

Draft bill

of the Federal Ministry of Food and Agriculture

Draft Act amending the Tobacco Products Act

A. Problem and objective

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 obligates Member States, in Article 29, to adopt legislation by 20 May 2016 that is necessary in order to transpose Directive 2014/40/EU. Directive 2014/40/EU is transposed by the Tobacco Products Act of [...] (Federal Law Gazette I p. [...]) and the Tobacco Products Ordinance enacted on the basis of this Act.

In addition to the stipulations under the directive, nicotine-free electronic cigarettes and refill containers are also to be regulated by equating them with products which contain nicotine if this is necessary in order to protect consumers from adverse health effects. Furthermore, provision is to be made for additional bans on advertising in relation to tobacco products, electronic cigarettes and refill containers.

B. Solution

By means of the Amending Act, nicotine-free electronic cigarettes and refill containers are classed with those which do contain nicotine if this is necessary in order to protect consumers from adverse health effects. Additional advertising bans for tobacco products, electronic cigarettes and refill containers are incorporated. Moreover, the provision regarding plant protection products in or on tobacco products is revised.

Since the regulatory content referred to represents supplementary provisions regarding the stipulations under Directive 2014/40/EU and go beyond the scope of the stipulations in the directive, this content has to be notified in accordance with the Information Directive 98/34/EC. So as not to jeopardise the schedule for transposing the directive, these parts are carried forward as a separate draft Act amending the Tobacco Products Act.

C. Alternatives

None.

D. Budget expenditure without compliance costs

None.

E. Compliance costs

E.1. Compliance costs for citizens

No compliance costs shall be incurred by citizens.

E.2 Compliance costs for businesses

By including nicotine-free electronic cigarettes and refill containers in the regulatory scope, a one-off expense of just over EUR 1 million and ongoing annual compliance costs of EUR 300 000 shall accrue.

Of which bureaucratic costs arising from obligations to provide information

By including nicotine-free electronic cigarettes and refill containers, one-off compliance costs in the region of approximately EUR 500 000, and ongoing annual compliance costs amounting to approximately EUR 8 000, both arising from obligations to provide information, shall accrue.

Businesses cannot be compensated for the compliance costs they incur on an ongoing basis within this draft legislation. It shall therefore have to be examined whether an appropriate prospect of relief can be demonstrated outside this draft.

E.3 Administrative compliance costs

No administrative compliance costs shall arise.

F. Additional costs

A ban on outdoor advertising is envisaged as of 1 July 2020. According to information from the tobacco industry, published in the Federal [German] Government's 2015 report on drugs and addiction, in 2013, EUR 69.8 million was spent on outdoor advertising.

Advertising in cinemas is restricted insofar as the showing of promotional films and programmes for tobacco products, electronic cigarettes and refill containers is only allowed if a film as per the procedure defined in § 14 of the Youth Protection Act is characterised as "Not suitable for persons under the age of 18". According to the Federal [German] Government's 2015 report on drugs and addiction, in 2013, EUR 7.7 million was spent on advertising in cinemas.

In future, this expenditure will be curtailed and lasting reductions achieved.

Draft bill of the Federal Ministry of Food and Agriculture

Draft Act amending the Tobacco Products Act¹⁾

dated ...

The *Bundestag* has adopted the following Act with the approval of the *Bundesrat*:

Article 1

Amending the Tobacco Products Act

The Tobacco Products Act of [...] (Federal Law Gazette I p.) is amended as follows:

1. In the Table of contents, the following entries are inserted after the statement relating to § 20:

"§ 20a Ban on outdoor advertising

§ 20b Ban on selling and displaying free of charge".

2. In § 1(1), after the statement "(OJ L 127 of 29 April 2014, p. 1).", the sentence "Article 2 points 16 and 17 shall apply with the proviso that the terms indicated therein also include nicotine-free electronic cigarettes and refill containers." is inserted.
3. § 2 is amended as follows:

- a) The following new point 9 is inserted after point 8:

"9. Outdoor advertising: any advertising away from business premises of specialist retailers involving a fixed installation which appeals to consumers directly or in another way, in particular by means of placards or posters, lettering, ornamental painting, sky advertising or signage,".

- b) The previous points 9 and 10 become the new points 10 and 11.

