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Old wine in new bottles: Tobacco industry's submission to European Commission tobacco product directive public consultation

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Abstract

Between September and December 2010 the European Commission Health & Consumer Protection Directorate-General (DGSANCO) held a public consultation on a possible revision of the European Union Tobacco Products Directive (2001/37/EC). We used content analysis of the tobacco industry's and related parties' 300 submissions to the public consultation to determine if tobacco industry and its allies in Europe are prepared to reduce harm of the tobacco products as their public statements assert. The industry submission resorted to traditional tobacco industry arguments where illicit trade and freedom of choice were emphasized and misrepresented the conclusions of a DGSANCO-commissioned scientific report on smokeless tobacco products. Retailers and wholesalers referred to employment and economic growth more often than respondents from other categories. The pattern of responses in the submission differed dramatically from independent public opinion polls of EU citizens' support for tobacco control policies. None of the major tobacco manufacturers or their lobbying organizations supported any of the DGSANCO's proposed evidence based interventions (pictorial health warnings, plain packaging or point-of-sale display bans) to reduce harms caused by cigarette smoking.

Keywords

Regulations; Public comments; Policy making

1. Introduction

Tobacco consumption is determined by the balance between the tobacco industry effort to maintain a policy environment that promotes and supports tobacco use and public health authorities seeking policies [1–3] designed to reduce tobacco consumption.

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Since at least the 1950s the cigarette companies have tried to remove toxins from tobacco products as a “harm reduction” strategy [4]. As of 2013 the tobacco companies active in Europe were again promoting harm reduction [5–8]. British American Tobacco (BAT) announced it was “engaging with the scientific community and regulators to build support for tobacco harm reduction as a pragmatic public health policy” [5]. Philip Morris International (PMI) was developing potentially reduced harm products (PREPs) and endorsed regulation based on the principle of harm reduction [6]. Imperial Tobacco said it was “being responsible with products” [7]. One of Japan Tobacco International's (JTI) “core principles” was “commitment to the development of reduced-risk products” [8]. The harm reduction paradigm suggests replacing cigarettes (which burn tobacco) with a cleaner source of nicotine, including nicotine replacement therapy, reform of the current systems of regulation of nicotine products to advance the development of and increase access to nicotine substitutes for cigarettes, and the unrestricted marketing of these products [9,10]. Until the 2000s tobacco control focused mainly on effectively reducing the harms of cigarette smoking, on the assumption that it was impossible to eliminate widespread use of nicotine. Rejecting this assumption, by 2013 Finland [11], Ireland [12], New Zealand [13], and Scotland [14] had set national targets to end smoking completely or to reduce it to negligible levels. These goals mark a shift in discourse from simply reducing tobacco consumption to denormalization of cigarette smoking and tobacco endgames [15].

Studlar [16] outlines two alternative prospects for future European Union (EU) tobacco policy making: (a) further denormalization of smoking behaviour, products and producers through plain packaging, more restrictions on where products are used, and higher taxes, or (b) measures focused on harm reduction. The EU Tobacco Product Directive (TPD) 2001/37/EC [17] implemented in 2001 aimed to facilitate the functioning of the internal market of the tobacco products, while ensuring a high level of protection of public health [18]. It mainly covers the maximum content of tar (10 mg), nicotine (1 mg) and carbon monoxide (10mg) per cigarette, the health warnings and other labelling requirements, reporting on the tobacco ingredients by the industry to the authorities, ban on misleading texts, names or signs in tobacco packages and ban on oral tobacco. In 2010 the European Commission (EC) Health & Consumer Protection Directorate-General (DGSANCO) held a public consultation on the possible revision of the TDP, because existing tobacco products had been made more attractive by changing their flavour and packaging and novel products such as electronic cigarettes had been entered the market [19].

