



EUROPEAN COMMISSION

Brussels, 25.6.2013
C(2013) 3881 final

Dear President,

The Commission would like to thank the Senato della Repubblica for its Reasoned Opinion 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) 788 final}.

The Commission would like to make the following remarks.

The Commission welcomes the Senato della Repubblica's support for the need to discourage young people from taking up tobacco smoking.

The Senato della Repubblica considers that the proposal would not be covered by its legal basis, Article 114 TFEU, on the grounds that it would allow Member States to adopt stricter measures under Article 24 of the proposal and would encourage Member States to act autonomously in various areas, such as measuring emissions other than tar, nicotine and carbon monoxide, and with regard to regulating novel products. The Commission would like to underline that in areas not covered by a Directive, Member States remain free to take measures provided they comply with the Treaty. Also in areas covered by a Directive stricter measures remain possible, even if subject to stringent conditions. Article 114 TFEU contains a legal basis for full, partial or minimum harmonization and can leave certain matters to the Member States to regulate. The already achieved level of harmonisation needs to be taken into account when assessing the compatibility of stricter national measures with the Treaty.

Moreover, the Senato della Repubblica considers that the proposed delegation of powers in the proposal, such as in Article 3(2) on the adaptation of the maximum levels of tar, nicotine and carbon monoxide yields to scientific developments and internationally agreed standards, would not meet the requirements laid down by Article 290 TFEU. The Commission would like to stress that in order to make this Directive fully operational in the view of technical, scientific and international developments in the tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 TFEU has been deemed necessary. The delegations of power in the proposal provide for clear and concise criteria, giving limited discretion to the Commission. The Commission would involve the Member

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States in the preparation of these acts and would ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Furthermore, the Senato della Repubblica considers that the proposal would violate the principle of subsidiarity by de facto banning low-risk or novel products, thus preventing Member States from implementing a health policy that reduces the risks associated with tobacco smoke. The Commission would like to emphasize that the proposal would not impose restrictions on the placing on the market of low-risk products and would not discourage investment in research, innovation and development into such or other products. The regulatory framework for novel products would not be modified in substance compared to the regime under the current Tobacco Products Directive. Any claims that certain products were less harmful than others could mislead consumers and are banned already under the current Tobacco Products Directive. The proposal only provides that novel tobacco products must be notified to the national authorities before they can be placed on the market. This represents a limited burden on the stakeholders concerned taking into account that the proposal foresees in its article 5.2. that information on ingredients is provided to the national authorities for any new or modified tobacco product before the product is placed on the market.

The Senato della Repubblica also considers that the prohibition of slim cigarettes and products with a characteristic flavour, as well as the prohibition of packets of 10 cigarettes would not be justified, would lead to fragmentation of the internal market, standardisation, a decrease in prices and the spread of the black market. The Commission would like to underline that it has provided scientific evidence with regard to all of the mentioned issues, showing the misleading nature of slim cigarettes and the attractiveness of products with a characteristic flavour especially for young people. Several studies have found that slim cigarettes can mislead consumers by creating the impression that they are less harmful¹.

Moreover, it has been found that the shapes and colours of individual cigarettes can mislead consumers e.g. by creating the impression that they are less harmful.

With respect to characterising flavours, scientific studies and market data have shown that flavours influence and enhance smoking initiation. Moreover, as Member States have started to adopt measures to regulate flavours, the Commission proposes harmonisation to prevent distortions of the market. This will facilitate the free movement of goods, whilst remaining neutral in terms of tobacco varieties. The Framework Convention for Tobacco Control guidelines also recommends its Parties, including the EU and Italy, to take action in this area. The Commission would also like to stress that the proposal would only standardise certain aspects of the pack such as the number of cigarettes contained in a pack and the size of health warnings, which is beneficial for the circulation of the products on the internal market whilst ensuring the full visibility of the health warnings. In the Commission's opinion, the proposed rules on packaging would not increase the risk of illicit trade. During the public consultation no evidence was presented to substantiate any such claims. In any event the proposal foresees effective measures against illicit trade. The Commission is therefore of the view that its proposal would reduce illicit trade.

¹ see 24th recital of the proposal

Finally, the Senato della Repubblica considers that greater attention should be paid to electronic cigarettes. The Commission would like to underline that the proposal would extend the product scope to nicotine containing products, requiring a market authorisation under pharmaceutical legislation for such products as is already foreseen in some Member States, and imposing health warnings for all other such products. Currently binding safety standards do not exist for such products and the efficacy of the products as a smoking cessation aid are not verified. In this light subjecting the products with a high nicotine content to an authorisation under pharmaceutical legislation would be a major step forward.

The Commission hopes that these clarifications address the comments and concerns raised by the Senato della Repubblica and looks forward to continuing our constructive political dialogue in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*