4. § 9 is amended as follows:

- a) The wording is preceded by the following paragraph 1:

"(1) Tobacco products which contain plant protection products within the meaning of Article 2(1) of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 of 24 November 2009, p. 1) or their breakdown or reaction products, or to which plant protection products or their breakdown or reaction products adhere, may only be placed on the market if the plant protection products

¹⁾ Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241 of 17 September 2015, p. 1).

1. are authorised in Germany for the respective area of application or may still be utilised in accordance with § 12(5) of the Plant Protection Act, or

2. are authorised for the respective area of application in a Member State of the European Union or in another Signatory State to the Agreement on the European Economic Area in accordance with the provisions of Article 4(1b) to (1e) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230 of 19 August 1991, p. 1) or in accordance with the provisions of Regulation (EC) No. 1107/2009.

A plant protection product which is authorised for the respective area of application in a third country and which is used there is the equivalent of a plant protection product within the meaning of sentence 1."

b) The previous wording becomes paragraph 2.

5. § 14 is amended as follows:

a) In paragraph 1, after the words "Electronic cigarettes and refill containers" the words "which contain nicotine," are inserted.

b) In paragraph 2, after the words "Electronic cigarettes" the words "which contain nicotine," are inserted.

6. The wording under § 15(1) point 2a is preceded by the words "of electronic cigarettes and refill containers which contain nicotine,".

7. The following §§ 20a and 20b are inserted after § 20:

"§ 20a

Ban on outdoor advertising

It is prohibited to engage in outdoor advertising for tobacco products, electronic cigarettes or refill containers. Sentence 1 shall not apply to advertising on the external surfaces of buildings on business premises of specialist retailers.

§ 20b

Ban on selling and displaying free of charge

(1) It is prohibited to supply cigarettes, roll-your-own tobacco or water pipe tobacco on a commercial basis free of charge.

(2) It is prohibited to supply smokeless tobacco products and electronic cigarettes or refill containers, other than those smoking tobacco products mentioned in paragraph 1, away from business premises of specialist retailers on a commercial basis, free of charge.

(3) It is prohibited to display tobacco products, electronic cigarettes or refill containers on a commercial basis."

8. § 21(1) is worded as follows:

"(1) It is prohibited to use promotional information when dealing with tobacco products, electronic cigarettes and refill containers or in advertisements for tobacco products, electronic cigarettes and refill containers

1. which gives the impression that enjoyment or use of the product as intended is harmless to health or shall have a positive effect on how the body functions, performance or well-being,

2. which, according to its type, is especially suitable for inducing young people or adolescents to consume such products or for strengthening this conviction to consume,

3. which presents the inhalation of tobacco smoke or vapour as recommendable, and

4. which gives the impression that the ingredients are natural or unadulterated."

9. § 22 is amended as follows:

a) The following paragraph 3 is inserted after paragraph 2:

"(3) By way of deviation from paragraph 2 points 1 and 2, any party which wishes to engage exclusively in cross-border distance selling to European Union consumers of nicotine-free electronic cigarettes and refill containers only has to be registered domestically with the competent authority."

b) The previous paragraphs 3 to 6 become paragraphs 4 to 7.

10. § 34(1) is amended as follows:

a) Point 4c is worded as follows:

"c) § 9(1) sentence 1 or § 11".

b) In point 5, the statement "paragraph 2" is inserted after the statement "in accordance with § 9".

11. § 35 is amended as follows:

a) Paragraph 2 is amended as follows:

aa) The following points 10 and 11 are inserted after point 9:

"10. engages in outdoor advertising contrary to § 20a,

11. supplies or displays a tobacco product, an electronic cigarette or a refill container on a commercial basis, contrary to § 20b."

bb) The previous points 10 to 13 become points 12 to 15.

b) In paragraph 3 point 2b, the statement "or 10" is replaced by the statement "or 12".

c) In paragraph 4, the statement "or 10" is replaced by the statement "or 12".

12. In § 43(2), the statement "paragraph 2" is inserted after the statement "§ 9".

13. The following paragraphs 6 and 7 are added to § 47:

"(6) § 20a shall apply as of 1 July 2020.

(7) § 20b(2) shall apply as of 20 May 2020. Sentence 1 shall not apply to electronic cigarettes and refill containers."

