

Advisory Opinion of the German Cancer Research Center

on the

Proposal 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”

2012/0366 (COD)

prepared by

Unit Cancer Prevention / WHO Collaborating Centre for Tobacco Control

who-cc@dkfz.de

The German Cancer Research Center (Deutsches Krebsforschungszentrum, DKFZ) welcomes the Proposal for a new Tobacco Products Directive that implements a number of tobacco control measures laid down in the WHO Framework Convention on Tobacco Control (FCTC) and defined in more detail in the respective guidelines. DKFZ considers the introduction of large combined health warnings particularly well accomplished. Health warnings as defined in the proposal can unfold almost maximum impact due to their size, their position in the upper area of the package's front and back, and the large pictures. They can contribute to preventing young people from starting to use tobacco and motivate smokers to quit. About three quarters of Europeans wish for such warning labels to be introduced.

Also very positive are the regulations on product description and packaging as well as the ban on cigarettes with a diameter of less than 7.5 mm. With this ban on slim cigarettes, which are particularly appealing for young women, the European Union is assuming a pioneering role worldwide. DKFZ also approves of maintaining the ban on snus in the European Union except for Sweden, because snus is a harmful product with addictive potential that also appeals to young people.

DKFZ also welcomes the inclusion of novel tobacco products and nicotine-containing products in the Proposal for the new Tobacco Products Directive (TPD), since such products are expected to play an ever increasing role in the market for nicotine products. DKFZ equally welcomes the introduction of a tracking and tracing system for tobacco products as well as of security features that have the potential of curbing tobacco smuggling. The ban on tobacco additives is also seen as positive, because additives make a harmful product more attractive and promote tobacco use.

However, from DKFZ's perspective, the phrasing of a number of regulations in the current proposal needs to be optimized for the measures to unfold their full effectiveness. Tobacco products – particularly cigarettes – are different from all other products sold over-the-counter because of the great health hazards associated with them and because of their high addictive potential. No other over-the-counter product causes so much morbidity and mortality as tobacco products. This fact justifies regulating tobacco products very strictly. Regulatory measures must be apt to reduce the attractiveness of tobacco products as much as possible in order to contribute to reducing tobacco use.

In order to exploit the full potential of the measures implemented in the proposal and to achieve maximum effect for health protection, DKFZ recommends taking into consideration various suggestions for modification, which are set out in detail in the following.

1. Exemptions

In several items ("*Ingredients and emissions*" as well as "*Labelling and packaging*"), the proposal for a revised Tobacco Products Directive exempts tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products from provisions. The text justifies this exemption with the argument that the exempted products are mainly consumed by older consumers, while the focus of the proposal is to prevent young people from starting to use tobacco. The definition of these exemptions is unsuitable. DKFZ is generally opposed to granting any exemptions.

Exemption:

"[...] tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products, e.g. cigars, cigarillos and pipe tobacco [...]"

Suggested modification:

"[...] tobacco products other than cigarettes, roll-your own tobacco, waterpipe tobacco and smokeless tobacco products, e.g. cigars, cigarillos and pipe tobacco [...]"

Explanatory statement:

The exemption of "*tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products, i.e. cigars, cigarillos and pipe tobacco*" is insufficient. "*Tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products*" comprise not only cigars, cigarillos and pipe tobacco, but also waterpipe tobacco, because it does not fall into any of the listed categories of cigarettes, roll-your-own tobacco or smokeless tobacco products. However, the text cites only cigars, cigarillos and pipe tobacco as explicit exemptions. It is unclear whether or not waterpipe tobacco is subsumed under 'pipe tobacco'.

The use of waterpipes is associated with the same health risks as cigarette smoking. Waterpipe tobacco is strongly flavoured and waterpipes are increasingly popular among young people¹. In line with the aim of not encouraging young people to start using tobacco (this includes using waterpipe tobacco), waterpipe tobacco should on no account be exempted, but instead be explicitly treated like cigarettes.

