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Opinion

of the German Association for the Protection of Intellectual Property

regarding the Proposal of the European Commission for a Directive of the European Parliament and of the Council 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, COM(2012) 788 final

The German Association for the Protection of Intellectual Property (GRUR) is a recognised non-profit-making, academic association of the members of those groups of occupations and organisations active in the field of intellectual property and copyright. The association comprises in particular academics, judges, civil servants, lawyers and patent attorneys as well as the representatives of associations and enterprises. According to its statutes, the purpose of the GRUR is the academic advancement and the development of intellectual property and copyright law at German, European and international level.

In the following, GRUR comments on the European Commission's draft revised Directive in respect of the manufacture, presentation and sale of tobacco and related products (**"Draft Directive"**):

With this proposal, which has meanwhile been modified by a decision of the Council of Ministers of 21 June 2013, Union-wide harmonisation measures have taken on a new quality. The significant restrictions placed on tobacco manufacturers as regards the format of their products and the design of product packaging obstruct the use of intellectual property rights, especially trademarks and patents. Moreover, the proposal extends the approach of imposing a blanket prohibition on descriptive elements on tobacco packaging irrespective of whether or not there is a risk of the consumer being misled – an approach which is highly questionable from a competition law perspective.

I. The provisions at a glance

The Commission's proposals link back to Directive 2001/37/EC. The following new provisions are considered critical and require revision:

- Member States shall prohibit the placing on the market of tobacco products with a characterising flavour, for example menthol (Art. 6(1)).
- Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The combined health warnings shall cover 75% (Council of Ministers: 65%) of the external area of both the front and back surface of the unit packet (Art. 9(1)). This includes a pictoral warning.
- A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall have the form of a pouch, i.e. a rectangular pocket with a flap that covers the opening (Art. 13(1)).
- A cigarette packet can be of carton or soft material and shall not contain an opening that can be re-closed or re-sealed after the opening is first opened, other than the flip-top lid. The flip-top lid of a cigarette packet shall be hinged only at the back of the packet (Art. 13(2)).
- The packaging of the tobacco product shall not include any element or feature that refers to flavour, taste, any flavourings or other additives or the absence thereof (Art. 12(1)). Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading pursuant to Art. 12(1)(a) and are thus prohibited.
- Nicotine-containing products with a nicotine level exceeding 2 mg per unit or a nicotine concentration exceeding 4 mg/ml may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.
- Far-reaching powers are conferred on the Commission to adopt delegated acts.

II. Concerns as regards competence

The Commission's draft is based on Art. 114 of the Treaty on the Functioning of the European Union ("**TFEU"**), which provides the competence for acts of harmonisation within the internal market (see Recital 4). However, it is doubtful whether as a measure for the harmonisation of the internal market for tobacco products the draft truly fulfils the requirements of Art. 114 TFEU.

Art. 114(1) TFEU does not present any high hurdles in terms of factual requirements. As such, it is sufficient for there to be either obstacles to trade or an appreciable distortion of competition on the market for tobacco products between individual Member States. Obstacles to trade already exist if there is a sufficient future likelihood of differences in the legislative provisions enacted by Member States with regard to tobacco products. The Draft Directive does not fulfil even these requirements, however. Insofar as the proposed harmonisation covers new matters not previously covered, such as the regulation of ingredients, the required obstacles to trade are absent. Moreover, the draft fails to meet the stated purpose of Art. 114 TFEU since the provisions neither promote nor ensure the free movement of tobacco products.

The particulars are as follows:

1. Lack of a situation requiring harmonisation

In Recital 14 of the present draft it is assumed that the absence of a harmonised approach to ingredients regulation would impede the functioning of the internal market and free movement of goods across the EU. Reference is also made to the fact that some Member States have adopted legislation or en-

tered into binding agreements with the industry allowing or prohibiting certain ingredients, with the result that some ingredients are regulated in some Member States but not in others. Based on this, it would indeed be the case that a harmonisation requirement would exist since it cannot be denied that free movement of goods will be impaired in the area of tobacco products if tobacco products can only be marketed in some Member States and not in others owing to the ingredients or additives contained in them.

For additives that bring about a characterising flavour, however, there is no such harmonisation requirement as these substances are permitted throughout the EU as a whole. This applies in particular to menthol as a "classic" flavour added to tobacco and now to be prohibited as an additive pursuant to the proposed amendment insofar as it is capable of producing a distinguishable aroma or taste other than tobacco (Art. 2(4) Draft Directive).

