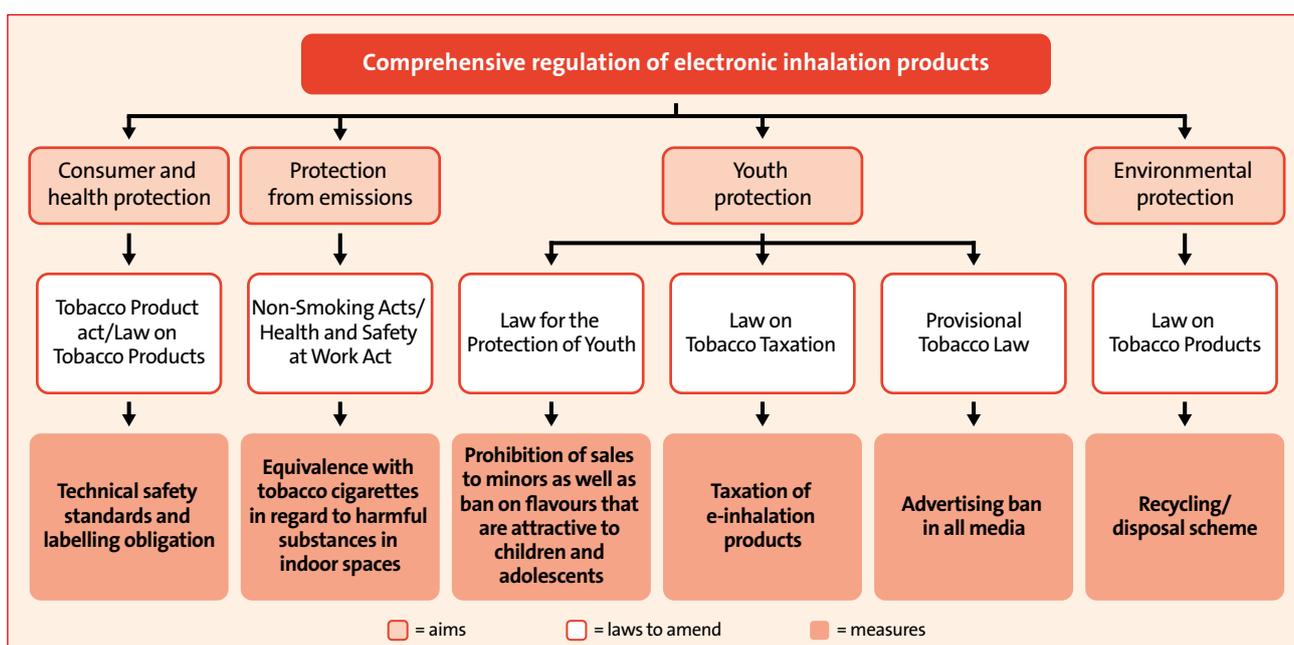


Figure 1: Aims and measures of the regulation of electronic inhalation products and laws to amend in Germany. Illustration: German Cancer Research Center, Unit Cancer Prevention, 2014

depending on the device, fill amount, battery voltage and the puffing intensity^{23,38,47,51}. As e-inhalation products can be used for hundreds of puffs without interruption, overheating due to excessive use and, in the case of nicotine products, poisoning may occur^{6,27}.

In order to improve consumer protection, the EU Directive 2014/40/EU enforces the following safety regulations for e-cigarettes:

- Maximum volume of the refill containers: 10 ml; maximum volume of the cartridges: 2 ml; maximum nicotine concentration: 20 mg/ml.
- Only additives of high purity must be used; other substances may only be included in trace amounts, if unavoidable during production.
- E-cigarettes must deliver the nicotine at consistent levels under normal conditions of use.
- E-cigarettes and refill containers must be child-proof, tamper-proof and breakage-proof and must ensure refilling without leakage.
- An information leaflet must be included with an instruction manual and instructions for storage – including a warning that the product is not recommended for adolescents and non-smokers, and warnings for specific risk groups and possible adverse effects as well as addictiveness and toxicity.
- The packaging must list: all ingredients, nicotine content, batch number, the warning to keep the product out of reach of children and the warning that nicotine is a highly addictive substance.

- **These regulations should be introduced immediately for e-inhalation products.**

According to the EU Directive, these regulations only apply to nicotine-containing products. However, not only the potentially contained nicotine, but also any other ingredient may pose health risks. The substances used are authorised for use in food – the physiological effect they may have, if inhaled repeatedly and daily over a long period, is unknown.

