EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Report on the public consultation on the possible revision of the Tobacco Products Directive (2001/37/EC)

Health and Consumers Directorate-General –
Directorate D – Health systems and products
D4 – Substances of human origin and Tobacco control
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Executive Summary

- The public consultation generated over 85 000 contributions, which illustrates a great interest in EU tobacco control policy. Citizen contributions accounted for 96% of the survey response. Almost 2/3 of the contributions were from just two Member States: Italy and Poland.
- It is difficult to draw firm conclusions from the outcome of the public consultation procedure. In general, opinions varied significantly between and also within categories of respondents. Arguments provided by respondents in the 'free text' sections of the consultation present a variety of different justifications for policy action.
- Those who were in favour of extending the scope of the Directive to all tobacco and nicotine products argued that these products present hazards to public health. Some respondents suggested nicotine products should be regulated under pharmaceutical legislation. Others arguing against the extension of the scope raised concerns about the lack of scientific evidence and claimed that the use of many novel forms of tobacco and nicotine products are healthier than cigarette use.
- Respondents in favour of keeping the ban on oral tobacco (snus) or banning all smokeless tobacco argued that, although some of these products are considered 'reduced risk' tobacco products, oral tobacco is harmful to health. . Those who were in favour of lifting the current ban on oral tobacco, referred to snus as a healthier alternative to tobacco smoking and a potentially effective way to quit smoking.
- Respondents in favour of mandatory pictorial warnings and plain or generic tobacco packaging stressed that these measures would eliminate the advertising and marketing effects utilized by the industry and will provide equal protection of European citizens. According to the opponents of these measures, implementing mandatory pictorial warnings and generic packaging would have little to no impact on the uptake of smoking, especially among youth. Opponents also expressed legal concerns about intellectual property and suggested that generic and plain packaging could increase illicit trade in tobacco.
- Most of the respondents were in favour of a common compulsory reporting format, underlining that it would facilitate the comparison and analysis of ingredients information.
- Respondents in favour of regulating ingredients said that restricting certain additives alongside sweet, fruity, floral, and candy flavours could prevent young people from taking up smoking. Additionally, these actions would have the added benefit of facilitating intra-EU trade by synthesizing current ingredients regulation in Member States. Opponents, on the contrary, said that ingredients and additives do little to influence youth uptake and that a regulation of ingredients could discriminate against certain varieties and brands of tobacco.
- Respondents in favour of banning the sale of tobacco products over the internet and from vending machines indicated that these actions would reduce the advertisement of tobacco products through these channels and better restrict young people's access to tobacco products. It was also argued that a tobacco display ban at the point of sale would limit youth smoking and deter tobacco purchasing by adults. Opponents raised concerns about a lack of scientific evidence, market difficulties for new, unadvertised products and excessive intervention in consumers' right to product choice.

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1. Introduction

The present Tobacco Products Directive[1] was designed to facilitate the functioning of the internal market of tobacco products, while ensuring a high level of protection of public health.

Focusing on:

- Determining the maximum content for tar, nicotine, and carbon monoxide,
- Labelling and health information requirements,
- Reporting on tobacco ingredients,
- Restricting the use of misleading texts, names, and signs on tobacco packaging, and
- Banning the use of oral tobacco,

the Directive sets basic requirements for tobacco products regulation in the European Union. However, market and scientific developments over the past decade as well as legislative developments at Member States and at international level have led to market fragmentation and increased the need for a revision.

For example, some Member States have made picture health warnings mandatory on cigarette packs sold in their territory. Some have regulated or even banned some ingredients, which are not regulated in other Member States. Emerging new nicotine products are subject to different rules in different Member States. In addition, the EU and 26 of its Member States are Parties to the WHO Framework Convention on Tobacco Control (FCTC), which entered into force in February 2005 and have a legal obligation to implement the Convention.

The Directorate General for Health & Consumers (DG SANCO), as part of the preparatory work on the revision of the current Directive, has conducted a public on-line consultation. The aim of this public consultation was to give an early opportunity for all stakeholders to provide input on both the need to revise the Tobacco Products Directive and on a range of policy options considered in the revision process. The public consultation lasted from 24 September 2010 until 17 December 2010.

Public consultations are a core element of the Better Regulation Policy, which stipulates the need to reinforce the constructive dialogue between stakeholders and all regulators at the EU and Member State level. The need for public consultation is further strengthened in the Commission's Communication "*Smart Regulation in the European Union*"[2]. Public consultations aim at prioritising openness and accountability in the policy development process, as outlined in the *General Principles and Minimum Standards for Consultation of Interested Parties*[3].

2. Methodology

The on-line consultation document on a "Possible Revision of the Tobacco Products Directive 2001/37/EC"[4] and the response form were provided in English. However, submissions were accepted in any official EU language, as well as via e-mail and regular postal mail.

[1] Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products
[2] COM(2010) 543 (8 October 2010)
[3] http://ec.europa.EU/civil_society/consultation_standards/index_en.htm
[4] http://ec.europa.eu/health/tobacco/docs/tobacco_consultation_en.pdf

The respondents first had to identify themselves and indicate their affiliation among the following four categories: citizen, government, NGO or industry. They were then asked for feedback in six areas:

1. Scope of the Directive;
2. Smokeless tobacco products;
3. Consumer information;
4. Reporting and registration of ingredients;
5. Regulation of ingredients;
6. Access to tobacco products.

Within each area, there were three types of questions. First, respondents were asked to agree or disagree with a problem definition provided. Second, they were asked to choose one of the possible specific policy options presented within each area. Third, for each of the six areas, 'additional information' boxes allowed respondents to present feedback (free text) on the problem definition, available options, and the topic as a whole[5].

It was not obligatory to submit answers for each and every area; therefore, the survey results will have small fluctuations in the total number of responses for each category.

