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Delegations will find attached Commission document SWD(2012) 452 final (Part 2).

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Part 2

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

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

(Text with EEA relevance)

{COM(2012) 788 final}
{SWD(2012) 453 final}

A.1 OUTCOME OF CONSULTATIONS AND STAKEHOLDERS' OPINIONS

This annex summarises the comments and opinions expressed by stakeholders in the context of the revision of the Tobacco Products Directive. The first part of the annex refers to comments and opinions expressed by stakeholders in targeted discussions throughout the process. The second part contains a summary of the public consultation organised between September and December 2010. The third part of the annex presents a more detailed picture of citizens' attitudes towards tobacco control measures, as published in the latest Eurobarometer survey on "Attitudes of Europeans towards Tobacco."[1]

[1] Special Eurobarometer 385, May 2012.

A.1.1. SUMMARY OF STAKEHOLDERS' POSITIONS IN THE CONTEXT OF TARGETED STAKEHOLDER CONSULTATIONS ON THE REVISION OF THE TOBACCO PRODUCTS DIRECTIVE

A.1.1.1. Health NGOs

General

- Concerns were expressed regarding some of the data and estimates presented by the external contractor RAND Europe in its study assessing the impacts of revising the Tobacco Products Directive. Health NGOs claimed that the health impacts and health costs of various policy options were underestimated and that industry costs were overestimated. The assumption made by the contractor that smoking prevalence would decline without further intervention was questioned. It was also expressed that tobacco companies are already reducing employment through efficiency savings. The "transferable" nature of tobacco tax revenue and employment should also have been recognised. Money not spent on tobacco would be spent on something else.

Smokeless tobacco products (STP), Nicotine Containing Products (NCP) and herbal products for smoking

- Health NGOs expressed support for keeping or even extending the current ban on oral tobacco and argued that oral tobacco cannot be seen as a rational substitute to cigarettes.
- Health NGOs expressed concerns that many of the NCP, in particular electronic cigarettes, are not subject to any specific safety rules and argued that they should be regulated similarly to pharmaceuticals.
- Health NGOs were in favour of including herbal products for smoking in the scope of the TPD.
- The European Respiratory Society (ERS) is opposed to the use of all (tobacco and) unapproved nicotine delivery products, including electronic cigarettes.[1]

Labelling

- It was concluded that plain packaging and pictorial warnings reduce the attractiveness of tobacco.
- It was argued that plain packaging would not increase illicit trade.
- It was suggested that the costs for plain packaging estimated by the external evaluator (RAND Europe) were overestimated.
- The importance of a quit-line number placed on the cigarette packages was emphasised.
- It was mentioned that there is a difference in the extent of knowledge between Member States regarding the harmful effects of tobacco consumption and that information should be equally provided within the EU.
- Health NGOs expressed support for mandatory pictorial health warnings of 80% on both sides of the packs.

[1] European Respiratory Society statement on E-cigarettes and emerging products, February 2012: http://www.ersnet.org/news/item/4494-european-respiratory-society-statement-on-e-cigarettes-and-emerging-products-.html

Ingredients

- Additives in cigarettes often transform tobacco smoke into an even more complex chemical mixture and thereby increase the carcinogenic and harmful effects of tobacco.
- Too little is mentioned on how additives increase the attractiveness of tobacco products, in particular among young people.
- Support was expressed for banning flavours and sweeteners which increase the palatability and make tobacco uptake more attractive among young people.

Access to tobacco

- It was pointed out that Internet-sales lead indirectly to advertising on the Internet.
- It was concluded that the discussions regarding Internet sales raise questions of identification and enforcement as well as proportionality.
- It was concluded that different rules apply among the Member States in this area.
- Health NGOs argued that stricter regulations on tobacco vending machines, promotion and display of tobacco at point of sale and cross-border distance sale of tobacco were effective means for reducing tobacco consumption among young people. They emphasised, however, the importance of not losing what has already been achieved at national levels.