As such, however, the requirements of Art. 114(1) TFEU are not fulfilled since the planned provisions as regards ingredients do not have the functioning of the internal market as their object but constitute independent regulations in the area of health protection. The Union consequently lacks the competence for ingredients regulation even just for the reason that there are no obstacles to trade which a Union-wide provision would eliminate.

2. Failure to achieve harmonisation objective: obstruction of the internal market

Moreover, the draft falls short of its ostensible harmonising objective. Even if and to the extent that Union-wide regulations may eliminate differing national provisions, this is insufficient for an approximation of laws on the basis of Art. 114(1) TFEU. The proposed regulations would in fact have *to improve* the functioning of the internal market in real terms in the specific case. Consequently, it is insufficient for the application of Art. 114(1) TFEU simply for there to be differences in national law – that is, a merely abstract risk as regards the free movement of goods. A harmonisation of laws would have to generate "added value" for the internal market.[1] In the present case, however, no such "added value" exists for the specific reason that the Draft Directive does not provide a conclusive list of the prohibited, respectively the permitted, additives but instead simply sets out a general prohibition without specifying particular ingredients, respectively maximum levels.

Harmonisation requires that the free movement of those products in conformity with the Directive be promoted in real terms. The minimum requirement for this purpose is a free-movement provision ensuring that those products conforming with the provisions of the Directive can be marketed within the Union.[2] The Draft Directive does not meet these requirements in its present: neither is the Directive as a whole aimed at securing the internal market for tobacco products nor does it have the consequence of making those tobacco products that meet its conditions capable of being legally marketed within the Union.

This is owing to the fact that Art. 24(2) expressly permits Member States to maintain or introduce more stringent national provisions "*on grounds of overriding needs relating to the protection of public health*". Whilst Art. 114(4-8) TFEU permits national unilateral actions of this type subject to strict procedural conditions, such conditions are bypassed by Art. 24(2) of the Draft Directive, which merely obliges the Commission to verify whether the stricter national provisions are proportionate to their aim. Materially, therefore, the same test applies as would do so if no harmonisation measure were to exist and restrictions on the free movement of goods were to be judged based on Art. 34 and 36 TFEU.

1 Cf. CJEU, case no. C-376/98 – *Deutschland/Parlament und Rat,* vol. 2000, I-8419 para. 84.
2 CJEU, case no. C-376/98, *Deutschland/Parlament und Rat,* vol. 2000, I-8419, para. 104.

As in the area of ingredients, the Directive would not result in a harmonisation that promotes the internal market in real terms. On the contrary, the Draft Directive encompasses measures that, contrary to Art. 34 TFEU, do not work to ensure the internal market but specifically impede it. The individual measures – in particular the increase in the size of the warnings to 75% (respectively 65%) of the front surface of the unit packet in conjunction with pictures designed to shock, full standardisation of the packaging size and design and also the far-reaching prohibition on product descriptions – would in fact establish barriers to market entry in that they would substantially eliminate the scope for effective product differentiation, in particular effective branding.

The significantly enlarged written and pictoral warnings would leave tobacco manufacturers with insufficient room on the packet to print trade marks, logos, colours and other distinctive elements and by this to indicate to the consumer the product's trade origin. This is despite the Court of Justice of the European Union ("CJEU") having recently reiterated the central importance of trade marks as "*an essential element in the system of undistorted competition*"[3]. Without the possibility to design cigarette packets in a striking way by using trade marks and other elements that describe the product, there will be foreclosure of national tobacco markets, with current market positions being cemented and new manufacturer and brand entries impeded.

It is for this reason that in its merger control decisions the European Commission has consistently acknowledged possibilities for effective branding as "*most important factors for the ability to compete*"[4] in the highly regulated tobacco sector since in such circumstances trade marks constitute the "*key communicator with the final customer*"[5]. Going against this, the Commission expressly leaves it open to Member States to introduce further-reaching provisions such as standardised packaging (Recital 41). Given that the Directive does not itself provide for plain packaging, the Commission appears to presume that it therefore does not have a negative blocking effect in this regard such that the Member States could themselves introduce it. This makes it clear that the Directive is neither aimed at securing the internal market for tobacco products nor puts in place arrangements appropriate to this goal being achieved.

