



EUROPEAN COMMISSION

Brussels, 25.6.2013
C(2013) 3896 final

Dear President,

The Commission would like to thank the Vouli ton Ellinon 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 Vouli ton Ellinon considers that the proposal would violate the principle of subsidiarity by prohibiting any special claims with regard to novel tobacco products. The Commission would like to underline that the proposal would not impose restrictions on the placing on the market of novel products (including 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 need to 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 would be provided to the national authorities for any new or modified tobacco product before the product is placed on the market.

*The Vouli ton Ellinon considers that the differences in national policies would not justify legislation at EU level. The Commission would like to stress that recourse to Article 114 TFEU as a legal basis is also possible if the aim is to prevent the emergence of future obstacles to trade resulting from divergent development of national laws. The emergence of such obstacles must be likely and the measures in question must be designed to prevent the discrepancies (see C-491/01 *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.* [2001] ECR I-11453, p 61). This (existing or likely) disparity must have (actually or probably) the effect of creating an obstacle to trade, by preventing a product or service from moving freely within the Union or by appreciably distorting competition on the internal market. Measures related to scope, labelling and ingredients typically are product*

Mr Evangelos MEIMARAKIS
President of the
Vouli ton Ellinon
11, Av. Vassilissis Sofias
GR – 10021 ATHENS

requirements that are liable, in the absence of harmonisation at EU level, to constitute obstacles to the free movement of goods. The Commission would also like to stress that in already harmonised areas it is possible to adapt the level of harmonisation in the light of new scientific evidence. It is also legitimate to propose measures under Article 114 TFEU that ensure that the safeguards of EU legislation are not undermined, e.g. through illicit trade.

The Vouli ton Ellinon also considers that the prohibition of slim cigarettes and products with a characterising flavour such as menthol would not be justified, would lead to interference with the internal market, prevent free competition in the tobacco industry and would increase smuggling. The Commission would like to emphasize 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 characterising flavour especially for young people. Several studies have found that slim cigarettes can mislead consumers by creating the impression that they are less harmful.¹ 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 would 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 Greece, to take action in this area. It is not compatible with international law to exempt certain flavours from the ban on products with characterising flavours.

The Vouli ton Ellinon furthermore considers that the proposal would abolish differentiation in packaging and impact negatively on the quality of tobacco. It also questions the usefulness of pictorial health warnings, referring to data from Eurobarometer 2012. The Commission would like to mention that various studies have shown the effectiveness of pictorial health warnings and that there are currently important disparities in national regulations on packaging and labelling creating market distortions and unequal protection of EU citizens. The Commission would like to point out that according to the Eurobarometer 2012, 76% of EU citizens are in favour of using pictorial warnings, and in 17 Member States pictorial health warnings attract the highest level of support among all possible tobacco control measures. The Commission would also like to underline that the proposal would only standardise certain aspects of the pack such as the number of cigarettes contained in a packet 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.

The Vouli ton Ellinon further considers that Article 24 (2) of the proposal allowing Member States to adopt stricter measures would go against the basic aim of harmonising national policies. The Commission would like to point out that Article 114 TFEU

¹ see 24th recital of the proposal

contains a legal basis for full, partial or minimum harmonization and can leave certain matters to the Member States to regulate.

Finally, the Vouli ton Ellinon 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 development and internationally agreed standards, would not meet the requirements laid down by Article 290 TFEU. The Commission would like to underline 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 Member 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.

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

Yours faithfully,

*Maroš Šefčovič
Vice-President*