Propylene glycol, usually the main substance of the liquids used in e-inhalation products, may cause irritations of the eye and respiratory tract as well as cough^{32,50}. Some of the flavours used in the liquids, such as menthol and vanillin, are known contact allergens. Therefore, the use of e-inhalation products might cause allergies. Moreover, a carcinogenic effect cannot be excluded, as small amounts of nitrosamines^{22,45}, as well as formaldehyde and acetaldehyde⁴¹ were detected in a few liquids; also in the aerosol of various e-cigarettes, formaldehyde, acetaldehyde, and acrolein^{22,37,45} was found, along with nickel and chrome⁵².

- **Therefore, the same safety standards should apply to ALL e-inhalation products according to Directive 2014/40/EU – regardless of their nicotine content.**
- **Because the aerosol of e-inhalation products is inhaled similarly to tobacco smoke, e-inhalation products should be regulated as tobacco products.**

In addition to the guidelines of Directive 2014/40/EU, the following regulatory measures are appropriate:

Protection of children/adolescents

Initially, e-inhalation products were mainly used by smokers, ex-smokers and smokers willing to quit^{2,12,19,31,33,35}. In the meantime, more and more adolescents have been trying e-inhalation products; particularly e-shishas, usually available in colourful packages and many child-friendly flavours (gummy bears, bubble-gum, chocolate, cookies, etc.), are appealing to young consumers. Most of the young consumers of e-inhalation products are smokers, but up to 20 percent are non-smokers and the percentage of non-smokers is markedly higher amongst the younger (13–15 year olds) than amongst the older adolescent consumers (16–17 year olds)^{1,8,9,14,17,28,42}. The current data are not sufficient to draw conclusions whether particularly smoking adolescents are interested in e-cigarettes or, on the contrary, whether non-smoking adolescents initiate with e-cigarettes and then switch to tobacco. Nevertheless, it is to be feared that e-inhalation products might be a gateway to smoking of traditional cigarettes for children and adolescents^{7,11}. This is also pointed out in Directive 2014/40/EU in Reason 43: “Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking.” While using e-inhalation products, adolescents practice the smoking ritual. Moreover they may start with supposedly harmless, nicotine-free products, try countless flavour variations from chocolate and pizza to tobacco, and finally may switch to nicotine-containing products as soon as the nicotine-free products lose their thrill. When even this is no longer attractive, they may ultimately switch to tobacco cigarettes.

To protect youth from products which could facilitate smoking initiation, several measures are reasonable:

1. Prohibition of sale to minors

It is currently legal to sell e-inhalation products to children and adolescents. Some traders voluntarily refrain from doing so, and some manufacturers indicate on the packaging that the products are not suitable for minors (< 18 years). Despite

Publisher's Information

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Suggested citation: German Cancer Research Center (ed.) Recommendations on the Regulation of Electronic Inhalation Products. From Science – to Politics, Heidelberg, 2014

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Support provided by the Klaus Tschira Foundation gGmbH

these voluntary restrictions and indications, children and adolescents in Germany can buy electronic inhalation products. According to media reports, the use of e-shishas by pupils is increasing^{4,44}. A ban to sale e-inhalation products to minors makes it more difficult for children and adolescents to purchase these products.

and supermarket cashiers) for tobacco products are still permitted. If this regulation also applies to the advertising for e-inhalation products and liquids, children and adolescents will be permanently and everywhere exposed to the advertisements for products that might facilitate smoking initiation. Therefore, the advertising ban should be extended.

- Therefore, the sale to minors should be prohibited for ALL e-inhalation products – regardless of their nicotine content.
- In Germany, such a prohibition of sale can be enacted using the Law for the Protection of Youth (§10).

- The advertising ban prescribed by Directive 2014/40/EU should be implemented immediately for all e-inhalation products.
- A ban on outdoor advertising and advertising at the point of sale should be included.
- In Germany, a comprehensive advertising ban can be enacted through the Provisional Tobacco Law.

2. Extension of advertising ban

E-inhalation products are primarily marketed as healthier alternatives to smoking and as smoking cessation aid. Some manufacturers also claim that they can be used everywhere to circumvent non-smoking legislation. However, in addition to smokers, adolescents and young adults are also an important target group for advertising: The models in the ads are of an age which easily makes them role models for young people (Fig. 2). In order to protect adolescents and young adults from the use of a potentially addictive product, which might facilitate smoking initiation (see Reason 43 of the Directive 2014/40/EU), any advertisement for these products should be banned. The Directive 2014/40/EU requires a ban on advertising for nicotine-containing e-cigarettes on the internet, in print, on the radio and on television, as well as the sponsorship of cross-border initiatives.