Between September and December 2010 DGSANCO invited citizens, businesses, non-governmental organizations and national authorities in a public on-line consultation to comment on the policy options that a revised TPD might include [18]. In particular, the consultation document proposed to extend the TPD's scope to include reduced harm products such as novel forms of oral tobacco, herbal cigarettes, and electronic nicotine delivery systems, insofar as they are not already covered by other EU food and pharmaceutical legislation [19]. DGSANCO asked for feedback in six areas (Table 1). 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 free text boxes allowed respondents to present feedback as additional information.

EU directive 1992/41/EEC had already established general prohibition of tobacco for oral use [20], defined as all tobacco products except those intended to be smoked or chewed. When joining European Community in 1995 Sweden was granted a permanent exemption to sell snus, a form of oral tobacco, on its territory. Directive 2001/37/EC continued the ban on oral tobacco. The largest oral tobacco producer, Swedish Match, together with PM and BAT have aggressively lobbied the European Commission since 2008 to lift the ban on snus [20,21].

DGSANCO's 2010 consultation document [19] noted that Directive 2001/37/EC made it optional for Member States to mandate health warnings with pictures, which has led to disparity in labelling throughout the EU with consequences for consumers' awareness and subsequent smoking behaviour. As of 2010 four Member States (Belgium, Romania, United Kingdom and Latvia) had made picture warnings compulsory and by October 2013 nine EU countries had done so. The consultation document also proposed expanding pictorial warnings and raised the option of requiring generic or plain packaging. The consultation document also noted that as of 2010 there was no common list of allowed or prohibited tobacco ingredients at the EU level; some Member States allowed a number of listed ingredients (a “positive list”) while some others had banned certain ingredients (a “negative list”).

Participants in the consultation had to identify themselves and indicate their affiliation among the four categories (citizen, government, NGO or industry). The consultation generated over 85 513 contributions, including 82 117 from citizens, far more than any other previous consultation [22]. (By comparison, the 2007 consultation on smokefree environments resulted in 306 contributions [23].) DGSANCO provided the on-line consultation document and the response form in English. Submissions were accepted in any official EU language, as well as via e-mail and postal mail.

DGSANCO found that 99% of the 31 336 submission from Italy (in Italian) and 95% of the 7355 UK submissions 95% were duplicates, which led DGSANCO to conclude that the results of the consultation were affected by an organized campaign [18].

2. Methods

DGSANCO received 2320 contributions (3697 pages) from those self-identified as “industry” and provided the authors pdf-files containing all online responses from industry (which represented 99.6% of all industry submissions). We excluded 1940 submissions which gave only “yes” or “no” answers with no arguments supporting the selected options and 60 written in Italian, Spanish, French, Polish, Portuguese, Hungarian, Dutch, Czech, Slovak, Latvian, Lithuanian and Estonian as well as 20 whose respondents could not be identified, yielding 300 submissions for analysis.

We divided the 300 industry submissions into six categories: retailers and wholesalers (97), third party lobbying organizations [61], tobacco companies [53], tobacco lobbying organizations [50], tobacco related industry [35] and tobacco industry employees [4] (Table 2). When necessary we used respondents' names and e-mail addresses for Google searches to determine their category.

The maxim number of answers in a single submission was 18 (six answers for each areas: problem definition, available option and the topic as a whole). We analyzed to total of 1233 answers. Tobacco manufacturers provided on average 6.4 answers per contribution, while retailers and wholesalers gave 2.7 answers. The largest number of answers came from tobacco manufacturers (Table 2).

We identified the arguments used by respondents in 'additional information' free text boxes, which allowed the respondents to present feedback on the problem definition, available options, and the topic as a whole (Table 3). We coded whether the industry submission used harm reduction or traditional industry lobbying arguments to justify their position on the proposed change to the directive. Harm reduction arguments included citing smokeless tobacco products as less harmful, informing customers about the different risk levels of tobacco products and giving reduced harm products preferential position (e.g., tax treatment) over traditional combustible tobacco products [9,10]. Traditional arguments included opposing tobacco control as infringing upon basic freedoms, promoting illicit trade [24,25], and impeding employment and economic growth [24,26–29]. We also identified arguments against denormalization of tobacco, tobacco use and the tobacco industry [15]. (Tobacco industry denormalization is defined as educating the public about the tobacco industry's deceptive practices and the industry's role in the tobacco epidemic, while tobacco use denormalization focused on the addicted individual aiming to remove the cause of addiction [2]. Denormalization was not mentioned in DGSANCO materials.) The tobacco industry has traditionally sought to preempt state level and country level regulation of tobacco products by influencing national regulation in the US [30–35]; we coded arguments supporting EU preemption of stronger action than the TPD by Member States.