Article 2

Amending the Youth Protection Act

The Youth Protection Act of 23 July 2002 (Federal Law Gazette I p. 2730), last amended by Article 2(55) and Article 4(36) of the Act of 7 August 2013 (Federal Law Gazette I p. 3154), is amended as follows:

14. § 11 is amended as follows:

a) In paragraph 5, the words "tobacco goods or" are deleted.

b) The following paragraph 6 is added:

"(6) Promotional films and advertising programmes which promote tobacco products, electronic cigarettes or refill containers within the meaning of § 1(1) of the Tobacco Products Act of [...], as amended by the Act of [...], may only be shown in connection with films which have been characterised as "Not suitable for persons under the age of 18" in the context of the procedure as per § 14(6) by the supreme Federal State authority or a voluntary self-regulation body."

15. § 28(1) point 14a is worded as follows:

"14a. shows a promotional film or advertising programme, contrary to § 11(5) or (6)."

Article 3

Amending the Tobacco Duty Act

The Tobacco Duty Act of 15 July 2009 (Federal Law Gazette I p. 1870), last amended by Article 12 of the Act of 3 December 2015 (Federal Law Gazette I p. 2178), is amended as follows:

16. § 25 sentence 2 is worded as follows:

"He may, however, open the packages in order to examine or show the contents."

17. § 26(1) sentence 1 is worded as follows:

"The package price indicated on the tax stamp, or the retail price following from this, may not be undercut by the retailer when supplying consumers with tobacco goods."

18. § 29 is deleted.

19. § 36(2) is amended as follows:

- a) In point 3, the word "contravenes" is replaced by the words "contravenes or".
- b) In point 4, the words "combines or" are replaced by the word "combines".
- c) Point 5 is deleted.

Article 4

Entry into force

This Act shall enter into force on the day following promulgation.

Explanatory statement

A. General Part

I. Objective and necessity of the provisions

Directive 2014/40/EU is transposed by the Tobacco Products Act of [...] (Federal Law Gazette I p. [...]) and the Tobacco Products Ordinance enacted on the basis of this Act.

Over and above the stipulations of the directive, nicotine-free electronic cigarettes and refill containers are also to be regulated if this is necessary in order to protect consumers from adverse health effects. Furthermore, provision is made for additional bans on advertising, and advertising restrictions, in relation to tobacco products, electronic cigarettes and refill containers. The provision regarding plant protection products in or on tobacco products is revised.

Since the regulatory content referred to goes beyond the scope of the stipulations in Directive 2014/40/EU, this content has to be notified in accordance with the Information Directive 98/34/EC. So as not to jeopardise the schedule for transposing the directive, these parts are separated and carried forward as a separate draft Act amending the Tobacco Products Act.

II. Main content of the draft

Regulation of nicotine-free electronic cigarettes and refill containers

In addition to tobacco products and herbal products for smoking, Directive 2014/40/EU also regulates nicotine-containing electronic cigarettes and refill containers.

Over and above the stipulations of Directive 2014/40/EU, by means of this Act, nicotine-free electronic cigarettes and refill containers are classed with those containing nicotine if this is necessary in order to protect consumers from adverse health effects.

The attendant health risks posed by these products follow from inhaling an aerosol which, regardless of the nicotine, contains substances that are harmful to health. The Federal Institute for Risk Assessment ([German designation:] BfR), in its scientific evaluation of 25 February 2015, and the German Cancer Research Centre ([German designation:] dkfz), in its opinion from 2015, have arrived at these findings. Both the aforementioned institute and centre state that carbonyl compounds, including formaldehyde, acrolein and acetaldehyde, originate when consuming both electronic cigarettes containing nicotine and those which are nicotine-free. Carbonyl compounds and acetaldehyde are suspected of causing cancer. As of 1 April 2015, formaldehyde is classified as carcinogen category 1B in Annex VI to Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006 (OJ L 353 of 31 December 2008, p. 1) (Commission Regulation (EU) No. 605/2014 of 5 June 2014 amending, for the purposes of introducing hazard and precautionary statements in the Croatian language and its adaptation to technical and scientific progress, Regulation (EC) No. 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, OJ L 167 of 6 June 2014, p. 36), which means that the carcinogenic effect shall be regarded as probable in the case of people. Acrolein can also cause irritation and inflammation of the exposed mucous membranes

and lead to necrosis of the lung tissue when inhaled. Under certain conditions, exposure to formaldehyde and other carbonyl compounds may be similar to that experienced with traditional tobacco cigarettes. There is no threshold value below which a blending of these substances would be quite safe.

