The devil is in the detail: Tobacco industry political influence in the Dutch implementation of the 2001 EU Tobacco Products Directive

Jessamina L.Y. Lie[1], Marc C. Willemsen[1 2], Nanne K. de Vries[1], Gary Fooks[3]

[1] CAPHRI, Maastricht University, Maastricht, the Netherlands

[2] Dutch Alliance for a Smokefree Society, the Hague, the Netherlands

[3] School of Languages and Social Sciences, Aston University, Birmingham, United Kingdom

Corresponding author: Jessamina Lih Yan Lie, CAPHRI, Maastricht University, P. Debyeplein 1, 6229 HA Maastricht, The Netherlands. Email: J.Lie@maastrichtuniversity.nl; Tel: +31 70 30 688 35

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ABSTRACT

Introduction: The Dutch implementation of the black border provision in the 2001 European Union Tobacco Products Directive (TPD) is studied to examine the implications of tobacco industry involvement in the implementation phase of the policy process.

Methods: A qualitative analysis was conducted of Dutch government documents obtained through Freedom of Information Act requests, triangulated with in-depth interviews with key informants and secondary data sources (publicly available government documents, scientific literature, and news articles).

Results: Tobacco manufacturers' associations were given the opportunity to set implementation specifications via a fast-track deal with the government. The offer of early implementation of the labelling section of the TPD was used as political leverage by the industry, and underpinned by threats of litigation and arguments highlighting the risks of additional public costs and the benefits to government of expediency and speed. Ultimately, the government agreed to the industry's interpretation, against the advice of the European Commission.

Conclusions: The findings highlight the policy risks associated with corporate actors' ability to use interactions over technical product specifications to influence the implementation of health policy and illustrate the difficulties in limiting industry interference in accordance with FCTC Article 5.3. The implementation phase is particularly vulnerable to industry influence, where negotiation with industry actors may be unavoidable and the practical implications of relatively technical considerations are not always apparent to policymakers. During the implementation of the new TPD 2014/40/EU, government officials are advised to take a proactive role in stipulating technical specifications.

INTRODUCTION

Health warnings on cigarette packages are among the most direct means of communicating smoking's health risks. Research indicates that they can discourage youth smoking initiation, encourage smoking cessation, and disrupt brand imagery by restricting available package space.[1, 2] However, their impact is determined by their design, positioning, and size: with larger warnings both improving recall and shaping risk magnitude perceptions.[2, 3] Additionally, there is debate about which information should be offered for the warnings to be effective.[4, 5]

On 1st May 2002 the Netherlands became the first European Union (EU) Member State to introduce new textual health warnings on tobacco packages, following the 2001/37/EC Tobacco Products Directive (TPD). Cigarette packages were required to contain a warning label with one of two general warning texts covering 30% of the front of the package and a warning label with one of 14 different texts covering 40% of the back of the package.[6] The Directive included a provision stating that the warnings should be "surrounded by a black border not less than 3 mm and not more than 4 mm in width which in no way interferes with the text of the warning or information given".[6] Despite the appearance of precision, this guidance permitted two different interpretations, with the border either being included in or excluded from the prescribed surface percentages. In practice, 15 Member States, including the Netherlands, interpreted the provision to mean that a 3 mm border should be *included* in the surface percentages, making the text warnings smaller than if the border had been excluded (see Figure 1).[7] However, in the first report on the application of the TPD, the Commission stated that the black border should not be counted as part of the warning area.[8]

This paper examines how corporate actors shaped this process and builds on two separate bodies of knowledge: research on the implementation of EU legislation, which has typically studied how public and elected officials at the national level have influenced the way EU directives are implemented in national legislation,[9, 10] and studies of tobacco industry political activity aimed at shaping labelling legislation[11-22]. This study analyses industry political activity during the

implementation phase of the policy process, focusing on industry actions aimed at policymakers' interpretation of ambiguously formulated EU legislation.

METHODS

The analysis is largely based on documents in the Legacy Tobacco Documents Library (LTDL) (http://legacy.library.ucsf.edu/). LTDL contains the Dutch Tobacco Industry Special Collection (DTISC), which hosts Dutch government documents obtained through two Freedom of Information Act requests in the Netherlands in 2000 and 2011 by a Dutch investigative journalist.[23] Between April and September 2014, searches of the full LTDL were undertaken using a "snowball strategy". Initially, broad Dutch search terms were used such as "gezondheidswaarschuwing" (health warning) and "zwarte kader" (black border). Comparable English search terms and terms relating to the EU 2001/37/EC TPD were also combined with "Dutch" or "the Netherlands". Further searches were conducted using terms identified from retrieved information, including names of organisations (e.g. 'Vereniging Nederlandse Kerftabakindustrie'; Dutch fine-cut tobacco industry association), policy officials and dates of letters and meetings mentioned. 91 documents (33 originating from the DTISC) were identified, dated between June 1998 and March 2005. The DTISC documents may not be a complete record of written correspondence on the black border, since they were obtained through Freedom of Information Act requests.

