

Germany: Electronic Cigarettes

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Germany: Electronic Cigarettes

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SUMMARY Electronic cigarettes in Germany are currently not subject to any age-related access restrictions. The Federal Administrative Court concluded recently that nicotine-containing liquids in electronic cigarettes are not medicinal products and therefore can be sold without approval in accordance with the Medicinal Products Act. It is still unclear whether such liquids are covered by tobacco regulations and antismoking laws.

I. Introduction

Electronic cigarettes (e-cigarettes) are defined by the German Federal Institute for Risk Assessment as battery-operated products that typically resemble conventional cigarettes. Instead of tobacco, they contain cartridges filled with liquids that are generally composed of nicotine, flavor, and other chemicals. During consumption, the liquids are heated and thereby vaporize.¹ The US Food and Drug Administration (FDA) employs a similar definition.²

Because of their relative novelty and the lack of legal provisions specifically addressing them, the status of e-cigarettes in Germany remains ambiguous, which in turn causes legal uncertainty for consumers and businesses. E-cigarettes are either not regulated at all and therefore freely available to everyone or are treated as medicinal or tobacco products by various German states, cities, and municipalities, which place restrictions on their sale and use.

Even though the Federal Administrative Court (Bundesverwaltungsgericht) has decided that e-cigarettes cannot be classified as medicinal products,³ it has so far not had to rule on the applicability of tobacco and antismoking laws. Classifying e-cigarettes as a medicinal product would mean that they could not be sold without approval in accordance with the Medicinal Products Act (Arzneimittelgesetz).⁴ If e-cigarettes were treated as tobacco products or products closely resembling tobacco products, they would be subject to antismoking laws, and their consumption would be banned in public indoor spaces and restaurants.

¹ BUNDESINSTITUT FÜR RISIKOBEWERTUNG [BfR] [GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT], FREQUENTLY ASKED QUESTIONS ABOUT E-CIGARETTES (Mar. 1, 2012), <http://www.bfr.bund.de/cm/349/frequently-asked-questions-about-e-cigarettes.pdf>.

² *Electronic Cigarettes (e-Cigarettes)*, U.S. FOOD AND DRUG ADMINISTRATION (FDA), <http://www.fda.gov/News/Events/PublicHealthFocus/ucm172906.htm> (last updated June 4, 2015).

³ Bundesverwaltungsgericht [BVerwG] [Federal Administrative Court], Nov. 20, 2014, Docket No. 3 C 25.13, <http://www.bverwg.de/201114U3C25.13.0>; BVerwG, Nov. 20, 2014, Docket No. 3 C 26.13, <http://www.bverwg.de/201114U3C26.13.0>; BVerwG, Nov. 20, 2014, Docket No. 3 C 27.13, <http://www.bverwg.de/201114U3C27.13.0>.

⁴ Arzneimittelgesetz [AMG] [Medicinal Products Act], Dec. 12, 2005, BUNDESGESETZBLATT [BGBL.] I at 3394, as amended, § 21, unofficial English translation available at http://www.gesetze-im-internet.de/englisch_amg/medicinal_products_act.pdf.

II. Legal Age for Use of E-Cigarettes

Currently, no age-related restrictions apply to the use of e-cigarettes in Germany. Section 10 of the Youth Protection Act (Jugendschutzgesetz) prohibits only the sale of all tobacco products to children and adolescents in public places and prohibits children and adolescents from smoking.⁵

An adolescent is defined in section 1 of the Act as a person between the ages of fourteen and eighteen.⁶ “Tobacco products” are in turn defined in section 3 of the Provisional Tobacco Act (Vorläufiges Tabakgesetz) as products made of or derived from raw tobacco intended for smoking, chewing, other oral use, or sniffing.⁷ The Act equates the following products with tobacco products: raw tobacco and products closely resembling tobacco products intended for smoking, chewing, other oral use, or sniffing; cigarette papers, cigar binders, and other components that are firmly attached to the tobacco products; and other noncommercially available cigarette papers used for rolling cigarettes.⁸