3. Summary

The Commission consequently cannot base its planned measures for the amendment of the Tobacco Product Directive on Art. 114 TFEU.

III. Regulation of ingredients

1. Description of regulation

Art. 6 "Regulation of ingredients" of the Draft Directive contains merely rudimentary provisions on the use of additives. "Additive" is defined in Art. 2(2) as a substance contained in a tobacco product, its unit packet or any outside packaging with the exception of tobacco leaves and other natural or unprocessed parts of tobacco plants. In contrast, pursuant to the definition in Art. 2(18), "ingredient" means not only an additive but also the tobacco itself as well as any substance present in a finished tobacco product including paper, filter, inks, capsules and adhesives. Art. 6 does not, however, regulate for ingredients by including a positive list and/or by setting out the substances prohibited as dangerous, respectively as

3 CJEU, case no. C-10/89, *HAG*, para. 13.

4 Case no. COMP/M.4581, *Imperial Tobacco/Altadis*, para. 68. Cf. also case no. M.2779, *Imperial tobacco/Reemtsma Cigarettenfabriken*, para. 57.

5 Case no. COMP/M.4581, *Imperial Tobacco/Altadis*, para. 68.

increasing the addictiveness of tobacco products (negative list). Rather, Art. 6(4) provides that Member States shall prohibit the use of the certain additives in tobacco products, namely:

a) vitamins and other additives that crease the impression that a tobacco product has a health benefit or presents reduced health hazards;

b) caffeine and taurine and other additives and stimulant compounds that are associated with energy and vitality;

c) additives having colouring properties for emissions.

In addition, Art. 6(5) provides for Member States to prohibit the use of flavourings in the components of tobacco products such as filters, papers, packages, capsules or any technical features allowing modification of flavour or smoke intensity. Filters and capsules shall also not contain tobacco. Finally, the Member States shall prohibit the placing on the market of tobacco products with a characterising flavour. This is defined in Art. 2(4) as a distinguishable aroma or taste other than tobacco, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy, menthol or vanilla observable before or upon intended use of the tobacco product.

The present Tobacco Product Directive provides in Art. 12 for a common list of authorised ingredients, whereby the term "ingredient" is differently defined and essentially accords with the term "additive" in the Draft Directive. This present Directive, however, provides in Art. 12 for the submission of a common list of ingredients authorised for tobacco products taking into account, *inter alia*, their addictiveness.

2. No health protection grounds

Putting aside the fact that the EU lacks the competence to issue regulations in health protection as such, the mentioned regulations on ingredients are also unable to found an "indirect" need for harmonisation on the basis that the Member States themselves might at any time restrict the use of additives in tobacco products on grounds of health protection.

That is to say, the restriction placed on the addition of characterising flavours is justified neither by the especial danger posed by these substances nor by their potential to increase addictiveness. It is controversial whether there are indications of the substances being dangerous in themselves and whether reliable studies presently exist demonstrating their potential to increase addictiveness.[6]

As an example the discussion about menthol can be mentioned. In this respect it is claimed in Recital 15 that studies indicate that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people. However, the studies and reports to which the Commission refers contain no information on the proportion of young people among those smokers who smoke cigarettes, respectively tobacco products, that contain menthol. Rather, the European Commission's most recent Eurobarometer survey contains indications that the assumption that menthol cigarettes make it easier for young people to take up smoking is incorrect: according to the survey only 3% of the smokers surveyed said

6 *Brooks/Palmer/Strom/Rosenberg*, Menthol Cigarettes and Risk of Lung Cancer, American Journal of Epidemiology, February 2012, 1, 2; *Muscat/Chen/Knipe/Stellmann/Lazarus/Riechie*, Effects of Menthol on Tobacco Smoke Exposure, Nicotine Dependence and NNAL-Glocuronidation, Cancer Epidemiology, Biomarkers and Prevention, 2009, 35, 39; *Gaworski/Dozier/Gerhart/Rajendran/Brenneke/Arany/Heck*, 13-Week Inhalation Toxicity Study of Menthol Cigarette smoke, in *Food and Chemical Toxicity* 1997, 683; *Giovino/Sidney/Gfroerer/O´Malley/Allen/Richter/Cunnings*, Epidemiology of menthol cigarette use, *Nicotine & Tobacco Research* 2004, 67, 69.

they had started smoking because they liked the taste of menthol cigarettes.[7] Moreover, there are no studies into the promotion of tobacco product consumption by other substances that produce a "characterising flavour" in terms of the Draft Directive.