In Germany, outdoor advertising (billboards, city lights) and advertising at the point of sale (petrol stations, stationers

3. Uniform packaging

In Reason 48 for the enactment of Directive 2014/40/EU it is clarified: “In any case, the presentation and advertising of those products should not lead to the promotion of tobacco consumption or give rise to confusion with tobacco products. Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so.” Currently, products with names and logos that remind of brand names and logos of cigarettes are sold (Fig. 3). In addition, the packaging of e-inhalation products is sometimes clearly derived from that of traditional cigarettes (Fig. 4).

In order to avoid an association of e-inhalation products with cigarettes, packaging which is similar to cigarette packaging should be banned – as well as logos and brand names which recall cigarette brands. Instead, packaging of electronic

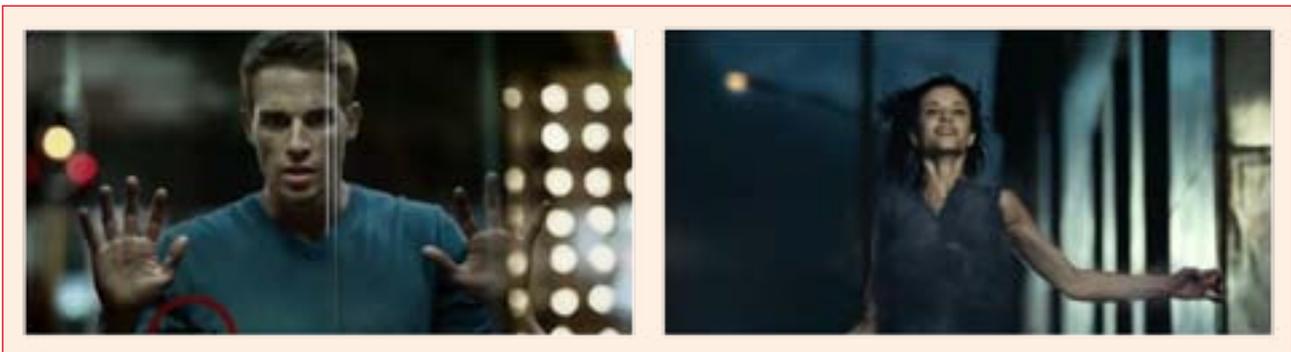


Figure 2: Screenshots from a TV advertisement for the e-cigarette “Vype“ by British American Tobacco. Source: Vype 2014⁴⁹



Figure 3: Names and logos of liquids which recall known cigarette brands. Left: Colins's New Star and Lucky Strike cigarettes, right: MB Liquid by Liquid.de (detail from a Screenshot²⁹) and Marlboro print advertisement from 2006. Photos: German Cancer Research Center, Unit Cancer Prevention, 2014



Figure 4: Packaging similar to cigarette packaging. Details from screenshots of internet pages of Vype (British American Tobacco), Mark Ten (Philip Morris) and blu (Lorillard). Sources: Vype 2014⁴⁸, MarkTen 2014³⁰, blu 2014⁵

inhalation products and liquids should be standardised in the following manner:

- Unicoloured packaging;
- text only without graphic elements;
- white reverse for the indication of ingredients and warnings in black Helvetica script, minimum font size 9 points
- same format and opening mechanism as medicine packaging.

An example of an already existing packaging similar to standardised packaging is given in Figure 5.

- For e-inhalation products and refill containers, standardised packaging should be mandatory.
- In Germany, a uniform packaging can be enacted through the Law on Tobacco Products.

4. Standardised form for e-inhalation products

Not only the packaging, the names and the logos of e-inhalation products and liquids clearly imitate cigarettes' names and logos; currently, numerous products are on the market which could be mistaken for cigarettes and may only differ in their size (Fig. 6). Some advertising even claims that the mouthpiece of the e-cigarette feels almost exactly like the filter of a traditional cigarette.



Figure 5: Example of a simple packaging of liquids. Photo: German Cancer Research Center, Unit Cancer Prevention, 2014

Other products are attractive to children and adolescents due to their youthful design (Fig. 7): They are printed similarly colourfully to pens, are decorated with rhinestones or are come with special additional functions which are attractive to adolescents. The Dutch company Supersmokerclub, for example, developed an e-cigarette which is not only for vaping, but which can also be used as an MP3 player or as a phone via Bluetooth – a gimmick that particularly appeals to young people. In order to avoid confusion with tobacco cigarettes and to prevent that products entice adolescents into tobacco consumption, a standardised form should be introduced for e-inhalation products. This form should clearly differ from cigarettes in shape and colour and should be as unattractive as possible to adolescents. Therefore, only grey or black should be permitted as colours for the products.

