EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels,
D(2012)

Opinion

Title **DG SANCO – Impact Assessment on a Proposal for a Revision of the Tobacco Product Directive**

(revised draft version of 11 June 2012)*

(A) Context

The current Directive 2001/37/EC 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 products (Tobacco Products Directive) regulates the functioning of the internal market in tobacco products and sets out certain requirements in terms of tobacco products content, labelling and reporting. The present revision seeks to bring the Directive in line with market, scientific and international developments, and to further improve the functioning of the internal market.

(B) Overall assessment

While the report has been improved to some extent along the lines of the Board's first opinion, the evidence presented, in terms of concrete obstacles for economic operators affecting the functioning of the relevant markets, remains weak. It does not adequately support internal market based EU legislative action in the non-harmonised areas, particularly for restrictions on tobacco promotion at the point of sale, and to prohibit chewing and nasal tobacco. The report should better explain why not all Member States are expected to implement their legal obligations stemming from the WHO Framework Convention on Tobacco Control (FCTC). It should also better clarify to what extent the principle of establishing equality in health protection is compatible with the discretion of Member States in defining their health policies. The report should further demonstrate the proportionality of subjecting nicotine-containing products (e-cigarettes) to the same authorisation process as medicinal products or of introducing a notification procedure for internet sales. The report should also better explain how the regulatory divergences which are likely to persist at national level (e.g. on regulation of ingredients) were taken into account in the analysis of costs and benefits. It should then assess in greater detail the administrative costs for national authorities, particularly those stemming from the new notification system for internet sales. Finally, uncertainties related to the effectiveness of the identified tobacco control measures should be reflected in the conclusions.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

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(C) Main recommendations for improvements

(1) Better present the problems. Based on the improved description of the current Directive and the concrete obligations stemming from the WHO FCTC on Member States, the report should further strengthen the problem definition by presenting separately the problems related to: (i) the effectiveness, (ii) implementation and (iii) enforcement of the Directive and (iv) the currently non-harmonised issues. For the non-harmonised areas (i.e. e-cigarettes, herbal products for smoking, packaging, tobacco vending machines) and for the issue of tobacco promotion and display at the point of sale (PoS) in particular, the report needs to further demonstrate that the conditions for recourse to Article 114 TFEU are fulfilled. In doing so, it should better take into account that the presented evidence does not suggest any significant negative impacts of the current situation on the functioning of the internal market. Finally, the report should clarify to what extent the strengthened argumentation on inequality in health protection is compatible with Member States' competences in defining their health policies.

(2) Develop a robust baseline scenario. The report indicates that the tobacco market is likely to grow, despite the foreseeable actions at national level. It should further explain why not all Member States are expected to take further actions, despite their legal obligations stemming from the WHO FCTC. The report should analyse in greater depth the likely take-up of smokeless tobacco products (STP), taking into account the currently outdated health warnings, better explaining the circumvention possibilities of the ban on oral tobacco and better acknowledging the uncertainty related to the role of STP as a substitution to smoking and its possible health implications.

(3) Better demonstrate the proportionality of policy options. This could be done by separately presenting the measures that go beyond the provisions of the existing Directive and the legally binding WHO FCTC obligations and by discussing a wider range of discarded policy options. In particular, the report should better justify the legal feasibility and proportionality of prohibiting STP altogether (i.e. chewing and nasal tobacco on top of the currently banned oral tobacco), as well as the proportionality of subjecting e-cigarettes to the medicinal regulatory framework and introducing a notification procedure for internet sales. With respect to alternative ban options (e.g. on internet sales, tobacco vending machines or PoS) the report still does not provide evidence-based justification for presenting these as internal market enhancing measures. In addition, the report should explain which Member States would qualify for derogation from an STP ban, based on the criteria of "significant prevalence" and how the electronic age verification for tobacco vending machines and the authorisation of e-cigarettes would work in practice. Finally, it should provide greater clarity on the underlying obligations on traceability stemming from the WHO FCTC and the forthcoming Illicit Trade Protocol.

(4) Improve the assessment of impacts. While being more transparent on the overall costs and benefits for economic actors and consumers, the report should better explain how the divergences that are likely to persist at national level (such as those related to the regulation of ingredients) were taken into account. The cost/benefit ratios based on discounted values of costs and benefits should be presented in the main text of the report. It should also assess in greater detail the administrative costs for national authorities, particularly linked to the notification system for internet sales, which the revised report considers to be "limited". The report should better present the overall health impacts and risks related to new products and ingredients and on this basis it should clarify how the contributions of individual policy areas to the reduction of tobacco consumption were

calculated. In doing so, it should adequately show where the available evidence on the effectiveness of tobacco control measures is inconclusive, such as with respect to STP, packaging or PoS. The report should analyse the overall benefits of further market harmonisation in a more differentiated manner and acknowledge more explicitly the trade-offs between impacts on the internal market and public health protection, for instance in the area of PoS restrictions.

(D) Procedure and presentation

The report exceeds the recommended page limit and should be shortened. In particular, numerous duplications should be avoided and overlapping sections merged. Furthermore, the detailed overview of the market could be moved to an Annex.

(E) IAB scrutiny process	
Reference number	2010/SANCO/014
External expertise used	No
Date of Board Meeting	Written procedure This opinion concerns a resubmitted draft IA report. The first opinion was issued on 20 April 2012.

EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels,
D(2012)

Opinion

Title **DG SANCO – Impact Assessment on a Proposal for a Revision of the Tobacco Product Directive**

(draft version of 21 March 2012)

(A) Context

The current Directive 2001/37/EC 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 products (Tobacco Products Directive) regulates the functioning of the internal market in tobacco products and sets out certain requirements in terms of tobacco products content, labelling and reporting. The present revision seeks to bring the Directive in line with market, scientific and international developments, and to further improve the functioning of the internal market.

(B) Overall assessment

The report requires significant further work on several important aspects, particularly with regard the need for further EU harmonisation of tobacco and related products. First, it should better evaluate the functioning of the existing Directive and identify more clearly problems related to its effectiveness, implementation and enforcement while clarifying related public health aspects. In this context, the report should better explain the rationale for more stringent tobacco control measures implemented or envisaged at national level and should demonstrate to what extent the present Directive may prevent Member States from maintaining a high level of health protection. It should provide more convincing evidence on the scale of problems related to the fragmentation of the internal market as well as their likely evolution, particularly in view of the implementation of international obligations. Second, the report should better explain measures envisaged under each of the policy options, including the foreseen delegated powers, and should demonstrate their proportionality vis-à-vis the enhancement of the internal market. Third, the report should better assess and substantiate the overall economic and social/health impacts of further harmonisation. Against this background, the report should better justify the preferred policy options in terms of their effectiveness, efficiency and coherence. Finally, the different views of stakeholders should be transparently reported throughout the report and the evidence and data sources properly referenced.

Given the nature of these recommendations, the Board asks DG SANCO to submit a revised version of the report, on which it will issue a new opinion.

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(C) Main recommendations for improvements

(1) Better present the problems. The report should provide a clearer explanation of the Directive's role in wider tobacco control policies at national, EU as well as international level. It should better present existing evaluations of the Directive and clearly explain which problems are related to its effectiveness (i.e. adequacy of existing harmonised provisions), to implementation (such as the failure to implement a common list of authorised ingredients or the tracing requirements) and to enforcement. The report should better explain the rationale and strengthen the evidence base for more stringent tobacco control measures at national level and should demonstrate to what extent the present Directive may prevent Member States from maintaining a high level of health protection. Importantly, the magnitude of problems related to the internal market fragmentation should be better demonstrated by drawing more comprehensively on all existing evidence related to: (i) cross-border trade and consumption patterns across all five main categories of products, (ii) the detailed views of economic actors and (iii) notifications under the Directive 98/34 (of national technical regulations) or the General Product Safety Directive (of dangerous products). On this basis, the report should better demonstrate that the conditions for recourse to Article 114 TFEU are fulfilled for all the problems identified, including those related to the new concept of "attractiveness". Finally, the report should explain why the lack of equal protection of public health within and between Member States is regarded as a problem demanding EU level action.

(2) Develop a robust baseline scenario. The report should better explain which internal market and related problems are likely to increase or decrease in magnitude, taking into account: (i) the observed trends in the trade and consumption of tobacco and related products, (ii) experience with the implementation of the existing Directive and (iii) the expansion of the tobacco control measures at national level, including those arising from WHO FCTC obligations. The report should also present a more detailed analysis of trends and underlying drivers in smoking prevalence, particularly of young people. This should include health impacts of new products, ingredients or marketing measures to increase "attractiveness", as informed by behavioural and other scientific studies.

(3) Better explain policy options and demonstrate their proportionality. The report should provide a fuller explanation and justification for the measures envisaged under each of the policy options, and for the foreseen delegated measures in particular. In so doing, it should better describe how they differ from the baseline and how feasible they are (such as the definition of "traditionally" used smokeless tobacco products or common criteria on "characterising" flavour of ingredients, prior-authorisation of nicotine containing products or plain packaging). The report should present more extensively the policy options discarded throughout the impact assessment process, and should explain the reasons for having done so. On this basis, and building on a revised problem definition and baseline scenario, the report should better demonstrate the EU value added and proportionality of the policy options under consideration. In doing so, it should reconsider presenting as an enhancement of the internal market measures aimed at removing products from the market, banning cross-border distance sales or limiting product differentiation.

(4) Improve assessment of impacts by providing a clearer assessment and presentation of the overall costs and benefits of further market harmonisation, particularly for economic stakeholders and consumers, while taking into account that, given the

discretion of Member States in protecting health of their citizens and the foreseen exemptions, divergences are likely to persist. The report should be more transparent concerning any lack of supporting evidence, or when this is inconclusive. Such uncertainty (for example related to impacts on businesses, competition, substitution or smoking prevalence) should be explicitly signalled and reflected in the assessment and comparison of policy options. The report should also better present the impacts on SMEs/micro-enterprises and discuss in greater detail possible mitigating measures. Distributional impacts across Member States as well as impacts on administrative costs for national authorities should be better described.

(5) Improve the comparison of options. The presentation of the comparison of options should better incorporate all the available quantitative information on costs and benefits and all policy options should be assessed against the criteria of effectiveness, efficiency and coherence. The report should highlight the synergies created by the individual measures in the preferred policy package (compared to alternative feasible packages), and clearly analyse any trade-offs between impacts on internal market and public health protection.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

The different views of stakeholders and how they have been taken into account should be transparently reported throughout the report. All evidence and data sources used throughout the report should be properly referenced and their robustness indicated. Given the number of extensive annexes, they should be better referenced throughout the main text in order to facilitate the retrieval of essential background information.

(E) IAB scrutiny process	
Reference number	2010/SANCO/014
External expertise used	No
Date of Board Meeting	18 April 2012