3. No obligation following from the WHO Framework Convention on Tobacco Control ("FCTC")

The WHO Framework Convention on Tobacco Control, which is mentioned in Recital 1 of the Explanatory Note, equally does not give rise to an obligation to introduce a prohibition on substances with a characterising flavour or on other additives that neither are harmful to health nor increase the addictiveness of tobacco products.

Art. 9 FCTC simply places an obligation on the signatories to the Framework Agreement to propose guidelines for testing and measuring the contents and emissions of tobacco products and to later enact appropriate measures. It is not possible to derive from this an obligation to regulate ingredients that affect in particular the taste of tobacco.

Whilst the Partial Guidelines on the Implementation of Article 9 contain some comment about tobacco products commonly being made attractive in order to encourage their use and about there being no justification from a public health perspective for permitting the use of ingredients such as flavouring agents that help make products more attractive, even putting aside the fact that the Guidelines are not binding and thus even just for this reason alone cannot give rise to obligation on the EU to regulate ingredients that are supposedly attractive, the attractiveness criterion mentioned in Recitals 12 and 38 is not suited to substantiate a scientifically sound regulation on tobacco additives. The report "Addictiveness and Attractiveness of Tobacco Additives" complied by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) establishes that there are no validated methods and also no secure data on the quantification or assessment of the attractiveness of additives in tobacco products.[8]

This apart, as set out in b) above, it is controversial whether certain odorants or flavourings that are not inherent to tobacco work to increase the attractiveness of tobacco products. As such, given that such substances are currently used in order to ensure that tobacco products have a consistent quality and a stable, brand-specific taste, restricting their use would result in legislation on product formulation, which is not justified on any objective grounds.

For this reason there is also no justification for a prohibition on the use of flavourings in other tobacco product (paper, filters, etc.) components.

4. Poor quality of the provision

On closer inspection, the term "characterising flavour" as defined in Art. 2(4) of the Draft Directive is not suited to determine which additives are not to be prohibited by the Member States since what constitutes "a distinguishable aroma … other than tobacco" cannot easily be identified. Many traditionally produced tobaccos contain flavour additives, e.g. sugar or cocoa, which, whilst they may be able to be tasted in a taste comparison, nonetheless do not lend the tobacco a taste other than that of tobacco.

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7 European Commission: Special Eurobarometer 385 "Attitudes of Europeans towards Tobacco", Brussels, May 2012, p. 70.

8 SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Addictiveness and Attrac tiveness of Tobacco Additives, 2010, p. 85.

This difficulty is recognised by even the Commission itself, see Art. 6(2) Draft Directive. Taken as a whole, this situation leads to the provision's current approach being one which brings about exactly the opposite of that which EU-wide harmonisation is supposed to achieve – namely a uniform law applied consistently across all Member States.

IV. Enlargement of warnings

In Art. 9(1)(c) the Commission plans not only to enlarge the warnings to 75% of the front and back surface of the unit package but to supplement the written warning with a shocking graphic picture. From a marketing viewpoint he aim of the proposal is an alarming scaring mobilisation. From a legislative viewpoint extreme emotionalism is contrary to the consumer model that is based on the jurisdiction and legislation in the EU, namely a rationally considering and deciding economic citizen. Furthermore the intended communication to the consumer contrasts with the prohibition of public advertising in improper and alarming terms in other areas of health marketing (see art. 90 lit. k) Directive 2001/83/EC on the Community code relating to medicinal products for human use).

Such a provision would also seem questionable in the light of existing trademark rights. The CJEU has repeatedly emphasised the significance of trade marks for effective competition within the Union. Furthermore, intellectual property is now expressly protected by Art. 17(2) Charter of Fundamental Rights of the European Union ("**CFR**"). Consequently, pursuant to Art. 52(1) CFR, any limitation of trade mark rights must observe the principle of proportionality and respect the essence of property rights in trade marks.