An exception from this regulation should be granted for products which are regulated by Directive 2001/83/EC (human medicines) or 93/42/EEC (medical devices). These products would then only be intended for smokers, sold by pharmacies and therefore would not be accessible to adolescents.

- A standardised shape should be mandatory for e-inhalation products which do not come under Directive 2001/83/EC or 93/42/EEC.
- In Germany, a standardised form for e-inhalation products can be determined using the Provisional Tobacco Law (Article 17 prohibition for protection against deceit).



Figure 6: Traditional tobacco cigarette (above) and e-cigarette in the design of a traditional cigarette (below). Photo: German Cancer Research Center, Unit Cancer Prevention, 2014



Figure 7: E-inhalation products with youthful design: sticker for design e-cigarettes (EGO CE-5) with large selection of images (detail of a screenshot), rhinestone-decorated rechargeable batteries for eGo e-cigarette (detail of a screenshot), e-cigarette with Bluetooth to listen to music and telephone. Sources: E-Liquid.org 2014¹⁸, Dampferinsel.de 2014¹³, Die Tabak Zeitung 2014¹⁶

5. Ban on child-friendly flavours

E-inhalation products are attractive to children and adolescents due to child-friendly flavours (gummy bears, bubble-gum, marshmallow or fantasy flavours such as Skark's Breath, Walking down the Mall, Surfer, 4-Play). E-inhalation products allow the imitation and practice of smoking in a supposedly harmless manner. With increasing habituation, new stimulation is sought; accordingly, a switch from nicotine-free products to nicotine-containing products, as well as from candy flavours to tobacco flavour and finally to cigarettes, could take place. Some of the designs of the liquid bottles also appear very youthful (Fig. 8).

In order to make e-inhalation products as unattractive as possible for children and adolescents, child-friendly flavours should be banned for all products which are not intended for tobacco cessation. The only flavour permitted should be tobacco, which holds relatively little attraction for children and adolescents.

Smokers, on the other hand, often initially start with tobacco flavour when they try e-cigarettes for the first time, and only later use other flavours²¹. For products indicated for smoking cessation (regulation according to Directive 2001/83/EC or Directive 93/42/EEC), a limited range of flavours should be available in addition to tobacco flavour, in order to make the

products as attractive as possible for smokers who wish to switch from traditional cigarettes to e-cigarettes.

- For lifestyle products no child-friendly flavours should be permitted, but only tobacco flavour.
- For smoking cessation products an expanded flavour selection should be permitted.
- Instead of child-friendly packaging design, standardised packaging should be mandatory.
- In Germany, regulation should be ensured via the Law on Tobacco Products and the Ordinance on the Production of Pharmaceutical and Active Pharmaceutical Ingredients.

Protection against emissions

During the use of e-inhalation products substances are released into indoor air, which are also inhaled by non-consumers who are present in the area, so a health impact on bystanders cannot be excluded²⁴. The aerosol produced by e-inhalation products may contain nicotine, flavours, tobacco-specific nitrosamines, volatile organic compounds,



Figure 8: Liquids with designs that are attractive to adolescents. Details from screenshots of the distributors. Sources: Shisha-world.com 2014^{39,40}, Totally wicked 2014⁴³, Puff King promotional flyer 2014, Photos: German Cancer Research Center, Unit Cancer Prevention, 2014

acetone, formaldehyde, acetaldehyde and benzo[a]pyrene as well as various metal particles, some of which are carcinogenic^{22,36,37,41,45,52}.

Particularly relevant to health are fine and ultrafine particles, which probably consist mainly of propylene glycol. These ultrafine droplets can be deposited in the lungs³⁶. The distribution of particle size in the aerosol of e-inhalation products is similar to that in the smoke of tobacco cigarettes. Most particles released during the use of e-cigarettes are ultrafine particles with a dimension of 10 to 100 nanometres³⁷. The release of the particles appears to depend on the nicotine concentration in the liquid – nicotine-free liquids release more particles than liquids containing nicotine³⁶. This effect on indoor air is a potential health risk to non-consumers – however, currently there is no data on this, as e-inhalation products have only been on the market for a few years.