In the opinion of the German Federal Ministry for Food and Agriculture and the German Federal Ministry for Family Affairs, Senior Citizens, Women, and Youth, e-cigarettes are outside the scope of section 10 of the Youth Protection Act. These Ministries issued a joint press release on April 23, 2015, which stated their intention to introduce a bill to update section 10 of the Youth Protection Act in order to prohibit the sale of e-cigarettes to children and adolescents.⁹ According to the press release, the liquids from e-cigarettes may be detrimental to a person’s health—regardless of whether they contain nicotine—because of, *inter alia*, the additional ingredients of the liquids, such as carbonyl compounds (formaldehyde, acrolein, and acetaldehyde), which may cause cancer and affect proper lung function.

Despite reports to the contrary,¹⁰ the Tobacco Products Directive of the European Union (EU) does not ban e-cigarettes or impose an age limit, smoke-free environments, or rules on flavors.¹¹

⁵ Jugendschutzgesetz [JuSchG] [Youth Protection Act], July 23, 2002, BGBl. I at 2730, as amended, § 10, <http://www.gesetze-im-internet.de/bundesrecht/juschg/gesamt.pdf>.

⁶ *Id.* § 1, para. 1, no. 2.

⁷ Vorläufiges Tabakgesetz [Provisional Tobacco Act], Sept. 9, 1997, BGBl. I at 2296, as amended, § 3, para. 1, http://www.gesetze-im-internet.de/bundesrecht/lmg_1974/gesamt.pdf.

⁸ *Id.* § 3, para. 2.

⁹ Pressemitteilung Nr. 113 vom 23.04.15 [Press Release No. 113 of Apr. 4, 2015], Bundesministerium für Ernährung und Landwirtschaft [Federal Ministry for Food and Agriculture], E-Zigaretten und E-Shishas – Novellierung des Jugendschutzgesetzes [E-Cigarettes and E-Shishas – Update of the Youth Protection Act], <http://www.bmel.de/SharedDocs/Pressemitteilungen/2015/113-SC-EZigaretten.html>.

¹⁰ EUROPEAN COMMISSION, E-CIGARETTES MYTH BUSTER (Feb. 26, 2014), http://ec.europa.eu/health/tobacco/docs/tobacco_mythbuster_en.pdf.

¹¹ Council Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products and Repealing Directive 2001/37/EC, preamble, recitals 47, 48, 2014 OFFICIAL JOURNAL OF THE EUROPEAN UNION (O.J.) (L 127) 1, http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf.

The Directive only aims to harmonize, *inter alia*, some aspects relating to the placing on the market and labelling of e-cigarettes.

III. Legal Classification of E-Cigarettes

A. Medicinal Products

The Federal Administrative Court, overturning three decisions of the Higher Administrative Court of North Rhine-Westphalia,¹² ruled on November 20, 2014, that e-cigarettes filled with nicotine-containing liquids do not fall under the definition of medicinal products in the Medicinal Products Act.¹³

The three court cases all dealt with store owners who had appealed administrative decisions that prohibited them from selling liquids containing more than ten or fifteen milligrams of nicotine. The cities argued that the nicotine-containing liquids should be classified as medicinal products and could therefore not be sold without approval in accordance with the Medicinal Products Act.¹⁴

The definition of medicinal products in section 2 covers both “medicinal products by presentation” and “medicinal products by function.” The Federal Administrative Court first defined “medicinal products by presentation” and subsequently concluded that the nicotine-containing liquids in e-cigarettes are not covered by that definition. “Medicinal products by presentation” are substances or preparations made from substances that are intended for use on or in the human or animal body and are intended for curing, alleviating, or preventing human or animal diseases or disease symptoms.¹⁵ According to the Court, a product fulfills these requirements if it is explicitly presented as possessing such characteristics or if the presentation of the product gives the average consumer, either explicitly or implicitly, the unambiguous impression that the product possesses these traits.¹⁶ As the nicotine-containing liquids were not presented or advertised as substances to cure nicotine and tobacco addictions, they cannot be classified as medicinal products in accordance with section 2 of the Medicinal Products Act.¹⁷