Overall, the public consultation generated over 85 000 responses via the online form. DG SANCO also received around 300 letters and pieces of background material sent to the functional mailbox created for the consultation. Moreover, a large number of letters were sent to Commissioner John Dalli, as well as to other Commissioners and their services.

In addition, the Commission also received 10 petitions from citizens, retailers, traders, wholesalers, gas station owners and trade unions. In total these petitions counted for around 18 650 signatures. Four of the petitions collected more than 1000 signatures each.

It should be noted that no previous public consultation launched by the European Commission had ever registered such significant participation. The amount of participation clearly underlines the great interest of both stakeholders and the general public in the policy making process.

Regarding the general consultation methodology, first, the contributions received on-line, by electronic or regular mail were transformed into a single format. Subsequently, identical responses were identified in order to facilitate analysis of substantial individual contributions. These individual responses were then reviewed and analysed. Several methods were used, including review of the textual responses in many different languages, with particular attention to the responses of key stakeholders.

However, it is to be noted that the responses to the consultation do not represent a survey of a diverse cross-section of society, which is visible when comparing these responses to a recent Eurobarometer survey, published in May 2010[6]. Between the two studies, we find that respondents from the Eurobarometer were considerably more supportive of all proposed changes presented in the public consultation. A possible explanation for such difference is that the Eurobarometer survey captures responses from a random sample of citizens across the

[5] This open feedback mechanism will also be referred to as 'free text' throughout the document.
[6] http://ec.europa.eu/health/tobacco/docs/ebs332_en.pdf

EU, while the public consultation attracted responses from citizens and organizations who perceived they would be directly impacted by changes to the Tobacco Products Directive.

Finally, while the space limitations of this report make it necessary to summarise respondents' views, DG SANCO services have taken the greatest care to provide an analysis which reflects the original intentions of survey respondents. Given the high number of contributions, it is not considered to be useful to release an online database of individual submissions.

3. Responses to the Consultation

The Commission received a total of 85 513 contributions. Almost all of these contributions were submitted online, but this number also includes 910 responses which were submitted in a paper format following the structure of the online questionnaire.

Respondents were able to identify themselves as a citizen, government representative, industry representative, or non-governmental organisation (NGO) representative. No confirmation mechanism existed on the survey; therefore, improper classification by respondents could not be verified or excluded.

The following table shows the self-declared affiliation of survey respondents:

Affiliation	Number of Responses	Percentage
Citizens	82117	96,03%
Industry Representatives	2320	2,71%
NGO Representatives	640	0,75%
Government Representatives	436	0,51%
Total	**85513**	**100,00%**

4. Contributions by Affiliation

4.1 Citizens

The public consultation drew a wide response from citizens: 82 117 responses in total. While it is encouraging to see a great number of responses, it should also 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. One such 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[7].

Several different methods of mobilising and encouraging participation in the consultation process were utilizied: from producing websites providing detailed information and guidance on how to participate, to establishing a free telephone hotline for answers to questions regarding the consultation, to producing and distributing videos via YouTube about the need to limit changes to tobacco product regulation and tobacco control policy.

The actions and efforts of these campaigns and their ability to mobilise citizens seem to have affected the overall results of the public consultation. One of the side effects of these campaigns is that there were a significant number of pre-programmed responses to the public

[7] European Voice, 10 February 2011

consultation document. When searching for duplicates and 'form' responses, 46 792 files could be identified[8]; about 57 % of all citizen responses.

4.2 Industry Representatives

The Commission received 2 320 contributions from those identifying themselves as industry representatives. Again, it is important to recognise the limitations in verification, especially when many respondents did not include information about the organisations they represented. From the e-mail addresses of these contributors, the vast majority of the submissions within this category appear to be from private persons and retailers. Other stakeholders included in this category were organisations representing manufacturers' entrepreneurs, trade chambers, retailers, grocers, etc. Most responses under this category came from Poland, Italy, the United Kingdom, and Germany.

4.3 Non-Governmental Organisations

The public consultation received 640 responses identifying themselves as a representative of a Non-Governmental Organisation. The significant majority of these responses came from seven Member States: the United Kingdom, France, Austria, Germany, Hungary, Sweden and Poland. It is however important to note that many of these NGOs operate at a regional or pan-European level, so their responses do not exclusively represent these seven Member States.

While most contributions from NGOs were from the public health sector, many submissions included representatives that seemed to be involved in the tobacco sector, such as tobacco farmers, retailers, manufacturers, trade unions and others.

Given the extreme diversity of this group, the report will not include an overall assessment of "NGO responses", but rather report the results by subgroup.

4.4 Governmental Representatives

The public consultation received 436 responses within this category. There was no obligation for Member States to respond to the public consultation and some Member States have made known their positions through other channels, including in the context of the Regulatory Committee under the Tobacco Products Directive. However, about one third of the Member States submitted their contributions to the on-line consultation, and another third sent their contributions in letter form or via the functional mail-box. In some cases, these contributions present the view of the government in question while in others they represent the view of a specific Ministry. This can result in more than one response from the same country.