Advertising

Ban on outdoor advertising, restrictions on advertising in cinemas and a ban on supplying tobacco products free of charge

In addition to the existing bans on advertising on the radio, in the press and other printed media, in information society services and in other audiovisual commercial communication, including television, the draft Act makes provision for a ban on outdoor advertising in relation to tobacco products. This ban is to enter into force on 1 July 2020 following the expiry of a transitional period. In addition, the existing restriction on advertising tobacco products in cinemas until after 18:00 in accordance with § 11(5) of the Youth Protection Act is replaced by a restriction on advertising tobacco products in cinemas which is tied in with the classification of the feature film. In future, the showing of promotional films and programmes for tobacco products, electronic cigarettes and refill containers is only permitted in connection with films which are characterised as "Not suitable for persons under the age of 18" as per the procedure defined in § 14 of the Youth Protection Act. In addition to the ban on the free distribution of tobacco products which already exists in connection with the ban on the sponsorship of cross-border events, provision is made for a ban on supplying cigarettes, roll-your-own tobacco and water pipe tobacco to consumers free of charge. Smoking tobacco products other than cigarettes, roll-your-own tobacco and water pipe tobacco, smokeless tobacco products and electronic cigarettes, as well as refill containers, may only continue to be supplied free of charge within the business premises of the specialist retailer. In the case of smoking tobacco products other than cigarettes, roll-your-own tobacco and water pipe tobacco, as well as in the case of smokeless tobacco products, the ban on provision free of charge away from business premises of the relevant specialist retailer shall only apply after the expiry of a four-year transitional period, i.e. from 20 May 2020.

The Federal [German] Government estimates that bans on outdoor advertising and the continuing restriction on advertising in cinemas, as well as a ban on provision free of charge, combined with the advertising bans which are already in force, are an effective way of bringing about a further reduction in the smoking rate. Outdoor advertising for tobacco products is generally prevalent. Cinema advertising takes place in the positively perceived context of entertainment. Especially for price-conscious consumers, such as young adults, for example, provision free of charge may incentivise them to start or continue smoking.

The Federal [German] Government regards the encroachments accompanying these measures on the civil rights and liberties of the enterprises in question and the tobacco industry, as well as on the advertising industry, in particular on the basic rights of freedom of expression and the freedom to pursue a professional activity, as vindicated for reasons to do with the protection of public health. In two decisions, i.e. in its decision of 22 January 1997 – 2 BvR 1915/91 – (Federal Constitutional Court Decisions 95, 173) concerning warnings to be shown on unit packets of tobacco products and in its decision of 30 July 2008 – 1 BvR 3262/07, 1 BvR 402/08, 1 BvR 906/08 (Federal Constitutional Court Decisions 121, 317) concerning protection for non-smokers in restaurants and public houses, the Federal Constitutional Court dealt with the issue of tobacco control. The Court emphasises that a high level of importance is assigned to protecting the health of the population in the system of values under the Basic Law. An obligation incumbent upon the State to protect, which involves the prevention of risk in relation to health hazards, could therefore follow from Article 2(2) of the Basic Law. In view of the number of deaths which, on the basis of scientific findings, can be attributed to diseases caused by

second-hand smoke, moreover, human safety is also affected. The constitution also substantiates in this respect an obligation incumbent upon the State to protect which dictates that it protects and promotes the life of every individual (Federal Constitutional Court Decisions 121, 356 with further references). Since health and, even more so, human life constitute particularly important assets, their protection may also be sought using means which seriously infringe the fundamental right of freedom to pursue a professional activity (Federal Constitutional Court Decisions 121, 357).

With regard to the ban on outdoor advertising, the protection of children and young persons shall also be cited as a further justification since young people are not able to evade this form of advertising which is generally prevalent. The correlation between young people encountering tobacco advertising and the likelihood of smoking, or starting to smoke, has been investigated on a statistically representative basis in several studies also related to Germany (e.g. Hanewinkel/Isensee/Sargen/Morgenstern, Cigarette advertising and adolescent smoking, *Am J PrevMed* 2010; 28(4), pp. 359-366; Morgenstern/Sargent/Isensee/Hanewinkel, From never to daily smoking in 30 months: the predictive value of tobacco and non-tobacco advertising exposure, *BMJ Open* 2013; 3 e002907). Hence, for example, the data obtained from the last mentioned study confirms a link between the frequency of contact with cigarette advertising and the smoking behaviour of young people.