3. Legal Elements of the Proposal

3.1 Ingredients and emissions

"The proposal exempts tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products, i.e. cigars, cigarillos and pipe tobacco from some provisions [...]"

Suggested modification:

Generally no granting of exemptions.

Explanatory statement:

Generally, DKFZ is of the opinion that no exemptions should be granted at all. It is doubtlessly a very important aim to prevent young people from taking up tobacco consumption, as young people still have

¹ European Commission (2012) Attitudes of Europeans towards Tobacco. Special Eurobarometer 385, http://ec.europa.eu/public_opinion/archives/ebs/ebs_385_en.pdf, pp. 24 and 25

their whole lives ahead of them. The fewer young people start using tobacco, the lower tobacco-attributable morbidity and mortality will become in the future. However, older people have a right to the same level of health protection as young people. A high level of health protection is the basis of the various regulatory policies: *"In line with Article 114 TFEU a high level of health protection has been taken as a basis when choosing between different policy options identified in the review of the TPD. In this context, the proposal seeks to regulate tobacco products in a way that reflects their specific characteristics [...] and the negative consequences of their consumption [...]"*.

The exemptions granted for tobacco products which are consumed mainly by older people lead to inequalities in health protection of young people and of older people and they fail to take account of the fact that smoking cessation at any age of life leads to substantial gains in quality of life and life expectancy. Moreover, the different labelling might mislead young people into believing that tobacco products carrying the old warning labels are less damaging to health.

2. Regulation of ingredients

In its provisions for the regulation of ingredients, the proposal does not take sufficient account of the attractiveness-enhancing effect of tobacco additives. Well-known expert panels such as the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Tobacco Products Scientific Advisory Committee (TPSAC) of the U.S. Food and Drug Administration (FDA) confirm the particular relevance of the attractiveness-enhancing effect of tobacco additives in tobacco product regulation. The WHO Study Group on Tobacco Product Regulation already pointed out in its 2007 report entitled "*The scientific basis of tobacco product regulation: report of a WHO study group*"² that the regulation of contents and designs that influence product appeal for consumers is of fundamental importance, because these contribute indirectly to harm by influencing initiation of tobacco consumption, tobacco use, choice of product and long-term persistence of use.

In accordance with these expert opinions, the Partial Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC stipulate: "*From the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive.*" The text also emphasizes the particular relevance of the attractiveness-enhancing effect for tobacco product regulation: "*Attractiveness and its impact on dependence should be taken into account when considering regulatory measures. The guidelines on implementation of Article 13 of the WHO FCTC, on tobacco product advertising, promotion and sponsorship, recommend that restrictions apply to as many as possible of the features that make tobacco products more attractive to consumers.*"

2.1 Tobacco products with characterising flavour

Article 6.1

"Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.

Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products, as long as the additives do not result in a product with a characterising flavour."

Suggested modifications:

"Member States shall prohibit all additives which can increase the attractiveness or palatability of tobacco products. These include, among others, fruit, spices, herbs, alcohol, candy, menthol or vanilla and sweeteners.

Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products, as long as the additives do not increase attractiveness or palatability or fall under any of the categories listed in 7 a-c.

Explanatory statement:

Prohibiting "*tobacco products with characterising flavour*" is unsuitable. It is not specific tobacco products that should be prohibited but rather the use of specific additives. The Partial Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC point to the importance of additives that increase attractiveness, with 'attractiveness' being defined as follows: "*'Attractiveness' refers to factors such as taste, smell and other sensory attributes, ease of use, flexibility of the dosing system,*

² World Health Organization (2007) The scientific basis of tobacco product regulation: report of a WHO study group. WHO technical report series, no. 945, http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf, p. 18

cost, reputation or image, assumed risks and benefits, and other characteristics of a product designed to stimulate use." Furthermore, the text explains that various additives increase the attractiveness of tobacco products by making them more palatable: *"The harsh and irritating character of tobacco smoke provides a significant barrier to experimentation and initial use. Tobacco industry documents have shown that significant effort has been put into mitigating these unfavourable characteristics. Harshness can be reduced in a variety of ways including: adding various ingredients, [...]. Masking tobacco smoke harshness with flavours contributes to promoting and sustaining tobacco use."* Examples named of additives that can be used to improve the palatability of tobacco products include sweeteners, flavouring substances, spices and herbs.