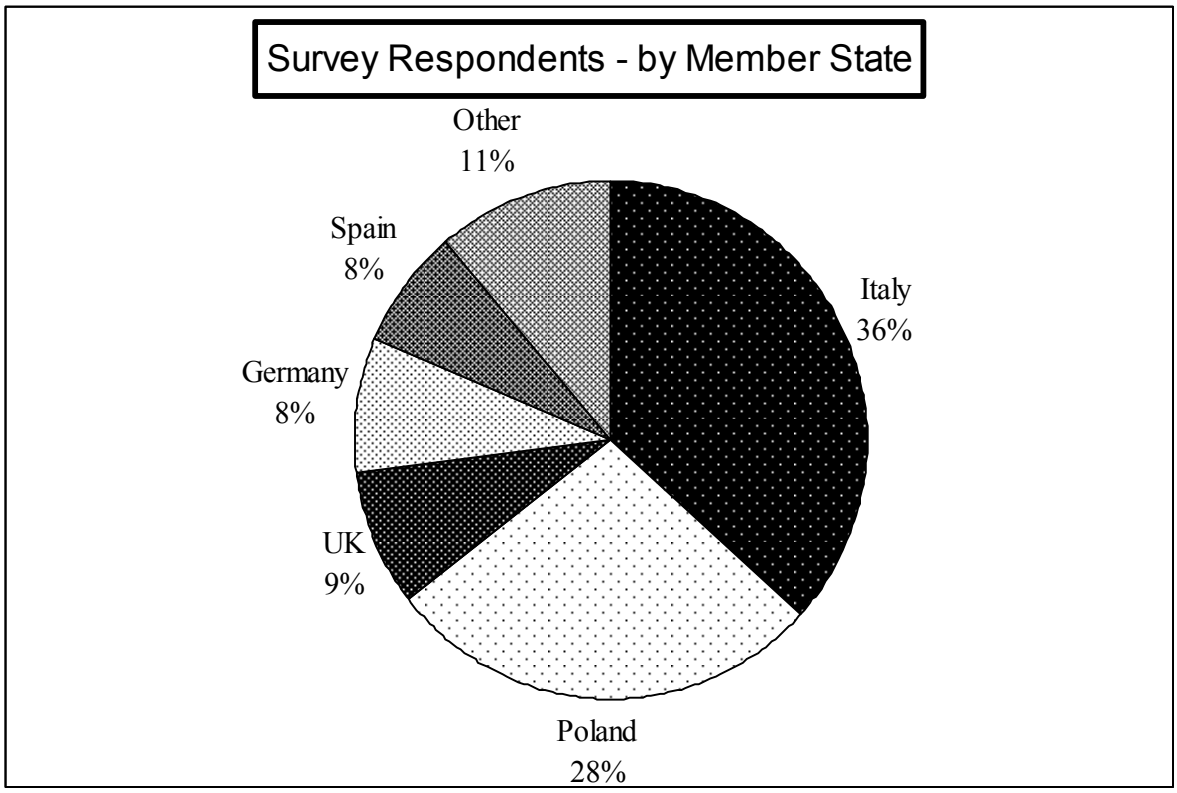
Many of the responses that classified themselves as 'government' appeared to be from private persons working for government bodies which made the process of sub-classifying these responses quite challenging. While hand-processing the responses, it was found that most of them should not have been classified as governments. In many cases, respondents who classified themselves as government representatives were either citizens or represented non-governmental organisations.

Among the responses in this group five main types of sub-categories could be identified:

[8] For a text submission to be considered as a duplicate response, it had to fulfil the following criteria: 1. There had to be at least six duplicate responses containing the same text, 2. The text box had to contain more than three words (thus eliminating answers only indicating n/a, no comments, blanks etc.), 3. The text box had to contain text which was not only a copy/paste directly from the consultation document (1-3 jointly) or petition-like contributions.

- National Government/Ministry level Representatives, presenting the views of the government in question or of a specific Ministry;
- Regional/Local Authorities, presenting the views of a broad range of public authorities from local municipalities, to larger, more regional representation. The vast majority of them were sent from Poland, Italy and Greece;
- Members of the European Parliament and National Parliaments. The number of MEP responses represented approximately 6% of the total size of the European Parliament. Responses by Members of National Parliaments represented less than 1% of the total number of Parliamentarians across the EU-27;
- Private persons who could be part of a Member State Government. These contributions were submitted by citizens working in assorted government offices, agencies, parliaments or ex-politicians;
- Others (NGOs, citizens, industry, etc.). This broad category includes the responses self-identified as government representatives, but in fact they do not represent government. The group consists of citizens representing NGOs (a substantial amount of these were from the UK), citizens who improperly classified themselves, and a small selection of unusable responses[9]

5. Geographic Distribution of Replies



Almost 2/3 of the total response came from only two countries: Italy (31 336) and Poland (23 711). Most likely, the overwhelming Italian response was due to the popularity of the above-mentioned campaign. This is confirmed by the high level (99%) of duplicate responses[10]. The

[9] Which included insulting responses
[10] *See footnote 8*

following table details the number of responses, percentage of duplicates, and percentage of total responses, indexed by country:

Country	Number of Responses	Percentage of Duplicates	Percentage of Total Response
Italy	31336	99%	36.64%
Poland	23711	0,3%	27.73%
UK	7355	95%	8.60%
Germany	7097	4%	8.30%
Spain	6627	5%	7.75%
Other countries	9387	*	10.98%
Total	**85513**	*	**100,00%**

In total, the public consultation received responses from 50 countries. The worldwide appeal of the public consultation certainly highlights the global importance of such an issue.

6. Responses

6.1 Scope of the Directive

The public consultation's questions about the scope of the Directive presented information about the changing market of tobacco and nicotine products and a need to implement reforms based on an evolving market. Respondents were asked if they agreed with the problem definition, and then offered two options for policy change: status quo or extension of the scope of the current Tobacco Products Directive.

6.1.1 Governmental Representatives

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.

Those Member States in favour of extending the scope of the Directive argued that all tobacco and nicotine products presented hazards to public health, both directly and indirectly. They argued that the most desirable option would be to include all products containing tobacco or nicotine in the Tobacco Products Directive, with the exception of those products exclusively and purposefully designed to assist in smoking and nicotine cessation. While the present Tobacco Products Directive has the objectives of facilitating the functioning of the internal market while ensuring a high level of health protection, it was also argued that the Directive is not functioning satisfactorily in this respect.