An argument was coded as appearing in an answer no matter how many times it appeared in that specific answer; one answer could include several arguments. The key words (Table 4) were used to identify occurrences of arguments but the actual coding was based on close reading of the each answer. The coding was done by one of the authors (HH) using Atlas.ti version 6.

3. Results

Tobacco companies, their lobbying organizations, third party lobbying organizations, and retailers and wholesalers used traditional tobacco industry lobbying arguments more frequently than harm reduction arguments (Table 4).

The most cited argument in all categories of industry answers was that the proposed revisions to TPD would increase illicit trade. Freedom arguments came second for tobacco manufacturers and retailers and wholesalers. Retailers and wholesalers referred to employment and economic growth more often than respondents from other categories. Tobacco manufactures and their lobbying organizations opposed denormalization.

3.1. Traditional lobbying arguments

Stressing tobacco is a legal product and established part of the global market, the industry argued that tobacco control measures (plain packaging, point-of-sale display ban, and bans

on vending machine and internet sales) would lead to illicit trade in 261 answers, almost half of all the coded arguments.

Of all the proposed policy options the industry most often criticized proposed changes in packaging requirements. The European Smokeless Tobacco Council (ESTOC), a smokeless tobacco manufacturers' lobbying organization [21], argued “the pack is one of the key components in the fight against counterfeit. Overt and covert elements are incorporated into the pack design to frustrate counterfeiters and to facilitate identification of illegal products. Making all tobacco products available in the same, easy-to-copy plain packaging would lead to a significant increase in counterfeit and smuggled products, undermining the extensive efforts being undertaken jointly by the tobacco companies and customs authorities worldwide to combat illicit trade” ([36], p. 1381).

Bundesverband Deutscher Tabakwaren, Grosshändler und Automatenaufsteller ([36], p. 1758), the German tobacconists' organization, claimed that plain packaging would turn cigarettes into a low price commodity business and encourage illicit trade that “will increase consumption and make cigarettes more easily available to youth”. The Food Chamber of Slovakia ([36], p. 839), representing farmers and food producers, argued that larger health warnings would increase illicit trade, which would lead into the loss of control over the content of tobacco product and endanger EU citizens' health.

The Irish Business and Employers Confederation argued against a point-of-sale display ban, another policy option frequently criticized in the industry answers, claiming that it would lead to illicit trade, which, in turn, would make more low cost tobacco products available to youth ([36], p. 3013). Industry answers also claimed that a point-of-sale advertising ban would make it more difficult for consumers to distinguish between legal and illegal products and promote illicit trade. Confindustia, a third party lobbying organization representing all Italian manufacturing and services companies, inadvertently supported the effectiveness of ban in reducing cigarette consumption by claiming that it would bankrupt small retailers and thereby increase illicit trade ([36], p. 33).

Fifty-three answers presented economic arguments. The tobacco companies, their lobbying organizations, third party allies, retailers and wholesalers claimed that pictorial health warnings, plain packaging, a point-of-sale display ban and restrictions on internet and vending machine sales would kill jobs and generate economic losses for EU Member States, in part by increasing illicit trade.