The guidelines give the following recommendation for regulating additives that increase attractiveness: *"Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products."* The current phrasing, *"tobacco products with characterising flavour"* is unsuitable, because it prohibits specific tobacco products but not the use of specific additives. Instead, a ban on using additives that increase attractiveness should be phrased.

The restriction on characterising flavours is also unsuitable. Even the definition of *"characterising flavour"* is useless. It is defined 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."* According to a publication in British American Tobacco, it is the mixture of different types of tobacco which determines the character of a cigarette brand. The selection of tobacco varieties forms a brand's specific taste and aroma; additives only have the purpose of refinement³. Since each tobacco blend already has its own taste, it is not possible to clearly define *"the tobacco taste"* and, moreover, to define the flavours that modify it in a *"distinguishable"* or *"characterising"* way. In addition, the purpose of additives is precisely to refine the taste of tobacco, i.e. modify it without adding a clearly observable taste of its own.

For example, liquorice is added to tobacco products in quantities that do not make it unfold a characteristic flavour that could be distinguished from the tobacco's smell and taste. It just balances the tobacco flavour and, thus, improves its palatability. Moreover, glycyrrhizin contained in liquorice smoothes the harshness of the smoke and reduces dryness in the mouth and throat. Thus, it eases the smoking experience and hence also facilitates smoking initiation.

Sugar, which has no characteristic flavour of its own other than its sweetness, forms aromatic substances by pyrolysis, thus mitigating the harshness of the tobacco taste and enhancing the product's palatability. In addition, sugar, honey and other sweetening substances form carcinogenic substances by pyrolysis and, thus, contribute to the products' potential health hazards. Even completely odourless and tasteless additives such as the humectant propylene glycol produce carcinogenic substances during pyrolysis.

The restriction on characterising flavours made in the proposal does not satisfy the recommendation of the Partial Guidelines for Implementation of Article 9 and 10 of the WHO FCTC and fails to take into account that even substances which do not have a characteristic flavour of their own can increase the palatability of a tobacco product, particularly if used in combination with other additives.

Moreover, other substances that do not impact flavour or odour also increase the attractiveness of tobacco products. These include, for example, humectants, which increase product attractiveness by preventing tobacco from drying out and thus ensuring prolonged and constant product quality⁴. Yet another example are colours, which can be used for manufacturing coloured cigarettes, which are particularly appealing to youth.

3 British American Tobacco, BAT (2006) Cigaretten: Mehr als nur Tabak? Fragen und Antworten zur Verwendung von Zusatzstoffen. pp. 7, 9 and 13

4 Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR (2010) Addictiveness and Attractiveness of Tobacco Additives. http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_029.pdf, pp. 35 and 46

The second sentence of Article 6.1 does not define the additives that are essential for the manufacture of tobacco products. Additives that increase the attractiveness or palatability of tobacco products must not be permitted. On no account should it be permitted to use additives which contribute to toxicity, carcinogenicity or addictiveness of tobacco products in any way (see Explanatory statement under 2.3 and Appendix 2: Suggested list of additives to be banned).

Article 6.5

"Member States shall 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 not contain tobacco."

Suggested modifications:

"Member States shall prohibit the use of additives in the components of tobacco products such as filters, papers, packages, capsules or any technical features allowing modification of taste, smell or smoke intensity. In addition, filters and capsules shall not contain tobacco."

Explanatory statement:

Other substances apart from flavourings may also modify the smell, taste or smoke intensity (cf. Explanatory statement for Article 6.1). Therefore, the term "*flavourings*" should be replaced by "*additives*" and the term "*flavour*" should be replaced by "*smell*" and "*taste*".

2.2 Amplification of toxicity and addictiveness

Article 6.7

"Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of tobacco products [...]."