1. Effects on trade mark law

Pursuant to the case law of the CJEU, warnings may only be prescribed in a proportion to the pack's size "*which leaves sufficient space for the manufacturers of those products to be able to affix other material, in particular concerning their trade marks*".[9] Likewise, in 1997 the German Federal Constitutional Court ruled with regard to significantly smaller warnings that the "*differing and dominant overall impression of the various packet designs*" should be preserved "*despite the warning*".[10] It seems doubtful that the Draft Directive observes these limits. After accounting for the prescribed revenue stamps, traceability markings and security features, the available surface area on the front of the packet to print manufacturer logos, trade marks and product information will be reduced to approximately 20%. Moreover, a large shocking graphic picture in conjunction with a text warning will prevent any trade marks from having a decisive impact on the overall impression left by the product packaging. The enlargement of the warnings and their expansion by a pictorial element is designed precisely so as to impair any significant impact by trade marks. This applies in principle to all trade marks but especially to word/device marks, device marks, positional marks, etc. In the case of these marks, a function-appropriate use and, as such, a use in a way which ensures the rights are preserved would no longer be guaranteed.

Thus, for example, the Hanseatic Higher Regional Court decided in 1984 that there is no longer a function-appropriate use of a tobacco trade mark "*if the mark is so inconspicuously affixed that it is not perceived by the relevant public as an indication of trade origin."*[11] Similarly, the German Federal Patent Court decided in 1976 that printing a tobacco product trade mark in a very small size is insufficient to

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9 CJEU, case no. C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, vol. 2002, I-11453, para. 132.

10 German Federal Constitutional Court, NJW 1997, 2871 – *Warnhinweise.*

11 Hanseatic Higher Regional Court, GRUR 1984, 449, 451 – *King II.*

preserve the rights attached to the mark if and because the relevant public would then overlook the respective mark.[12]

2. Commission's lack of sensibility for fundamental rights

Despite this clear relevance of the proposed measures to fundamental rights, the Explanatory Memorandum to the Draft Directive contains no proportionality assessment in respect of legally protected rights. There is a consistent omission to balance the conflicting rights of tobacco manufacturers and consumers against the general interests pursued by the provision. In the Explanatory Memorandum to the Draft Directive, the Commission tersely states: "the obligations imposed on manufacturers, importers and distributors of tobacco products are necessary to improve the functioning of the internal market while ensuring a high level of health and consumer protection …". There is no detailed analysis in respect of fundamental rights whatsoever. The CJEU has recently once again ruled that a stricter legal test is to be selected in the case of measures impacting on fundamental rights. The Court today requires that the Union institutions "strik[e] a proper balance between the various interests involved" – and this "before adopting" legislation.[13] Interferences with fundamental rights must be limited to what is "strictly necessary" and, furthermore, "a fair balance […] struck between the demands of the public interest and the interest of the individuals concerned".[14] These requirements are not met by the Draft Directive now submitted.

Similarly in the Impact Assessment, the Commission fails to discuss the milder measure of leaving the present size and presentation of the warnings untouched. In contrast, "RAND Europe", an advisor commissioned by the Commission to provide support in assessing various options for revising the Tobacco Products Directive, did weigh these options and failed to establish a difference in the effectiveness of 50%-sized warnings compared to larger 75%-sized warnings.[15] The Commission nevertheless simply concluded to the contrary that there was no less intrusive alternative than enlarged warnings.[16] This does not satisfy the requirements for a balancing of interests as part of applying the principle of proportionality – as is constitutionally required.

3. Shocking graphic pictures as a potential expression of opinion?

Given that cigarette packets will be characterised in the future not by their trade marks but by the combined warnings, the question arises whether this might not constitute a violation of the right of tobacco manufacturers not to express an opinion. In 1997 the German Federal Constitutional Court decided in favour of much smaller text warnings so that consumers would recognise the mandatory information in the warnings to originate from a third party and would not attribute the warnings to the tobacco manufacturers themselves. The warnings at the time were also considerably smaller than the combined warnings now under discussion and were prefaced with the words "The EU Minister for Health". Whether consumers will continue to make this connection when faced with 75%-sized, respectively 65%-sized, warnings that include distinctive shocking graphic pictures and dominate the packet is highly doubtful.