The documents were triangulated with semi-structured interviews with key informants conducted by the first author and with secondary data sources. Key informants involved in tobacco related issues in the Netherlands during the period 2001-2002 were approached, as were academic experts on health warnings. Between July and October 2014 twelve semi-structured interviews were undertaken (see Table 1 for a list of interviewees). The Dutch cigar industry association (Nederlandse Vereniging voor de Sigarenindustrie; NVS) was also approached, but declined to participate. Upon request, representatives of the Dutch fine-cut tobacco industry association (Vereniging Nederlandse Kerftabakindustrie; VNK) and the Dutch cigarette industry association (Stichting Sigarettenindustrie; SSI) were interviewed together and notes were made, instead of recordings. All other interviews

were conducted individually, recorded and final transcriptions were sent to key informants for approval. Additionally, the researcher's account of the interview was sent to the VNK and SSI representatives, along with several follow-up questions. Feedback was received, consisting mostly of elaborations on existing statements, together with answers to the follow-up questions. The introduction of working practices consistent with FCTC Article 5.3, which occurred after the events we described, might have distorted how actors - particularly policy makers - think and talk about earlier contacts between the government and the tobacco industry.

Secondary data sources consisted of publicly available government documents, scientific literature, and news articles, obtained through Google searches, government websites, and LexisNexis.

All textual data were read repeatedly and thematically coded by the first author in an inductive manner. Excerpts used of original Dutch texts were translated to English by the first author.

RESULTS

The introduction of new health warnings: the black border issue

On 24th January 2001 the Minister of Health, Welfare and Sport (Volksgezondheid, Welzijn en Sport; Health) Borst-Eilers published the Draft Labelling Decree for tobacco products. This decree aimed to make health warnings and tar- and nicotine yields on tobacco packaging "as clear as possible".[24] At the time, labelling legislation was determined by the EU Directive 89/622/EEC.[25] The Draft Labelling Decree, which was set to commence on 1st July 2001, required new typographical provisions, but did not propose a change in the text or size of the health warnings.[24]

VNK, on behalf of the three tobacco manufacturers' associations in the Netherlands (SSI, VNK and NVS), sent a 20th February 2001 letter to the Director-General of the Health Ministry, pointing to the EU TPD provisions, which "will come into force in 2002".[26] These provisions would go beyond those of the Draft Labelling Decree, by requiring significantly larger health warnings and a thicker black border, amongst other typographical requirements. Not wanting to have to adjust the warnings

twice "within months", VNK proposed to "combine the adjustments to the Labelling Decree" with those required by the TPD.[26] Emphasising that this would limit compliance costs, VNK described how the industry had already made preparations to incorporate the TPD's labelling requirements and that requiring other labels would lead to considerable costs, which had not been properly considered, since research into the business impacts was lacking.[26]

In a 14th March 2001 letter directed to the Parliamentary Committee on Health, the Health Minister reiterated the tobacco manufacturers' associations' request, indicating that she was "not unsympathetic", but noted that "in return […] the new Directive will have to be implemented in an accelerated manner, well before the ultimate deadline."[27] On 20th March 2001 VNK wrote to the Parliamentary Committee on Health referring to this letter, indicating that they were happy with this decision and willing to "enter into consultation on the implementation of the forthcoming European Directive".[28] A meeting was held on 7th April 2001, in which SSI showed mock packages with the new health warnings with the border included in the surface percentages of 30% and 40% to a Health Ministry officer, who responded that they "looked good and were clearly legible".[29] Additionally, on 3rd July 2001 SSI sent their labelling proposals to the Health Ministry in the form of work drawings.[29]

On 17th July 2001 the adjusted Draft Labelling Decree for tobacco products was published. The black border provision was a translation of the EU TPD provision, with no mention of whether the border should be included in or excluded from the warning space. Additionally, it stated that tobacco manufacturers had already begun to develop a proposal for the warning labels' technical specifications.[30]