Suggested modifications:

"Member States shall prohibit all additives that

- a) are, in an unburned state, themselves toxic, carcinogenic or addictive or are suspected to cause cancer (these include, among others, glyoxal, salts and oxides of cobalt, talc),*
- b) contribute to toxicity, carcinogenicity or addictive effect (these include, among others, nitrate or ammonia compounds, cocoa),*
- c) during pyrolysis or if used as intended produce substances that are toxic, carcinogenic or addictive or that contribute to the toxic, carcinogenic or addictive effects of tobacco products (these include, among others, paraffins, waxes, oils, fats, sugars, pectins, starch, cocoa)."*

Explanatory statement:

In the explanatory memorandum of the proposal for a revised Tobacco Products Directive it says: "*In line with Article 114 TFEU a high level of health protection has been taken as a basis when choosing between different policy options identified in the review of the TPD.*"

In demanding to prohibit "*the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of tobacco products*," the proposal has not taken a high level of health protection as a basis. The proposal foresees only a ban on additives that increase in an appreciable manner the toxic or addictive effect. Considering the tremendous health risks and high addictive potential of tobacco products as such, it may be difficult to prove an increase in toxic and addictive effects, particularly since there are no approved measuring and testing methods for doing so. If at all, such effects are usually determined only for individual substances. Summations and interactions occurring in complex mixtures of substances such as tobacco smoke are not taken into account; neither is the effect of substances that are formed when the substances studied are pyrolysed.

Taking a high level of health protection as a basis, the regulation must be devised in a way that keeps toxic and addictive effects of tobacco products as low as possible. To ensure this, it is mandatory to prohibit all additives which by themselves are toxic, carcinogenic or addictive or contribute to the toxic or addictive effect (not: increase it in an appreciable manner). Only additives which are non-hazardous may be permitted. These are additives which by themselves are not toxic, carcinogenic or addictive as well as additives which, when consumed as intended, particularly when burned, do not form any toxic, carcinogenic or addictive substances.

2.3 Maximum levels

Article 6.3

"In case the experience gained in the application of paragraphs 1 and 2 shows that a certain additive or a combination thereof typically impart a characterising flavour when it exceeds a certain level of presence or concentration the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives or combination of additives that cause the characterising flavour."

Suggested modifications:

Delete this clause without replacement.

Explanatory statement:

Maximum values for individual additives do not make sense. There are no reliable methods for determining the level above which an additive imparts a flavour that is distinguishable from the tobacco taste or a taste that is distinguishable from the tobacco taste. Tobacco products contain complex mixtures of additives for which it is not possible to set maximum levels for individual substances. The substances may interact with each other and this may lead to new effects or increase the effect of individual substances. Consequently, maximum levels for individual substances in the mixture would not be valid. In addition, tobacco manufacturers can use several substances in small quantities, which are below the relevant maximum levels, and thus, by combining different substances, achieve similar effects as by using a higher dosage of an individual substance. Tobacco manufacturers are constantly refining these mixtures using both known and new substances. In this way, they can circumvent maximum levels.

Moreover, additives are used for fine-tuning tobacco taste without creating a specific flavour by themselves. This can be done using extremely small quantities so that, if only for this reason, setting maximum levels becomes irrelevant.

Likewise, it is not possible to define, using reliable methods, the levels below which an increase in attractiveness can be excluded.

Therefore, the option of setting maximum levels should be abandoned.

Article 6.9

"In case scientific evidence and the experience gained in the application of paragraphs 7 and 8 shows that a certain additive or a certain quantity thereof amplify in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives."

Suggested modifications:

Delete this clause without replacement.

Explanatory statement:

There are no reliable methods that could be used for setting maximum levels for additives that contribute to the toxic, carcinogenic or addictive effect of a tobacco product. Carcinogenic substances, in particular, do not have a threshold value below which there is no potential of health hazards.

Therefore, the option of setting maximum levels should be abandoned.