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12 German Federal Patent Court, order of 19 October 1976, 26 W (pat) 180/76 – *Flip-Top-Box*; cf. also German Federal Patent Court, GRUR 1983, 509 – *Guy.*

13 CJEU, joined case nos. C-92/09 and C-93/09, *Schecke und Eifet /Land Hessen*, EuZW 2010, 939, para. 79.

14 CJEU, case no. C-402/05 P, *Kadi*, vol. 2008, I-6351, para. 360.

15 RAND Europe, Assessing the Impacts of Revising the Tobacco Products Directive, Study to Support a DG SANCO Impact Assessment, Final Report, September 2012.

16 Impact Assessment, p. 97.

V. Packet design

In Art. 13 of the Draft Directive, the Commission proposes a rule by which cigarette packets shall have a cuboid shape, be of carton or a soft material and contain no opening other than the flip-top lid.

This provision should be deleted without replacement since it will make industrial property rights – primarily patents and utility models in the field of cigarette packaging – obsolete. Such rights would no longer be permitted to be used. The specific effect of a patent, however, is to entitle the patent holder to use the patented invention within the scope of the applicable law (section 9 sentence 1 German Patents Act). The prohibition on innovative packaging design would therefore frustrate the use right on the part of patent holder, which falls under Art. 17(2) CFR, thus rendering the patent worthless. Such a prohibition seems disproportionate in particular because the Commission presents no arguments as to why other packaging designs, for example designs with rounded-off edges, with other lids or with innovative closing mechanisms, should be suited to cause consumers to take up smoking.

The specific form of packaging chosen in Art. 13 would therefore seem to be arbitrary in terms of substance and cannot justify a *de facto* expropriation of rights from holders of innovative packaging patents.

VI. Prohibition on product descriptions

In Art. 12 of the Draft Directive the Commission aims to prohibit production descriptions on cigarette packaging, including elements relating to the flavour, taste, any flavourings or other additives or the absence thereof (Art. 12(1)(c)). Furthermore, cigarettes with a diameter of less than 7.5 mm "shall be deemed" misleading and thus prohibited under Art. 12(1)(a) as a misleading indication.

The Commission intends these provisions to supplement Art. 7 of the existing Tobacco Product Directive, which provides that names, trade marks and other signs suggesting that a particular tobacco product is less harmful than others are not to be used on the packaging of tobacco products. This current measure, which is essentially appropriate, is based on experiences with statements such as "light" or "mild" which, whilst actually referring to the nicotine or tar level, were capable in certain circumstances of giving the consumer the impression that consuming the cigarettes in question was less harmful than smoking so-called full-flavour products. This impression was incorrect because lowering the nicotine level of a tobacco product does not contribute to manufacturing a "less harmful" product. Rather, the many other constituents of cigarettes, which were not found in any lesser number or in a lesser concentration in light cigarettes compared to traditional cigarettes, are suspected of causing harm to health.

The currently proposed provision goes significantly further, however, and, in doing so, overstretches the concept of abstract protection from misleading statements in that it also prohibits submissions of a non-misleading nature. It is not obvious and nor has the Commission in any way argued that indications as regards, for example, an absence of additives (e.g. "additive free") would be suitable to mislead consumers about the risks of smoking. Equally, descriptive statements such as "spicy" would be prohibited despite it not being obvious how such statements supposedly influence the uptake of smoking among consumers.

Fictions such as found in Art. 12(2) are especially debatable. According to this provision, cigarettes with a diameter of less than 7.5 mm "shall be deemed" to be misleading without there being any evidence for why a cigarette with a diameter of 7 mm should encourage the uptake of smoking among consumers. The Commission essentially bases its entire arguments on the "attractiveness" of tobacco products – which is then to be reduced by appropriate means. However, such a line of argumentation does not

eliminate the need to show precisely how the relevant provisions are supposed to prevent the consumer being misled. Consistent with this, the Council of Ministers has meanwhile voted for the prohibition on slim cigarettes to be removed from the Draft Directive.

Regarding the right to freedom of expression as protected by Art. 11(1) CFR it must be taken into account that there can be no prohibition of certain statements or advertising measures based on mere abstract considerations of consumer protection. Instead, there must be a specific risk to the object afforded legal protection in order to justify the infringement of fundamental rights. By its very nature, this requirement is the product of a balancing of legally protected interests.