A.1.1.2. Tobacco industry

General

- The study assessing the impact of revising the Tobacco Products Directive prepared by the external contractor RAND Europe was heavily criticised. The respondents claimed that the study does not sufficiently analyse the impacts on the functioning of the internal market, EU competence, subsidiarity, proportionality and legal basis. They also stressed that other vital elements such as illicit trade, intellectual property rights and competition aspects were missing. The effects on SMEs and growers should have been analysed further and the study does not provide enough scientific data. Respondents in this group also argued that the methodology of the study was weak, and the analysis poor.

Oral tobacco

- It was argued by some of the stakeholders in this group that the health statistics showing that Swedish men consume fewer cigarettes (even though they have the highest consumption of oral tobacco) and have a lower incidence of lung cancer compared to the overall EU population supports lifting the ban on oral tobacco.
- Oral tobacco was presented as a substitute to cigarettes which could help smokers quit and it was argued that Swedish oral tobacco is less harmful than other smokeless tobacco products currently allowed on the EU market.
- The current ban on oral tobacco was seen as discriminatory compared to other STP.
- Some stakeholders within this group also referred to the negative economic consequences of the current ban on oral tobacco as well as the current unequal treatment of similar products. They also referred to the unfavourable position of the Aland Island.

Labelling

- It was suggested, by respondents in this group, that the introduction of plain packaging would increase the amount of counterfeit goods. It would also reduce the possibilities to protect IP-rights and make it harder for consumers to make informed purchases.
- It was stressed that there is no evidence that plain packaging would reduce the smoking prevalence.
- It was also argued that bigger pictorial warnings would have no effect on smoking prevalence.

Ingredients

- Support was expressed for **mandatory reporting on ingredients** in a common format and the tobacco industry referred to commercially sensitive data and the importance of keeping this confidential.
- It was argued that there is no scientific basis to regulate attractiveness of cigarettes as this was considered inherently subjective.

Access to tobacco

- In particular wholesalers and tobacco vending machine operators questioned the legal competence of the EU for regulating or banning tobacco vending machines. The same stakeholders also argued that an ID age verification system provided a good protection from underage purchasing.
- Stakeholders from the tobacco industry also claimed that there is no evidence to justify a ban on tobacco display at point of sale.

Cigars and pipe tobacco

- Cigar manufacturers argued that cigars are mainly used by adult users and not by young people taking up smoking.
- It was explained that most of the economic stakeholders involved in this business are SMEs.
- Cigar manufacturers argued against stricter rules on labelling, ingredients and on display at points of sale.
- Pipe tobacco manufacturers also stressed the need for a different treatment compared to cigarettes due to different production methods and consumer profiles. It was emphasised that pipes are not used by young people.

A.1.1.3. Retailers

- Tobacco retailers argued against a tobacco display ban at points of sale and stressed that such a ban would be very burdensome for retailers and have no effect on smoking prevalence. In particular it was indicated that many SMEs would be affected by such a regulation and that is would increase illicit trade.
- Tobacco retailers also argued against plain packaging.
- Concerning the issue of internet-sale, CEDT (European retailer association) has recognised that this activity should be regulated at the national level by each Member State, considering the negative impact on the sale network and its possibility of public health control.[2] CEDT has also underlined that internet-sale would increase the risks for public health, since it is easier to bring non-genuine products onto the market

[2] Correspondence of 12 March 2012.

while tobacco retailers ensure both a control on minors purchase and the actual collection and precise transfer of state revenues.

A.1.1.4. Tobacco growers

- The main concern of tobacco growers expressed throughout the revision process was in relation to ingredients, where they argued against a full ban. It was said that sugar and some other flavours are necessary for the manufacturing of certain varieties of tobacco (e.g. Burley and Oriental tobacco).
- The tobacco growers also emphasised that a ban on ingredients would have important negative impacts on employment, in particular as a vast majority of growers have tobacco growing as their principal source of income and many live in poor and rural areas.