3. Reporting of ingredients and emissions

Article 5.1

"Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields. Manufacturers or importers shall also inform the competent authorities of the concerned Member States if the composition of a product is modified affecting the information provided under this Article. Information required under this Article shall be submitted prior to the placing of the market of a new or modified tobacco product."

The list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. The list shall indicate their status, including whether the ingredients have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)⁴⁷ as well as their classification under 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 mixtures⁴⁸. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health of consumers and taking into account, inter alia, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product. Other than for tar, nicotine and carbon monoxide and for emissions referred to in Article 4 paragraph 4, the manufacturers and importers shall indicate the measurement methods used. Member States may also require manufacturers or importers to carry out other tests as may be laid down by the competent national authorities in order to assess the effects of substances on health, taking into account, inter alia, their addictiveness and toxicity."

Suggested modifications:

*Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities **a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields as well as their complete toxicological characterisation.** [...] **Information required under this Article shall be submitted for all tobacco products that are available on the market as well as prior to the placing on the market of a new or modified tobacco product."** **For each additive, manufacturers and importers must demonstrate, by means of analysis methods according to state-of-the-art analytical science, that the substance does not fall within any of the categories defined in Article 6.1, 6.4, 6.5 or 6.7 that the substance itself is not toxic, carcinogenic or addictive, that the pyrolysis products of the substance are also not toxic, carcinogenic or addictive and that neither the substance nor its pyrolysis products contribute to the addictive effects of the tobacco product.** [...]*

The list shall also be accompanied by the toxicological data produced by the manufacturer or importer required under this Article regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health of consumers and taking into account, inter alia, any addictive effects.

Explanatory statement:

According to the current proposal by the European Commission for a new TPD, the Commission or a Member State must take measures for reviewing whether an additive falls within the categories

defined in Article 6.1, 6.4, 6.5 or 6.7. The same applies to reviewing whether an additive amplifies the toxic, carcinogenic or addictive effects of a tobacco product. This means that for an additive to be checked it must first seem suspicious to the Commission or a Member State. Thus, any additives which do not seem suspicious to a Member State or the Commission will not be reviewed.

Furthermore, Article 5.1 requires manufacturers and importers to submit only the toxicological data available to them, not all available data relating to this. Thus, it is left up to manufacturers and importers to select toxicological data and it is not ensured that toxicological data relevant for regulation are provided.

However, from a health policy perspective, it is necessary to make sure that no potentially harmful additives are used. To prevent the use of unchecked or insufficiently checked additives, manufacturers and importers must be required to check every additive for its harmlessness using measuring methods that correspond to the state of the art in analytical science. Moreover, they must provide proof that the additive does not increase either the attractiveness or the palatability of the product (cf. Explanatory statement on Article 6.1). The toxicological characterization must exclude any possibility of the substance itself or its pyrolysis products contributing in any way to the tobacco product's toxic, carcinogenic or addictive effects. Only additives whose harmlessness has been proven in this way may be used in tobacco products.

4. Labelling and packaging

Health warnings defined in the proposal correspond to FCTC recommendations and the respective guidelines. Standardised packaging may increase the effectiveness of warning labels.

5. Nicotine-containing products

Article 18

"Nicotine-containing products

1. *The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC: (a) products with a nicotine level exceeding 2 mg per unit, or (b) products with a nicotine concentration exceeding 4 mg per ml or (c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.*
2. *The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.*
3. *Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:*
This product contains nicotine and can damage your health.
4. *The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:*
 - (a) be printed on the two largest surfaces of the unit packet and any outside packaging*
 - (b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.*
5. *The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings."*

Suggested modifications:

Delete 1.-5. and replace by:

"Nicotine-containing products or nicotine-free products that are consumed in the same way as tobacco for smoking, may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC."

Explanatory statement:

Article 18.1 makes novel nicotine-containing products such as electronic cigarettes subject to the same legal framework as nicotine-containing products that have already received market authorisation pursuant to Directive 2001/83/EC (Nicotine Replacement Therapies, NRTs). Since authorisation of already approved nicotine-containing products was dependent on their nicotine content, the proposal applies the same authorisation method to novel nicotine-containing products. This implies potential use of novel nicotine-containing products in tobacco cessation.

