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OPINION

of the Committee on Legal Affairs

for the Committee on the Environment, Public Health and Food Safety

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
(COM(2012)0788 – C7-0420/2012 – 2012/0366(COD))

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SHORT JUSTIFICATION

It is universally accepted today that tobacco consumption poses serious risks to human health. In this regard, it is particularly worrying that most smokers start before the age of 18. Therefore, young people in particular have to be fully informed about the toxicity and addictiveness of tobacco products. For those who already consume tobacco products, the promotion and development of less harmful products and products for smoking cessation is essential.

There is no doubt that efforts to reduce tobacco consumption should continue at national as well as at international level. However, certain provisions of the Commission's proposal raise significant legal concerns. These concerns relate, *inter alia*, to the legal base chosen by the Commission, to fundamental rights such as the right to property and to the principle of proportionality.

The Commission bases its proposal on Article 114(1) TFEU. This provision allows approximation measures aimed at improving the conditions for the establishment and functioning of the internal market. The measures must "*genuinely have that object, actually contributing to the elimination of obstacles to the free movement of goods or to the freedom to provide services, or to the removal of distortions of competition*".¹ Some of the measures proposed by the Commission, however, do not aim at improving the conditions of the internal market, but have as their only objective the protection of public health.

For example, it is difficult to see how the proposed (de facto) ban on menthol and on slim cigarettes could improve the functioning of the internal market. It is true that even prohibitions may, in certain circumstances, be regarded as harmonising measures, but this is only the case where "*there are obstacles to trade or it is likely that such obstacles will emerge in future*".² Currently, however, not a single Member State has banned slim cigarettes or menthol or is even considering it. Thus, the ban will neither remove nor prevent the emergence of obstacles to fundamental freedoms.³

As reflected in the recitals of the Commission's proposal, the true aim of these measures is the achievement of a higher level of health protection. It is feared that menthol and slim cigarettes might be particularly attractive to young people.⁴ While the protection of health is of the utmost importance, it is up to the Member States and not the European Union to take measures in that regard. Article 168(5) TFEU explicitly excludes any harmonisation regarding measures "*having as their direct objective the protection of public health regarding tobacco*".

¹ Case C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 60.

² Case C-210/03, *Swedish Match*, paragraphs 30, 33.

³ There is also no obligation to ban menthol only because other flavours are banned. The Commission's proposal makes reference to a decision of a WTO Appellate Body (WTO Appellate Body, AB-2012-1, United States – Measures Affecting the Production and Sale of Clove Cigarettes (DS406)). This decision, however, only said that menthol and clove cigarettes were, under the specific circumstances of the case, "like products" and that they could not be treated differently. The WTO Appellate Body did not reason that the US could not distinguish between menthol and other characteristic flavours such as fruit and candy flavours.

⁴ See e.g. recital 15: "*A number of studies indicated that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people.*" and recital 23: "*A recent study has also shown that smokers of slim cigarettes were more likely to believe that their own brand might be less harmful. This should be addressed.*"

The Commission can only take a high level of health protection as a basis pursuant to Article 114(3) TFEU if the requirements of Article 114(1) TFEU are fulfilled.¹ Otherwise, the European Union could circumvent the clear division of competences resulting from Article 168(5) TFEU.

Some provisions in the Commission's proposal also raise serious doubts as to their conformity with fundamental rights such as the right to property, the right to freedom of expression and information and the freedom to conduct business. These rights are enshrined in the Charter of Fundamental Rights of the European Union ("the Charter") and may only be limited pursuant to Article 52(1) of the Charter if the limitation is necessary, genuinely meets objectives of general interest and is proportional.

Certain of the proposed measures, especially regarding the packaging, do not meet these requirements. One example is the proposed increase in size of the health warnings to 75 % of both the front and back surface of the packs (Article 9(1)(c)). This would severely reduce the space available for trademarks and product description. In practice, not even 25 % of the front and back surface would be available for the information provided by the producer, as national law requires additional features such as tax stamps and security features.