Extending the bans on advertising is also compatible with the principle of proportionality. Given only a slight decline in the smoking rate, warnings and other action taken previously in relation to tobacco control, in defiance of the highly cherished commodity which is press freedom, do not constitute a suitable alternative course of action in the face of the overriding importance of safeguarding health and young people. Advertising and presentation at the point of sale shall otherwise continue to be permitted. In this way, given the particularly important reasons of health protection and the protection of young people, the advertising measures shall be channelled in such a way that they primarily reach individuals who are already present in a relevant retail environment that includes presentation of merchandise and possibly promotional sales talks.

The Federal Republic of Germany has acceded to the WHO's Framework Convention on Tobacco Control of 21 May 2003 ("Tobacco Framework Convention"). This treaty entered into force in the Federal Republic of Germany on 16 March 2005. Article 13 of the Convention provides for obligations on the part of the signatories to the convention in relation to tobacco advertising, among other things (ban on advertising tobacco products in accordance with the constitution or constitutional principles), within a period of five years following its entry into force. Therefore, the bans envisaged can also draw on the Tobacco Framework Convention.

Advertising bans for electronic cigarettes and refill containers

Article 20(5) of Directive 2014/40/EU stipulates bans on advertising in relation to nicotine-containing electronic cigarettes and refill containers which comply with the requirements of Directive 2003/33/EC relating to the advertising and sponsorship of tobacco products and Directive 2010/13/EU concerning the provision of audiovisual media services (bans on advertising on the radio, in the press and other printed media, in information society services and in other audiovisual commercial communication).

Over and above the stipulations of Directive 2014/40/EU

- outdoor advertising and provision free of charge are also prohibited in relation to electronic cigarettes and refill containers, while advertising in cinemas continues to be restricted and, hence, the advertising provisions for these products are aligned with those relating to tobacco products, and

- nicotine-free electronic cigarettes and refill containers are classed with those containing nicotine in terms of the provisions relating to advertising.

According to Recital 55 of the directive, a Member State should remain free to maintain or introduce national laws [applying to all products placed on its national market] for aspects not regulated by this directive. Recital 48 makes it especially clear that domestic advertising for electronic cigarettes and refill containers is not to be harmonised. Member States are encouraged to lay down provisions in this regard.

The provisions are permitted under constitutional law. Encroachments on the civil rights and liberties of the manufacturers of electronic cigarettes and refill containers are justified on the grounds of health protection and the protection of young people.

As regards the ban on outdoor advertising, the continuing restriction on advertising in cinemas and the ban on provision free of charge, reference is made to the remarks made above regarding products containing nicotine. Here, already given the high level of toxicity exhibited by nicotine and its potential for addiction, no other assessment of the proportion of the fundamental rights affected can be made.

Bans on advertising, and advertising restrictions, are also justified in relation to nicotine-free electronic cigarettes and refill containers on the grounds of health protection and the protection of young people.

Primarily for the younger generation, electronic cigarettes have evolved into a lifestyle product. Almost 10 % of all 16-19-year-olds in Germany consumed electronic cigarettes in 2014 (German Cancer Research Centre (publisher) (2014), E-cigarettes: Awareness and consumption in Germany 2012-2014). As a result of the revision of the Youth Protection Act [...], a restriction on the sale of nicotine-free electronic cigarettes and refill containers, and those which do contain nicotine, to young people under the age of 18 was introduced. In addition to this, advertising in relation to nicotine-free electronic cigarettes and refill containers is to be prohibited on prevention grounds.

Regardless of the nicotine content, health risks exist in the case of electronic cigarettes as a result of evaporation agents and the release of volatile substances and particles or as a result of the fact that many of the flavoured liquids have cytotoxic properties.

The Federal Institute for Risk Assessment, in its scientific evaluation of 25 February 2015 (Federal Institute for Risk Assessment: The risk to the health of children and young people posed by so-called electronic shisha pens; Scientific evaluation of the Federal Institute for Risk Assessment of 25 February 2015) and the German Cancer Research Centre, in its opinion from 2015 (German Cancer Research Centre (publisher), Risk to the health of children and young people posed by e-cigarettes: Ban on selling to young people under the age of 18 required regardless of the nicotine content. *Aus der Wissenschaft – für die Politik*, Heidelberg, 2015), arrived at these findings.

Moreover, the smoking ritual as a result of using electronic cigarettes and their "flavours", which are especially attractive to children and young people, can be studied through children and young people who are particularly susceptible to this end and, as a result, can generally be encouraged to start smoking or have corresponding behavioural patterns imprinted on them.