Ninety-four industry answers opposed warning label initiatives and point-of-sale display bans on the grounds that they limited customers' freedom of choice and manufacturers' freedom of expression, pursuit of free enterprise, and free trade. The answers relied on freedom arguments most often with regard to lifting the ban on snus. The industry submissions argued that the ban does not allow the EU citizens to choose between snus and combustible tobacco products. ESTOC ([36], p. 1391) and Swedish Match ([36], p. 2462) argued that banning snus denies millions of EU smokers access to “a traditional and a non-combustible tobacco alternative to their cigarettes”. Swedish Match ([36], p. 2462) also argued that ban on snus deprives European tobacco farmers from the opportunity to produce

high quality tobacco with methods that guarantee low levels of carcinogenic substances. The Swiss Business Federation ([36], p. 1190) and International Chamber of Commerce in Switzerland ([36], p. 1770) referred to entrepreneurial freedom with regard to selling oral tobacco. Confindustria ([36], p. 31) stated that ban on snus is a distortion of free movements of goods inside the EU.

In arguing for lifting the snus ban, industry answers relied extensively on the so-called Swedish experience [21], which was mentioned in 17 answers. Studies from Sweden [37–41] and Norway [42,43] (where snus is available because Norway is outside the EU) were cited to support claims that free access to snus resulted in a low level of cigarette smoking among males and that the use of snus was a as smoking cessation aid; these comments ignored evidence from other countries that showed free availability of snus did not lead to public health benefits [44]. Only two small-German manufacturers, Pöschl Tabak ([36], p. 2886) which makes nasal tobacco (snuff) that is not considered oral tobacco and therefore freely available within the EU, and Joh. Wihl von Eicken ([36], p. 784), which makes smoked tobacco products, supported the ban on snus.

The tobacco manufacturers insisted that possible regulation on ingredients should not extent to products manufactured within the EU for export purposes. Sixty-five answers stated that issues such as warning labels and tobacco ingredients should remain as prerogatives of national governments.

Tobacco companies stated that denormalization [16] of the tobacco products is not justified. The answers did not discuss denormalization of tobacco industry. Imperial Tobacco and Swedish Tobacco Manufacturers Association argued that “denormalization of tobacco products is not by itself a sufficient or legitimate public policy objective, as regulation should always be evidence-based” ([36], p. 1747).

3.2. Harm reduction arguments

Despite tobacco companies' nominal public support for harm reduction policies, harm reduction arguments seldom appeared in industry answers. Only 27 answers claimed, either directly or through citing a report [45] DGSANCO commissioned as part of its policy development, that smokeless tobacco is less harmful than combustible tobacco.

As part of the preparation for the TPD revision DGSANCO commissioned the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), an independent scientific committee made up of external experts providing EC with scientific advice, to prepare a report “Health Effects of Smokeless Tobacco Products” [45]. The report focused on snus, since the snus ban was the most contested part of current EC tobacco policy [20]. SCENIHR's main conclusion was that “STP [smokeless tobacco products] are addictive and their use is hazardous to health. Evidence on the effectiveness of STP as a smoking cessation aid is insufficient, and relative trends in progression from STP into and from smoking differ between countries. It is thus not possible to extrapolate the patterns of tobacco use from one country [Sweden] where oral tobacco is available to other countries” [45].

In their three hundred thirty eight answers the tobacco industry cited the SCENIHR report 153 times, never highlighting the report's main conclusion. Instead the industry submissions presented out-of-context quotes regarding the differences in form and content of toxicants among smokeless tobacco products (ESTOC ([36], p. 1382)), use of Swedish snus as cessation aid (Confindustria ([36], p. 30)), the nature of tobacco additives (Imperial ([36], p. 1492)), specific health risks (myocardial infarction (ESTOC ([36], p. 1382)), oral cancers ESTA ([36], p. 1760), Swedish Match ([36], p. 2463)) and the relative hazards of smokeless tobacco products in comparison with cigarettes (PMI ([36], p. 2332)), to support the assertion that free availability of oral tobacco would produce public health benefits. The U.S. Smokeless Tobacco company ([36], p. 3281), owned by Altria/Philip Morris, urged DGSANCO “to review what we believe to be overwhelming scientific, medical and public health consensus that moist smokeless tobacco products, including those widely available in the United States and in Sweden (snuff and snus), are substantially less hazardous than cigarettes” ([36], p. 3310). JTI stated, “An individual substitution of smoking by the use of smokeless products would probably decrease the incidence of some tobacco-related disease” ([36], p. 3184).