Intellectual property rights such as trademarks are explicitly covered by the right to property in Article 17 of the Charter. The CJEU held that warnings on the unit packages are admissible *"in a proportion which leaves sufficient space for the manufacturers of those products to be able to affix other material, in particular concerning their trademarks"*.² Reducing the space available on the front and back surfaces to less than 25% would, however, make it difficult to sufficiently distinguish the products of one producer from those of others, thereby depriving the trade marks of one of their main functions. The trade marks could also not properly fulfil their other functions such as its advertising function. This would also not be in accordance with national constitutional law³ as well as international treaties such as the TRIPS Agreement.⁴

Bearing in mind the impact on intellectual property rights, it is more than surprising that the Commission did not even consider less restrictive measures such as smaller health warnings. Taking into account the importance of intellectual property rights and legitimate health objectives, it is suggested that health warnings should cover 50 % of the front and back surface. This would also be in line with the FCTC, the implementation of which is one of the aims of the Commission's proposal. Pursuant to Article 11(1) of the FCTC, health warnings describing the harmful effects of tobacco use *"should be 50% or more of the principal display*

¹ See C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 62.

² Case C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 132.

³ See for example the judgment of the German Federal Constitutional Court, BVerGE 95, 173, paragraph 70.

⁴ See e.g. Article 8.1 and 20 TRIPS. Contrary to what is sometimes asserted, the decision of the Australian High Court of 15 August 2012 regarding the compatibility of the so-called plain packaging rules with the Australian Constitution does not in any way suggest that plain packaging or similar measures would be in accordance with European law. Pursuant to section 51 of the Australian Constitution, a law violates the Australian Constitution if it deprives a person or company from its property and provides the Australian government with some proprietary benefit from that property. The plain packaging requirement was upheld because the Australia had not "acquired" the property. However, the Court found that plain packaging does indeed "deprive" tobacco manufacturers of their property. Under Article 17 of the Charter and thus EU law, an "acquisition" of property is no precondition for a breach of the right to property – a deprivation is sufficient. Therefore, if anything, the judgment of the Australian High Court speaks against the admissibility of similar measures under EU law.

areas but shall be no less than 30% of the principal display areas".

Other measures proposed by the Commission regarding the size and appearance of unit packs and regarding the product description meet similar concerns regarding fundamental rights. They deprive manufacturers of their intellectual property rights, reduce customer choice and do not contribute to a better functioning of the internal market.

By prohibiting any labelling that suggests that a particular tobacco product is less harmful than others, the proposal causes an additional problem. The development and promotion of less harmful means of tobacco use is essential in order to support tobacco users to stop smoking cigarettes and the like. Manufacturers must be able to communicate that a certain product is less harmful than others if this is scientifically proven and if it is not misleading. This is not the only measure proposed that would make it more difficult to access reduced risk products. Article 18 of the proposal prohibits nicotine-containing products (NCP) such as e-cigarettes containing a certain nicotine level if they are not authorised pursuant to Directive 2001/83/EC (the Medicinal Products Directive). It is, however, quite unclear if these products (which are much less harmful than tobacco products) even fall under the scope of the Medicinal Products Directive.¹ For products which do not fall under the Directive, this would effectively constitute a ban. Banning products which are less harmful than tobacco products and which can be a means of smoking cessation is certainly not in line with the public health aims of the proposal.²

Finally, the Commission's proposal contains a large number of provisions delegating powers to the Commission. However, pursuant to Article 290 TFEU, a delegation of powers is only possible with regard to non-essential elements of the legislative proposal. Some of the proposed provisions providing for delegated acts do not fulfil this requirement. For example, Article 3(2) in conjunction with Article 2(19) would grant the Commission to set the maximum yield of nicotine for cigarettes placed on the market to 0, effectively prohibiting cigarettes for good.

AMENDMENTS

The Committee on Legal Affairs
calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

¹ Relying on the strict jurisprudence of the CJEU, several national courts have already held that e-cigarettes cannot be qualified as a medicinal product by function under the Medicinal Products Directive, see e.g. Oberverwaltungsgericht Nordrhein-Westfalen, 24 April 2012, 16 L 2043/11.

² Article 18 also lacks a valid legal base as it is in no way aimed at improving the conditions for the establishment and functioning of the internal market. Pursuant to the Commission, the provision will allow NCP to move freely across borders as they would benefit from the mutual recognition procedure under the Medicinal Products Directive (Impact Assessment, page 8). However, this is already the case without Article 18, as any NCP which qualifies as a medicinal product is already now subject to the Medicinal Products Directive. The only effect Article 18 has is that it prohibits the placing on the market of NCP that are not authorised pursuant to the Medicinal Products Directive.