As regards the future regulation of 'electronic cigarettes' in tobacco legislation, Member States seemed to be more 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. Those in favour of extending the scope suggested that the current market of novel products should be regulated, but product bans should only be implemented based on

significant scientific evidence. Those against extending the scope of the directive suggested that the EU should develop a concrete scientific assessment process to test the health impacts of new products *before* making a decision about their availability inside the EU.

6.1.2 Non Governmental Organisations

Among the many different sub-categories of stakeholders within this group a wide range of opinions appeared. The key arguments can be categorised as follows:

Public health organisations universally supported regulating tobacco and nicotine products, on the grounds of the potential health dangers of these products. Many argued for the strict limitation of novel forms of nicotine delivery systems, whereby these nicotine systems should only be sold as smoking cessation aids, subject to the regulatory framework on pharmaceutical products. They also argued for the inclusion of herbal cigarettes into this framework, citing that the most harm from these products has to do with the combustion and inhalation of smoke, which is identical to cigarette usage. Some of the respondents within this category also expressed concern regarding the current differential treatment between NRTs (Nicotine Replacement Therapies) and novel forms of nicotine products freely available on the market.

On the other hand, arguments against changing the current scope of the Directive explained that the problem definition was framed inaccurately and incorrectly. Respondents within this sub-category argued that any proposed new regulation should be based solely on strong and precise scientific evidence. For example, smokers' rights groups generally found the scope of the Directive to be fundamentally flawed, citing the fact that electronic nicotine delivery systems and nicotine drinks feature no tobacco, and should be regulated in a separate framework. They also claim that the European Commission's consultation not only ignores the issue of consumer choice, but "is also looking for problems that do not exist." They argue, based on this reasoning, for no change to the current scope of the Directive.

6.1.3 Industry Representatives

The industry representatives almost universally disagreed with the problem definition. They argued 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. Additionally, they advocated that many of these products are considerably healthier, when compared to their 'combustible' counterparts, and should not be subject to an outright ban until scientific evidence suggests otherwise.

Retailers and growers commonly raised concerns about the lack of scientific evidence used to categorise these 'novel' forms of tobacco- and nicotine products, citing that many of these products were fundamentally different from one another. This prompted retailers and growers to reason that large, 'blanket' policies for these types of products might not be in the best interests of manufacturers or consumers.

The Pharmaceutical industry favoured extending the current regulation of tobacco and nicotine products, claiming that the Tobacco Products Directive has brought significant progress to the regulation of tobacco products, but that it is not well or evenly applied across the whole of Europe. They argue for a comprehensive approach to tobacco control policies and are in favour of including tobacco-free nicotine products in the scope of the Tobacco Products Directive insofar they are not otherwise regulated by EU food or pharmaceutical legislation – because of the significant linked history that tobacco and nicotine have had for

decades. Additionally, the pharmaceutical industry is concerned about addiction transference between tobacco and non-tobacco based products.

6.1.4 Citizens

A significant majority of respondents were against extending the scope of the Directive. While many presented that the problem definition was incorrect, vague, or unclear, the group as a whole demanded more scientific inquiry about the relative safety of novel forms of tobacco and other nicotine products. These respondents also argued about the consumer's freedom of choice, so long as they are properly informed with the risks involved, and they criticised the tendency to over-regulate and prohibit products in this area.

6.2 Smokeless Tobacco

The current regulatory framework bans some smokeless tobacco products (snus) while others (e.g. chewing tobacco) are still freely available in many Member States. Respondents were asked if they agreed with the problem definition included in the public consultation document and then presented with three policy options: status quo, reducing the scope of the current Directive by lifting the current ban on snus, or extending the scope of the Directive to ban all types of smokeless tobacco products.

6.2.1 Governmental Representatives

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. The main arguments for this solution came from the concerns about the harmful health effects of these types of products. Those in support of banning smokeless tobacco argued that while some of these products present a reduced risk, all smokeless tobacco use entails health risks. Respondents also linked the use of snus to an increase in smoking rates, as snus users are more likely to switch to cigarettes or to consume both snus and cigarettes. They also argued that the commercial import and sale of smokeless tobacco products needs to be banned across the EU while these products still have relatively limited market shares and popularity among consumers. It is likely, they argue, that the supply of novel forms of smokeless tobacco products will increase as cigarette smoking decreases.

Those Member States in favour of maintaining the status quo by keeping the current ban on oral tobacco, but not extending the ban further, argued that even though smokeless tobacco products are harmful and unhealthy, they are popular and embedded in some cultures, particularly by ethnic minority populations. They reasoned that a ban would make it more difficult to engage with users to offer help with quitting. A better option for these contributors would be to tighten regulation, instead of completely banning these products.

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, arguing that it is illogical for snus to be the only tobacco product prohibited within EU without scientific evidence to treat it any differently than other tobacco products.

Very few MEPs provided a response to this question, and of those who did, a 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. Those in favour of lifting the ban on snus argued that, compared to combustible tobacco products, snus were a less harmful alternative. Those against lifting the current ban on snus, or in favour of extending the ban to all smokeless products, stressed that all tobacco products are inherently harmful products.

6.2.2 Non-Governmental Organisations

Public health organisations emphatically maintained the 'high priority' status of the current ban on snus within the EU. According to these respondents, there is no legitimate reason to introduce a dangerous product onto the market, because it is impossible to predict how snus would be perceived or used in other countries. 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.

Some of the proponents of banning all smokeless tobacco products presented the difficulty in doing so, citing the current usage trends across the EU. They juxtapose the benefits of a tightly regulated market in place against the potential of a black market for these goods, where no regulation can reduce the risks associated with these products.

Citizen smokers' rights groups pushed for lifting the ban on snus. They argued that smokeless products could help reduce cigarette consumption, as snus is considered a reduced harm product. They also agreed that health information should be presented clearly and accurately on tobacco products, but ultimately, consumers should be left to choose which tobacco products they wish to consume.