A.1.1.5. Tobacco suppliers

- The tobacco cartons manufacturers, fine paper industry and cellulose acetate industry expressed some concerns in relation to plain packaging and the risk for increased illicit trade.
- The flavouring industry emphasised the need for basing the revision on science based criteria, rather than subjective concepts such as attractiveness.

A.1.1.6. Electronic cigarettes Industry Trade (ECITA)[3]

- ECITA argued that electronic cigarettes are neither pharmaceuticals nor tobacco products and that these products do not require further regulation. A self-regulation document has been established by ECITA to regulate electronic cigarettes.
- ECITA stated that although they view existing regulations as sufficient, they are not always properly enforced. ECITA urged the European Commission to encourage stricter enforcement in Member States.

A.1.1.7. Pharmaceutical industry

General

- It was stressed that it is very hard to assess the impact of switching from tobacco to nicotine products.
- Production can drop quite a lot before there is an effect on employment. There are other factors which affect employment.

Scope

- Smoking addiction should be seen as a disease which should be treated with medicine (for example nicotine products).
- It was suggested, by some respondents within this group, that non-tobacco nicotine products should be put more firmly into the medicinal area and consequently fall into the scope of pharmaceutical regulation.
- Other respondents argued that all nicotine containing products, which are not otherwise regulated by EU food or pharmaceutical legislation, should be included in the scope of the EU Tobacco Products Directive.

[3] Representing vendors of electronic cigarettes in the UK

Labelling

- Health warnings are a good way to decrease smoking prevalence.
- The regulatory procedures are very different for pharmaceuticals, this means it might be hard to compare. Control of packages is more rigorous in the pharmaceutical area.

A.1.1.8. Tobacco vending machine manufacturers[4]

- Stricter national regulations on tobacco vending machines (TVM) have affected different companies in different ways. Some companies were negatively affected by national TVM bans and their sales dropped, while others had anticipated the development and benefitted from new areas of activities, e.g. "ban-compliant" dispensers of tobacco.

A.1.2. SUMMARY ON THE OUTCOME OF THE PUBLIC CONSULTATION ON A POSSIBLE REVISION ON THE TOBACCO PRODUCTS DIRECTIVE

A.1.2.1. General

The public consultation generated over 85 000 contributions. Citizen contributions accounted for 96% of the survey response. While it is encouraging to see such a large number of responses, it should be noted that this volume appears to be a result, to a large extent, of several citizen mobilisation campaigns that took place in some Member States. For example, a campaign was organised by a group representing over 75% of Italian Tobacconists. This action was followed by submissions of personal signatures by over 30,000 tobacconists across Italy.[5]

The actions and efforts of these campaigns seem to have affected the overall results of the public consultation. This is illustrated by the significant number of pre-programmed "duplicate" responses which counted for 57% of all citizens' responses.[6]

The full report, including arguments used by respondents can be found on:
http://ec.europa.eu/health/tobacco/docs/consultation_report_en.pdf

A.1.2.2. Government representatives

Scope

A significant majority of Member States who submitted contributions to the public consultation were either in favour of extending the scope of the Directive or did not refer to the question in a detailed manner. Two EFTA States were also in favour of extending the scope of the Directive. A small number of respondents were in favour of either maintaining the status quo or extending the directive to all tobacco products, but not to tobacco-free nicotine products, ENDS (Electronic Nicotine Delivery Systems), or herbal cigarettes.

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[4] Interviews with four main manufacturers of tobacco vending machines in Europe carried out by the external contractor, Matrix insight. See Matrix Report 2012.
[5] European Voice, 10 February, 2011
[6] A response considered "duplicate" in the public consultation was a response fulfilling the following criteria: 1. At least six duplicate responses containing the same text. 2. Text box containing more than three words. 3. Text box not containing text directly copied from the consultation document.

As regards the future regulation of 'electronic cigarettes' in tobacco legislation, Member States responding to the consultation seemed to be divided, with some presenting arguments for regulating the product as a pharmaceutical or medical device, and others arguing for the inclusion of electronic cigarettes in the Tobacco Products Directive.