III. Alternatives

None.

IV. Legislative powers

The Federal Government's legislative powers follow from Article 74(1) point 11 of the Basic Law – the law relating to economic matters, and from Article 74(1) point 20 of the same – the law on drink and tobacco. The legislative powers relating to the sanctioning of individual provisions follow from Article 74(1) point 1 of the Basic Law.

The Federal Government is entitled to legislate in this area of concurrent legislation if and insofar as the establishment of equal living conditions throughout Federal territory and the preservation of legal or economic unity in the national interest makes a Federal-wide uniform regulation necessary (Article 72(2) of the Basic Law). The aim of contributing to effective protection for the population, especially children and young people, against health damage which may result from tobacco consumption can only be achieved if, throughout Federal territory as a whole, uniform provisions shall apply to tobacco products and electronic cigarettes or other related products. The provisions of this Act are designed to create uniform Federal law and ensure a consistent practice on the part of the administrative and supervisory authorities for the Federal territory as a whole so as to avoid unequal treatment of the economic operators in question and, hence, considerable disadvantages for the economy as a whole.

The legislative powers in terms of amending the Tobacco Duty Act follow from Article 105(2), in conjunction with Article 106(1), of the Basic Law.

V. Compatibility with European Union law and international treaties

If nicotine-free electronic cigarettes and refill containers are regulated over and above the stipulations of the directive, this is compatible with European Union law. According to Recital 55 of the directive, a Member State should remain free to maintain or introduce national laws [applying to all products placed on its national market] for aspects not regulated by this directive.

The provisions envisaged in the area of advertising bans are compatible with European Union law. They supplement the bans on tobacco goods envisaged in accordance with Directives 2003/33/EC and 2007/65/EC, and which have been transposed into German law, as well as the stipulations of Article 20(5) of Directive 2014/40/EU, in areas where the European legislator does not have any regulatory competence.

VI. Legal consequences

1. Legal and administrative simplification

Essentially applying the same regulations to nicotine-free electronic cigarettes and refill containers and those which do contain nicotine represents an administrative simplification for the supervisory authorities in the Federal States.

2. Sustainability aspects

The draft Act is in keeping with the basic ideas of the Federal [German] Government regarding sustainable development in the context of the sustainability strategy. The Act is designed to reduce avoidable risks for human health, especially in the case of children and young people. Consideration is thereby given to the indicator "Living Longer and in a healthier way". The measures laid down in this Act assist in improving the state of health of the population.

3. Budget expenditure without compliance costs

None.

4. Compliance costs

Compliance costs for citizens

No compliance costs shall be incurred by citizens.

Compliance costs for businesses

As regards the estimate of the number of cases, the report from the consulting firm PwC (PricewaterhouseCoopers), which compiled this report on behalf of *Interessengemeinschaft Tabakwirtschaft e.V.* (an association concerned with safeguarding the specialised interests of the tobacco industry vis-à-vis politics, business and the media), was taken as a basis. This report includes data on annual rates of change as well as information regarding the respective total number of tobacco products.

On the basis of the regulation of nicotine-free electronic cigarettes and refill containers envisaged in this Amending Act, the obligations provided for in the Tobacco Products Ordinance for nicotine-containing electronic cigarettes and refill containers, which shall result in compliance costs for businesses, shall also apply to nicotine-free electronic cigarettes and refill containers.

In the absence of reliable data, it is assumed that the compliance costs for nicotine-free electronic cigarettes and refill containers are of the same order of magnitude as for nicotine-containing electronic cigarettes and refill containers.

Notification obligations are introduced in relation to electronic cigarettes by means of § 24 of the Tobacco Products Ordinance. The expenditure associated with the first-time inclusion of the notification obligations for nicotine-free products is estimated at EUR 503 200. Assuming an annual rate of change of 8 %, resulting in new or change notifications, ongoing compliance costs amounting to EUR 6 254 shall ensue.

The annual compliance costs arising from obligations to provide information as per § 25 of the Tobacco Products Ordinance are estimated at EUR 1 824 for nicotine-free products.

One-off personnel costs associated with drawing up the instruction leaflet as per § 26 of the Tobacco Products Ordinance are assessed at EUR 14 594. Instruction leaflets must be enclosed with all electronic cigarettes and refill containers, resulting in annual costs in connection with printing and materials. It is assumed that printing for 10 million units of nicotine-free products can be undertaken economically, resulting in assumed ongoing costs of EUR 300 000.