A few answers suggested that the use of smokeless tobacco is not harming third persons. JTI/Austria Tabak argued for lifting the snus ban because doing so would encourage development of potentially reduced exposure products ([36], p. 1478).

Thirteen answers mentioned informing consumers of the different risk levels of tobacco products. BAT ([36], p. 1068) and JTI ([36], p. 1478) recommended “educating” consumers that snus is less harmful than cigarettes. BAT called for “information for consumers to enable them to understand the relative risks of different products” ([36], p. 2958) Swedish Match ([36], p. 2462) suggested as a minimum requirement that European consumers be informed of the risks linked to the use of tobacco/nicotine products, including information on levels of substances such as tar, nicotine and carbon monoxize. Dr Andrew Manson, working for BAT's Research and Development in Germany called for “advice on how to reduce the risks of smoking such as smoking fewer cigarettes, inhaling less, substituting cigarettes with snus and allowing regulated low delivery products to be communicated to customers” ([36], p. 1067).

Only three answers suggested that smokeless tobacco products be given preferential treatment over combustible products, none from tobacco companies, their lobbying organizations or employees. Borgwaldt, a German flavouring company, suggested that reduced harm products should be given “beneficial position for consumers in a functioning internal market” ([36], p. 2216).

3.3. Tobacco industry's support for policy options

The multinational companies - BAT, PMI, Imperial and JTI (through subsidiary Austria Tabak) - that dominate European cigarette markets submitted identical “yes” and “no” answers as major tobacco industry lobbying organizations regarding policy options that would align with harm reduction (Table 5). They only accepted establishing common compulsory reporting format from the set of DGSANCO's proposed policy options. The dominant European oral tobacco producer Swedish Match [21] diverged from the united

front (Table 5) by supporting extending the TPD to include novel forms of oral tobacco, herbal cigarettes and electronic nicotine delivery systems. It also agreed to improve customer information, establish common list of tobacco ingredients and limit access to tobacco products ([36], p. 2462). Swedish Match argued that all tobacco and nicotine products should be "labeled with health warning that are in parity with their relative risks" ([36], p. 2465).

4. Discussion

Despite nominally supporting harm reduction, the tobacco industry opposed all but one new regulatory initiative in their answers to the EU public consultation. Rather, the companies and their lobbying organizations resorted to traditional industry arguments of increased illicit trade and freedom of choice to oppose strengthening regulations. None of the major tobacco manufacturers or their lobbying organizations supported any proposed evidence-based interventions that would actually reduce the harm caused by cigarettes including pictorial health warnings, plain packaging or point-of-sale display bans [46-48]. The industry quoted the SCENIHR report out of context and ignored its central conclusion that there was not evidence to support the use of smokeless tobacco products for harm reduction [45]. These results are consistent with the conclusion, based on analysis of internal industry documents, that the major tobacco companies investments in smokeless products was done as defensive move to eliminate competition between snus and cigarettes rather than to actually implement a harm reduction strategy [21]. In October 2009, a year before the public consultation, DGSANCO commissioned a Eurobarometer special survey on tobacco issues that included some of the tobacco control measures that eventually appeared in the draft TPD [49] that showed that European adults strongly supported tobacco control measures, the opposite conclusion one would draw from than responses to the public consultation (Table 6). Strong majorities of Europeans supported all the suggested tobacco control measures (from 52% to 75%), while only negligible portion (from 1.5% to 3.3%) of the public consultation submissions supported them [18]. This result was confirmed in 2012 when a new Eurobarometer survey on "Attitudes of Europeans towards Tobacco" showed that EU citizens strongly favoured of most policy measures contained in the Commission proposal [50] (Table 6).

The statement that banning the sale of snus outside Sweden is against freedom of choice echoes the traditional industry freedom discourse employed to defend cigarette smoking since the 1950s [4,51,52]. The industry has always opposed tobacco control by calling for fundamental freedoms and liberties of adults to make personal decision about their lifestyle. The support of such discourse has prevented public health interventions also in other areas of political debate such as motorcycle helmets, milk pasteurization or fluoridation of public water supplies [3,29]. The answers did not consider the fact that majority of European citizens take up smoking before adulthood [53]. Similarly, the answers gave no considerations on how free availability of snus would affect nonsmokers and those considering quitting all kinds of tobacco products [44].