Reactions from MEPs, National Parliamentarians, and local/regional authority respondents were mixed.

Smokeless tobacco

The majority of Member States were in favour of banning all types of smokeless tobacco products, which was also the position of the two EFTA countries responding to the consultation. A very small number Member States proposed that the EU considers lifting the ban on snus. One Member State expressed a particularly strong interest in this. The main arguments for this solution came from the concerns about the harmful health effects of STP, STP as a gateway to FMC consumption and dual use. It was also argued that all STP need to be banned while these products still have relatively limited market shares as the supply of novel forms of STP is likely to increase.

Very few MEPs provided a response to this question, and of those who did, the majority was in favour of keeping the existing ban on oral tobacco products. Most responses from National Parliamentarians, and local/regional authorities favoured lifting the current ban on snus products, while a small group of respondents were interested in extending the current ban to all smokeless tobacco products.

Consumer information

Almost half of the respondents among Member States supported the introduction of plain packaging alongside the other suggested recommended changes including mandatory pictorial warnings, but several indicated that plain packaging should be more carefully analysed. A small number of Member States were in favour of maintaining the existing regulations, noting a strong reservation against plain packaging.

Overall, almost all Member States were in support of removing the tar, nicotine and carbon monoxide levels.

MEPs, National Parliamentarians, and local/regional authority representatives responding to the consultation were split over this issue.

Reporting on ingredients

Member States were in favour of establishing a common compulsory reporting format for communicating ingredients information. A majority of them referred to the Electronic Model Tobacco Control (EMTOC), an application already used for this purpose in some Member States, as the basis on which such a system should be established. There were also proposals encouraging the Commission to consider a reporting system where tobacco industry would report directly to the Commission in order to enable the further development of European legislation in this field.

Almost all responses from MEPs, National Parliamentarians and local/regional authorities were in favour of establishing a common compulsory reporting format.

Regulation of ingredients

As a whole, a majority of Member States supported some sort of ingredients regulation, though when asked to select a specific policy option, Member States were less likely to provide a response. Some supported a positive common list of ingredients, while others supported the use of a negative common list of ingredients. Two EFTA countries supported the use of a negative common list of ingredients, insofar as it is not an exhaustive list.

A few Member States expressed concerns about the EU's ability to quantify the term 'attractiveness'. Others were against any change to the status quo.

Most responses from MEPs, National Parliamentarians, and local/regional authority representatives were not in favour of introducing EU-level ingredients regulation.

Access to tobacco

Almost all Member States supported some form of increased tobacco control across the range of options, though the specific breakdown of options was quite varied. Most Member States supported a ban on internet sales or a ban on vending machines. About one fourth of Member States, and the two EFTA States were in favour of a wide ban in all three cases. Finally, a small number of Member States were in support of leaving these areas to Member State competence.

Very few responses from MEPs, National Parliamentarians, and local/regional authority representatives were in favour of an outright ban on all three options i.e. internet sales, vending machines and retail displays.

A.1.2.3. Non-governmental organisations

Scope

Public health organisations universally supported regulating tobacco and nicotine products. They also argued for the inclusion of herbal cigarettes into this framework.

Smokeless tobacco

Public health organisations emphatically maintained the 'high priority' status of the current ban on snus within the EU. It was also argued by some NGOs that other forms of smokeless tobacco products should be regulated but not necessarily banned, because many are only popular within specific ethnic groups.

Smokers' rights groups pushed for lifting the ban on snus.

Consumer information

Public health organisations supported increasing the size of pictorial warnings to 80% of the pack, to regularly rotate warning messages to maintain the 'freshness' of each statement, and to include information on the packaging about a 'quit line' to help stop smoking.

Additionally, public health organisations opted for plain packaging.

Smokers' rights groups, argued against plain packaging and pictorial warnings.