On the basis of the obligation contained in § 27(1) of the Tobacco Products Ordinance to affix a list to the package and outer packaging of the electronic cigarette or refill container, a one-off material cost for nicotine-free products amounting to approximately EUR 1 million shall accrue.

Businesses cannot be compensated for the compliance costs they incur on an ongoing basis within this draft legislation. It shall therefore have to be examined whether an appropriate prospect of relief can be demonstrated outside this draft.

Compliance costs for administration

No administrative compliance costs shall arise.

5. Additional costs

A ban on outdoor advertising is envisaged. According to information from the tobacco industry, published in the Federal [German] Government's 2015 report on drugs and addiction, in 2013, EUR 69.80 million was spent on outdoor advertising.

Advertising in cinemas is restricted insofar as the showing of promotional films and programmes for tobacco products, electronic cigarettes and refill containers is only allowed if a film as per the procedure defined in § 14 of the Youth Protection Act is characterised as "Not suitable for persons under the age of 18". According to the Federal [German] Government's 2015 report on drugs and addiction, in 2013, EUR 7.7 million was spent on advertising in cinemas.

In future, this expenditure will be curtailed and lasting reductions achieved.

In the case of nicotine-free electronic cigarettes and refill containers, marginal price increases can be expected since these products have been included in the scope of the regulations under tobacco law for the first time and new provisions therefore arise for manufacturers and importers which could be apportioned among the prices as appropriate.

VII. Time limitation; evaluation

A time limitation cannot be imposed on the Act.

B. Specific Part

Re Article 1 (Amending the Tobacco Products Act)

Re Point 1

The Table of contents is supplemented to include the newly to be inserted §§ 20a and 20b concerning the ban on outdoor advertising and the ban on selling and displaying free of charge.

Re Point 2

The definitions mentioned in Article 2 of Directive 2014/40/EU under points 16 and 17 are expanded to include nicotine-free electronic cigarettes and refill containers. If a situation of equality is not to be achieved, the individual provisions shall contain a corresponding clarification.

Re Point 3

Re Letter a

The definition relating to outdoor advertising is inserted. The list included is not definitive.

Re Letter b

Consequential amendment.

Re Point 4

Re Letter a

The newly inserted paragraph 1 stipulates that tobacco products which contain plant protection products within the meaning of Article 2(1) of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 of 24 November 2009, p. 1) or their breakdown or reaction products, or to which plant protection products or their breakdown or reaction products adhere, may only be placed on the market if the plant protection products are authorised for this area of application in Germany, in another Member State, or in another Signatory State to the Agreement on the European Economic Area. Plant protection products which are authorised for this area of application in a third country, and which are used there, shall be treated as equal.

Re Letter b

Consequential amendment.

Re Point 5

Re Letter a

Clarification is provided of the fact that the provision under § 14(1) of the Tobacco Products Act shall only apply to nicotine-containing electronic cigarettes and refill containers. Paragraph 1 transposes the stipulations under Article 20(3a) and (3b) of Directive 2014/40/EU. According to this, liquids containing nicotine may have a maximum nicotine content of 20 mg/ml. Maximum volumes are also laid down in relation to refill containers and single-use electronic cigarettes and non-refillable cartridges. It is therefore not possible, or necessary, to apply this provision to nicotine-free electronic cigarettes and refill containers as well.

Re Letter b

Clarification is provided of the fact that the provision under § 14(2) of the Tobacco Products Act shall only apply to nicotine-containing electronic cigarettes and refill containers. According to this, in order to ensure protection of health and safety, e.g. to avoid the risk of inadvertently consuming high doses of nicotine, electronic cigarettes containing nicotine may only be placed on the market if the nicotine dose is provided on a consistent level under normal conditions of use throughout its operating life. It is not necessary to apply this provision to nicotine-free electronic cigarettes and refill containers as well.

Re Point 6

Clarification is provided of the fact that the provision under § 15(1) point 2a of the Tobacco Products Act shall only apply to nicotine-containing electronic cigarettes and refill containers. Point 2a serves to transpose Article 20(4b)(iii) of Directive 2014/40/EU and stipulates that packages and outer packaging of nicotine-containing electronic cigarettes and refill containers shall carry a health warning. According to Article 20(4b)(iii), this health warning shall relate to the nicotine content. The provision cannot apply to nicotine-free products.