Deliberations on the placement of the black border began on 20th July when the Health Ministry indicated that it should not be part of the warnings' prescribed surface percentage, as described in a 27th July letter from SSI to the Health Ministry.[29] In that letter SSI stated that in their preparations tobacco manufacturers had assumed that the borders were to be included in the surface area and that the negotiated date (1st March and 1st May for all but a minority of packages)

would only be met if the Ministry agreed to attached detailed proposals reflecting this assumption.[29] Additionally, SSI stated that "given this date, we need to have a written approval of the Health Ministry before the next meeting of the SSI board (9th August), with reference to the continued practical preparations and implementation. If we do not hear from you before 9th August, we will assume that you agree with these proposals and the SSI members will continue on the course they have set."[29]

Based on advice received from the Netherlands Food and Consumer Product Safety Authority and several Ministry legal officers, the DG Health director stated in a 10th August 2001 letter to SSI, that he could "agree to the viewpoint of SSI that the prescribed black border is part of the required warnings."[31] On 12th September 2001, VNK sent draft technical specifications to the Health Ministry indicating that the black border was to be included in the surface percentages.[32] In a 15th October 2001 letter NVS also reaffirmed that the border was to be part of the allocated warning space.[33]

The black border issue was revisited in a 21st November 2001 letter by the Health Minister to the three tobacco manufacturers' associations. In the correspondence she referred to a letter (dated 28th June 2001) from the European Commission to the United Kingdom (UK) Department of Health which she had only become aware of subsequent to the 10th August letter to SSI. She wrote that the Commission had stated that the black border was to be added to the prescribed surface percentages, instead of included and that "an official opinion of the European Commission could perhaps resolve the matter".[34] In response, SSI on 7th December 2001 expressed their surprise and reminded the Ministry that "the whole purpose was to quickly implement the labelling section of the EU Directive".[35] SSI argued that "it makes no sense" to ask the Commission's opinion as "only the European Court of Justice can judge on matters concerning the interpretation of the TPD."[35] A 7th December response letter from VNK referred to the draft technical specification of 12th September which had been verbally approved by the head of the Ministry's tobacco team. The letter stated that VNK was continuing its preparations despite not yet having received confirmation of the technical

specification and requested written approval of the specification before 19th December 2001. In the context of fast-track implementation, they threatened to withhold cooperation by stressing that "the voluntary implementation, as the word already implies, is voluntary."[32] Finally, the letter stated that "insofar you are of the opinion that different preparations should be made, VNK and/or her members will consider holding the State accountable for the costs of preparations already made."[32] NVS also wrote to the Minister on 10th December 2001, responding to the European Commission's letter to the UK Department of Health.[36] NVS stated that during a Council Working Party meeting on 12th/13th January 2000 [37] the Commission had expressed the exact opposite and that this, among other things, had formed the basis on which Member States had agreed to the TPD proposal.[36]

The final document in our sample pertaining to the border discussions between the Health Ministry and the tobacco manufacturers' associations is a letter from the Health Minister responding to the above mentioned letters from the tobacco manufacturers' associations, dated 12th February 2002.[38] She noted that the definitive amendments to the Labelling Decree had been made official on 21st January 2002 [39], the date of entry into force having been set for 1st May 2002. Also, she stated that from these definitive amendments it would have become clear that the government "for the time being" did not require the black border to be excluded from the prescribed surface percentages.[38] This would remain unchanged until the present day.

Health Ministry perspective

During the period 2001-2002 the Health Minister, Els Borst-Eilers, was nationally and internationally known for her commitment to tobacco control.[40] (Interview managing director STIVORO, interview policy officer 3) Two of the four policy officers of the Ministry's tobacco team, which fulfilled a supporting and executive role, dealt with the details surrounding the introduction of the new tobacco health warnings. (Interview policy officer 2, interview policy officer 3) When asked about the reasoning behind the fast-track implementation, it was mentioned that "in this case the consumer would be warned sooner […]. We always thought, the sooner the better." (Interview policy officer 1)

The fact that the Netherlands would be first to implement the new warning labels was a source of "pride", since the Netherlands was usually "rather slow" in these matters. (Interview policy officer 1)

On the topic of the black borders, it was said that at the time "we personally did not find it that important. We believed that the text of the warnings was more important." (Interview policy officer 1) Tobacco industry lobbying surrounding the introduction of the new health warnings - by letter, telephone, email and meetings - was characterised as "extremely proactive" and like "having to keep the flies away." (Interview policy officer 1) One policy officer's strategy was always to "meet as little as possible". However, whilst officers considered that they "did not need [industry] information", meetings were sometimes required from "higher authorities" to avoid accusations of not being prepared to consult and to comply with minimal requirements of stakeholder consultation. (Interview policy officer 1) Additionally, business impact assessments meant that the tobacco team was "dependent on information from the industry on the business impacts of […] the warnings." (Interview policy officer 1)