According to some NGOs who seek to lift the ban on snus, the current regulations are illogical because according to scientific evidence, snus are have been shown to be less harmful than cigarettes, and could replace cigarette usage in some populations. Yet, the current policies make combustible tobacco products legal, which have clearly been shown to be more harmful.

6.2.3 Industry Representatives

The great majority of respondents from the tobacco industry were in favour of lifting the ban on snus across the EU. They argued that the benefits of opening up the product to the European market are two-fold. First, they argue that the use of snus can be an effective way to reduce or quit smoking. Secondly, they reason that by not lifting the ban on snus, the EU is effectively blocking the industry from developing other forms of products which are less harmful than cigarettes, as smokeless products do not involve combustion or smoke inhalation.

There was almost universal criticism from industry representatives, smokeless tobacco advocates, flavouring representatives, retailers, and growers about the way the SCENIHR study was mentioned in the consultation.[11] In the public consultation document, the Commission quoted from the study that" all tobacco products are addictive and can cause cancer." Many brought up that the Commission used one statement from the scientific opinion, while failing to mention that the same study states that smokeless tobacco products are less hazardous than cigarette smoking.

Advocates from the smokeless tobacco industry disagreed with the problem definition. They argued that smokeless product can play a role in smoking cessation, and that the reduced harm from these products makes smokeless tobacco a safer alternative. The industry representatives claim that there is universal consumer demand to lift the ban on snus. Any actions, they argue, for banning some or all smokeless tobacco products, should be scientifically based, include product-specific and product-appropriate regulations to ensure safest possible usage, and to provide consumers with accurate information on the differing risks of different types of tobacco and nicotine products.

[11] http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

6.2.4 Citizens

A vast majority of respondents not only disagreed with the problem definition but were in favour of lifting the ban on snus. With the problem definition, several respondents were concerned that the Commission's approach was too simplistic and overstated – referring to the complex nature and health effects of a diverse smokeless tobacco products market. Those in favour of lifting the ban on snus argued that scientific evidence showed that smokeless products were much healthier alternatives to tobacco smoking. Several respondents pushed for smokeless tobacco products to be priced cheaper than combustible products, in order to reduce the demand for cigarettes. Others were concerned about their freedom of choice as consumers, with several arguing that those over 18 years old should be free to decide for themselves. Still others felt that the EU already had too many regulations in place to begin creating more.

However, not all respondents were in favour of lifting the ban on snus. Those who agreed to keep – or extend – the ban on smokeless products did so because they believed that lifting the existing ban would introduce more products into the tobacco market. They argued that all of these types of products are dangerous to health and should not be allowed on the internal market. Additionally, because snus has been banned for so long, some respondents argued that it would be difficult to estimate the patterns of use if introduced into the market.

6.3 Consumer Information

The third question identified the current disparities in tobacco labelling throughout the EU and highlighted the role of tobacco packaging as an advertising tool. Currently seven Member States require the use of pictorial warnings on tobacco packaging, with another two set to implement this requirement by mid-2012.

This section proved to be the most controversial, as it generated the greatest number of responses featuring free text answers. In this set of questions, several options were presented in an effort to improve consumer information: mandatory picture warnings, replacing information on the levels of tar, nicotine and carbon monoxide (TNCO) with more general information, mandating the use of informative inserts, and including health warnings on water pipes. Additionally, respondents were asked about introducing generic or plain packaging on all tobacco products.

6.3.1 Governmental Representatives

While most Member States were in favour of all proposed policy options for improving consumer information, plain packaging proved to be the most controversial. Almost half of respondents supported the introduction of plain packaging alongside the other recommended changes, but several indicated that the solutions to these problems 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.

Those in favour of picture health warnings argued that because several Member States have already made pictorial warnings on tobacco products compulsory in their territory, the only way to guarantee equal protection of European citizens would be to make such warnings compulsory at EU level. The current situation, they claim, creates disparities in the internal market.

They argued that additional information, both through replacement of the (TNCO) yields and informational tobacco inserts (a small sheet of paper slipped inside the tobacco package),

would deliver more accurate information. They also suggested that a smoker who consumes roughly one pack per day would be exposed to these messages over 7000 times annually. Overall, almost all Member States were in support of removing the TNCO-levels from the pack.

Those in favour of standardized packaging argued that the use of plain packaging would eliminate the advertising effects from both selling and carrying tobacco products. They claim that by introducing these changes, young people are less likely to be attracted by features of tobacco packaging, which is seen as a key factor of youth smoking uptake.

Those against plain packaging, or those with hesitations, cited legal challenges and concerns about the potential for an expansion of the illegal tobacco market, increasing consumer confusion between tobacco products, negative impacts to the economy through reduced sales and tax revenue, and concerns about limited scientific evidence about the effectiveness of this policy change.

MEPs, National Parliamentarians, and local/regional authority representatives responding to the consultation were equally split over this issue. Several argued that pictorial warnings should be mandatory based on research suggesting that pictorial warnings were much more effective than text warnings, especially with young people. Smaller groups of respondents were in favour of mandating tobacco warnings on water pipes, removing TNCO information from cigarette packaging, and including tobacco inserts inside packs. Those against proposed changes in this category were almost universally opposed to all possible options, voicing concerns about intellectual property rights, illicit trade, and the right to chose.

6.3.2 Non-Governmental Organisations

Public health organisations were largely in favour of the changes outlined by the public consultation. They recognised current disparity between warning labels on tobacco packaging within the internal market, which increases the inequality of consumer information across Member State lines. Arguments were presented to increase the size of the 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 on the grounds that branding tactics used today can give the consumer a false sense that one pack may be safer than another. While the Directive has restricted the use of terms such as light, mild, etc., these organisations argued that manufacturers are still able to imply those messages with designs and colours. Not only would the usage of plain packaging remove all branding from the goods, its plainness would inherently reinforce the visibility and effectiveness of the health warnings on the front and back of the package.