One approach in tobacco cessation is stepwise reduction of nicotine intake. For this purpose, conventional nicotine replacement therapy uses products with varying nicotine levels. Novel nicotine-containing products available for stepwise reduction also include products with very low nicotine levels and those containing no nicotine at all. Novel nicotine-containing products differ from already authorised ones in an important aspect: the way in which nicotine is delivered. Novel nicotine-containing products are consumed like tobacco for smoking so that the smoking habit and the characteristic smoking process are initially maintained. Thus, even products containing no nicotine are capable of mitigating withdrawal symptoms^{5,6,7}. Consequently, low-nicotine and nicotine-free products are part of the therapy process and hence need to be regulated in the same way as products with higher nicotine levels.

In addition, nicotine-containing products currently available on the European market allow one to load basic delivery devices with various nicotine quantities. The regulation as proposed can easily be circumvented because it is possible to load commercially available low-nicotine products with higher nicotine quantities from the pharmacy.

Therefore, all nicotine-containing products regardless of their nicotine content as well as nicotine-containing and nicotine-free products which are consumed like tobacco for smoking must be regulated according to Directive 2001/83/EG.

5 Etter JF & Bullen C (2011) Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction* 106(11): 2017-2028

6 Bullen C, McRobbie H, Thornley S, Glover M, Lin R & Laugesen M (2010) Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial. *Tob Control* 19(2): 98-103

7 Dawkins L, Turner J, Hasna S & Soar K (2012) 2012 The electronic cigarette – Effects on desire to smoke, withdrawal symptoms and cognition. *Addict Behav* 37/8: 970-973

Appendix 1

Some of the cited modifications make it necessary to modify various other text passages in the proposal which refer to the modified items.

Changes pertaining to the exemptions:

1) Explanatory memorandum, 1. Context of the proposal:

This is also reflected in the selection and focus of the proposed policy areas and the products primarily targeted (cigarettes, roll-your-own and smokeless tobacco products).

Replace by:

This is also reflected in the selection and focus of the proposed policy areas and the products primarily targeted (cigarettes, roll-your-own tobacco, waterpipe tobacco and smokeless tobacco products).

2) Explanatory memorandum, 3. Legal elements of the proposal, 3. Ingredients and emissions, 3.1 Ingredients and emissions:

The proposal exempts tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products, i.e. cigars, cigarillos and pipe tobacco from some provisions such as the prohibition of products with characterising flavours.

Delete exemption or at least replace by:

The proposal exempts tobacco products other than cigarettes, roll-your own tobacco, waterpipe tobacco and smokeless tobacco products, i.e. cigars, cigarillos and pipe tobacco from some provisions such as the prohibition of products with characterising flavours.

3) Explanatory memorandum, 3. Legal elements of the proposal, 3. Ingredients and emissions, 3.2 Labelling and packaging:

The proposal exempts tobacco products other than cigarettes and roll-your own tobacco from larger health warnings.

Delete exemption or at least replace by:

The proposal exempts tobacco products other than cigarettes, roll-your own tobacco and waterpipe tobacco from larger health warnings.

4) Proposal 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

- *(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco which are mainly consumed by older consumers, should be granted an exemption from certain ingredients requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people.*

Delete exemption or at least replace by:

Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco, waterpipe tobacco and smokeless tobacco which are mainly consumed by older consumers, should be granted an exemption from certain ingredients requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people.

- (24) Tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers, should be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people.

Delete exemption or at least replace by:

Tobacco products for smoking, other than cigarettes, roll-your-own tobacco and waterpipe tobacco products, which are mainly consumed by older consumers, should be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people.

- (38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, , the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products.

Delete exemption or at least replace by:

In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, , the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco, waterpipe tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products.

5) Title I - Common Provisions

- **Article 2 Definitions: Add definition for waterpipe tobacco**
- **Article 6.10:** Tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products shall be exempted from the prohibitions laid down in paragraphs 1 and 5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is a substantial change of circumstances as established in a Commission report.

