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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.

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#### 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.

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

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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 (10 mg) 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

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