Those NGOs against the proposed changes, such as smokers' rights groups, argued that little credible evidence suggests that packaging affects or increases smoking uptake. While pictorial warnings do have an initial effect on smoking cessation, the medium- and long- term effects are negligible, as these graphic images become normalised and eventually expected on cigarette packaging. Finally, they questioned how those risks are communicated to consumers. ‘Smoke or die’ language might shock consumers but it comes at the cost, they argue, of presenting effective and detailed information to consumers.

6.3.3 Industry Representatives

Tobacco industry representatives were almost universally opposed to all changes in this section of the public consultation. Many groups underlined that the question's topic, "Consumer Information," was incorrect as it addresses only tobacco packaging and not alternative forms of communicating information to tobacco customers. According to industry representatives, 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. They argued that changes to packaging, pack labelling, and informative inserts infringe upon the fundamental legal, economic, and commercial rights of tobacco manufacturers and consumers. Many stated that the voluntary approach to pictorial warnings was sufficient, and should not be extended beyond the several Member States who already require it.

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. They suggest the potential requirement for large, permanent labels would be incompatible with current product packaging – as many cigars are packaged in fine wooden boxes, crates, and metal tins. Additionally, they argue that the requirements to insert additional information about tobacco consumption and health effects inside the package would create a greater burden within the cigar industry, compared to others. Many manufacturers of these products are small- or medium-sized outlets, which would have to rely on hand folding and manually inserting these warning into packages.

Other concerns from trade industry representatives suggest that many of these changes encourage the expansion and development of illicit tobacco trade. They claim that the proposed policy solutions would enable counterfeiters to more easily replicate simpler, plain packaging, thus opening up the market to potentially more dangerous, unregulated cigarettes. In addition, illicit products are sidestepping tax requirements, at the expense of Member States' tax revenues.

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 that are rotated regularly to maintain effectiveness. Finally, the pharmaceutical industry expressed support for the replacement of the TNCO information on packaging, claiming that such information gives the impression that certain tobacco products are healthier than others.

6.3.4 Citizens

Largely in favour of maintaining the status quo, most respondents suggested that little, if any, scientific evidence exists to show that many of these options are effective ways to reduce smoking rates, or reduce youth uptake. They also argued that the EU did not need to establish more restrictions; smokers were already facing too much regulation to use a product they are legally entitled to consume. Education, they suggest, should not only be limited to the tobacco packaging, but should also be increased in schools and public campaigns. Finally, some respondents were worried that the use of plain packaging not only prevented free competition between manufacturers, but also increased the likelihood of counterfeit products entering the market.

6.4 Reporting and Registration of Ingredients

The fourth question in the Public Consultation document was dedicated to the reporting and registration of ingredients and the possible introduction of fees and sanctions in order to finance data collection and analysis work on ingredients. The question provided three policy options: status quo, establishing a common compulsory reporting format, and introducing fees and sanctions to ensure standardized, timely reporting. Respondents were allowed to select multiple policy options.

6.4.1 Governmental Representatives

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 a base 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.

Member States also argued that the current situation of reporting mechanisms and varied formats was unsatisfactory. The results from current standards were difficult to compare across Member States, the EU, and the globe. They stressed that tobacco manufacturers and importers should be subject to the same reporting requirements, which allows for the gathering and analysis of relevant data. Such data should be freely available and usable, in order to ensure high level of consumer safety and information.

Also, Member States generally supported introducing fees and sanctions relating to the registration of products and the reporting of ingredients.

Almost all responses from MEPs, National Parliamentarians and local/regional authorities were in favour of establishing a common compulsory reporting format. Those in favour argued that wide-spread implementation would improve the functioning of the internal market, so long as the common system respected trade secrets inside the industry. Many were also in favour of introducing sanctions and fees, though others pointed out that Member States are already capable of introducing fees and sanctions for ingredients reporting, and felt that it should remain a competency of the Member States.

6.4.2 Non-Governmental Organisations

For many stakeholder organisations, the solution was clear cut: the current situation which allows for different formats and reporting mechanisms is unsatisfactory. It is not only difficult to collect the data, but the disparities in reporting present challenges for authorities to compare and analyse the information. 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.

Almost all respondents pushed for the need to establish a common compulsory reporting format and to introduce fees and sanctions to cover the costs of data collection and analysis work on ingredients. Respondents also cited the current disparity in reporting standards across the Member States, which in turn reduces the amount of data available to provide a high level of consumer safety information.

Other organisations saw the status quo as a satisfactory policy option at this time. Member States may already introduce fees and sanctions for non-compliance and lax reporting. The

responsibility for enforcement should remain exclusively within the Member States' competency. For example, smokers' rights groups argued that such information is already appropriately mandated by the Directive on an annual basis. However many of these groups did not indicate if establishing a European standardisation would be a step-backward from the current system of reporting.

6.4.3 Industry Representatives

The tobacco industry representatives seemed to be in favour of synthesising reporting standards. The process would not only reduce compliance costs for industry, but also reduce the sheer volume of testing necessary to meet EU standards. However, many of the representatives from the tobacco industry argued that it is the EU and Member States who are to blame for the vast differences in reporting and ingredients registration. Synthesising information reporting standards would provide more useful and measurable information.

The flavouring industry also echoed the voices of industry. They stated that most Member States have policies in place for ingredients reporting, though they vary widely from state to state. A common compulsory format would not only reduce costs, but ease the administrative burden of ingredients', flavourings', and tobacco manufacturers. These systems would also make it far easier to deliver consistent ingredient information to consumers and health organisations.

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. That being said, a vast majority argued for the common compulsory format, as long as it provided avenues to ensure trade secrets would be maintained. Several organisations raised concerns that common reporting standards could release information about trade secrets.