The industry answers suggested that the proposed tobacco control measures including point-of-sale display ban would lead to illicit trade. Actual experience shows otherwise. In Ireland,

where a display ban has been in place since 2009, tobacco tax revenue increased following the ban [54]. Previously tobacco industry has used preemption to maintain favourable regulatory environment by removing authority of the subordinate jurisdiction [30-35]. The fact that industry submissions argued for national regulation of tobacco issues may reflect EU's leading role in curbing tobacco epidemic [16]. The companies may believe they can influence tobacco policies of national governments more successfully than those on EU level.

Tobacco manufacturers and their lobbying organizations attacked denormalization of smoking as a policy option. Denormalization of smoking and the tobacco industry is an efficient means to improve public health [2]. Allowing the products with alleged less harm such as snus to proliferate could re-enforce the image of tobacco products as normal and desirable [55-57]. This image was once achieved through tobacco industry's savvy marketing and sales promotion. Instead of reducing the harms of tobacco products the aim of the tobacco industry's support for free availability of snus may lie in reframing tobacco as a legitimate product and recast industry's history of denial and deception. Our results confirm earlier findings, which show that tobacco companies' harm reduction discourse is an opportunistic tactical adaptation to policy change rather than a genuine commitment to harm reduction [58].

The united industry front of cigarette manufacturers was only broken by Swedish Match, which is concentrated on smokeless tobacco and does not sell cigarettes. Surprisingly, Swedish Match's positions diverged from those of ESTOC's, which is the joint European lobbying organization of companies producing smokeless tobacco products and whose chairman is a director from Swedish Match. Another Swedish snus manufacturer, Skruf, owned by Imperial Tobacco, gave identical answers with cigarette companies (Table 5). This result suggests friction not only between the tobacco companies specializing in smokeless products and those currently selling mainly cigarettes but also smokeless tobacco.

There was a stark contrast between the tobacco industry submissions and the submissions from the one pharmaceutical company that made a submission, Pfizer ([36], p. 3004), a major nicotine replacement products manufacturer. Pfizer advocated the ban on all types of smokeless tobacco products mentioning their carcinogenic effects (pancreas/oral) as well as the fact that they increase initiation and continuation of nicotine dependence.

Despite earlier successes in influencing EU regulation [59,60] and the fact that during the legislative process there was shifts towards the tobacco industry's submissions [61], the tobacco industry did not broadly succeed in convincing the European Parliament to adopt its positions. In February 2014 the European Parliament approved a revised EU Tobacco Products Directive, which include large (65%) mandatory photo and text warnings on both sides of the pack of cigarettes and eventually banning characterizing flavours (including menthol) in tobacco products [62]. For e-cigarettes the directive sets mandatory safety and quality requirements on nicotine content, ingredients and devices, as well as refill mechanisms. The directive makes health warnings and information leaflets obligatory and introduce notification requirements for manufacturers and importers of e-cigarettes, stricter rules on advertising and monitoring on market developments. Member States are entitled to

prohibit cross-border distance (internet) sales of tobacco products if they choose and retailers will not be permitted to supply consumers located in those Member States. In Member States, which do not prohibit such sales, retailers must follow stricter notification rules and make use of an age verification system.

Limitations

It was not possible to determine if tobacco companies and related parties co-operated in drafting their answers to EC public consultation.

Conclusions

The tobacco industry submissions to the EU TPD public consultation used traditional industry arguments emphasizing illicit trade and freedom of choice. None supported any proposed evidence based interventions such as pictorial health warnings, plain packaging or point-of-sale display bans to reduce harms caused by cigarette smoking.

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Table 1

Options for the respondents in the DGSANCO public consultation on the possible revision of tobacco product directive.