The Federal Administrative Court then elaborated on the definition of “medicinal products by function” and determined that the nicotine-containing liquids in e-cigarettes could also not

¹² Oberverwaltungsgericht Nordrhein-Westfalen [OVG NRW] [Higher Administrative Court NRW], Sept. 17, 2013, Docket No. 13 A 2448/12, http://www.justiz.nrw.de/nrwe/ovgs/ovg_nrw/j2013/13_A_2448_12_Urteil_20130917.html; OVG NRW, Sept. 17, 2013, Docket No. 13 A 2541/12, http://www.justiz.nrw.de/nrwe/ovgs/ovg_nrw/j2013/13_A_2541_12_Urteil_20130917.html; OVG NRW, Sept. 17, 2013, Docket No. 13 A 2448/12, http://www.justiz.nrw.de/nrwe/ovgs/ovg_nrw/j2013/13_A_2448_12_Urteil_20130917.html.

¹³ BVerwG, Nov. 20, 2014, Docket Nos. 3 C 25.13, 3 C 26.13, 3 C 27.13. Docket No. 3 C 25.13, available at <http://www.bverwg.de/201114U3C27.13.0>, will be published in the official compilation of decisions of the Federal Administrative Court and is used as an example in this report. AMG § 2, para. 1.

¹⁴ BVerwG, Docket No. 3 C 25.13, para. 4.

¹⁵ AMG § 2, para. 1, no. 1.

¹⁶ BVerwG, Docket No. 3 C 25.13, para. 14.

¹⁷ *Id.* at para. 15.

qualify as medicinal products. Section 2 of the Medicinal Products Act defines “medicinal products by function” as

substances or preparations made from substances which . . . can be used in or on the human or animal body or can be administered to a human being or an animal . . . to restore, correct or influence the physiological functions through a pharmacological, immunological or metabolic effect.¹⁸

The decision of whether a product falls under this definition must be made on a case-by-case basis, taking into account all the characteristics of the product, in particular its composition; its pharmacological properties, to the extent to which they can be established in the present state of scientific knowledge; the manner in which it is used; the extent of its distribution; its familiarity to consumers; and the risks that its use may entail.¹⁹ It is not sufficient that the product have properties beneficial to health in general—it must objectively have the function of treating or preventing disease, the Court said.²⁰

The Court applied the definition to the nicotine-containing liquids in e-cigarettes and concluded that even though nicotine is a substance with pharmacological effects, an overall assessment shows that the liquids are food products by function and not medicinal products.²¹ The Court noted that nicotine-containing e-cigarettes closely resemble tobacco cigarettes in their appearance, presentation, and use. The variety of flavors the liquids come in are intended to taste good, and the flavors differentiate the liquids from approved medicinal products used as smoking cessation aids that contain only menthol and nicotine. In addition, the liquids do not contain the dosage instructions typical of medicinal products. Moreover, even if the liquids provide temporary relief from withdrawal symptoms, they cannot objectively be used for therapeutic purposes because nicotine can damage health.²²

The possibility that they pose a risk to health may eventually necessitate labelling them, as foreseen in the EU Tobacco Products Directive,²³ but this would not justify their classification as medicinal products, according to the Court.²⁴

As e-cigarettes do not fall under the definition of medicinal products, they can be sold without approval in accordance with the Medicinal Products Act, the Court concluded.

¹⁸ AMG § 2, para. 1, no. 2, letter a.

¹⁹ BVerwG, Docket No. 3 C 25.13, para. 18 (citing settled case law of the European Court of Justice, because the definition of medicinal products in the German Medicinal Products Act is an implementation of the definition in EU Directive 2001/83/EC).