Almost all industry groups raised concerns over introducing fees to cover the costs of data collection and analysis work on ingredients. Since Member States already have testing infrastructures in place, this would not require new laboratories, just harmonisation of the processes to be used in these facilities. Others questioned the EU's competence in assessing such fees, let alone doing so without conducting a proper impact analysis on the market effects of introducing such costs.

On the contrary, the pharmaceutical sector advocated both a common compulsory reporting format and the introduction of fees and sanctions. As an industry which is already subject to fees of a similar nature, they argued that the costs have increased compliance across the industry. These fees would cover administrative and testing costs for the new universal reporting standards and should also be assessed when the industry fails to comply with reporting standards or deadlines. Addressing the point of undue burden on tobacco industries with the introduction of new fees, the pharmaceutical industry argued that because of the inherent danger from using such products, these industries should be responsible for bearing the burden of compliance costs.

6.4.4 Citizens

Respondents were generally in favour of establishing a common compulsory reporting format, insomuch as the format was based on appropriate scientific criteria, and not based on concepts such as attractiveness. They, like many of the organisations and governments above, argued that the current ingredients reporting situation is fragmented, making it difficult for authorities to compare and analyse ingredients data. Manufacturers and importers, they reasoned, should be subject to the same reporting standards. Other respondents furthered this point by

demanding that consumers have a right to know what is inside the products they use. However, many were sensitive to the issue of trade secrets, noting that any reporting standards should respect this information from manufacturers. An easy way to publicise this information, some respondents pointed out, would be to require ingredients to be listed in large, clear print on the outsides of packages.

While there was limited support for fees and sanctions for tobacco manufacturers, some respondents advocated that sanctions should be drastic, to guarantee tobacco industry compliance.

However, on the whole, not all respondents were in favour of changes to the status quo. Many advocated no restrictions, no further bans, and no changes, resulting in more freedom for tobacco products and their users. Others utilised this section to insert more general commentary on the EU's role in standardising product regulation.

6.5 Regulation of Ingredients

The majority of Member States regulate ingredients used in tobacco production at the national level, resulting in disparities inside the internal market. Potential policy options listed in the public consultation include maintaining the status quo, introducing basic criteria at EU level without a common list, or establishing a common (positive or negative) list of tobacco ingredients.

6.5.1 Governmental Representatives

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 apt 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. Supporters of both options argued that Member States have different standards when it comes to allowing and regulating specific ingredients, therefore a common standard would better synthesise tobacco ingredient regulation and help facilitate intra-EU trade.

However, not all Member States were in favour of ingredients regulation. 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, underlining their positions that many of the ingredients in cigarettes are a necessary part of the production process. From a technological point of view, many of these substances enhance humidity, elasticity, and product life. They point out that the focus of this policy should be to target ingredients which have carcinogenic effects, enhance the overall toxicity of the product, accelerate addictiveness, or give an unnatural taste to the tobacco product (i.e. sweet or fruity flavours).

Most responses from MEPs, National Parliamentarians, and local/regional authority representatives were not in favour of introducing EU-level ingredients regulation. They argued that the EU needs to develop scientific methods to assess the safety of ingredients and not to regulate based on overall attractiveness. Those in favour argued that a common ingredients list should be based on scientific knowledge, take account for necessary sugars used to reconstitute sugars lost in the drying and curing process, and should establish a mechanism designed to review regulated ingredients as science continues to research their impacts on public health.

6.5.2 Non-Governmental Organisations

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.

Many linked this issue of ingredients regulation to the role of a common standard of ingredients reporting, suggesting that without one, the EU is unable to enforce the other, and vice versa. The current state of ingredients management, they claim, has lead to a situation whereby some ingredients are legal in some Member States, but banned in others.

6.5.3 Industry Representatives

Across the tobacco industry, a significant amount of representatives did not agree with the problem definition, nor did they support the establishment of a common list of ingredients. Their main argument is that ingredients do little to influence youth uptake and are not designed to do so. Rather, the inclusion of specific ingredients is designed to create a particular taste and flavour, ultimately differentiating products within the marketplace. Legislation aimed at reducing the range of ingredients available to manufacturers deliberately homogenises the range of tobacco products available. Additionally, industry representatives worry that such a list could be expanded to include ingredients at the core of the tobacco making process.

The flavouring industry, retailers, and growers raised many concerns about establishing a positive or negative ingredients list. Their main concerns regard the concept of 'attractiveness.' Like the tobacco industry, they question the scientific credibility of judging an ingredient's attractiveness, and worry that such actions will arbitrarily limit certain flavours from the market. Retail and growing industries also stated that a ban on certain additives and flavours could discriminate against certain varieties of tobacco. Arguments were also put forward claiming that flavours, such as menthol, did little to increase youth uptake and simply provided adult consumers with other varieties they might find more pleasant and flavourful.

On the contrary, the pharmaceutical industry pushed for regulation of ingredients through a positive common list of tobacco ingredients. The use of this list would not only promote consistency across the sector, but also ensure that a high level of health protection is universally applied across the internal market. The goal with this list should be consistent with the goals of the WHO Framework Convention on Tobacco Control: reducing or preventing tobacco dependence.

6.5.4 Citizens

A significant majority of respondents disagreed with the regulation of ingredients at the EU level. The majority of respondents referred to the lack of scientific evidence for such regulation on reducing tobacco consumption or youth uptake. Additionally, they criticised the term 'attractiveness' as a justification for the EU to arbitrarily decide which ingredients will be allowed and which not. The other arguments referred to a consumer's freedom of choice and a generally critical response to the EU's tendency to over-regulate.

While respondents in favour of regulating ingredients were in minority, they believed that regulation of ingredients which are harmful and hazardous is strongly desired as far as public health and decreasing in smoking prevalence is concerned.