Re Point 7

The newly inserted § 20a includes the ban on outdoor advertising in relation to tobacco products, electronic cigarettes and refill containers. Advertising on the external surfaces of

business premises of specialist retailers (brickwork and windows) shall continue to be permitted.

In addition to the ban on the free distribution of tobacco products which already exists in connection with the ban on the sponsorship of cross-border events, provision is made in paragraph 1 of the newly inserted § 20b for a ban on supplying cigarettes, roll-your-own tobacco and water pipe tobacco to consumers free of charge. According to paragraph 2, smoking tobacco products other than cigarettes, roll-your-own tobacco and water pipe tobacco, smokeless tobacco products and electronic cigarettes, as well as refill containers, may only continue to be supplied free of charge within the business premises of the specialist retailer.

§ 20b(3) sets out the ban hitherto contained in § 29 of the Tobacco Duty Act concerning the displaying of tobacco products on a commercial basis and extends this ban to include electronic cigarettes and refill containers.

Re Point 8

The area of application of § 21 of the Tobacco Products Act is expanded to include electronic cigarettes and refill containers. Manufacturers of electronic cigarettes and refill containers should also be prohibited from suggesting, either through the use of names or other assertions, that electronic cigarettes do not present any health risk. Promotional information which particularly appeals to young people or adolescents, but also, for instance, the pictorial representation of young people and adolescents, or of situations and environments which are typical for young people, are also prohibited. The use of names or assertions which point to the fact that ingredients of electronic cigarettes or refill containers are natural or unadulterated is prohibited.

Re Point 9

Re Letter a

Compulsory registration, as provided for by Directive 2014/40/EU, with both the competent authority at its place of business and with the competent authorities in the Member State in which the distance selling takes place, or is intended to take place, cannot be envisaged in this way in relation to nicotine-free electronic cigarettes and refill containers. The question as to whether registration for individuals who exclusively place nicotine-free electronic cigarettes and refill containers on the market for the purpose of distance selling is possible or necessary in other Member States is determined by national law in the Member State in question. In this respect, it can merely be stipulated that these individuals have to be registered with the competent authority at home.

Re Letter b

Consequential amendment.

Re Point 10

Re Letter a

A penalty for the new § 9(1) is added.

Re Letter b

The consequential amendment follows from the insertion of the new § 9(1).

Re Point 11

Re Letter a

A reinforcement of infringements of the new §§ 20a and 20b is added.

Re Letter b

Consequential amendment.

Re Letter C

Consequential amendment.

Re Point 12

The consequential amendment follows from the insertion of the new § 9(1).

Re Point 13

In § 47 (Transitional provisions), paragraphs 6 and 7 are added.

Paragraph 6 stipulates that the ban on outdoor advertising shall apply as of 1 July 2020.

According to paragraph 7, the ban on provision free of charge away from business premises of the relevant specialist retailer shall only apply to smoking tobacco products other than cigarettes, roll-your-own tobacco and water pipe tobacco, as well as to smokeless tobacco products, following the expiry of a four-year transitional period, i.e. from 20 May 2020.

Re Article 2 (Amending the Youth Protection Act)

Re Point 1

Re Letter a

This change is made since in future, the restriction on advertising in cinemas shall no longer be tied to the time at which the film is shown but shall be geared to whether a film is characterised as "Not suitable for persons under the age of 18" as per § 14 of the Youth Protection Act.

Re Letter b

The showing of promotional films and programmes for tobacco products, electronic cigarettes and refill containers is only permitted in connection with films which are characterised as "Not suitable for persons under the age of 18" as per the procedure defined in § 14 of the Youth Protection Act.

Re Point 2

A reinforcement of infringements of the new § 11(6) is added.

Re Article 3 (Amending the Tobacco Duty Act)

The amendment follows from the insertion of the new § 20b(2).

Re Point 1

The regulatory content regarding provision to consumers free of charge in the previous § 25 sentence 2 of the Tobacco Duty Act is deleted.

Re Point 2

The ban on displaying tobacco goods on a commercial basis is incorporated in § 20b(3). § 29 of the Tobacco Duty Act can therefore be rescinded.

Re Point 3

Consequential amendments relating to point 2.

Re Article 4 (Entry into force)

Article 4 contains the provision relating to entry into force.