Health organisation perspective

Amongst Dutch Health NGOs, STIVORO was the main party active on the health warning issue at the time. (Interview chair CAN) With regards to an earlier version of the TPD proposal, the managing director of STIVORO had advised the Health Ministry in February 2000 to exclude the black border from the allocated warning space.[41] This advice was based on a common position formulated by European health organisations and health lobbyists at a consensus conference in January 2000, although at the time STIVORO considered the warning texts to be of greater significance than the black border. (Interview secretary general ENSP, interview managing director STIVORO)

Tobacco industry perspective

When interviewed, SSI and VNK representatives highlighted the importance of avoiding needless costs "[since] millions are involved in the adjustment of packaging". Communication with the government on the black border was said to be driven by this concern and not "protection of

interest." The industry had lobbied when the TPD could still be adjusted, but once legislation was set it only wanted "to implement it as quickly as possible." (Interview vice chair SSI and current chair VNK)

When asked about communications between the tobacco manufacturers' associations and the Health Ministry, SSI and VNK representatives mentioned that "the pace of the industry and the government is different", since "the industry always wants to know as quickly as possible how something needs to be implemented". It was also emphasised that dialogue on technical details of implementation benefits both industry and the government. On the one hand, companies need clear information on how measures should be implemented to avoid litigation risks. On the other hand, dialogue supports policy makers, since they are not always aware of the practical issues involved. Industry actors saw it as their "role" to "relate practice to the Health Ministry" and, therefore, that it was important that the industry "arrives at acceptable implementation of legislation together with the government". Industry representatives emphasised that in respect to "technical aspects of implementation", the Health Ministry's view was that dialogue with industry actors remained necessary despite the subsequent introduction of working practices consistent with FCTC Article 5.3. (Interview vice chair SSI and current chair VNK) Finally, industry actors emphasised the greater costs involved when legislation was implemented differently across EU Member States: "the more uniformity, the less divergent packaging material, the less machine changeover time, the less costs". (Interview vice chair SSI and current chair VNK)

DISCUSSION

The present study illustrates how in the Netherlands the tobacco industry was able to reduce the size of health warnings by successfully exploiting uncertainty over an ambiguous implementation provision in the EU TPD's labelling section. More generally, the findings highlight the policy risks associated with government-industry interactions during the implementation phase of the policy process and the potential for deliberations over what seem like minor technical specifications to have far-reaching health policy consequences.

Case studies of EU Directives in the Netherlands recognise that where a consensus exists between public and elected officials over implementation, an interpretation of the Directive reflecting the consensus is adopted.[9] This contrasts with circumstances where no consensus exists, in which case a literal translation is claimed to follow.[9] What these scenarios ignore, however, is the role that non-state actors, in this case corporate actors, play in actively steering public and elected officials towards specific interpretations of EU legislation.

Our findings indicate four techniques that increased the tobacco industry's leverage in discussions over how to implement the TPD. First, tobacco manufacturers' associations sought to set the agenda for implementation by proactively preparing mock packages and work drawings and by starting preparations on packaging redesign early on. This technique was underpinned by efforts to control the pace of negotiations, which centred on giving the Ministry short deadlines to respond to delivered technical specifications. Second, they endeavoured to facilitate acceptance of their interpretation by emphasising the importance of expediency and threatening to withdraw their earlier offer of fast-track implementation. This technique capitalised on public officials' professional interest in moving forward quickly with public health measures. Third, they sought to preserve the essentially private nature of negotiations over TPD implementation by seeking to discourage communication between the Dutch Health Ministry and the European Commission and by arguing that another policymaking venue (the European Court of Justice) had ultimate responsibility on this matter. Although technically correct, the industry's reaction is consistent with insider political strategies that aim to "contain" negotiations in order to optimise control over outcomes.[42] This approach was reinforced by efforts to portray the European Commission as having taken an opposing view to the Dutch Health Ministry at a Council Working Party meeting, even though the Commission's statements applied to an earlier, abandoned version of the TPD proposal.[37]. Finally, tobacco manufacturers' associations emphasised the additional compliance costs associated with contesting their interpretation of the TPD with a view to highlighting the litigation risks (to the state) of acting independently and the extra costs this might incur.

These findings illustrate the difficulties that policymakers face in limiting industry interference in health policy by restricting government-industry interactions in accordance with FCTC Article 5.3.[43, 44] During the TPD implementation phase, the Dutch government gave tobacco manufacturers' associations a legitimate status as "political insiders"[45, 46]. Providing industry access to policymakers is often an unavoidable part of implementing health measures that require changes to product specifications, a process which is difficult to manage through legal instruments alone. This point is underlined by FCTC's Recommendation 2.1 of the Guidelines for Implementation for Article 5.3, which specifies that Parties should interact with the tobacco industry "only when and to the extent strictly necessary to enable them to effectively regulate the tobacco industry and tobacco products."[44] The risks of such interactions are intensified by the fact that the practical implications of relatively technical considerations are not always apparent to policymakers.