Delete exemption or at least replace by:

Tobacco products other than cigarettes, roll-your-own tobacco, waterpipe tobacco and smokeless tobacco products shall be exempted from the prohibitions laid down in paragraphs 1 and 5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is a substantial change of circumstances as established in a Commission report.

- *Article 10.1: Tobacco for smoking other than cigarettes and roll-your-own tobacco shall be exempted from the obligations to carry the information message laid down in Article 8(2) and the combined health warnings in Article 9.*

Delete exemption or at least replace by:

Tobacco for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco shall be exempted from the obligations to carry the information message laid down in Article 8(2) and the combined health warnings in Article 9.

- *Article 13.4: The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to make either cuboid or cylindrical shape mandatory for unit packets of tobacco products other than cigarettes and roll-your-own tobacco if there is a substantial change of circumstances as established in a Commission report.*

Delete exemption or at least replace by:

The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to make either cuboid or cylindrical shape mandatory for unit packets of tobacco products other than cigarettes, roll-your-own tobacco and waterpipe tobacco if there is a substantial change of circumstances as established in a Commission report.

- *Article 14.10: Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the application of paragraph 1 to 8 during a period of 5 years following the date referred to in paragraph 1 of Article 25.*

Delete exemption or at least replace by:

Tobacco products other than cigarettes, roll-your-own tobacco and waterpipe tobacco shall be exempted from the application of paragraph 1 to 8 during a period of 5 years following the date referred to in paragraph 1 of Article 25.

Changes pertaining to tobacco products with characterising flavours:

1) Explanatory memorandum, 3. Legal elements of the proposal, 3. Ingredients and emissions, 3.1 Ingredients and emissions:

The proposal foresees that tobacco products with characterising flavours, such as fruit flavours or chocolate, are prohibited.

Replace by:

The proposal foresees that tobacco products with additives that can increase the attractiveness or palatability of tobacco products are prohibited.

2) Proposal 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

- *(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufactures to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives necessary for manufacturing of tobacco products should be allowed, as long as they do not result in a characterising flavour.. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.*

Delete this paragraph without replacement.

- *(37) In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting, the determination of products with characterising flavours or with increased levels of toxicity and addictiveness and the methodology for determining whether a tobacco product has characterising flavour, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.*

Replace paragraph by:

In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting, the determination of products with additives that can increase the attractiveness or palatability of tobacco products or with increased levels of toxicity and addictiveness and the methodology for determining whether a tobacco product contains additives that can increase the attractiveness or palatability of tobacco products, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

3) Title I – Common provisions, Article 2, Definitions (4):

Delete this definition without replacement

4) Title II – Tobacco products, Chapter I: Ingredients and emissions, Article 6.2:

The Commission shall at the request of a Member State or may on its own initiative determine by means of implementing acts whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

The Commission shall adopt by means of implementing acts uniform rules on the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Replace by:

The Commission shall at the request of a Member State or may on its own initiative determine by means of implementing acts whether an additive falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

The Commission shall adopt by means of implementing acts uniform rules on the procedures for determining whether an additive falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Changes pertaining to maximum levels:

Proposal 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

(38) [...] *setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, [...]*

Delete this sentence without replacement.

Changes pertaining to nicotine-containing products:

1) Explanatory memorandum, 3. Legal elements of the proposal 3.7 Nicotine-containing products:

[...] NCP that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance. NCP with nicotine levels below this threshold can be sold as consumer products provided they feature an adapted health warning. The nicotine threshold identified in this proposal has been established by considering the nicotine content of medicinal products (Nicotine Replacement Therapies, NRTs) for smoking cessation which have already received a market authorisation under the medicinal products' legislation. [...]

The labelling requirement set out in this proposal for NCP containing nicotine below the identified threshold will better inform consumers about the health risks associated with the products.

Replace by:

Nicotine-containing products or nicotine-free products that are consumed in the same way as tobacco for smoking may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance.