	Scope of the directive	Smokeless tobacco products	Consumer information	Reporting and registration of ingredients	Regulation of ingredients	Access to tobacco products
Current directive (2001/37/EC)	Limited to products containing tobacco (i.e. e-cigarettes and herbal cigarettes are not subject to the TPD)	Oral tobacco (snus) banned outside Sweden	General health warning, (e.g. “Smoking kills”), covering not less than 30% of the front side, and a specific text warning (e.g. “Smoking causes fatal lung cancer”), covering not less than 40% of the back side	Member States apply various forms and reporting mechanisms	No regulation besides maximum levels of tar, nicotine and carbon monoxide	National measures on limiting access to tobacco products
Revision option 1	No change	No change	No change	No change	No change	No change
Revision option 2	Extend the scope of the Directive to include novel forms of oral tobacco, herbal cigarettes and electronic nicotine delivery systems	Lifting the ban on snus	Improve consumer information by (a) making picture warnings mandatory, (b) placing tar, nicotine and carbon monoxide levels with general information on harmful substances in tobacco products (TP), (c) placing information on harmful substances in TP that cannot be placed on the package inside the package, (d) putting health warnings on water pipes	Establish a common compulsory reporting format	Introducing the basic criteria for tobacco product ingredients on the EU level without common list of allowed or banned ingredients	Controlled supply and access to tobacco products by (a) setting age verification of buyers and other legal conditions for cross-border retail sale, (b) restricting access to vending machines to adults, (c) restricting tobacco display and promotion at points of sales
Revision option 3		Ban all types of smokeless tobacco products	Introduce generic or plain packaging	Introduce fees to be paid for national authorities and sanctions for manufacturers	Establish a common list of banned or allowed tobacco ingredients	Ban (a) cross-border retail sales of tobacco over the internet, (b) vending machines, (c) promotion and displays in retail stores

Table 2

Contributions by respondent category.

	Tobacco manufacturer	Tobacco lobbying organization	Tobacco industry employee	Third party lobbying organization	Tobacco related industry	Retailer & wholesaler	Total
Number of contributions	53	50	4	61	35	97	300
Number of answers	338	244	19	223	145	264	1233
Answers per contributions	6.4	4.9	4.8	3.7	4.1	2.7	4.1

Table 3

Code list for content analysis of industry submissions arguments.

Argument	Definition	Key words or expression used to identify arguments for coding*
Illicit trade	Illicit trade used as argument to opposed proposed regulation, mentioned as a threat	“Illicit trade”, “counterfeit”, “black market”, “smuggling”, “criminal”, “illegal”
Freedom	Arguments based on freedom to choose, freedom of commerce, freedom of speech or expression	“Freedom”, “free”
Employment & economic growth	Arguments for renouncing regulation due to economic reasons	“Employment”, “jobs”, “economy”, “competitiveness”
Smokeless tobacco products cited as being less harmful	Arguments claiming that smokeless tobacco products are less harmful than combustible products	“Hazard”, “less hazardous”, “less harmful”, “dangerous”
Avoid EU level regulation of tobacco products	Arguments for keeping tobacco regulation as prerogative of Member States	“Prerogative”, “responsibility”, “domain”, (state's) “duty”, (state's) “powers”, “EU-level”
Denormalization of tobacco products	Denormalization mentioned in relation to regulation	“Denormalization”, “denormalization”
Informing consumers on health risks	Arguments to provide customers with information on the different risk levels of different tobacco products	“Education”, “information”, “advice”, “risk”
Preferential treatment of smokeless tobacco products	Arguments for giving smokeless tobacco products preferential treatment over combustible tobacco products in regulation	“Tax”, “beneficial”, “preference”, “preferential”

* Corresponding words were used for German, Swedish and Finnish.

Table 4

Occurrences of different types of arguments in the industry answers by respondents' category.