The Commission must observe this requirement even if the interest to be protected by Art. 12 of the Draft Directive is not so much that of the integrity of effective competition but more that of the health of consumers. As an information-control provision, the sole aim of Art. 12 can only be to prevent consumers being misled with regard to the health-related properties of the product. Consequently, should the legislator wish to avoid a risk of the consumer being misled, it must formulate the provision such that there is no indiscriminate inclusion of both misleading and non-misleading product statements. In view of the protection afforded to intellectual property in Art. 17(2) CFR, Art. 12 of the Draft must therefore be limited in terms of its factual elements to make it consistent with fundamental rights such that non-misleading statements and non-misleading product forms, such as cigarettes with a diameter of less than 7.5 mm, are excluded from its scope of application.

VII. Regulation of nicotine-containing products as medicinal products

The proposal to regulate as medicinal products nicotine-containing products ("NCPs") with a nicotine level exceeding 2 mg per unit or a nicotine concentration exceeding 4 mg per ml runs contrary to the system underlying the European legal term "medicinal product", disregards the principle of consistency[17] and for no apparent reason introduces significant legal uncertainty to the already very difficult task of establishing the scope of this term. Such NCPs are often not intended for therapeutic purposes and nor do consumers use them to such ends. It is questionable whether a substance capable of influencing the body by metabolic means must nevertheless be treated like a medicinal product by function even if the way in which it is customarily used is not to therapeutic ends. The German Federal Supreme Court has recently submitted this issue to the CJEU for a ruling in connection with so-called "legal highs" (designer drugs). The Commission's proposal now pre-empts the Court's ruling for NCPs. In this, the consequences of the suggestion for other product groups, such as the legal highs, are entirely unclear and their implications not thought through.

If it is considered appropriate to regulate NCPs, this must be done by way of a threshold value that is logical and scientifically justifiable in terms of health protection. The Commission's proposal for products below the threshold for a medicinal product has as its basis the nicotine levels found in products for smoking cessation. As such, the values adopted are those found in medicinal products for therapeutic purposes. Products for smoking cessation help guard against the withdrawal symptoms experienced when quitting smoking. The nicotine level at which such products produce a therapeutic effect has nothing to do with scientifically justifiable threshold values for the prohibition of NCPs outside the field of medicinal products. However, precisely such a prohibition results the proposed provision as there can be no question of the nicotine products today in use being licensed as medicinal products for the simple

17 Cf. No. 6 of the common guidelines for the quality of drafting of Community legislation (1999/C 73/01) OJ No. 73 of 17 March 1999, p. 1,

reason that they are not targeted at therapeutic use. As such, the suggestion results in a prohibition on the marketing of products such as e-cigarettes insofar as they exceed the threshold value.

Such a threshold value exists for traditional cigarettes, too. The value in this regard, however, is independently justified on grounds of health protection. Thus, a meaningful and equal-treatment-orientated provision in respect of NCPs would have to be guided by the maximum values for other tobacco products, whereby the varying usages and methods of taking up the nicotine must be taken into account. In contrast, the proposed transferral of the values detected in medicinal products by presentation to medicinal products by function is not thinkable. It takes values which, as a means for treating withdrawal symptoms, tend to lie at the lower limit of the nicotine take-up from cigarettes and then makes them the upper limit for a new product group. As such, improper criteria are used to set the threshold value.

The authority given to the Commission to update the threshold values taking into account scientific developments and market authorisations granted to NCPs also leads to considerable problems. By this provision, a market authorisation granted to a medicinal product by presentation with a very low nicotine content is capable of causing a shift in the threshold values. Products capable of being marketed until such time would then be reclassified as not authorised and, taking into account their intended use, even as medicinal products not capable of authorisation. The change of circumstances would then not be justified on grounds of health protection but would result solely from a product of a different kind having received market authorisation as a medicinal product.

The definition of an NCP found in Art. 2(22) of the Draft Directive could also result in difficulties. NCPs are described there as products to which nicotine is either added during the manufacturing process or self-administered later by the user. As such, the definition does not cover products produced from the processing and concentration of substances with naturally occurring nicotine. Here again therefore, the draft results in a difficult-to-justify, unequal treatment of differing products with a comparable nicotine content.

VIII. Delegated acts

A large number of the Draft Directive's provisions empower the Commission to adopt delegated acts in accordance with Art. 290 TFEU[18] and, in doing so, greatly extend the legislative competence hitherto had by the Commission under the present version of the Tobacco Products Directive. According to Recital 38, only in this way is it possible to make the Directive "fully operational and to keep up with technical, scientific and international developments".