6.6 Access to Tobacco Products

This section identified problems with internet sales of tobacco, disparities in Member States' regulations regarding tobacco vending machines and the display of tobacco products at the point of sale. Respondents were asked to agree with the problem definitions provided, and then to choose from several options: maintaining the status quo, controlling supply and access, or banning sales. When respondents selected the 'controlling supply' or 'banning sales' options, they also selected which sales channels their selection would apply to (for example, respondents could opt to ban internet sales, or have the ban apply to internet sales, vending machines, and retail displays).

6.6.1 Governmental Representatives

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.

Those who were in favour of limited access to tobacco products claimed that banning the sale of tobacco products over the Internet and from vending machines is legally justified, as the disparity in existing Member State regulation is already damaging the functioning of the internal market. They indicated that all proposed options can reduce the promotional effects of tobacco industry marketing. Such solutions are desirable, they reason, as they help decrease access and consumption of tobacco products especially for youngsters.

On the contrary, opponents of these changes argued that there was no evidence that a display ban has any effect in reducing smoking rates and that introducing such a measure would have detrimental effects on counterfeiting and the use of trademarks.

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. Those against banning or restricting access across the policy options cited concerns about individual freedoms to choose products and a risk for increased illicit trade.

6.6.2 Non-Governmental Organisations

Public health organisations were universally in favour of banning all possible categories in this question. Banning sales of tobacco via the internet was argued to be a logical extension of the ban on cross-border advertising and promotion of tobacco products within the EU. Banning vending machine access was justified by public health organisations on the grounds that most Member States already have bans or restrictions in place, which have been shown to reduce youth smoking rates[12]. Finally, restricting display and promotion of tobacco products at the point of sale was claimed to be justified because it is or will soon be mandatory in some

[12] Several organizations stated that roughly 22 Member States have restrictions or bans on tobacco vending machine usage. However, based on information reported to DG SANCO, 12 have bans and 13 have restrictions on the use of tobacco vending machines.

Member States. Proponents argued that restricting display of tobacco products also helps limit youth smoking and could help deter tobacco purchases by adults.

Citizen smokers' rights group argued that little evidence exists that a ban on retail smoking displays help to reduce smoking. They expressed concern that the Commission's goals are not to legitimately restrict smoking by minors, but to 'eliminate' smoking as a whole, even though tobacco is a legal product commonly purchased by adult consumers. They argued that the real losers in this scenario will be smaller businesses who rely on the revenue generated by tobacco sales and have limited abilities to change the layout of their shops and stores to adhere to restrictive policies.

6.6.3 Industry Representatives

Access is a problem with two faces, according to the tobacco industry. While they firmly support policies which restrict minors from vending machines, they feel that a ban would restrict legitimate access by adult smokers and is at odds with the principle of proportionality. Retailers and growers stated that the Commission's problem definition was non-existent – they argued that declaring 'several Member States ban vending machines' does not really define a problem. Several organizations question the EU's competence in such matters, as no arguments had been provided in the public consultation document to address questions about the internal market or proportionality.

Additional concerns focused on the plight of small businesses. Requiring stores to remove or modify displays for tobacco products would create unnecessary and extraordinary costs to simply continue operating in a normal capacity. Additionally, they argued that without branding or displays, it would be quite easy for illicit tobacco to be introduced into retail stores.

Smokeless tobacco manufacturers raised concerns about restricting internet sales of tobacco. While they understand that legitimate issues exist, such as enforcing a minimum purchasing age and collecting appropriate tax revenues, a ban on sales through a specific channel distorts competition. They argue that such distortion is incompatible with the EU's goal of strengthening the internal market. Smokeless tobacco industry ultimately pushed for no change to the current policy, based on the fact that the enforcement of minimum purchasing age and appropriate tax collection is common to a wide range of internet products, not only tobacco.

The pharmaceutical industry pushed for a ban on all three distribution channels, in order to limit access to tobacco products inside the EU. Based on the evidence that many Member States have several of these policies in place, such actions would simply serve to harmonise existing standards inside the internal market. They made the additional claim that banning internet sales is of particular importance, since it is extremely unlikely that the warning information will be in the same language as the buyer's country of origin. Finally, they advocated the increased usage of tobacco education programs, as limiting access is only half of the current approach to reduce tobacco use.

6.6.4 Citizens

A significant majority of respondents opposed limiting access to tobacco products. The most commonly discussed issue was the display ban, where citizen arguments were similar to those used by industry representatives. The limitation of the legitimate use of the trademarks and branding displays, the lack of the possibility for customers to be fully informed about the accessibility, the price and characteristic of products and potential increase of the illicit trade were the most often used arguments. Some of the responses referred to the lack of scientific

evidence that bans on the point of sale display of tobacco would impact smoking behaviour. This argument also referred to a lack of research regarding both vending machines and internet sales. The significant majority of respondents perceived these restrictions as an excessive intervention in a consumer's right to decide. Rather, these respondents opted for more effective controls, such as age verification, in these channels of tobacco products.

7. Conclusion

This consultation is an example of the great interest of the general public and stakeholders in the EU policy making process.

The responses represent all EU Member States and almost two dozen other countries. They reflect the opinions of consumers, farmers, retailers, industry representatives, health advocates, healthcare professionals, government officials, and others – essentially all parties affected by changes in tobacco policy. Both the large turnout and the detailed nature of the responses highlighted how important the stakes are.

The experience gained with the management of the large volume of response will help shape how future consultations of this nature can be effectively and efficiently carried out.

The public consultation generated a great deal of data, increasing the common knowledge base. Many submissions included detailed scientific research, market data, consumer information, and legal opinions. This data was submitted from health advocates, healthcare professionals, intellectual property lawyers, industry representatives, amongst many others.

The opinions and information received in reply to the consultation will continue to be considered within the Impact Assessment and the formulation of the proposal for the revised Tobacco Products Directive.