	Tobacco manufacturer	Tobacco lobbying organization	Tobacco industry employee	Third party lobbying organization	Tobacco-related companies	Retailer & wholesaler	Total
Traditional tobacco industry lobbying arguments							
Illicit trade	90 (54.5%)	30 (45.5%)	5 (65.5%)	52 (47.7%)	34 (53.1%)	50 (41.7%)	261 (49.1%)
Freedom	37 (22.4%)	8 (12.1%)	0	16 (14.7%)	5 (7.8%)	28 (23.3%)	94 (17.7%)
Employment & economic growth	9 (5.5%)	5 (7.6%)	0	12 (11.0%)	6 (9.4%)	21 (17.5%)	53 (10.0%)
Avoid EU regulation	6 (3.6%)	12 (18.2%)	0	19 (17.4%)	12 (18.8%)	16 (13.3%)	65 (12.2%)
Denormalization of tobacco products	14 (8.5%)	2 (3.0%)	0	0	0	0	16 (3.0%)
Harm reduction arguments							
Smokeless tobacco products cited as being less harmful	8 (4.8%)	5 (7.6%)	1 (12.5%)	9 (8.3%)	2 (3.1%)	2 (1.7%)	27 (5.1%)
Informing consumers on health risk levels	1 (0.6%)	4 (6.1%)	2 (25.0%)	0	4 (6.3%)	2 (1.7%)	13 (2.4%)
Preferential treatment of smokeless tobacco products	0	0	0	1 (0.9%)	1 (1.6%)	1 (0.8%)	3 (0.6%)
Total	165 (100%)	66 (100%)	8 (100%)	109 (100%)	64 (100%)	120 (100%)	532 (100%)

Table 5

Industry positions in public consultation [36].

	Issue					
Party	**Scope of the directive**	**Smokeless tobacco products**	**Consumer information**	**Reporting and registration of ingredients**	**Regulation of ingredients**	**Access to tobacco products**
Large multinational tobacco companies in Europe (BAT, PMI, Imperial, JTI)	No change	Lift the ban on snus	No change	Establish a common compulsory reporting format	No change	No change
Main tobacco industry lobbying organizations (CECCM, ECMA, ESTA, ESTOC, GITES*)	No change	Lift the ban on snus	No change	Establish a common compulsory reporting format	No change	No change
Swedish Match	Extend the scope of the Directive to include novel forms of oral tobacco, herbal cigarettes and electronic nicotine delivery systems	Lift the ban on snus	Improve customer information Tar, nicotine and carbon monoxide levels to be placed with general information on harmful substances inTP	Establish a common compulsory reporting format	Establish a common list of tobacco ingredients	Control supply and access

ECMA is European Cigar Manufacturers Association, which represents the interests of the European manufacturers cigars. ESTA is European Smoking Tobacco Association, which represents the interests of the European manufacturers, distributors and importers of fine-cut (rolling) tobacco, pipe tobacco, traditional chewing tobacco and nasal snuff tobacco. ESTOC is European Smokeless Tobacco Council, where all major tobacco companies (BAT, PMI, Imperial and JTI) are members together with Swedish Match and four smaller producers and Tobacco Manufacturers Association of Denmark, Tabaksindustrien. GITES is Luxembourg based Groupement des Industriels Européenne du Tabac (GITES) representing small and medium size European tobacco products manufacturers.

*CECCM is Confederation of European Community Cigarette Manufacturers, an organization representing the view of three major European-based cigarette manufacturers, BAT, Imperial Tobacco Group and JTI. R.J. Reynolds tobacco company is observer members at CECCM.

Table 6

Support for tobacco control measures in DGSANCO public consultation and Eurobarometer surveys [22,49].

	Pictorial Health warning labels (%)	Plain packaging (%)	Banning flavours that make tobacco products more attractive (%)	Banning the sale of tobacco products via the Internet (%)	Keeping tobacco products out of sight in shop/points of sale (%)	Banning the sales of tobacco products through vending machines (%)
Eurobarometer (Oct 2009)	75	54	61	60	55	52
Public consultation (Sep–Dec 2010)	1.5	1.8	3.3	1.6	1.5*	1.6
Eurobarometer (Feb–Mar 2012)	76	57	63	62	58	54

*Support for option “Promotions and displays in retail stores to be banned”.