It is doubtful whether the extensive legislative competence provided for in the Draft Directive is in accord with Art. 290 TFEU. Pursuant to this provision, only those powers may be delegated to the Commission which supplement or amend certain non-essential elements of the respective legislative act (Art. 290(1) first sentence TFEU). In contrast, the "essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power" (Art. 290(1) second paragraph, second sentence TFEU).

Under the Treaty on European Union ("TEU"), the matter of essentiality tended to be generously interpreted by the CJEU to the benefit of the Commission's powers. A transfer of such powers, justified on

18 See in particular Art. 3(2) and (39, Art. 6(3), (9), (10), Art. 8(4), Art. 9(3), 10(5), Art. 13(3) and (4) of the Draft Directive.

functional grounds, was permitted because the Commission was most suited to realising Community objectives.[19] This line of case law can no longer be sustained based on the TFEU however.

Firstly, one aim of the Treaty of Lisbon was to enhance the democratic legitimacy of the Union[20]. This aim is met where the legislature itself, which enjoys democratic legitimacy, makes the essential basic decisions and where the legislature leaves the Commission with scope for decision-making only at the periphery when adopting delegated acts.

Secondly, account must be taken of the binding nature of the CFR pursuant to Art. 6 TEU. Art. 52(1) sentence 1 CFR provides that any "limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law". This legal reservation has as its consequence that interventions affecting fundamental rights must be contained in the very legal act authorising the Commission and not in a mere delegated act.[21] As such, the delegated acts provided for in the Draft Directive must meet stringent requirements. Any intervention in fundamental rights must be done in the basic instrument itself.[22] A violation hereof will give rise to the possibility of an action for annulment before the CJEU in accordance with Art. 263 TFEU.

It follows from all this that in practical terms all that can be reserved to the Commission is the fine-tuning and further specifying of the provisions contained in the basic instrument, in particular the enactment of detailed technical provisions or the more precise fleshing-out of indefinite legal concepts[23]. The majority of the delegation provisions do not meet these requirements.

In particular the powers in Art. 8(4)(b) of the Draft Directive – which provides that the Commission shall be empowered to adopt delegated acts "to define the position, format, layout and design of the health warnings laid down in this Article, including their font type and background colour" – and in Art. 9(3)(c) – which provides that the Commission shall be empowered to adopt delegated acts to "define the position, format, layout, design, rotation and proportions of the health warnings" – are likely to constitute essential provisions in terms of Art. 290(1) TFEU.

Moreover, account must be taken of the above-mentioned CJEU decision on the Tobacco Product Directive[24], according to which tobacco product manufacturers must be left sufficient room for their own indications, in particular trade marks, in order to avoid injury to the very substance of their fundamental rights. A further intensification of the already existing requirements on the presentation of tobacco products might therefore be classifiable as in conflict with the German basic law, in which case interventions in such a sensitive area – as far as permissible at all – may have to be done in the basic instrument itself and not through delegated acts.

Dr. Kunz-Hallstein
President

Prof. Dr. Loschelder
Secretary general

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19 Cf. CJEU, case no. C-240/90 – *Deutschland/Kommission*, vol. 1992, I-5383, paras. 36 f. and 40; CJEU, case no. C-356/97 – *Molkereigenossenschaft Wiedergeltingen*, vol. 2000, I-5461, para. 21 ff.

20 Cf. Preamble to the Treaty of Lisbon.

21 Cf. *Kingreen* in *Calliess/Ruffert*, EUV/AEUV, 4th edition, 2011, Art. 52 CFR, para. 62; *Borowsky* in *Meyer*, Charta der Grundrechte der Europäischen Union, 3rd edition, 2010, Art. 52 CFR, para. 20a; *Nettesheim* in *Grabitz/Hilf/Nettesheim*, Das Recht der Europäischen Union, 50th set of supplements, 2013, Art. 290 TFEU, para. 42.

22 *Ehlers* in *Ehlers*, Europäische Grundrechte und Grundfreiheiten, 3rd edition, 2009, § 14, para. 67.

23 *Gellermann* in *Streinz*, EUV/AEUV, 2nd edition, 2012, Art. 290 TFEU, para. 6.

24 CJEU, case no. C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, vol. 2002, I-11453.