In order to ensure a preventive health protection, the population should be protected against any pollution in indoor air. This can be achieved through the application of smoke-free policies to electronic inhalation products. E-inhalation products should not be used in enclosed public places including, but not restricted to public buildings, educational institutions, health care facilities, cultural and leisure facilities, sports clubs, pubs, public transport as well as all other facilities in which children and adolescents are present. Moreover, the inclusion of e-inhalation products in Non-Smoking Acts simplifies the enforcement of the laws, as it is often not evident at first glance whether someone is smoking a cigarette or vaping an e-cigarette.

Strict Non-Smoking Acts without exceptions have a greater effect on smoking behaviour – particularly in young people – than policies with exceptions³. This is because smokers crave for a cigarette when they see others smoking – they even feel an urge to smoke when they see people using electronic cigarettes²⁶. Therefore, the use of e-cigarettes may cause smokers to smoke more and provoke a relapse in ex-smokers. Thus the use of e-inhalation products in non-smoking areas undermines an important side-effect of the Non-Smoking Acts: the motivation to smoke less or to stop completely.

- **E-Inhalation products should be banned in non-smoking areas.**
- **In Germany, regulation could be ensured via the Non-Smoking Acts and the Health and Safety at Work Act (Article 5)**

Environmental protection

E-inhalation products might cause a substantial environmental problem.

Traditional cigarettes undisputedly have an environmental impact: cigarette butts are the most common rubbish worldwide¹⁵. In addition, the butts are often carelessly thrown onto the ground, so that toxins from the tobacco can leak into soil and water.

If increasing numbers of smokers switch to e-inhalation products, fewer butts may be found in the environment but, instead, mountains of plastic and hazardous waste will be

created by the devices made of plastic, metal and (rechargeable) batteries as well as the countless refill bottles.

For the preservation of resources, a recycling or deposit system must be developed, so that the materials can be reused.

- **A recycling or deposit system should be created for e-inhalation products and potentially a hazardous waste fee on basic devices.**
- **In Germany, regulation could be ensured via the Law on Tobacco Products.**

Taxation of the products

For smokers, e-inhalation products may be a motivation for smoking cessation; for adolescents, on the other hand, they might be a gateway to smoking. In order to promote their use as an alternative to conventional cigarettes and to simultaneously discourage adolescents from use, e-inhalation products should be expensive when sold as lifestyle products, but cheap when sold as tobacco cessation aid, because differentiated prices of different product types can influence consumer behaviour. If, for example, the consumption of recyclable products is to be encouraged, a ten percent price increase for disposable e-cigarettes can increase the consumption of re-chargeable e-cigarettes by around five percent²⁵. In a similar manner, the demand for lifestyle e-cigarettes could be transferred to e-cigarettes for smoking cessation. As a tax measurably can influence the price, e-inhalation products should be taxed in the same way as tobacco products, unless they are regulated under Directive 2001/83/EC or Directive 93/42/EEC. The tax on products sold as cessation aids should be substantially lower.

- **E-inhalation products which are sold as lifestyle products should be taxed in the same way as tobacco products.**
- **The tax on e-inhalation products used as smoking cessation aid should be lower.**
- **In Germany, the regulation should be enacted through the Law on Tobacco Taxation.**

Conclusion

Directive 2014/40/EU improves the product quality and safety of nicotine-containing e-inhalation products for consumers. Therefore, the regulation included should be transposed into national law without delay. For smokers, electronic inhalation products can be a motivation to stop smoking; for adolescents, on the other hand, they are inappropriate as they might be a gateway to smoking, due to the child-friendly flavours and the method of use (imitation of smoking). In order to improve the protection of consumers, non-smokers, youth and the environment, the following additional regulations are required:

- Same regulation for all e-inhalation products independent of their nicotine content (with and without nicotine)
- Prohibition of sale to minors

- Extension of the advertising ban set out by Directive 2014/40/EU to cover outdoor advertising and advertising at the point of sale
- Standardised packaging for e-inhalation products and refill containers
- New shape for e-inhalation products, which is clearly differentiated from tobacco products for e-inhalation products that were not authorised pursuant to Directive 2001/83/EC or 93/42/EEC
- For lifestyle products, only tobacco flavours
- For smoking cessation products (pharmacy sale), restricted flavour selection
- No use of e-inhalation products in non-smoking areas
- Recycling or deposit system for e-inhalation products
- Differentiated taxation according to use:
 1. Taxation according to tobacco tax on e-inhalation products sold as lifestyle products;
 2. Taxation as a medicine (with the appropriate VAT rate) on products for smoking cessation.

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