Our findings indicate that contrary to what industry actors claimed in interview, corporate political activity is an ongoing practice that continues after legislation has been passed. As Parties to the FCTC introduce restrictions on industry lobbying, this phase is likely to become an increasingly important administrative milieu for corporate political influence, carrying distinctive risks for policy formation due to the co-operative dynamic that may emerge. Our findings thus underline the value of prescriptive detail in EU tobacco directives, which reduce the scope for negotiation and contestation by the industry. In contrast to the TPD border provision, other aspects of the labelling section with more precise technical specifications (e.g. on the font and the position of the text within the warning labels), were consistently implemented across EU Member States. Although the supranational nature of the EU creates practical obstacles in drafting prescriptive detail, the certainty provided by this is likely to work for both tobacco manufacturers – who emphasised the cost advantages of legislative precision – and public health.

Additionally, our results support the findings of existing research which underlines how Better Regulation practices are likely to create opportunities for industry lobbying[47, 48]. Our findings indicate that estimating cost impacts via impact assessments - a key characteristic of Better

Regulation initiatives - may provide an institutional anchor for industry arguments that focus on the legal ramifications of additional costs involved in implementation decisions that are inconsistent with the industry's preferred option. Moreover, our results provide further support for the notion that impact assessments help to formalise corporate actors' information advantage in health policymaking [49-52].

Finally, in accordance with the spirit of Article 5.3, the results underline the importance of governments taking a proactive role in stipulating technical specifications concerning the new TPD 2014/40/EU and carefully considering the implications of tobacco industry information, even when such information may be provided in good faith.

WHAT THIS PAPER ADDS

- In contrast to previous studies which have examined tobacco industry efforts to shape labelling legislation, this paper focuses on the implementation phase of the policy process, concentrating on how tobacco industry actors influence political decision-making during the implementation of EU legislation.
- The paper exemplifies the policy risks associated with government-industry interactions during the implementation phase of tobacco policy and illustrates the difficulties involved in limiting industry interference in accordance with Article 5.3 of the Framework Convention on Tobacco Control. In addition, it highlights the importance of government officials taking a proactive role in stipulating technical aspects of implementation.

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CONTRIBUTORS

The idea for the study was conceived by JL and MW. JL performed the data collection and data analysis, with GF and MW providing input. JL prepared the first draft and with input from GF, MW and NdV the first draft was transformed into the final manuscript.

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COMPETING INTERESTS

None.

PROVENANCE AND PEER REVIEWED

Commissioned; externally peer reviewed.

Ethical approval of the Regional Medical Ethics committee in the Netherlands was not necessary because participants in this study were not “subjected to procedures or required to follow certain rules of behavior” (http://www.ccmo.nl/en/your-research-does-it-fall-under-the-wmo).

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Table 1 Interviewed key informants

Face-to-face interviews (n=4)	Telephone interviews (n=8)
Policy officer 1 from the tobacco team of the Ministry of Health, Welfare and Sport	Policy officer 3 from the tobacco team of the Ministry of Health, Welfare and Sport
Policy officer 2 from the tobacco team of the Ministry of Health, Welfare and Sport	Chair of the non-smokers association Clean Air Netherlands (CAN)
Managing director of the national expert centre on tobacco control STIVORO	Secretary general of the European Network for Smoking Prevention (ENSP)
Vice chair of the Dutch cigarette industry association & current chair of the Dutch fine-cut tobacco industry association	Head of strategy and communication of STIVORO
	President of the International Network of Women Against Tobacco (INWAT) and member of the ENSP
	International academic expert 1 on health warnings
	International academic expert 2 on health warnings
	International academic expert 3 on health warnings

Figure 1: actual Dutch health warning with border 'included' (left), approximation of Dutch health warning with border 'excluded' (right)

(For online publication)

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"The devil is in the detail: Tobacco industry political influence in the Dutch implementation of the 2001 EU Tobacco Products Directive"

Tobacco Control

Dear editor,

Thank you very much for giving us the opportunity to revise our paper on tobacco industry political influence in the Dutch implementation of the 2001 EU Tobacco Products Directive.

We are pleased to hear that you will accept the paper for publication, provided we check and adjust the reference list. We have done so accordingly. Please let me (Jessamina), know if any more adjustments need to be made.