Reporting on ingredients

For many stakeholder organisations, the solution was clear cut: the current situation which allows for different formats and reporting mechanisms is unsatisfactory. They argued that

tobacco companies should be required to use a standardised reporting format and pay a registration fee to cover the costs of administering the data collection.

Smokers' rights groups argued that information on ingredients is already appropriately mandated by the Directive on an annual basis.

Regulation on ingredients

In general, public health organisations were in favour of establishing common ingredients lists. As an example they often referred to the Guidelines on Article 9 and 10 of the WHO FCTC, adopted by consensus at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

While respondents were split over what type of list should be included, they almost universally supported that the main purpose of such a list should be to regulate flavours and ingredients that mainly enhance attractiveness, encourage youth initiation and discourage cessation.

Access to tobacco

Public health organisations were universally in favour of banning sales of tobacco via the internet, tobacco vending machines and display of tobacco at point of sales.

Smokers' rights group were against changes in this area.

A.1.2.4. Industry and tobacco growers

Scope

The tobacco industry representatives argued almost universally that a fundamental difference exists between products which use tobacco to deliver nicotine and those that do not. They claim that the Directive is aimed at regulating tobacco products, and no further regulation is needed for other products.

The Pharmaceutical industry favoured regulation of nicotine products, some of them in the context of the pharmaceutical legislation and others by including them in the scope of the Tobacco Products Directive.

Smokeless tobacco

The great majority of respondents from the tobacco industry and EU tobacco growers were in favour of lifting the ban on smokeless tobacco (snus) across the EU.

Consumer information

According to tobacco industry representatives and EU tobacco growers, packaging and labelling does not affect or help predict the rates of youth uptake, and thus without a direct link, the basis for change is inaccurate.

Representatives from the cigar industry cited additional challenges with the changes proposed, as many of these changes would impose an excessive financial burden on a relatively small industry.

The pharmaceutical industry argued in favour of improving consumer information about smoking, especially smoking cessation services. They cited evidence suggesting that advertising quit lines and cessation services on tobacco packaging results in increased usage of these services in the short- and medium-term. Representatives also argued for mandatory

pictorial warnings and expressed support for the replacement of the tar, nicotine and carbon monoxide information on packaging.

Reporting on ingredients

The tobacco industry representatives and the flavouring industry seemed to be in favour of synthesising reporting standards.

Other stakeholders, such as smokeless tobacco manufacturers, retailers and growers questioned the validity of this issue, as several organisations stated they were completely unaware of difficulties within the compliance processes.

Several organisations raised concerns that common reporting standards could release information about trade secrets.

The pharmaceutical sector advocated a common compulsory reporting format.

Regulation of ingredients

Across the tobacco industry, a significant amount of representatives did not support the establishment of a common list of ingredients. EU tobacco growers were particularly concerned that a general ban on ingredients would put EU blends at a disadvantage and have a devastating effect on employment. Burley organisations were particularly concerned over a possible ban on sugars. The flavouring industry and retailers also raised concerns about establishing a positive or negative ingredients list.

On the contrary, the pharmaceutical industry pushed for regulation of ingredients through a positive common list of tobacco ingredients.

Access to tobacco

The tobacco industry, retailers and growers were against regulating or restricting tobacco vending machines, tobacco display at point of sales and internet sale of tobacco. Smokeless tobacco manufacturers raised particular concerns over restricting internet sales of tobacco.

The pharmaceutical industry pushed for a ban on all three distribution channels.

A.1.2.5. Citizens

Scope

A significant majority of respondents were against extending the scope of the Directive.

Smokeless tobacco

A vast majority, but not all, of respondents were in favour of lifting the ban on snus.

Consumer information

Most respondents were largely in favour of maintaining the status quo.

Reporting on ingredients

Respondents were generally in favour of establishing a common compulsory reporting format.

Regulation of ingredients

A significant majority of respondents disagreed with the regulation of ingredients at the EU level.