And

Delete without replacement:

NCP with nicotine levels below this threshold can be sold as consumer products provided they feature an adapted health warning. The nicotine threshold identified in this proposal has been established by considering the nicotine content of medicinal products (Nicotine Replacement Therapies, NRTs) for smoking cessation which have already received a market authorisation under the medicinal products' legislation. [...]

The labelling requirement set out in this proposal for NCP containing nicotine below the identified threshold will better inform consumers about the health risks associated with the products.

2) Proposal 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

- (34) [...] *Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework [...]*

Replace by:

Subjecting all nicotine-containing products or nicotine-free products that are consumed in the same way as tobacco for smoking to the same legal framework [...]

- (35) *Labelling provisions should be introduced for nicotine containing products below the threshold set out in this Directive drawing the attention of consumers to potential health risks.*

Delete this paragraph without replacement.

Appendix 2

Suggested list of additives to be banned in the proposed revision of EUTPD

Banned additives in Tobacco products

I. Synthetic and natural substances in any form (pure substances, extracts, oils, distillates, balms, among others), with flavoring properties that can impart, intensify, modify or enhance the flavor of the product, including additives identified as flavoring agents including

- *additives identified as flavouring agents by the Joint FAO/WHO (Food and Agriculture Organization of the United Nations /World Health Organization) Expert Committee on Food Additives in the Committee's evaluations, as published from time to time in the WHO Technical Report Series*
- *additives identified as flavouring substances by the Flavor and Extract Manufacturers Association (FEMA) Expert Panel in its lists of GRAS (Generally Recognized as Safe) flavouring substances referred to as "GRAS 3" to "GRAS 24" and subsequent GRAS lists, as published from time to time, if any*

II. Additives with nutritional properties

1. *Fruits, vegetables or any product obtained from the processing of a fruit or vegetable*
2. *Ameliorants*
3. *Amino acids*
4. *Essential fatty acids*
5. *Spices, seasonings and herbs*
6. *Sugars and sweeteners such as honey molasses,*
7. *Vitamins and Probiotics*
8. *Mineral nutrients, excluding those necessary to manufacture the tobacco product*

III. Additives associated with alleged stimulating or invigorating properties e.g.

1. *taurine*
2. *guarana*
3. *caffeine*
4. *glucuronolactone*

IV. Ammonia or any compounds and derivatives

V. Pigments /Colouring agents

excluding those used to whiten paper or the filter or to imitate a cork pattern on tipping paper

The following additives are excluded from the ban for the next [date to be set] years*:

- *benzoic acid (CAS 65-85-0) and its salts*
- *butylated hydroxytoluene (CAS 128-37-0)*
- *carboxy methyl cellulose (CAS 9000-11-7)*
- *citric acid (CAS 77-92-9) and its salts*
- *ethanol (CAS 64-17-5)*

- *ethoxylated sorbitan monolaurate (CAS 9005-64-5)*
- *fumaric acid (CAS 110-17-8)*
- *glycerol (CAS 56-81-5)*
- *guar gum (CAS 9000-30-0)*
- *n-propyl acetate (CAS 109-60-4)*
- *paraffin wax (CAS 8002-74-2)*
- *propylene glycol (CAS 57-55-6)*
- *rosin glycerol ester (CAS 8050-31-5)*
- *sodium acetate anhydrous (CAS 127-09-3)*
- *sodium alginate (CAS 9005-38-3)*
- *sorbic acid (CAS 110-44-1) and its salts*
- *triacetin (CAS 102-76-1)*
- *tributyl acetylcitrate (CAS 77-90-7)*
- *activated charcoal*
- *starch*

* A period of 24 months to be granted to manufacturers for modifying tobacco products to exclude additives such as glycerol, polypropylene glycol, guar gum that are known to produce toxic pyrolysis products. For examples technology exists for replacing humectants with water as exemplified by several brands in Germany and UK which claim to contain only tobacco plus water according to the manufacturers.

In the future any further additive that the manufacturer wants to use should be proven harmless, and approved by an Expert committee of independent scientists.