²⁰ *Id.* at 19.

²¹ *Id.* at 21.

²² *Id.* at 22.

²³ Council Directive 2014/40/EU, *supra* note 11.

²⁴ BVerwG, Docket No. 3 C 25.13, para. 23.

B. Tobacco Products

The Federal Administrative Court so far has not had to rule on whether e-cigarettes should be regulated as tobacco products or covered under antismoking laws. Lower state courts are divided in their legal classification of e-cigarettes,²⁵ which leads to legal uncertainty.

The Higher Administrative Court of North Rhine-Westphalia, the highest administrative court in that state, decided that smoking e-cigarettes inside a restaurant did not violate the Anti-Smoking Act of North Rhine Westphalia.²⁶ This decision might influence other courts, because North-Rhine Westphalia is Germany's most populous state. The Higher Administrative Court of NRW did not allow an appeal to the Federal Administrative Court.

The Higher Administrative Court of NRW answered in the negative the essential question of whether the consumption of electronic cigarettes can be qualified as “smoking” and therefore subject to antismoking laws. According to the Court, “smoking” is generally defined as inhaling smoke produced by burning tobacco products (pyrolysis).²⁷ The consumption of e-cigarettes does not involve pyrolysis; rather the liquids are heated and thereby vaporize.²⁸

Furthermore, the intention of the North-Rhine Westphalian Anti-Smoking Act is the protection of nonsmokers in public places from the dangers of secondhand tobacco smoke.²⁹ E-cigarettes generally do not contain tobacco. Instead, they contain propylene glycol, various flavorings or aromas, and usually nicotine.³⁰

E-cigarettes without any nicotine do not qualify as tobacco products.³¹ In the Court's view, even nicotine-based liquids cannot be classified as tobacco products in a legal sense. It opined that such liquids do not fall under the definition of tobacco products under section 3 of the Provisional Tobacco Act³² or under the definition in the EU directive on which the German Act is based because they are not “intended for smoking, chewing, other oral use, or sniffing.”³³ The Court added that EU law differentiates between nicotine and tobacco products, even when the

²⁵ For a decision in favor of applying tobacco and antismoking laws to e-cigarettes, see, e.g., the suit in the Administrative Court of Gießen, in which the Court decided that a teacher had violated the Education Act and the Anti-Smoking Act of Hesse by consuming an e-cigarette on school property. *Verwaltungsgericht Gießen [VG Gießen]* [Administrative Court of Gießen], Feb. 20, 2013, Docket No. Az. 5 K 455/12.GI. For a decision rejecting the applicability of tobacco and antismoking laws because the liquids in e-cigarettes are not “smoked,” see, e.g., *Verwaltungsgericht Köln [VG Köln]* [Administrative Court of Cologne], Docket No. Az. 7 K 4612/13.

²⁶ OVG NRW, Nov. 4, 2014, Docket No. Az. 4 A 775/14, http://www.justiz.nrw.de/nrwe/ovgs/ovg_nrw/j2014/4_A_775_14_Urteil_20141104.html.

²⁷ *Id.* at 25.

²⁸ *Id.* at 28.

²⁹ *Id.* at 36.

³⁰ *Id.* at 40.

³¹ *Id.* at 42.

³² Vorläufiges Tabakgesetz, BGBL. I at 2296.

³³ OVG NRW, Docket No. Az. 4 A 775/14, paras. 44–50.

nicotine is derived from raw tobacco, which means that nicotine itself cannot be a tobacco product.³⁴

The Court also rejected a teleological interpretation of the Anti-Smoking Act.³⁵ The intention of the legislature to qualify the consumption of e-cigarettes as “smoking” is not reflected in the wording of the Act. The legislature is obligated to define the scope of an act as clearly as possible, so that restrictions on the exercise of a right are foreseeable.³⁶ According to the Court, a clarification of the term “smoking” or an amendment to the Act was needed in order to include e-cigarettes.³⁷