Access to tobacco

A significant majority of respondents opposed limiting access to tobacco products and opted rather for more effective controls, such as age verification, in these channels of tobacco products.

A.1.3. SUMMARY OF CITIZENS' ATTITUDES TOWARDS TOBACCO CONTROL POLICY MEASURES

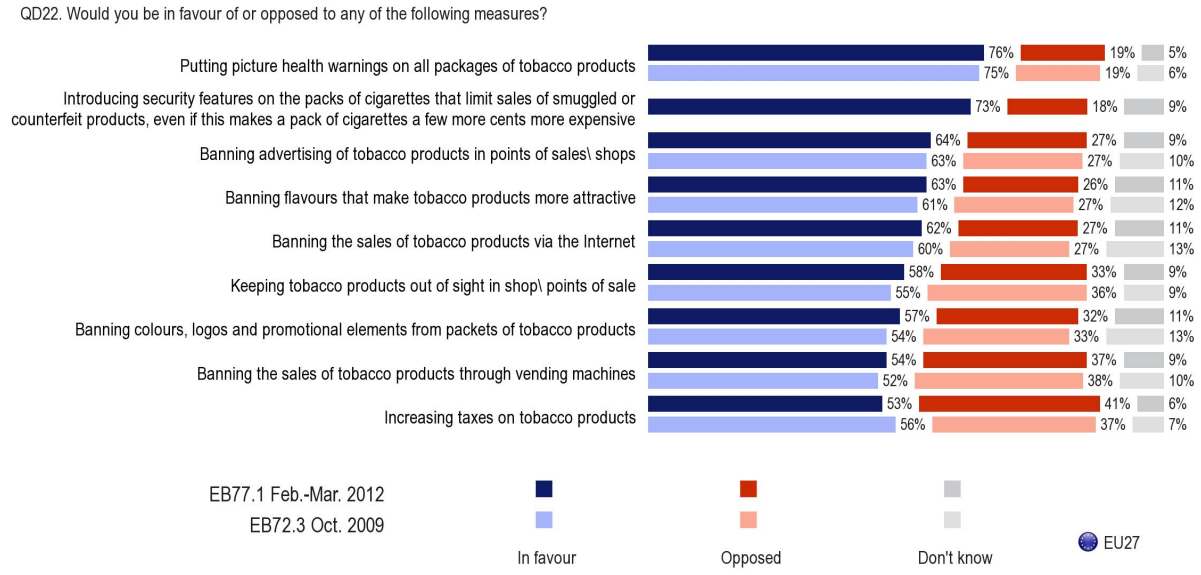
A.1.3.1. General

The Eurobarometer survey was carried out in all 27 Member States of the European Union in early 2012. [7] Face-to-face interviews were conducted with 26,751 respondents aged 15 and older. Citizens' were asked a number of questions related to tobacco consumption, including their support for various policy options considered in the revision of the Tobacco Products Directive. These figures were also compared to citizens' attitudes towards tobacco control measures three years ago in the 2009 Eurobarometer survey.[8]

A.1.3.2. Results

EU citizens, including smokers, were largely and increasingly in favour of tobacco control measures. As shown in the figure below, the absolute majority of EU citizens were in favour of the policy options polled.

Figure 1: European citizens' attitudes towards tobacco control policy measures[9]



Source: Special Eurobarometer 385, May 2012

[7] Special Eurobarometer 385, May 2012.
[8] Special Eurobarometer 332, May 2010.
[9] Eurobarometer 385, May 2012.

Three out of four citizens supported putting pictorial health warnings on all tobacco product packages (76% favourable). Over six in ten supported banning advertising at points of sale (64%) and almost six in ten supported keeping tobacco products out of sight in shops (58%). Roughly the same number believed that flavours that make tobacco products more attractive should be banned (63%). Slightly more than half of respondents were in favour of increasing taxes on tobacco products (53%), which made this the least popular policy option amongst citizens. In comparison to 2009, support for all policy measures, except increasing taxation, went up.