Furthermore, the intention of the Act to protect nonsmokers from the dangers of secondhand tobacco smoke does not automatically result in an inclusion of e-cigarettes.³⁸ E-cigarettes produce vapor and not tobacco smoke. Currently, there is not enough scientific research on the health risks of third parties that are exposed to vapor from e-cigarettes. An extension of the scope of the Anti-Smoking Act is therefore not warranted, in the view of the Court.³⁹

The arguments of the Court in North-Rhine Westphalia could be applied to similar state antismoking acts and the Federal Anti-Smoking Act, and other state courts and the Federal Administrative Court may rule similarly. The primary objective of antismoking acts is the protection of nonsmokers from secondhand tobacco smoke. A necessary condition for the applicability of antismoking acts is the act of “smoking.” Arguably, neither of the requirements is fulfilled with e-cigarettes.⁴⁰

IV. Future Developments

The EU Tobacco Products Directive must be implemented by the Member States by May 20, 2016.⁴¹ It aims to harmonize rules for the placing on the market and labelling of tobacco and related products.⁴² The Directive only applies to e-cigarettes with nicotine-containing liquids; e-cigarettes without nicotine are not subject to the Directive. It defines e-cigarettes as products that can be used for consumption of nicotine-containing vapor via a mouthpiece or any component of these products, including a cartridge, a tank, and devices without cartridges or tanks.⁴³ Among other things, Member States must ensure that nicotine-containing liquids do not

³⁴ *Id.* at 51.

³⁵ A teleological interpretation construes an act in light of its purpose and intention.

³⁶ OVG NRW, Docket No. Az. 4 A 775/14, paras. 63 & 67.

³⁷ *Id.* at 69.

³⁸ *Id.* at 78.

³⁹ *Id.* at 79.

⁴⁰ Rolf-Georg Müller, *Elektronische Zigaretten – Arzneimittel und Gegenstand des Nichtraucherschutzrechts?* [*Electronic Cigarettes – Medicinal Products and Subject to Antismoking Laws?*], 2012 PHARMA RECHT 137, 141.

⁴¹ Council Directive 2014/40/EU, *supra* note 11, art. 29, para. 1.

⁴² *Id.* art. 1(f).

⁴³ *Id.* art. 2, para. 16.

contain nicotine in excess of 20 mg/ml and do not contain other ingredients in heated or unheated form that may pose a risk to human health.⁴⁴

German Minister for Food and Agriculture Christian Schmidt and German Minister for Family Affairs, Senior Citizens, Women, and Youth Manuela Schwesig stated at their joint press conference that “e-cigarettes, with or without nicotine, are not harmless. By regulating the sale, we will protect children and adolescents from the dangers of smoking.”⁴⁵ In an article summarizing the current status of e-cigarettes and e-shishas (electronic glass-bottomed water pipes) in Germany, the Minister for Food and Agriculture underscored the need to enact regulations for e-cigarettes of all kinds and to impose age-related access restrictions.⁴⁶ He declared that it was regrettable that the EU Tobacco Products Directive did not impose stricter regulations for e-cigarettes and that Germany would take advantage of the option to enact stricter regulations when implementing it.⁴⁷

⁴⁴ *Id.* art. 20, para. 3(b) & (e).

⁴⁵ Press Release No. 113 of Apr. 4, 2015, *supra* note 9.

⁴⁶ *Elektrische Zigaretten bzw. E-Shishas [E-Cigarettes or E-Shishas]*, BUNDESMINISTERIUM FÜR ERNÄHRUNG UND LANDWIRTSCHAFT [FEDERAL MINISTRY FOR FOOD AND AGRICULTURE] (June 8, 2015), <https://www.bmel.de/DE/Ernaehrung/Gesundheit/NichtRauchen/Texte/E-Zigarette.html>.

⁴⁷ Council Directive 2014/40/EU, *supra* note 11, preamble, recital 54.